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THE GEORGE WASHINGTON UNIVERSITY MILKEN INSTITUTE SCHOOL OF PUBLIC HEALTH

Impacts of Pharmaceutical Marketing on Healthcare Services in the District of Columbia

Focus on Gifts to Organizations and Influential Physicians

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I. Executive Summary

Background

The District of Columbia AccessRx Act requires pharmaceutical companies that market products in the District to file annual reports on marketing expenditures. It also requires annual reports investigating how reported marketing activities may be affecting healthcare services in the District of Columbia. This report focuses on pharmaceutical-company payments to influential physicians and organizations that may influence the practice of medicine both within the District and nationwide.

Pharmaceutical marketing can influence prescribing behavior, and may also shape organizational treatment guidelines or other recommendations. Such influence is of concern when it results in patients receiving drugs whose risks of adverse events and costs are too high relative to the benefits the patients receive. Inappropriate prescribing can result in adverse health outcomes, increased utilization of care, and higher healthcare costs (Borkowski et al, 2013).

Data collected pursuant to the AccessRx Act have been compiled in a database and analyzed by the George Washington University Milken Institute School of Public Health and the District of Columbia Department of Health, with results reported most recently in "Pharmaceutical Marketing Expenditures in the District of Columbia, 2012." In 2012, 147 pharmaceutical companies reported spending a total of \$97.5 million on marketing activities in the District of Columbia, including \$61.5 million on employee and contractor expenses, \$30.5 million on gifts and payments, and \$5.4 million on advertising. Physicians received \$10.2 million of the gift dollars, approximately one-third (33.6%) of the total value of all gifts.

This report analyzes gifts pharmaceutical companies gave to leading health-focused organizations headquartered in Washington, DC, as well as gifts to influential physicians who may be key opinion leaders. These influential individuals may hold leadership positions in health organizations or be identified as influential by their peers.

Key Findings

While DC-based clinical organizations provide care to local residents, national organizations headquartered here influence healthcare services nationwide by researching new interventions, creating medical guidelines, affecting policies, and disseminating continuing medical education. The AccessRx data collection provides a unique resource to explore gifts the many organizations receive from pharmaceutical companies. In 2012, organizations as a whole received \$19.6 million; this represented a doubling (102.1% increase) from 2011, and a return to levels not seen since 2007, when organizations received \$19.9 million (George Washington University, 2013).

The AccessRx Act does not allow for the public disclosure of the names of groups or individuals receiving gifts from pharmaceutical companies. To characterize gift patterns without revealing identities, researchers used the AccessRx database to identify 190 organizations that received gifts totaling

\$50,000 or more over the 2007 – 2012 period, and then divided these recipients into the following five categories: *Research, Education, & Advocacy Organizations; Professional Organizations; Academic Organizations & Teaching Hospitals; Clinical Organizations;* and *Other*. Findings include:

- The majority of organizations receiving over \$50,000 from 2007-2012 were classified as Research, Education, & Advocacy Organizations and Professional Organizations; most gifts to these groups were monetary payments. Most gifts to Academic Organizations & Teaching Hospitals and Clinical Organizations took the form of food.
- Research, Education, & Advocacy Organizations and Professional Organizations received over 80% of total gifts to these 190 organizations from 2007-2012 (43.5% and 39.3%, respectively). Their gifts from pharmaceutical companies totaled \$70.9 million.
- The average annual gift total to these organizations was \$188,933 in 2012, with a median gift total of \$58,025.

Industry funding of organizations whose activities can influence providers' prescription patterns creates potential conflicts of interest. An important first step to managing these conflicts is disclosure of pharmaceutical-company gifts, which many organizations do by listing corporate donors on their websites. Researchers examined the websites and 2012 online annual reports of organizations to which pharmaceutical companies reported giving gifts totaling \$25,000 or more in 2012. Findings include:

- Eighteen (31.0%) of the 58 *Professional Organizations* and *Research, Education, & Advocacy* organizations that received \$25,000 or more in 2012 failed to disclose the names of corporate donors on their websites at the time of this report, or in online 2012 annual reports.
- Of the 40 organizations that disclosed the names of corporate sponsors on their websites, 23 reported these names on a webpage only; nine provided the information only in their online 2012 annual reports; and eight provided it on both their websites and in their online 2012 annual reports.
- Three of the 17 organizations that disclosed corporate donors in their online 2012 annual reports did not disclose the names of all the companies that reported making gifts to those organizations in AccessRx disclosures.

These analyses demonstrate that pharmaceutical companies are giving large sums of gift dollars to professional organizations and organizations engaged in research, advocacy, and education. Not all of the organizations receiving these gifts are following the best practice of clearly disclosing all sources of corporate funding.

Researchers also analyzed gifts to individuals to investigate whether pharmaceutical companies might be targeting marketing spending toward individuals who serve in leadership positions at health-focused organizations or who are recognized as influential. This analysis focused on organizations that received pharmaceutical-company gifts totaling \$100,000 or more over the 2007 – 2012 time period; on individuals who received gifts totaling \$100,000 over the 2007 – 2012 time period; on individuals who received gifts totaling \$10,000 or more in 2012; and on individuals identified recently as leading physicians by one of two sources that rely on identification by physicians' peers. Findings include:

- One hundred thirty-one organizations received pharmaceutical-company gifts totaling \$100,000 or more over the 2007 2012 time period.
- Seven physicians in DC who served in leadership positions at organizations that received over \$100,000 from pharmaceutical companies between 2007 and 2012 also received large gift sums themselves. In 2012 alone, these seven physicians received a total of \$467,668; their 2012 gift totals had an average of \$66,809 each and a median of \$56,291.
- Of 71 individuals in DC who received \$100,000 or more from 2007-2012, 10 were hematologists-oncologists, who received a total of \$3.1 million. The group also included six cardiologists, six psychiatrists, and six internal-medicine physicians.
- One hundred sixty-four individuals received gifts totaling \$10,000 or more from pharmaceutical companies in 2012.
- Among physicians in DC identified as influential by their peers in one or more sources, 70 received over \$10,000 from pharmaceutical companies in 2012, for a collective total of \$4.5 million. These individuals had an average gift total of \$64,630, significantly more than the average gift total of \$41,498 for 94 non-listed individuals who received \$10,000 or more in 2012.

These findings suggest that pharmaceutical companies are not specifically targeting DC healthcare providers who hold leadership positions with organizations that are already receiving large sums from pharmaceutical companies. In addition, pharmaceutical companies are giving large gifts to many physicians identified as influential by their peers; while they are by no means confining their gift spending to these influential physicians, companies appear to be giving them larger or more frequent gifts.

Heart disease and cancer are the top two causes of death among District residents, and cardiology and hematology/oncology are among the specialties with the most physicians receiving very high gift amounts. Drugs that may be marketed heavily to cardiologists include Crestor, Lipitor, Zetia, and Vytorin for lowering cholesterol, and Diovan, Benicar, Micardis, Avapro, and Blopress (all angiotensin receptor blockers for treating hypertension). Drugs heavily marketed to oncologists include Rituxan, Herceptin, Avastin, Gleevec, and Revlimid.

Recommendations based on these findings include expanding provider education and outreach around best prescribing practices; using AccessRx data to complement federal data on gifts to physicians and hospitals; strengthening the AccessRx Act to improve transparency and align with federal requirements; and providing for greater scrutiny of AccessRx submissions.

II. Healthcare and Pharmaceutical Marketing in the District of Columbia

Prescription drugs play an important role the District's ongoing efforts to ensure access to high-quality healthcare for all residents. Recent assessments have made clear that disparities by race and geography persist, even as the District has made strides to improve public health.

Health Outcomes and Healthcare Access in the District

In 2010, the life expectancy of the average District resident was 77.5 years. The District has the second-highest rate of health-insurance coverage in the U.S., second only to Massachusetts; 93% of adults and 96% of children living in the District are insured (District of Columbia Department of Health (DCDOH), 2013). Between 2006 and 2010, the infant mortality rate dropped from 11.3 per 1,000 live births to 8.0. This is still higher than the national average of 6.1, but marks a substantial improvement (DCDOH, 2014).

Heart disease and cancer accounted for half of all deaths in the District over the last five years, and are the leading causes of death regardless of sex and race (DCDOH, 2014). Disparities by race and ward persist, however:

- Life expectancy is longest in Wards 2 and 3 (85.9 and 85.1 years, respectively), and substantially shorter in Wards 7 and 8 (73.2 and 70.2 years, respectively) (DCDOH, 2014).
- Between 2006 and 2010, deaths due to heart disease decreased in all wards except Wards 6, 7, and 8. Wards 7 and 8 were the only wards where diabetes death rates increased, while declining in other wards (DCDOH, 2014).
- The District met its Healthy People 2010 goal of reducing mortality rates from several forms of cancer by 10% or more, but African-Americans still have higher cancer incidence and mortality rates than the population as a whole (DCDOH, 2014).

A 2013 Community Health Needs Assessment conducted for the DC Healthy Communities Collaborative by RAND Health identified six priority areas for improving health and healthcare in the city: asthma, obesity, mental health, sexual health, stress related disorders (e.g., headache, back pain), and general access to health services. The authors noted that healthcare services are not evenly distributed by wards, and Wards 7 and 8 in particular lack specialty services such as oncology and pain management (Chandra, Blanchard & Ruder, 2013).

The District has a high ratio of active physicians to residents (871 per 100,000 population) and active nurses to residents (1,483 per 100,000 population). It is home to over 200 healthcare facilities. Nonetheless, it has 17 areas designated by the federal government as Health Professional Shortage

Areas (HPSAs) or Medically Underserved Areas/Populations. The District still lacks sufficient providers to serve low-income and homeless populations (DCDOH, 2013).

Pharmaceutical Use and Spending in the District

Prescription drugs are an important element of healthcare for District residents. Nationally, nearly one-half of adults took at least one prescription drug, with a shift towards use for chronic conditions (NCHS, 2013). When prescribed appropriately, drugs can improve outcomes for people suffering from many health conditions, including diabetes, heart disease, HIV infection, and depression.

U.S. spending on prescription drugs totaled \$263.3 billion in 2012. Of that, 17.8% (\$46.8 billion) was covered by consumer out-of-pocket spending; 44.4% by private insurance (\$117.0 billion); 25.9% by Medicare (\$68.2 billion); and 7.5% by Medicaid (\$19.6 billion) (Centers for Medicare and Medicaid Services (CMS), n.d.). Although U.S. prescription-drug spending growth has slowed in recent years, this spending is projected to continue to increase over the next decade. Among individuals with prescription-drug expenses in 2011, the median expense was \$275 and the mean \$1,522. Low-income individuals with prescription-drug expenses spent a median of \$269 and a mean of \$1,492 (Agency for Healthcare Research and Quality, 2014).

In 2009, the most recent year for which data are available, the District's Medicaid program spent \$87.4 million on pharmaceuticals. Drug classes accounting for the largest expenditures were antivirals (\$26.0 million), antipsychotics (\$16.6 million), and antiasthmatics (\$4.3 million) (CMS, 2014a).

For payers and for individuals, high prescription-drug expenditures may crowd out spending on other important health priorities. In the Medicaid program, for instance, high drug spending could exert downward pressure on provider reimbursement rates. Higher Medicaid payment rates are correlated with greater physician acceptance of new Medicaid patients (Decker, 2012). In 2012, the District's Medicaid-to-Medicare fee ratio for physicians was 80%, far higher than the national average Medicaid-to-Medicare fee ratio of 66% (The Henry J. Kaiser Family Foundation, n.d.). In 2011, 75% of the District's office-based physician practices would accept new Medicaid patients, compared to 69% nationwide (Decker, 2012).

Pharmaceutical Marketing in the District

In 2012, 147 pharmaceutical manufacturers and labelers spent a reported total of \$97.5 million marketing their products in the District. Of this, \$61.5 million were expenses associated with employees and contractors (63.1%), \$30.5 million were gift expenses (31.3%), and \$5.4 million was spent for advertising (5.6%). Hospitals, medical societies, and other non-individual recipients received a total of \$19.6 million in gifts from these companies; gifts to individuals totaled \$10.8 million. Physicians received 79.8% of all gifts to individuals, for a total gift value of \$9.9 million (32.3% of the value of all reported gifts) (George Washington University, 2013).

Pharmaceutical marketing may influence organizational treatment guidelines and provider decisions about which drugs to prescribe. Physicians and other prescribers often have limited time to learn about pharmaceuticals and rely on information from pharmaceutical representatives and industry-funded educational materials. Industry-funded information may downplay adverse effects or exaggerate the superiority of a company's products. Marketing efforts may also encourage off-label use of drugs without an adequate evidence base to support such use. In addition to industry education, pharmaceutical representatives provide free food to physicians and their staffs; distribute free samples; compensate providers for travel and lodging expenses; and hire providers as consultants and speakers (Borkowski et al, 2013).

The Role of Organizations

The District of Columbia is home to many of the nation's leading healthcare organizations. While DC-based clinical organizations provide care to local residents, national organizations headquartered here influence healthcare services nationwide. Academic and teaching hospitals train physicians and researchers who ultimately work in different parts of the country. Specialty organizations create guidelines that shape providers' practices and influence payers' decisions about reimbursement. Organizations focused on specific disease conditions fund research, educate physicians and patients alike about treatment options, and may promote specific policies that affect reimbursement. Some organizations provide continuing medical education (CME), which can inform providers of new interventions. Through these and other avenues, DC-based organizations can influence healthcare services provided locally and nationwide.

Organizations rely on funding from a variety of sources, including the pharmaceutical industry. While pharmaceutical-company gifts can help support an organization's mission, they also create the potential for conflicts of interest among healthcare organizations. An important first step to managing conflicts of interest in organizations is disclosure of pharmaceutical-company gifts, which includes listing corporate donors on organizational websites and in online annual reports.

Conflicts of interest can exist at the individual or organizational level (Lo & Field, 2009). Organizations funded by pharmaceutical companies include medical societies and other professional organizations, patient advocacy groups, and hospitals and other clinical practice settings. Professional organizations are respected bodies that may generate clinical practice guidelines, influence consumers and legislators, and sway public opinion. Concerns have been raised over relationships between professional medical organizations and industry, and a proposal has been made to limit those relationships (Rothman, et al., 2009).

Psychiatry has been of particular concern. A study of 20 authors of clinical practice guidelines on the treatment of schizophrenia, bipolar disorder, and major depressive disorder found that 18 out of 20 (90.0%) had financial relationships with companies that manufactured drugs considered or included in the guidelines. Financial interests included research funding (77.7%), consultancies (72.2%),

membership on a corporate board (44.4%), and collaboration in industry-funded studies (44.4%). None of these financial associations were disclosed (Cosgrove et al, 2009).

Cosgrove and colleagues found that fewer than half of the recommendations in the American Psychiatric Association guidelines for major depressive disorder met criteria for high quality, and one-fifth (19.7%) of the references were not congruent with the recommendations. Every one of the guidelines' authors had relationships with industry (the number of relationships ranged from 9 to 33, with a mean of 20.5) (Cosgrove et al, 2013).

Two-thirds (69%) of the task force that updated the most recent DSM-5 (Diagnostic and Statistical Manual, the standard for diagnosing psychiatric disorders) reported having ties to the pharmaceutical industry. That included 67% of the members of the panel for Mood Disorders, 83% of the panel for Psychotic Disorders, and 100% of the panel on Sleep/Wake Disorders having financial ties to drug manufacturers that make medications used to treat these disorders, or to vendors to the pharmaceutical industry (Cosgrove & Krimsky, 2012).

In a report about industry funding of nonprofits, Michael Jacobson, head of the Center for Science in the Public Interest, notes that "industry appears either to influence an organization's positions or to limit an organization's freedom to speak out on matters of interest to the funders" (Jacobson, 2005). Nonprofit groups also include patient advocacy organizations, which raise public awareness of a particular disease, including treatment options. These nonprofits may promote disease research, and can play significant roles in public education and advocacy for legislation and regulation related to specific diseases. Some, including the American Cancer Society (ACS), also fund research. In 2011, ACS revenues were nearly \$1 billion (Rose, 2013).

Many advocacy groups do not adequately acknowledge their corporate funders. One study examined public disclosure data from a single company, Eli Lilly, and found that only one-quarter of health advocacy organizations that received Eli Lilly grants acknowledged Eli Lilly's contributions on their websites. Only 10% acknowledged Eli Lilly as an event sponsor, and none disclosed the exact amount of an Eli Lilly grant (Rothman, et al., 2011). Another international study examined websites for ten major health conditions (cancer, heart disease, diabetes, asthma, cystic fibrosis, epilepsy, depression, Parkinson's disease, osteoporosis, and rheumatoid arthritis) in the U.S., U.K., Australia, Canada, and South Africa. Researchers concluded that the extent of relationships with industry was inadequately disclosed, and policies varied widely (Ball, 2006).

It is rare for a health advocacy group not to receive funding from industry. A 2006 survey of U.S. patient advocacy organizations with annual revenues of more than \$100,000 by New Scientist found that only two of 20 randomly selected organizations refused to take money from pharmaceutical companies; the two groups were the National Women's Health Network and Breast Cancer Action. For instance, three-quarters of the Depression and Bipolar Support Alliance's revenue for 2005 came from 15 major donors, 12 of which were drug or device companies. The Restless Legs Syndrome (RLS) Foundation received approximately half of its \$1.4 million revenues from two companies: \$450,000 from GlaxoSmithKline

(GSK) and almost \$178,000 from Boehringer Ingelheim, both of which manufacture drugs used to treat RLS (Marshall & Aldhous, 2006). Between 2006 and 2008, The National Alliance on Mental Illness (NAMI) received over \$23 million – three-quarters of its budget – from drug companies. NAMI promoted medications from its sponsors and opposed FDA black-box warnings on serotonin reuptake inhibitor antidepressants that increased the risk of suicide in adolescents (Rose, 2013). It has been argued that industry influence corrupts the evidence base in diagnostic and practice guidelines and has compromised the informed consent process (Cosgrove & Wheeler, 2013).

Additionally, in recent years, advocates for healthcare transparency have directed public attention toward the potential for pharmaceutical-industry funding to influence CME. The pharmaceutical industry provides funding for nearly one-third of all CME events nationally, creating the potential for influence and bias in educational materials (Pew, 2013). While the Accreditation Council for Continuing Medical Education serves as the primary body for approval of CME, other organizations may serve as accreditors in their fields of expertise. Pharmaceutical companies provide grants to organizations for providing CME and to organizations that approve education, which may influence educational content delivered to healthcare providers (United States Senate Committee on Finance, 2007). A recent report found that organizations that receive funding from pharmaceutical companies have an increased likelihood of endorsing industry positions (Pew, 2013).

Although pharmaceutical-industry support of CME has decreased in recent years (Iskowitz, 2012), it is difficult to interpret these changes in light of the Accreditation Council for Continuing Medical Education (ACCME) change in standard of Commercial Support Reporting: Starting in 2011, CME providers are no longer required to include estimates of in-kind support; they are required only to report monetary commercial support (ACCME, 2014). As Figure 1 shows, much of drop in pharmaceutical-industry-funded-CME over the past decade has been due to reduced spending on Medical Education and Communication Companies (MECCs).

Figure 1

(Source: Pharma Marketing Blog, 2014)

The continued influence of the pharmaceutical industry on physicians and organizations may result in prescription of drugs that are less effective, less safe, or unnecessary, and this could compromise the health of District residents (Borkowski et al, 2013).

Federal and District Reporting Requirements

The Patient Protection and Affordable Care Act, signed into federal law in 2010, requires pharmaceutical companies to report any "transfer of value" worth \$10 or more to a physician or teaching hospital to the Secretary of Health and Human Services (HHS). The "Open Payments" system administered by the Centers for Medicare and Medicaid Services (CMS) began collecting this information in 2014 (see http://go.cms.gov/IUZDTj). By March 31, 2014, pharmaceutical companies were required to submit details about payments made to physicians and teaching hospitals from August 1, 2013 through December 31, 2013. Beginning in 2015, submissions must cover the entirety of the preceding calendar year. CMS will make the Open Payments data publicly available starting on September 30, 2014. Each year thereafter, the previous year's data will be publicly accessible by June 30.

In July 2014, CMS proposed to update the Open Payments reporting rules by eliminating the exclusion for reporting transfers of value to physicians for speaking at accredited CME events. Under current rules, payments to physicians who speak at CME events do not need to be reported if three conditions are met:

- The event is accredited by one of five organizations (Accreditation Council for Continuing Medical Education; the American Academy of Family Physicians; the American Dental Association's Continuing Education Recognition Program; the American Medical Association; or the American Osteopathic Association);
- 2. The pharmaceutical company does not select the speaker; and
- 3. The speaker does not receive payment directly from the pharmaceutical company.

CMS proposed to eliminate this exclusion after hearing from stakeholders who requested that the exclusion be extended to other accrediting organizations, and from stakeholders who recommended the exclusion's removal to allow for consistent reporting and transparency. However, CMS notes that another exclusion in the rule, for indirect payments when a manufacturer is unaware of the identity of the payment recipient, would apply to many CME situations. The July 2014 proposal states that when a manufacturer "provides funding to a continuing education provider, but does not either select or pay the covered recipient speaker directly, or provide the continuing education provider with a distinct, identifiable set of covered recipients to be considered as speakers for the continuing education program, CMS will consider those payments to be excluded from reporting." (CMS, 2014b) If pharmaceutical companies and providers follow these requirements for companies not to specify recipients, payments to physicians for CME presentations are unlikely to be reported in the Open Payments system even if this proposed change is finalized.

Several differences between the federal and District laws are noteworthy. The federal law has a lower dollar-value threshold for reporting (gifts of \$10 or more must be reported, as opposed to a \$25 cutoff in the District), and it requires manufacturers of biologics and devices, as well as pharmaceutical manufacturers, to file reports. The public availability of the collected federal data will be a major step toward transparency.

The District, however, collects some information not included in the Open Payments system. For example, the federal law does not require the reporting of expenses for advertising or for pharmaceutical sales representatives and other employees and contractors engaged in advertising and marketing, both required by DC law. The federal law, unlike Access Rx, also does not reveal payments and gifts provided to nurses, pharmacists, healthcare organizations, and clinical sites that are not teaching hospitals. Given that many healthcare-focused organizations are based in the District, the AccessRx law has allowed for a unique and valuable exploration of the gifts these organizations receive.

III. Gifts to Organizations

Organization Categories

Several large pharmaceutical companies, including Eli Lilly, GlaxoSmithKline, Merck, and Pfizer, disclose payments to individuals and organizations on their websites. In 2012, payments to DC-based organizations included more than \$1 million to the American Diabetes Association and the American Pharmacists Association from Eli Lilly, GlaxoSmithKline, Merck and Pfizer; \$629,000 to the American College of Cardiology Association Foundation from Merck and Pfizer; and \$259,760 to the American Cancer Society - Cancer Action Network from GlaxoSmithKline, Merck, and Pfizer (GlaxoSmithKline, 2014; Lilly Grant Office, n.d.; Merck, 2014; Pfizer, n.d.).

The AccessRx Act does not allow for the public disclosure of the names of groups or individuals receiving gifts from pharmaceutical companies. To characterize gift patterns without revealing identities, researchers used the AccessRx database to identify organizations (non-individual recipients) that received gifts totaling \$50,000 or more over the 2007-2012 period. They then divided these recipients into categories based on the organizations' structures and missions, using knowledge of local institutions and descriptions from organizations' websites. The categories are: Research, Education, & Advocacy Organizations; Professional Organizations; Academic Organizations & Teaching Hospitals; Clinical Organizations; and Other.

& Advocacy Organizations

Research, Education, Fund research, educate, or advocate about specific diseases or patient populations.

Professional Organizations

Healthcare providers with a shared specialty or focus.

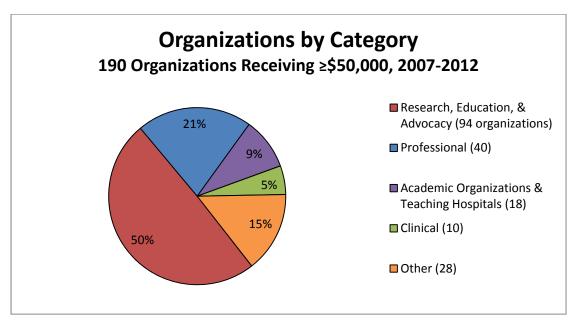
Academic Organizations Universities or academic institutions; Includes & Teaching Hospitals university-based hospitals.

Clinical Organizations

Private practices, non-university-based hospitals, and

Organizations not meeting above criteria; Includes medical education and communication companies. One hundred ninety organizations received gifts totaling \$50,000 or more between 2007 and 2012, and the majority met the definition of *Research, Education & Advocacy Organizations* (94 organizations, or 49.5% of those meeting the criteria) or *Professional Organizations* (40, 21.1%). Figure 2 shows the breakdown by category.

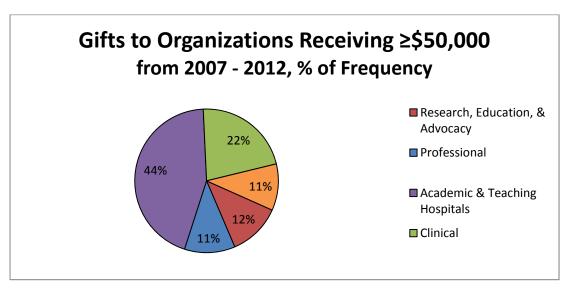
Figure 2



Gifts by Organization Category

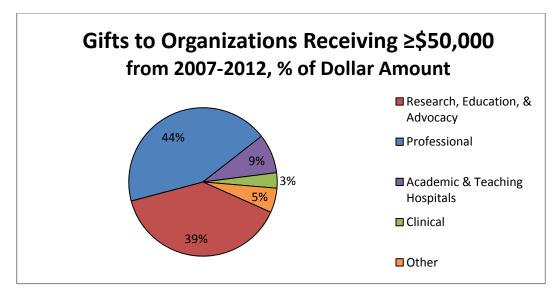
Academic Organizations & Teaching Hospitals received 44.3% of all gifts from pharmaceutical companies, followed by Clinical Organizations (21.9%), Research, Education, & Advocacy Organizations (11.9%), Professional Organizations (11.4%), and Other (10.5%).

Figure 3



The picture is somewhat different when considering the value of the gifts given, rather than the number of gifts. *Professional Organizations* (43.5%) and *Research, Education & Advocacy Organizations* (39.3%) together received the vast majority – 82.8% – of the dollar value of pharmaceutical-company gifts during the six-year period.

Figure 4



Overall Gifts from 2007 to 2012

Total annual gifts to the 190 organizations that received more than \$50,000 over the time period from 2007 – 2012 from pharmaceutical companies declined between 2007 and 2011. These organizations collectively received \$18.5 million in 2007; then, the total figure dropped for each of the next four years, with a low of \$9.1 million in 2011. This trend reversed dramatically in 2012, with organizations receiving a total of \$18.9 million. This represents a 108.5% increase from 2011, and a return to 2007 levels.

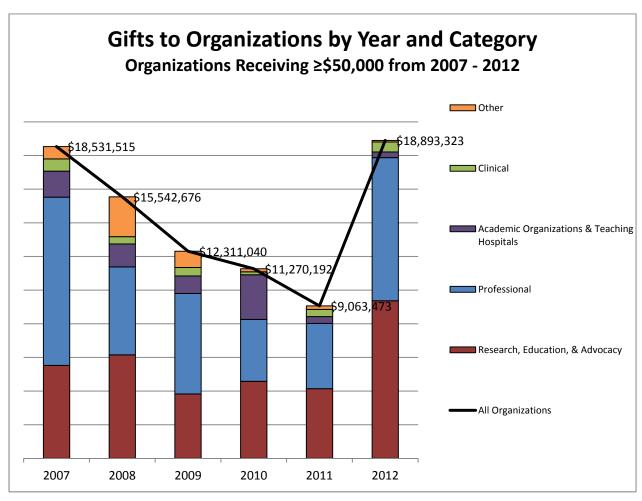


Figure 5

Although the pattern of pharmaceutical companies devoting the majority of their gift dollars to *Professional Organizations* and *Research, Education, & Advocacy Organizations* has been consistent, the effect became even more pronounced between 2011 and 2012, with gifts to these organizations doubling, while gifts to other organizations fell:

• Research, Education, & Advocacy Organizations received \$9.4 million in 2012, a 126.0% increase from \$4.1 million received in 2011.

- Professional Organizations received \$8.5 million in 2012, a 119.3% increase from \$3.9 million received in 2011.
- Academic Organizations & Teaching Hospitals received \$336,564 in 2012, a 15.9% decrease from \$400,282 received in 2011 and a 78.2% decrease from \$1.5 million received in 2007.
- *Clinical Organizations* received \$595,241 in 2012, a 39.2% increase from \$427,603 received in 2011.

Table 1: Gift Totals to Organizations Receiving ≥\$50,000 from 2007-2012, by Organization Category

							2007-2012
	2007	2008	2009	2010	2011	2012	Total
All Organizations	\$18,531,515	\$15,542,676	\$12,311,040	\$11,270,192	\$9,063,473	\$18,893,323	\$85,612,219
Research, Education,							
& Advocacy	\$5,527,781	\$6,154,645	\$3,827,077	\$4,580,362	\$4,145,474	\$9,368,101	\$33,603,440
Professional	\$9,995,580	\$5,226,075	\$5,974,089	\$3,680,276	\$3,878,901	\$8,505,882	\$37,260,803
Academic							
Organizations &							
Teaching Hospitals	\$1,545,252	\$1,362,337	\$1,038,794	\$2,650,516	\$400,282	\$336,564	\$7,333,744
Clinical	\$728,438	\$433,137	\$503,801	\$176,054	\$427,603	\$595,241	\$2,864,274
Other	\$734,464	\$2,366,482	\$967,279	\$182,984	\$211,212	\$87,535	\$4,549,957

Average and Median Gift Amount

To further identify patterns in pharmaceutical-company gifts to these organizations, average and median gifts were calculated for individual years. The highest average and median gift amounts were in 2007 with an average gift of \$210,585 and median gift of \$86,217. Researchers also calculated the average and median amount of all gifts to organizations in each category. In most, but not all, categories, the average and median gift values were highest in 2007 and dropped in subsequent years before increasing between 2011 and 2012.

- Research, Education, & Advocacy Organizations received an annual average total of \$187,362 in 2012, a 94.3% increase from the 2011 average of \$96,406. The median gift total was \$50,000 in 2011 and \$74,009 in 2012.
- Professional Organizations received an annual average total of \$340,235 in 2012, a 101.7% increase from the 2011 average of \$168,648. The median gift total was \$51,000 in 2011 and \$80,441 in 2012.

- Academic Organizations & Teaching Hospitals received an annual average total of \$25,890 in 2012, a 9.5% decrease from the 2011 average of \$28,592. The median gift was \$26,584 in 2010, \$8,773 in 2011, and \$7,040 in 2012.
- Clinical Organizations received an annual average total of \$85,034 in 2012, a 19.3% increase from the 2011 average of \$71,267. The median gift total was \$10,472 in 2011 and \$100,000 in 2012.

Table 2: Average & Median Gift Totals to Organizations Receiving ≥\$50,000 from 2007-2012, by Organization Category

		2007	2008	2009	2010	2011	2012
All Organizations	Average	\$210,585	\$140,024	\$119,525	\$122,502	\$102,994	\$188,933
All Organizations	Median	\$86,217	\$60,200	\$72,450	\$30,000	\$48,838	\$58,025
Research, Education,	Average	\$141,738	\$133,797	\$85,046	\$101,786	\$96,406	\$187,362
& Advocacy	Median	\$85,000	\$55,000	\$57,700	\$40,000	\$50,000	\$74,009
Professional	Average	\$454,345	\$201,003	\$238,964	\$167,285	\$168,648	\$340,235
Professional	Median	\$185,550	\$68,750	\$143,489	\$49,700	\$51,000	\$80,441
Academic	Average	\$96,578	\$90,822	\$74,200	\$203,886	\$28,592	\$25,890
Organizations &							
Teaching Hospitals	Median	\$77,584	\$38,466	\$49,166	\$26,584	\$8,773	\$7,040
Clinical	Average	\$145,688	\$61,877	\$71,972	\$44,014	\$71,267	\$85,034
Cillical	Median	\$25,523	\$29,632	\$19,983	\$12,910	\$10,472	\$100,000
Other	Average	\$122,411	\$139,205	\$80,607	\$22,873	\$105,606	\$17,507
Other	Median	\$85,406	\$87,196	\$49,663	\$16,429	\$105,606	\$250

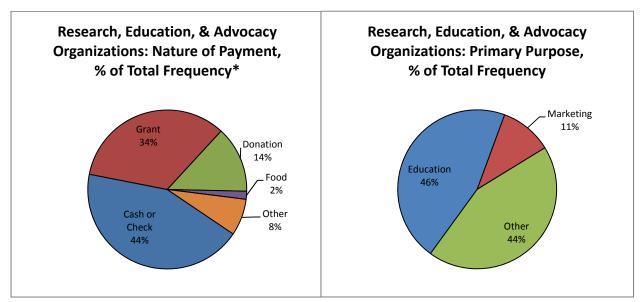
Payment Type and Primary Purpose

When submitting annual reports of gifts to the District, pharmaceutical companies must indicate the *Nature of Payment* and *Primary Purpose* of each gift. In analyzing the nature of payments to the organizations that received \$50,000 or more from pharmaceutical companies between 2007 and 2012, five *Nature of Payment* categories were used: *Cash or Check, Grant, Donation, Food,* and *Other*. Three *Primary Purpose* categories were used: *Education, Marketing*, and *Other*.

Research, Education, & Advocacy Organizations received the majority of gifts in the form of Cash or Check (43.6%), Grant (33.8%), and Donation (13.5%) – all of which represent monetary gifts. This was followed by gifts in the form of Food (1.6%) and Other (7.5%). In terms of dollar amount, Cash or Check gifts totaled \$9.9 million, Grants totaled \$18.1 million, and Donations totaled \$3.3 million, for a combined value of \$31.3 million in monetary gifts.

The most frequent *Primary Purpose* of gifts to *Research, Education, & Advocacy Organizations* was *Education* (45.6%), followed by *Marketing* (10.6%) and *Other* (43.8%).

Figure 6
Research, Education, & Advocacy Organizations: 2007-2012 Gift Frequency
Nature of Payment (Left) and Primary Purpose (Right)

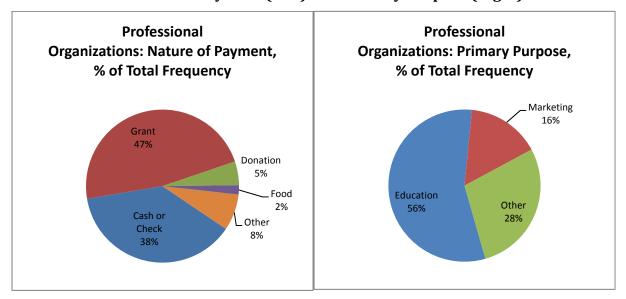


*Note: Percentages may not total 100% due to rounding.

Professional Organizations received the majority of gifts in the form of a *Grant* (47.4%), *Cash or Check* (37.9%), and *Donation* (5.0%) – again, representing monetary gifts. The remaining gifts came in the form of *Food* (1.9%) and *Other* (7.7%). In terms of dollar amount, *Grants* totaled \$18.5 million, *Cash or Check* gifts totaled \$12.4 million, and *Donations* totaled \$1.0 million, for a combined value of \$32.0 million in monetary gifts.

The most frequent *Primary Purpose* of gifts to *Professional Organizations* was *Education* (56.0%), followed by *Marketing* (15.6%) and *Other* (28.4%).

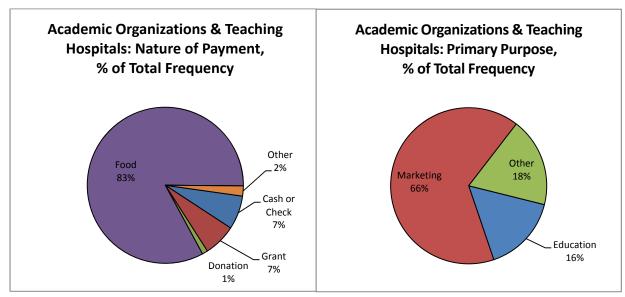
Figure 7
Professional Organizations: 2007-2012 Gift Frequency
Nature of Payment (Left) and Primary Purpose (Right)



Academic Organizations & Teaching Hospitals received most gifts in the form of Food (83.0%), followed by Cash or Check (7.0%), Grant (6.7%), Donation (1.2%), and Other (2.1%). In terms of dollar amount, however, Food gifts totaled less than \$650,000, while gifts classified as monetary (Cash or Check, Grant, or Donation) totaled \$6.5 million.

The most frequent *Primary Purpose* of gifts to *Academic Organizations & Teaching Hospitals* was *Marketing* (65.7%), followed by *Education* (15.9%) and *Other* (18.4%).

Figure 8
Academic Organizations & Teaching Hospitals: 2007-2012 Gift Frequency
Nature of Payment (Left) and Primary Purpose (Right)

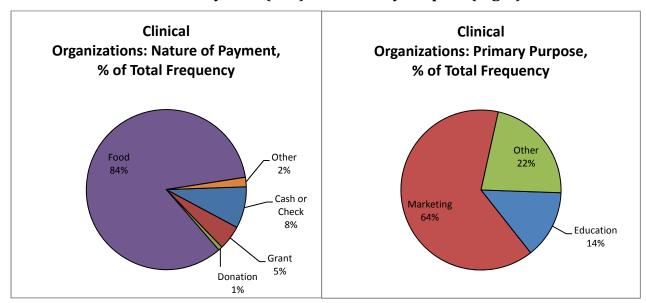


25

Clinical Organizations received most gifts in the form of Food (83.9%), followed by Cash or Check (8.4%), Grant (4.9%), Donation (0.8%), and Other (1.9%). In terms of dollar amount, however, Food gifts totaled slightly more than \$300,000, while gifts classified as Cash or Check, Grant, or Donation totaled \$2.5 million.

The most frequent *Primary Purpose* of gifts to *Clinical Organizations* was *Marketing* (64.1%), followed by *Education* (13.8%) and *Other* (22.1%).

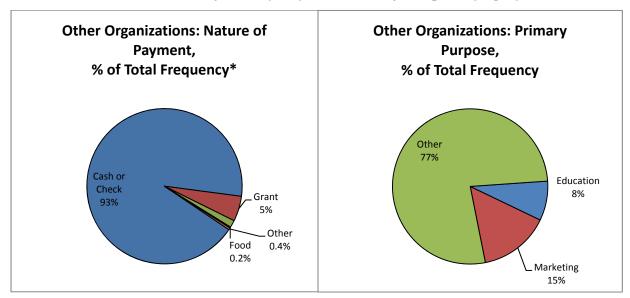
Figure 9
Clinical Organizations: 2007-2012 Gift Frequency
Nature of Payment (Left) and Primary Purpose (Right)



Other Organizations received the majority of gifts in the form of monetary payments, including Cash or Check (92.6%) and Grant (5.2%). In terms of dollar amount, Cash or Check gifts totaled \$3.4 million and Grants totaled \$930,000.

The most frequent *Primary Purpose* of gifts to *Other Organizations* was *Marketing* (14.7%), *Education* (8.2%), and *Other* (77.0%). *Other* gifts were further characterized with terms including "Philanthropic," "Overhead," and "Consulting."

Figure 10
Other Organizations: 2007-2012 Gift Frequency
Nature of Payment (Left) and Primary Purpose (Right)



*Note: Percentages may not total 100% due to rounding.

When pharmaceutical companies give gifts to District of Columbia *Research, Education, & Advocacy Organizations* and *Professional Organizations*, they are generally in form of a monetary payment (cash, checks, grants, or donations). Drug-company gifts to the other types of organizations – *Academic Organizations & Teaching Hospitals* and *Clinical Organizations* – most often take the form of food.

IV. Organization Gift Disclosures

Organization Disclosures

Research, Education, & Advocacy Organizations and Professional Organizations are the organization types most likely to influence reimbursement policies and medical practices in ways that affect large portions of the population (i.e., beyond patients at a specific facility or practice). Policymakers, physicians, and members of the public who seek guidance from these organizations should be able to discern potential conflicts of interest easily.

To investigate whether these organizations make information about their pharmaceutical-company gifts readily available, researchers examined the websites of *Research, Education, & Advocacy Organizations* and *Professional Organizations* that received more than \$25,000 in 2012 for listings of corporate donors, either on webpages or in online 2012 annual reports. When pharmaceutical companies specified that gifts went to a local chapter of a national organization, researchers sought the donor list and annual report from the local chapter, not the national organization. Organizations were considered not to be disclosing this information if researchers could find no listings of corporate supporters; if online annual reports were available but did not list corporate donors; if links to relevant pages (from their websites or from search results) were broken or resulted in "not found" messages; or if they listed corporate advisory boards, panels, or councils without specifying whether the member companies provided donations.

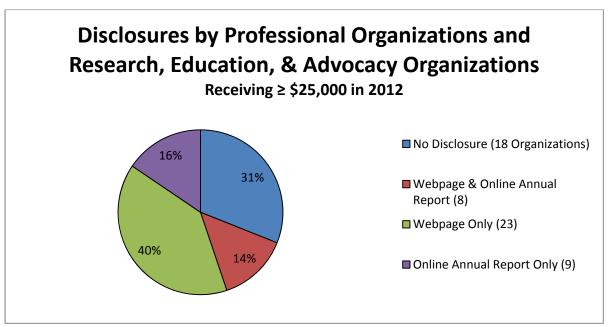
Of the 58 Research, Education, & Advocacy Organizations and Professional Organizations that received \$25,000 or more in 2012, no disclosure of corporate donors was found on 18 (31.0%) of the organizations' websites or in online annual reports. The remaining 40 (69.0%) listed corporate sponsors, donors, or partners on a webpage or in their online 2012 annual reports in publicly accessible locations.

Of the 40 organizations providing accessible information on corporate donors, the locations were as follows:

- Eight (20.0% of the 40) provided the information in both webpages and 2012 online annual reports;
- 23 (57.5%) provided it only on a webpage; and
- Nine (22.5%) provided it only in a 2012 online annual report.

Of the 40 organizations that disclosed the names of corporate donors, nine (22.5% of those disclosing) specified the monetary ranges into which corporate donations fell (e.g., more than \$1 million, \$500,000 - \$999,999, etc.). No website listed exact donation figures.

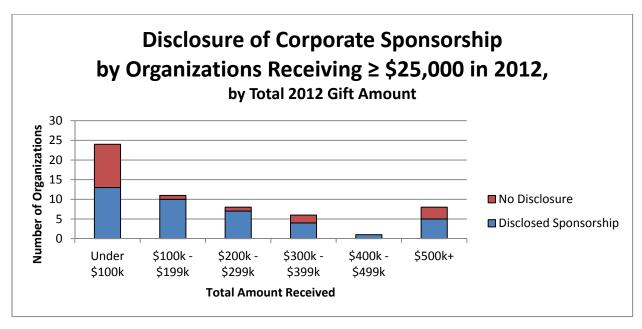
Figure 11



*Note: Percentages may not total 100% due to rounding.

Organizations were reviewed based on the amount received in 2012 and whether or not organizations disclosed sponsorship. Fifteen organizations received over \$300,000, and ten of them (66.7%) disclosed corporate sponsorship. In addition, 43 organizations received between \$25,000 and \$300,000, and 30 of them (69.8%) disclosed corporate sponsorship.

Figure 12



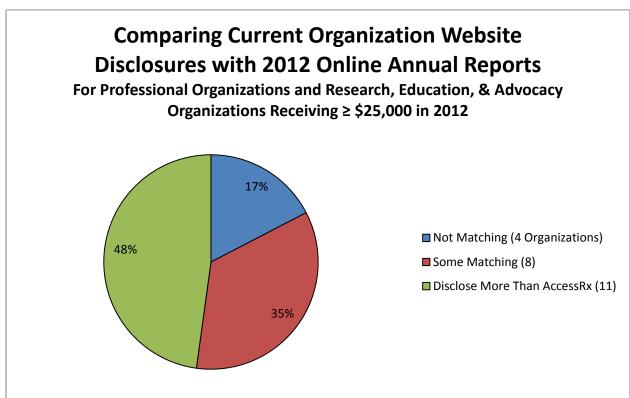
Gift Disclosures and Reported Gifts

Researchers also compared disclosures from companies' online annual reports and websites with information from the AccessRx database about each organization's gifts from pharmaceutical companies. Because the websites were examined in 2014 and the most recent gift information is from 2012, it is possible that some organizations acknowledged the 2012 gifts on their websites in 2012 and/or 2013 but had updated their online donor listings in 2014 to reflect more recent donations.

Donor lists from the 23 organizations that made disclosures on their websites only were compared to AccessRx data. As noted, the most recent 2012 AccessRx information was compared to information on organization websites at the time of this report, so discrepancies may be due to the time lag. The analysis found:

- Four (17.4% of the 23) organizations did not list companies for which funding was reported;
- Eight (34.8%) organizations listed only some companies for which funding was reported;
- Eleven (47.8%) organizations had additional companies listed for which funding was not reported in the AccessRx database; and
- No organization's donor list was an exact match with 2012 AccessRx reports.

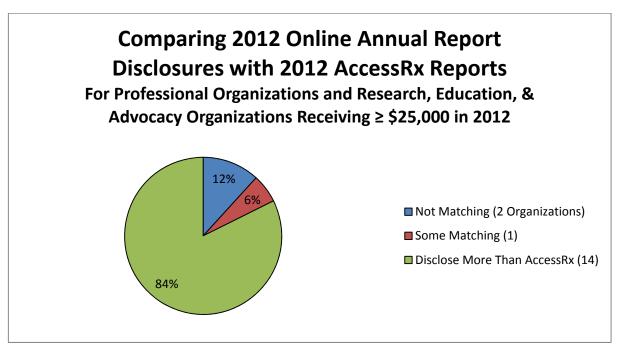
Figure 13



Donor lists from the 17 organizations that made disclosures in online 2012 annual reports were compared to AccessRx data; this included organizations that only listed donors in an annual report as well as those that listed this information in an online annual report and on their websites. Because annual reports contain information specific to the year for which they are issued, researchers expected a close match between AccessRx data and annual-report donor lists. The analysis found:

- Two (11.8% of the 17) organizations did not list companies for which funding was reported;
- One (5.9%) organization listed only some companies for which funding was reported;
- Fourteen (82.4%) organizations had additional companies listed for which funding was not reported in the AccessRx database; and
- No organization's donor list was an exact match with 2012 AccessRx reports.

Figure 14



The 17 organizations that reported corporate sponsorship in annual reports were reviewed based on the amount received in 2012 and whether or not company AccessRx disclosures matched what the organizations reported. Five organizations received over \$300,000, and two of them failed to list all (or any) of the pharmaceutical companies with 2012 gifts reported to these organizations in the AccessRx database. In comparison, 12 organizations received between \$25,000 and \$300,000, and one of these companies failed to list all of the companies with 2012 gifts in the AccessRx database.

Figure 15

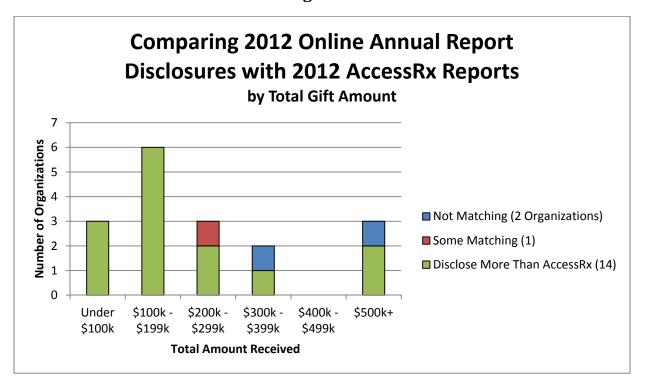


Table 3: Comparing 2012 Online Annual Report Disclosure with 2012 AccessRx Reports, by Total Gift Amount

Total Amount Organization Received	Disclosed Sponsorship in Online Annual Report	Some Matching	Not Matching	Online Annual Report Discloses More Than AccessRx Reports
Under \$100k	3	0	0	3
\$100k - \$199k	6	0	0	6
\$200k - \$299k	3	1	0	2
\$300k - \$399k	2	0	1	1
\$400k - \$499k	0	0	0	0
\$500k+	3	0	1	2

V. Gifts to Individuals and Organization Leadership

Giving gifts directly to organizations is not the only way pharmaceutical companies can potentially influence organizations' activities and positions. Gifts to individuals who serve in these organizations' leadership also have the potential to influence organizational decisions on treatment guidelines, advocacy efforts, and other activities that can shape prescribing patterns.

To explore the extent to which pharmaceutical companies may be targeting gifts toward individuals serving in organization leadership positions, researchers began by identifying two pools of gift recipients: individuals in DC who received \$10,000 or more from pharmaceutical companies in 2012, and organizations that received a total of \$100,000 or more over the 2007-2012 time period. Researchers compared the list of individuals receiving large gift sums to the leadership lists of organizations receiving large gift sums; after identifying individuals who appeared on both lists, researchers characterized the gifts these individuals received. Then, researchers explored whether individuals in DC receiving large sums might also serve in leadership positions with organizations that are not among those receiving the largest sums from pharmaceutical companies. For feasibility purposes, this last additional analysis was limited to individuals who received \$50,000 or more from pharmaceutical companies in 2012.

High-Gift Organizations and High-Gift Individuals

Researchers compiled lists of board and committee members for 131 organizations that received gifts totaling \$100,000 or more over the 2007-2012 time period. Most organization websites list names, affiliations, and locations of individuals serving in leadership positions. All available listings of leadership boards and subcommittees were obtained from organization websites for analysis. These names were linked with the organization name and compared to a list of individual gift recipients in the AccessRx database for 2012, the most recent year for which gift data are available.

Many physician-leaders of organizations that receive funding from pharmaceutical companies have also received individual gifts. Overlap between organizations that receive funding and individuals who serve in leadership roles may indicate areas of healthcare that are a focus of marketing by the pharmaceutical industry.

One hundred sixty-four individuals in DC received over \$10,000 in 2012, with a total of \$8.4 million in gifts; the average gift total was \$51,304, and the median gift total was \$26,874. Of these 164 individuals, seven (all physicians) served in leadership positions of organizations that also received over \$100,000 from pharmaceutical companies during the 2007-2012 time periods. These seven physicians received \$467,668 in gifts together in 2012 alone; the average gift total was \$66,809, and the median gift total was \$56,291. These seven individuals in leadership positions represent 4.3% of individuals

receiving over \$10,000 in 2012 and received 5.6% of the gift total. These individuals also received \$2.0 million from 2007-2012, with a six-year average of \$288,431 and median of \$124,837.

The seven individuals in DC who received gifts over \$10,000 and served in leadership positions for organizations receiving gifts over \$100,000 were analyzed. The majority (five) served in leadership positions within *Research, Education, & Advocacy Organizations*; one for a *Professional Organization*; and one for a *Clinical Organization*.

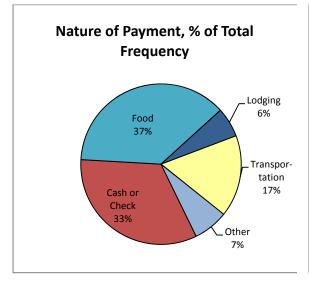
Organizations where these individuals served in leadership roles received \$3.2 million in 2012; their average gift total was \$533,352 and median gift total was \$225,514. This \$3.2 million received by six organizations represents nearly 17% of the \$18.9 million received by all organizations in 2012. (Two of the individuals served in leadership positions at the same organization.)

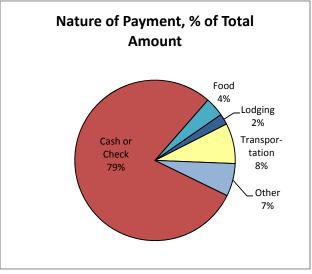
Nature of Payment and Primary Purpose of Individual Gifts

Gifts to individuals were analyzed based on *Nature of Payment* and *Primary Purpose*. For this analysis, five *Nature of Payment* categories were used: *Cash or Check, Food, Lodging, Transportation,* and *Other*. Five *Primary Purpose* categories were used: *Speaker Fee or Payment, Marketing, Education, Consulting,* and *Other*.

Gifts to the 164 individual recipients who received over \$10,000 in 2012 were reviewed to determine the *Nature of Payment* and *Primary Purpose*. These individuals received gifts most frequently in the form of *Food* (37.4%) and *Cash or Check* (33.1%), followed by *Transportation* (16.5%), *Lodging* (6.0%), and *Other* (7.0%). *Cash or Check* gifts made up an overwhelming majority of the total amount (79.2%), followed by *Transportation* (8.1%), *Food* (3.9%), *Lodging* (2.2%), and *Other* (6.6%).

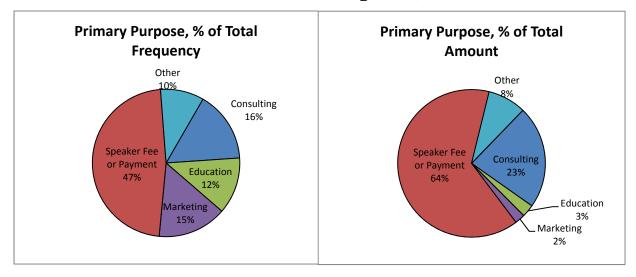
Figure 16
Gifts to Individuals Receiving ≥ \$10,000 in 2012





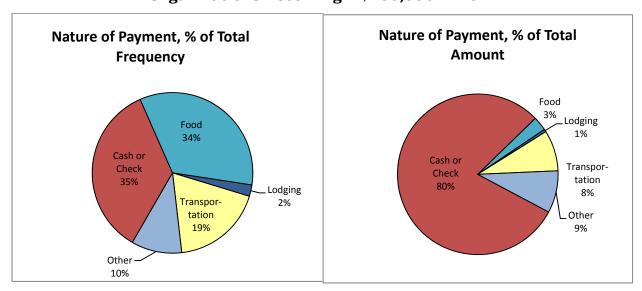
The most frequent *Primary Purpose* was *Speaker Fee or Payment* (47.3%), followed by *Consulting* (15.6%), *Marketing* (15.2%), *Education* (12.4%), *and Other* (9.6%). The *Primary Purpose* with the greatest dollar amount was *Speaker Fee or Payment* (64.1%), followed by *Consulting* (22.6%), *Education* (2.7%), *Marketing* (2.2%), and *Other* (8.4%).

Figure 17
Gifts to Individuals Receiving ≥ \$10,000 in 2012



Gifts to the seven individual recipients in DC who received over \$10,000 in 2012 and served in leadership positions for organizations receiving over \$100,000 from 2007-2012 were reviewed to determine the *Nature of Payment* and *Primary Purpose* of their gifts. These individuals also received gifts most frequently in the form of *Cash or Check* (35.1%) and *Food* (34.0%), followed by *Transportation* (18.5%), *Lodging* (2.3%), and *Other* (10.2%). *Cash or Check* gifts made up the majority of the total amount (80.0%), followed by *Transportation* (8.2%), *Food* (2.8%), *Lodging* (0.5%), and *Other* (8.5%).

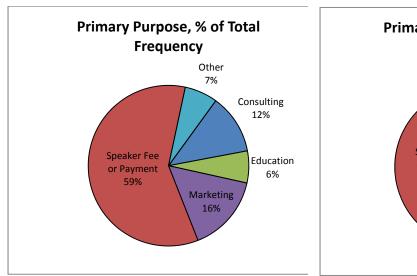
Figure 18
Gifts to Individual Recipients Receiving ≥ \$10,000 in Leadership at
Organizations Receiving ≥ \$100,000 in 2012

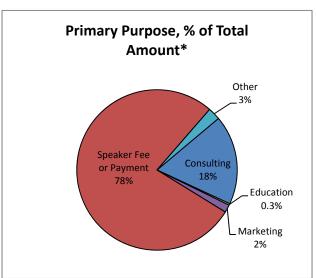


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For gifts to these seven physicians, the most frequent *Primary Purpose* was *Speaker Fee or Payment* (59.3%), followed by *Marketing* (15.6%), *Consulting* (12.0%), *Education* (6.4%), and *Other* (6.6%). The *Primary Purpose* with the greatest dollar amount was *Speaker Fee or Payment* (77.6%), followed by *Consulting* (18.0%), *Marketing* (1.6%), *Education* (0.3%), and *Other* (2.5%).

Figure 19
2012 Individual Recipients Receiving ≥ \$10,000 in Leadership at
Organizations Receiving ≥ \$100,000





*Note: Percentages may not total 100% due to rounding.

Gifts to the seven individuals in DC who received \$10,000 or more from pharmaceutical companies in 2012 and served in leadership positions at *Professional* or *Research*, *Advocacy*, *and Education Organizations* that also received more than \$100,000 did not differ substantially from gifts to all individuals who received \$10,000 or more in 2012 – although, the small size of the leadership group means that this finding should be interpreted with caution. For both groups, the majority of gifts and gift value came in the form speaking fees, and average gift amounts were between \$900 and \$1,000, while median gift totals were lower.

Table 4: 2012 Gifts to Individual Recipients

	Average Gift Amount	Median Gift Amount	Number of Gifts	Total Gift Amount
	7 iii Ouric	7 iiiouiit	Gires	7 tilloune
All Individual Recipients	\$369	\$89	29,184	\$10,758,566
Individuals Receiving				
≥ \$10,000	\$920	\$209	9,162	\$8,424,912
Individuals Receiving ≥				
\$10,000 and Serving as				
Leaders in Organizations				
Receiving ≥ \$100,000	\$970	\$250	482	\$467,668

Individuals with Leadership Roles in Other Organizations

The 131 organizations that received \$100,000 or more from pharmaceutical companies between 2007 and 2012 are not the only organizations that influence U.S. healthcare. To explore the extent to which pharmaceutical companies may be giving gifts to individuals holding leadership positions in other organizations, researchers conducted online searches to determine affiliations of individuals who received large sums from pharmaceutical companies in 2012. For feasibility purposes, the analysis was limited to those who received \$50,000 or more in 2012 from pharmaceutical companies.

Of fifty-three individuals in DC who received over \$50,000 in 2012, 25 had leadership roles in other organizations. These 25 individuals received \$3.2 million in 2012, with an average gift of \$128,158 and median gift of \$113,821. This may indicate that organizations with limited funding from the pharmaceutical industry may still have the potential to be influenced by individuals who hold leadership positions and receive gifts from pharmaceutical companies.

Together, these findings suggest that pharmaceutical companies may not be specifically targeting District individuals who hold leadership positions with organizations already receiving large sums from pharmaceutical companies. (Because boards and committees have members located all over the country, it is possible that companies are giving money to individuals holding leadership positions but practicing in jurisdictions where gift expenses have not been reported.) In fact, they may be targeting gift spending toward individuals holding leadership positions in organizations that are not already accepting substantial sums from pharmaceutical companies, although this is difficult to demonstrate without nationwide data.

VI. Specialties of Physicians Receiving Large Gift Sums and Relevant Pharmaceutical Marketing Concerns

Research has found that pharmaceutical companies often rely on "key opinion leaders" (who are usually, but not always, physicians) to alert their fellow practitioners to new treatments, or to drug-company recommendations to treat certain conditions more aggressively (Moynihan, 2008; Fugh-Berman & Melnick, 2008). Identifying specialties in which several physicians are receiving very large sums can help pinpoint areas where pharmaceutical companies may be focusing their marketing efforts. In these areas, prescribers may be more prone to inappropriate prescribing in the wake of marketing efforts. This section describes some top inappropriate-prescribing concerns in specialties in which pharmaceutical companies have been giving large sums to individual physicians.

Researchers identified individuals in DC who received pharmaceutical-company gifts totaling \$100,000 or more during the 2007-2012 time period and conducted online searches to determine their specialties. Seventy-one individuals received such large gift totals. Their specialties included Cardiology, Urology, Psychiatry, Endocrinology, Hematology, Oncology, Infectious Disease, Internal Medicine, Pulmonology, and Critical Care. Findings regarding physicians in these specialties are as follows:

- **Hematology/Oncology:** Ten physicians (14.1% of the 71) who received \$100,000 or more over the six-year period had a specialty of Hematology and/or Oncology (usually listed as a dual specialty) and received a combined total of \$3.1 million.
- Cardiology: Six cardiologists (8.5% of the 71) received a combined total of \$2.1 million.
- **Psychiatry:** Six psychiatrists received a combined total of \$1.5 million.
- Internal Medicine: Six physicians had a specialty of internal medicine and received a combined total of \$1.5 million. If internal medicine specialties are combined (internal medicine, cardiology, pulmonology, and infectious diseases), the number of internists rises to 25.

Areas for which four or more physicians with those specialties received \$100,000 or more over the 2007 – 2012 period are shown in Figures 20 and 21.

Figure 20

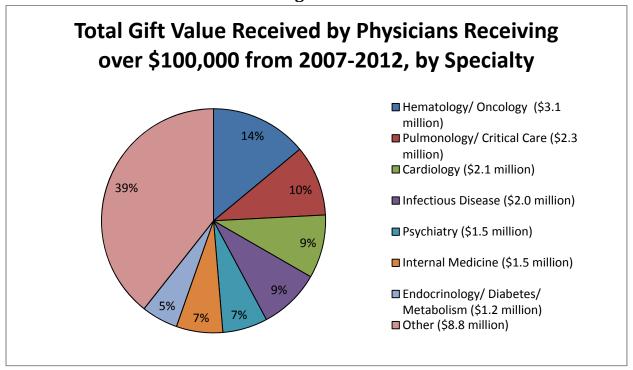
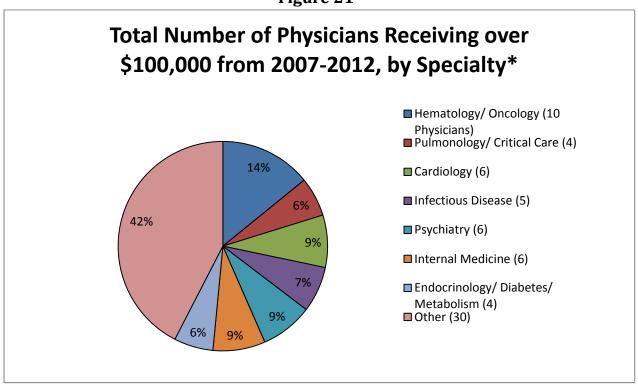


Figure 21



*Note: Percentages may not total 100% due to rounding.

Pharmaceutical Marketing Concerns in Key Specialty Areas

It is noteworthy that two of the specialties with the most physicians receiving very high gift sums are the specialties most relevant for the top two causes of death among District residents – hematologists/ oncologists, who treat those with cancer, and cardiologists, who treat heart-disease patients. For these specialties and two others with six or more physicians receiving very high gift sums – Psychiatry and Internal Medicine – concerns about inappropriate prescriptions of specific drugs or types of drugs exist. Such concerns could become the focus of future District educational efforts to assure prescribing that best meets patients' needs.

Table 5: 2012 Top Selling Drugs (Source: Drugs.com, 2014a)

Drug	Indications	Total Sales
Nexium	(esomeprazole, for acid reflux)	\$5.6 billion
Abilify	(aripiprazole, an antipsychotic)	\$5.6 billion
Crestor	(rosuvastatin, for lipid-lowering)	\$4.8 billion
Advair Diskus	(fluticasone/salmeterol, an antiasthmatic)	\$4.6 billion
Cymbalta	(duloxetine, an antidepressant)	\$4.5 billion
Humira	(adalimumab, an antirheumatic)	\$4.3 billion
Enbrel	(etanercept, an antirheumatic)	\$4.0 billion
Remicade	(infliximab, an antirheumatic)	\$3.7 billion
Copaxone	(glatiramer, for multiple sclerosis)	\$3.3 billion
Neulasta	(pegfilgrastim; stimulates white blood	\$3.3 billion
	cells in patients receiving chemotherapy)	

Table 6: 2013 Top Selling Drugs (Source: Drugs.com, 2014b)

Drug	Indications	Total Sales
Abilify	(aripiprazole, an antipsychotic)	\$6.3 billion
Nexium	(esomeprazole, for acid reflux)	\$6.0 billion
Humira	(adalimumab, an antirheumatic)	\$5.4 billion
Crestor	(rosuvastatin, for lipid-lowering)	\$5.2 billion
Cymbalta	(duloxetine, an antidepressant)	\$5.1 billion
Advair Diskus	(fluticasone/salmeterol, an antiasthmatic)	\$5.0 billion
Enbrel	(etanercept, an antirheumatic)	\$4.6 billion
Remicade	(infliximab, an antirheumatic)	\$4.0 billion
Copaxone	(glatiramer, for multiple sclerosis)	\$3.6 billion
Neulasta	(pegfilgrastim; stimulates white blood	\$3.5 billion
	cells in patients receiving chemotherapy)	

The primacy of several of these drugs raises questions for payers. Several best-selling drugs are examples of "evergreening" – a strategy for extending patents that includes minor changes in formulations (e.g., sustained-release preparations), combinations of drugs, and enantiomers (mirrorimage molecules) (Vernaz, et al., 2013). For example, the acid-reflux drug Nexium (esomeprazole), the best-selling drug in 2012 and the second-best-selling drug in 2013, is an enantiomer of Prilosec (omeprazole) (Harris, 2002). No head-to-head trials of equivalent doses of Prilosec and Nexium have been published, and there is no rational reason to prescribe Nexium over Prilosec, which is available generically.

A combination of a patented drug and a generic (off-patent) drug, or two generic drugs, can garner a new or extended patent. Best-selling combination drugs are usually far more expensive than purchasing the two drugs separately. An example is the antiasthmatic Advair, which was a best-selling drug in both 2012 and 2013.

Some of the best-selling combination drugs have no evidence of benefit. Ezetimibe (Zetia), a cholesterol-lowering drug with sales of over \$1.8 billion, and an ezetimibe/ simvastatin combination (Vytorin) are widely prescribed despite the lack of drug-trial evidence demonstrating the efficacy of ezetimibe for clinically important endpoints (Husten, 2014; Mitka, 2014).

Other top-selling drugs, such as the antipsychotic Abilify, may be prescribed to large numbers of patients for whom the risks outweigh the benefits. Physicians caution that antipsychotics have limited evidence for use in children; FDA approved the use of Abilify in adolescents with schizophrenia based on one six-week trial. Concerns have been raised about the increase in antipsychotic prescriptions for children, who may be especially vulnerable to adverse effects such as weight gain, diabetes, and even death (Borkowski et al., 2012).

The drugs listed in Tables 5 and 6 may be among those promoted by the companies that are giving large sums to District cardiologists, psychiatrists, and primary-care physicians. As it plans pharmaceutical-education efforts for District prescribers, the Department of Health may wish to consider addressing the risks and benefits of these drugs, as well as the overarching issue of companies promoting drugs for which there is little, if any, evidence of superiority when compared to generics or competitors' drugs.

VII. Influential Physicians

Identifying Influential Physicians

Several sources – including national and regional magazines and websites – publish listings of leading physicians, which can serve as a resource for patients seeking care (e.g., Castle Connolly Medical Ltd., n.d.; Rate MDs, n.d.; Super Doctors, n.d.; Washingtonian, n.d.). While these sources vary in their methods, most state that they use feedback from local providers to identify leading physicians. Physicians identified by their colleagues as leading physicians are likely to be influential, and potentially able to influence other providers' prescribing behavior.

Two sources of leading-physician listings were used to compile a pool of local physicians included on one or both of these sources' lists for the two most recent available years. Researchers then searched for these physicians' names on the AccessRx list of individuals who received \$10,000 or more from pharmaceutical companies in 2012, to investigate whether pharmaceutical companies might be targeting their gift spending toward this influential group.

Leading Physicians and Other Individuals

The pool of leading local physicians compiled from two sources yielded the names of 1,248 physicians. Researchers then determined which of the 164 individuals in DC who received over \$10,000 in 2012 also appeared in the pool of 1,248 influential physicians. Seventy (42.7%) of the 164 appeared in the leading-physicians pool, and they received a collective total of \$4.5 million in 2012 (53.7% of all gifts given to the group of 164).

The average total gift amount received by these 70 leading physicians in 2012 was \$64,630, and the median \$33,182. By comparison, the 94 individuals who received \$10,000 or more in 2012 but did not appear in the leading-physicians pool had an average total gift amount of \$41,499 and a median of \$26,621. There was a statistically significant difference between the gift totals of the physicians in the two groups (p = 0.01). Pharmaceutical companies spend large amounts of money to reach physicians identified as influential by their peers. While they are by no means confining gift spending to influential physicians, companies appear to be giving leading physicians larger or more frequent gifts.

Of the seven individuals in DC identified in Section V who received over \$10,000 in 2012 and served in a leadership role in an organization receiving large sums from pharmaceutical companies, five also appeared on the combined list of leading physicians. Together, these five physicians received \$374,771 in 2012; the average gifts total was \$74,954 and the median gift total was \$56,291. These five physicians represent 3.0% of individuals receiving over \$10,000 in 2012 and received over 4.5% of the gift total. During the 2007–2012 period, these individuals also received \$1.7 million, an average sum of \$335,500 per physician over the six-year period, with a median of \$124,837.

Figure 22

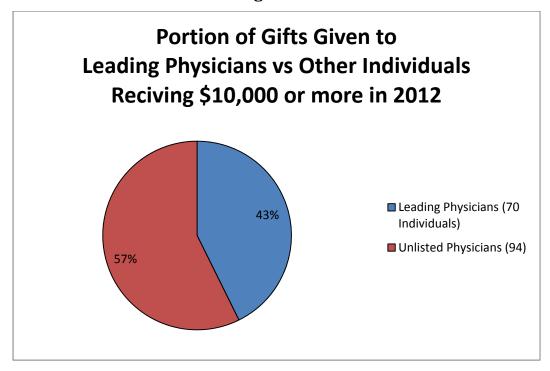
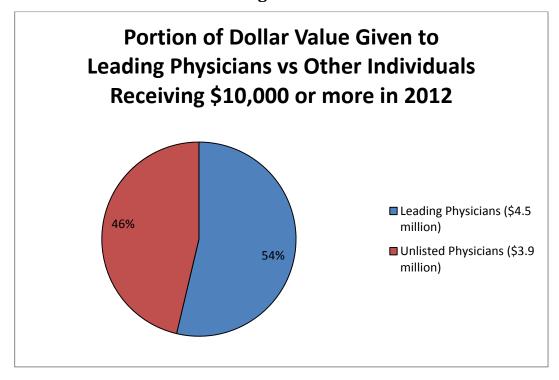


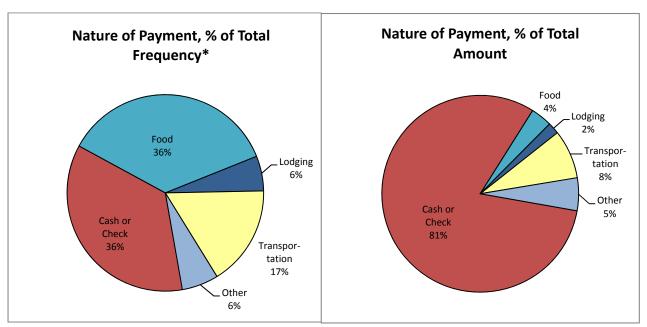
Figure 23



Payment Type and Primary Purpose

Gifts to the 70 physicians who appeared on the leading-physicians list and received a combined total of \$4.5 million from pharmaceutical companies in 2012 were reviewed to characterize the *Nature of Payment* and *Primary Purpose* of gifts. These physicians received gifts most frequently in the form of *Food* (36.0%) and *Cash or Check* (35.7%), followed by *Transportation* (16.5%), *Lodging* (5.7%), and *Other* (6.0%). *Cash or Check* gifts made up the majority of the total amount (81.2%), followed by *Transportation* (8.0%), *Food* (3.5%), *Lodging* (1.9%), and *Other* (5.4%).

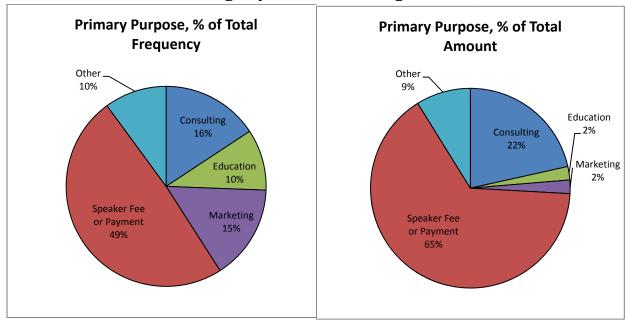
Figure 24
2012 Leading Physicians Receiving ≥ \$10,000



*Note: Percentages may not total 100% due to rounding.

The most frequent *Primary Purpose* of gifts to these 70 physicians was *Speaker Fee or Payment* (49.0%), followed by *Consulting* (15.7%), *Marketing* (15.3%), *Education* (9.9%), and *Other* (10.1%). The *Primary Purpose* with the greatest dollar amount was *Speaker Fee or Payment* (65.3%), followed by *Consulting* (21.5%), *Marketing* (2.2%), *Education* (2.2%), and *Other* (8.8%).

Figure 25
2012 Leading Physicians Receiving over \$10,000



VIII. Recommendations

To address the impacts of pharmaceutical marketing on health and healthcare in the District of Columbia in the Open Payments era, we have four main recommendations.

1. Expand provider education and outreach

Under the SafeRx Amendment Act of 2008, the District has already established a program to provide unbiased information to prescribers on the safety and efficacy of medications and other treatments. The District should consider expanding its efforts in this area by providing CME that is accessible to a greater number of District prescribers. Modules could focus on the specialty areas described in Section VI – cardiology, hematology/oncology, internal medicine, and psychiatry – that appear to be targets of pharmaceutical-marketing efforts and that affect the health of large segments of the District's population.

2. Use AccessRx data to complement Open Payments data

Information about gifts to District physicians and teaching hospitals from the federal Open Payments system will soon be available. In future years, the District's reports on AccessRx data should combine Open Payments information on gifts to District physicians and teaching hospitals with information the AccessRx program collects on gifts to other recipients. This will present a more complete picture of pharmaceutical-marketing patterns affecting District residents than would either source on its own.

Continued analysis of the District's AccessRx reports can also alert policymakers, the medical community, and the public to shifts in spending that may occur following Open Payments implementation. For instance, if the nationwide disclosure of physician gifts prompts some pharmaceutical companies to give more gifts to nurses, physicians' assistants, or other non-physician providers, AccessRx analyses can identify such patterns.

3. Strengthen the AccessRx Act to improve transparency and align with federal requirements

Two recommended changes to the AccessRx Act would both improve transparency and bring the District's reporting requirements closer to those of the federal Open Payments system:

• Make all reports submitted pursuant to the AccessRx Act publicly available: In the interest of informed healthcare decision-making, patients should have access to information about how much money their healthcare providers receive from specific companies and about which drugs are targeted by marketing efforts. A database that combines information from all individual companies' reports in a standardized format should be made available to the public in a timely fashion. Such a database is currently developed each year for use solely by the Department of Health, but the AccessRx Act requires that it remain confidential. Data from the federal Open Payments system will be publicly available.

Require "product marketed" information for gift expenses: The District does not require that
reports of gift expenses (e.g., food or honoraria for physicians) specify which product is being
marketed. Requesting "product marketed" information for gift expenses would help researchers
determine how much companies spend on marketing specific drugs. The Open Payments system
requires drug companies to specify the drug, device, biological, or medical supply associated
with each transfer of value.

4. Provide for greater scrutiny of AccessRx submissions

The District should establish procedures for identifying AccessRx submissions that may be incomplete and for following up with the relevant manufacturers or labelers. With several years' worth of reports now in the AccessRx database, it would be feasible to identify anomalies, such as a low reported total from a company that had consistently reported large expenditure amounts in previous years. A follow-up inquiry to the company could allow for correction of any inaccuracies, and allow for greater understanding of activities that influence spending patterns, such as decisions to curtail certain kinds of spending or corporate restructuring. The procedures for identifying and following up on anomalous submissions should be stated clearly on the AccessRx website.

In addition, the Department of Health should establish a mechanism, such as an online form, by which researchers, reporters, company employees, or members of the public could submit information about possible discrepancies in gift-spending amounts reported to the District. Once the Open Payments database is publicly accessible, in addition to the ProPublica "Dollars for Docs" database already online, there will be many more opportunities for public scrutiny of pharmaceutical-company gift spending. Those who identify anomalous results in publicly available data sources could alert the District to review the relevant companies' AccessRx reports.

Greater transparency and expanded provider education can allow more District residents to enjoy trusting patient-provider relationships and choose treatments with risk-benefit balances appropriate for their personal health.

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