

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

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**June 15, 2009**

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## **I. Executive Summary**

Prescription drugs represent a positive and high-value contribution to healthcare, but rapid growth in prescription-drug spending presents insurers, public programs, and individual patients with difficult choices about allocating limited healthcare dollars. Pharmaceutical marketing practices may encourage the use of new, expensive drugs when other alternatives may be safer, more effective, and more cost-effective. Of particular concern are cases in which pharmaceutical sales representatives attempt to downplay reports of serious side effects and encourage off-label prescribing that is not supported by strong scientific evidence or by FDA approval.

Pharmaceutical companies have many marketing methods, which include detailer visits with prescribers; distribution of gifts and free samples; hiring of medical professionals to speak or consult on behalf of their products; direct-to-consumer advertising; and funding of organizations that provide continuing medical education, practice guidelines, and patient information. Medical and public-health experts have raised concerns about how all of these practices may influence prescribers and patients to prefer brand-name drugs even when they do not compare favorably to other alternatives in terms of costs, effectiveness, or risks.

Several states and the District of Columbia now require that pharmaceutical manufacturers report their marketing expenditures, including gifts to prescribers, and Vermont and Massachusetts are acting to ban several types of gifts from pharmaceutical companies to healthcare providers. Several medical schools and hospitals have developed policies that limit the contact drug reps may have with providers, faculty, and students and that require disclosure of relationships that doctors, researchers, and faculty members have with pharmaceutical companies.

This report investigates the ways that these trends affect the cost, utilization, and delivery of health care services in the District of Columbia. Information in this report about pharmaceutical manufacturers' marketing expenditures in the District comes from pharmaceutical company reports, which the George Washington University School of Public Health and Health Services analyzed for the District of Columbia Department of Health. Many of the District-specific marketing figures mentioned in this report are described in greater detail in the report "Pharmaceutical Marketing Expenditures in the District of Columbia, 2007," which was prepared by the George Washington University School of Public Health and Health Services for the District of Columbia Department of Health.

### ***Healthcare in the District of Columbia***

The District has a relatively low rate of uninsurance, which is due in large part to its generous public programs, but insurance does not necessarily mean adequate access to healthcare. Wide health disparities based on race and ethnicity exist in the District, and almost all residents who are uninsured or rely on public health coverage live in medically underserved areas. Residents report high rates of several chronic conditions, including hypertension, asthma, diabetes, and HIV/AIDS.

The District's Medicaid program represents one of the largest health items in the city's budget, and one of the areas in which prescription-drug spending can be tracked and addressed. The most recent data available indicate that the District's Medicaid program dedicates much of its prescription-drug reimbursement spending to a few classes and groups of drugs:

- The therapeutic categories accounting for the largest share of DC Medicaid spending between 1999 and 2004 were:
  - Anti-infective agents, 25% or more
  - Central nervous system drugs, 15 – 20%
  - Cardiovascular disease drugs, 14 – 17%
- The drug groups accounting for the largest share of DC Medicaid spending between 1999 and 2004 also showed the highest rates of expenditure growth:
  - Antivirals, \$9.9 million in 1999 and \$24.9 million in 2004
  - Antipsychotics, \$4.5 million in 1999 and \$16.1 million in 2004

Since Medicare became responsible for prescription-drug coverage of dual eligibles (those eligible for both Medicare and Medicaid) in 2006 under the new Medicare Part D prescription-drug benefit, the District can no longer use prescription cost-control policies to control the prescription-drug expenditures for this population. Since dual eligibles accounted for more than half of the District's total Medicaid pharmacy reimbursement in 2003, this represents a significant setback in efforts to control Medicaid prescription-drug costs.

The District's Medicaid budget is likely to be strained if prescription-drug costs continue to grow at their current pace. Common state responses to Medicaid budget problems are cutting benefits and eligibility, which will leave some residents without services they need, and reducing provider payments, which can cause providers to see fewer Medicaid patients and exacerbate existing problems with access to healthcare.

### ***Findings on Pharmaceutical Marketing in the District***

Pharmaceutical manufacturers and labelers spent \$158.2 million on marketing in the District of Columbia in 2007. This included:

- \$116.6 million in expenses associated with employees and contractors engaged in marketing
- \$31.3 million in gifts and payments (not including free samples or expenses related to clinical trials or attendance at a conference or seminar); this included:
  - \$11.3 million to individuals (doctors, nurses, etc.)
  - \$19.9 million to non-individual recipients (clinical organizations, professional medical organizations, disease-specific organizations)
- \$10.3 million in advertising

The \$116.6 million in expenses for employees and contractors engaged in marketing activities (the “aggregate costs” category on the reporting form companies complete) is by far the largest of the expenditure categories, and suggests that pharmaceutical companies are dedicating large amounts of resources to pharmaceutical detailing visits to prescribers in the District.

In addition to sending employees to visit prescribers, pharmaceutical companies often pay doctors to speak to their colleagues about the benefits of a particular drug. To investigate the extent to which Medicaid providers might be acting as consultants or “key opinion leaders” for pharmaceutical companies, we prepared a list of physicians who received gifts or payments for speaking fees or consulting totaling \$1,000 or more from these companies in 2007. A total of 193 physicians were identified, and 60 of them also appeared on lists of District Medicaid providers. (It is likely that the actual total is higher than 193, since the pharmaceutical-company reports named individual physicians while the Medicaid provider lists gave practice names in some cases and individual practitioners’ names in others.) Of those 60, 16 were among the top Medicaid providers (the top 200 fee-for-service providers based on claims or the top 200 managed care providers based on number of Medicaid patients).

Other forces that may influence District providers’ prescribing patterns include direct-to-consumer advertising and the continuing medical education (CME), practice guidelines, and patient information provided by organizations. (Patient viewing of advertisements and information from organizations can shape prescribing patterns when patients mention specific medications they have seen advertised or recommended.) Pharmaceutical companies reported spending more than \$10 million in advertising in the District in 2007, but the actual figure is probably far higher because several companies did not separate their District-specific advertising from national ad campaigns.

Professional organizations and disease-specific organizations located in the district received large sums from pharmaceutical companies, but were rarely fully transparent about the sources of their funding. Findings regarding pharmaceutical-company payments in 2007 to these organizations include the following:

- Pharmaceutical companies reported making gift payments totaling approximately \$15.2 million for the purpose of “education”; although many did not provide additional details, \$2.3 million was specifically described as being for the purpose of CME.
- The ten professional organizations that received the most funding received a total of \$9.4 million, accounting for nearly half of all gift payments given to non-individual recipients.
- Seven of those ten professional organizations state on their websites that they offer CME or educational meetings, but only two of those seven disclose financial support from the pharmaceutical industry, and those two organizations are vague about funding amounts.
- The ten disease-specific organizations that received the most pharmaceutical-marketing money received approximately \$2 million.

- Only four of those ten disease-specific organizations name corporate sponsors on their websites, and none of them disclose the amounts of funding from these sponsors.
- Medical schools in the District do not report having policies that limit contact or gifts between pharmaceutical-company representatives and medical students, faculty, or doctors, although the Georgetown University School of Medicine is reportedly drafting a policy that will limit interactions that pharmaceutical representatives have with medical students and staff, and the Georgetown University Hospital already operates under the MedStar policy requiring that company representatives apply for badges in order to enter the facility.
- The George Washington University School of Medicine and Health Services and the Georgetown University School of Medicine are accredited through the Accreditation Council for Continuing Medical Education, whose guidelines are designed to limit conflicts of interest between organizations that conduct CME and their sponsors.

## ***Recommendations***

The following recommendations are based on research into both national and District-specific trends in pharmaceutical marketing and healthcare issues:

### **1. Strengthen the AccessRx Act by**

- Making information publicly available, in order to improve transparency and provide opportunities for scrutiny by researchers and members of the public;
- Eliminating the reporting exceptions for free samples, clinical trial expenses, and educational expenses;
- Requiring unique identifiers for gift recipients; and
- Requiring that reports of expenditures include information about the product being marketed.

**2. Educate prescribers with unbiased information about treatment options.** The District has already taken an important step in this direction by establishing an academic detailing program under the SafeRx Act. The District could also partner with organizations that offer lectures and other educational activities to groups of doctors and medical students to educate them about pharmaceutical marketing practices, teach them skills to resist inappropriate marketing, and present independent information.

**3. Focus on top expenditure categories.** Medicaid prescription-drug expenditures are dominated by a few classes and groups of drugs, which is likely due to a combination of high drug prices and high rates of the conditions that these drugs treat. The District can work to limit future growth of spending on these drugs by focusing its academic detailing program on the conditions for which these drugs are prescribed and by supporting programs that work to prevent these conditions.

## II. The Role of Pharmaceuticals in Healthcare

Prescription drugs have made significant contributions to health, and in many cases provide for cost savings; for instance, drug treatment for conditions such as ulcers and gallstones is far cheaper than surgery. Drugs that control chronic conditions such as diabetes offer quality-of-life improvements and can help patients avoid costly hospitalizations and disabilities.

Prescription-drug spending accounts for only around 10% of total US healthcare spending, but it is one of the fastest-growing components of healthcare. According to the Kaiser Family Foundation, spending for prescription drugs in the U.S. was five times higher in 2006 than in 1990, increasing to \$216.7 billion from \$40.3 billion. The main factors driving the increase in prescription-drug spending are changes in utilization, prices, and types of drugs used. Utilization and price have both been increasing steadily: From 1997 to 2007, the number of prescriptions purchased in the US increased 72%, and retail prescription prices increased an average of 6.9% a year during that same time period.<sup>1</sup>

The proportion of prescription drugs that are generics (as opposed to brand-name drugs) is also a major factor in prescription-drug spending; the Kaiser Family Foundation reports that in 2007, the average price for a brand-name prescription was more than three times higher than the average price for a generic prescription (\$119.51 vs. \$34.34). This ratio varies from year to year, and is influenced by the number of drugs under patent as well as by efforts to promote the use of generics. In 2007, 65% of total prescriptions dispensed were generics, but due to their lower costs they accounted for just 21% of the total prescription-drug sales figure.<sup>1</sup>

One group of researchers predicts that growth in prescription drug spending for 2008 will be only 3.5%, mostly due to effects of the recession, but will return to 8.6% by 2018. They expect that some of this increase will be due to a leveling off in the generic dispensing rate and new drug approvals, particularly for costly specialty drugs.<sup>2</sup>

Overall, prescription drugs represent a positive and high-value contribution to healthcare. However, continued rapid growth in prescription-drug spending will present insurers and public programs, as well as individual patients, with difficult choices about allocating limited healthcare dollars.

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<sup>1</sup> The Henry J. Kaiser Family Foundation. *Prescription Drug Trends*. September 2008. Accessed 5/20/2009. [http://www.kff.org/rxdrugs/upload/3057\\_07.pdf](http://www.kff.org/rxdrugs/upload/3057_07.pdf).

<sup>2</sup> Sisko A, Truffer C, Smith S, et al. Health Spending Projections Through 2018: Recession Effects Add Uncertainty To The Outlook. *Health Affairs*, Web Exclusive (February 24, 2009): w346-57.

## ***Pharmaceuticals and Healthcare in the District of Columbia***

Although generous public programs keep the District's uninsurance rate below the national average, wide disparities in health access and outcomes still exist in the District. High prescription-drug costs are a concern because they may reduce spending in other necessary areas and leave some residents – particularly those with chronic health conditions – struggling to obtain medicines they need. Individuals who are prescribed expensive drugs may struggle to pay for them, and as a result may fail to take prescriptions as directed; this is of particular concern for the District's uninsured and low-income residents.

Compared to the national average, District residents are less likely to have employer-sponsored insurance and more likely to have public coverage. Estimates of coverage rates vary due to methodology, but studies consistently find the District's uninsurance rate to be lower. The Urban Institute reports that employers provide insurance to just 56% of District residents (compared to 61% nationally) and public programs cover 23% (compared to 13% nationally), and that the this high rate of public coverage results in the District having an uninsurance rate of just 13%, compared to a national average of 18%. (This report notes that the District uninsurance rate may be even lower than 13%, since survey respondents may report that they are uninsured even when they are enrolled in the DC HealthCare Alliance, a comprehensive low-income coverage program that is available to all Medicaid-ineligible uninsured District residents with incomes below 200% of the federal poverty level.)<sup>3</sup> Trust for America's Health reports a District uninsurance rate of 9.5%, compared to a national average of 15.3%<sup>4</sup>

Insurance does not necessarily mean adequate healthcare access, however. The majority of DC residents with chronic conditions who are enrolled in Medicaid or the Alliance report at least one visit with a primary care provider, but few of them see specialists treating their conditions.<sup>5</sup> Three hundred thousand DC residents, and almost all residents who are uninsured or rely on public health coverage, live in medically underserved areas.<sup>6</sup> Residents in low-income neighborhoods are more likely to have chronic health conditions but three times less likely to have a regular doctor than residents in more affluent areas.<sup>7</sup>

Perhaps the most disturbing indicator of inequality within the District is the difference in the “mortality amenable to healthcare” rates by race. The Commonwealth Fund Commission on a

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<sup>3</sup> Cook A and B Ormond. *Who Has Insurance and Who Does Not in the District of Columbia?* The Urban Institute Health Policy Briefs, DC-SPG no. 3, December 2007. Accessed 5/28/09. <http://www.urban.org/url.cfm?ID=411589>.

<sup>4</sup> Trust for America's Health. *District of Columbia: Key Health Facts*. Accessed 5/28/09. <http://healthyamericans.org/states/?stateid=DC>.

<sup>5</sup> Lurie N, Gresenz CR, Blanchard J, et al. *Working Paper: Assessing Health and Health Care in the District of Columbia*. Prepared by RAND Health and George Washington University authors for the Executive Office of the Mayor, District of Columbia. January 2008. Accessed 5/28/09. [http://www.dcasthma.org/rand\\_health\\_reports\\_2008/rand\\_dchealth\\_phase1\\_0108.pdf](http://www.dcasthma.org/rand_health_reports_2008/rand_dchealth_phase1_0108.pdf).

<sup>6</sup> So Others Might Eat. *Health and Health Insurance in Washington, D.C.* Accessed 5/28/09. <http://www.some.org/Health%20Health%20Insurance%20in%20DC.pdf>.

<sup>7</sup> Lurie N and M Ross. *Health Status and Access to Care among Low-Income Washington, DC Residents*. The Brookings Institution & RAND. October 2006. Accessed 5/28/09. [http://www.brookings.edu/reports/2006/10cities\\_lurie.aspx](http://www.brookings.edu/reports/2006/10cities_lurie.aspx).



High Performance Health System reports rates of mortality amenable to healthcare, which includes “age-standardized death rates before age 75 from conditions for which timely and effective medical care can potentially delay or prevent mortality.” In the District, the overall rate of mortality amenable to healthcare in 2002 was 160 per 100,000 population; however, when the rates are broken down by race, the rate for black residents is more than three times higher than the rate for white residents – 216.0 deaths per 100,000 for black residents versus 61.1 for white residents. When compared to the 50 states, the District has the highest overall rate of mortality amenable to healthcare and the largest disparity between black and white rates.<sup>8</sup>

Rates of certain chronic conditions are high among District residents. More than 25% of District adults report having hypertension; 10% report having asthma; and 8% report having diabetes. Rates of mortality from diabetes are higher in the District compared to demographically similar locations.<sup>5</sup> Among metropolitan statistical areas nationwide, the District has one of the highest rates of reported AIDS cases; in 2007, the District’s rate was 30.5 AIDS cases per 100,000 population, and that was surpassed only by the rates in Baton Rouge (31.4), New Orleans-Metairie-Kenner (31.5), and Miami (33.1).<sup>9</sup>

The District’s Medicaid program represents one of the largest health items in the city’s budget, and one of the areas in which prescription-drug spending can be tracked and addressed. Data on prescription-drug expenditures for the District’s Medicaid program indicate that anti-infective agents, central nervous system (CNS) drugs, and drugs for cardiovascular diseases are the therapeutic categories on which DC Medicaid spends the most. Based on the most recent available five years of data (1999 and 2001-2004), anti-infective agents accounted for 25% or more of total DC Medicaid drug spending; CNS drugs for between 15% and 20%; and drugs for cardiovascular disease for between 14% and 17%.<sup>10</sup> (See Figure 1 and Table 1.)

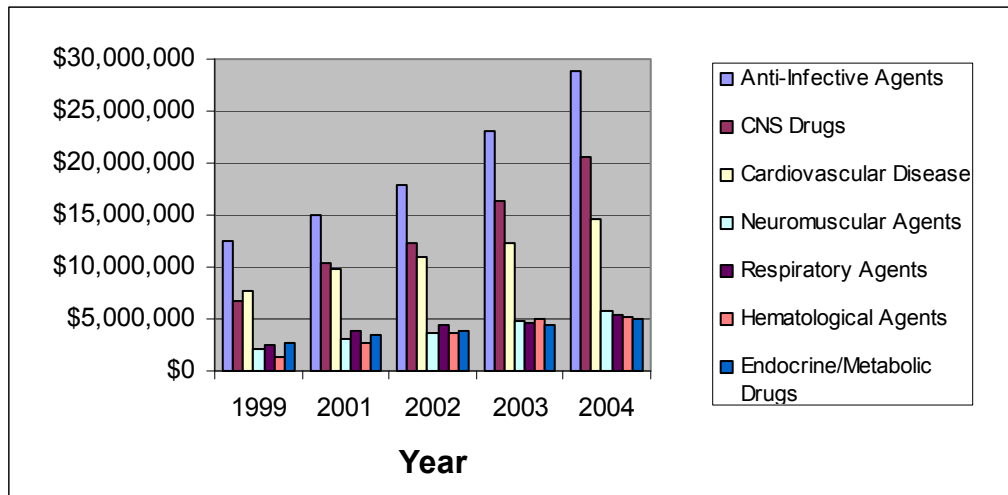
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<sup>8</sup> Commonwealth Fund Commission on a High Performance Health System. *Aiming Higher: Results from a State Scorecard on Health System Performance*. June 2007. Accessed 5/28/09. <http://www.commonwealthfund.org/Content/Publications/Fund-Reports/2007/Jun/Aiming-Higher--Results-from-a-State-Scorecard-on-Health-System-Performance.aspx>.

<sup>9</sup> Centers for Disease Control and Prevention. *Cases of HIV Infection and AIDS in the United States and Dependent Areas*, 2007. HIV/AIDS Surveillance Report, Volume 19.

<sup>10</sup> Mathematica Policy Research, Inc. for the Centers for Medicare and Medicaid Services. *Statistical Compendium: Medicaid Pharmacy Benefit Use and Reimbursement* for 1999, 2001, 2002, 2003, and 2004.

**Figure 1: DC Medicaid Reimbursement\* by Therapeutic Class<sup>11</sup>**



\* Reimbursement amounts do not reflect federally required rebates from drug manufacturers.

**Table 1: DC Medicaid Reimbursement\* for Top Three Therapeutic Classes**

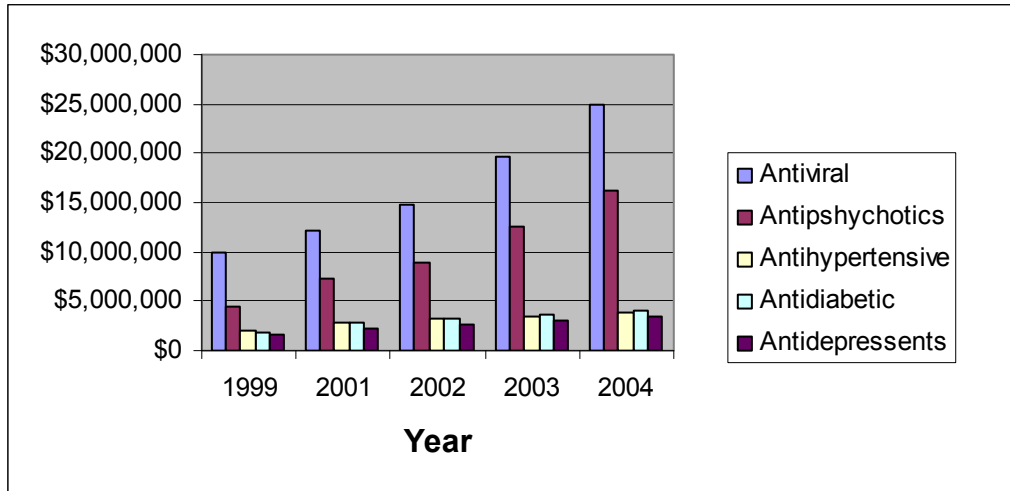
	Anti-infective Agents	CNS Drugs	Cardiovascular-disease Drugs
1999	\$12,457,007	\$6,772,286	\$7,658,732
2001	\$15,070,334	\$10,377,474	\$9,747,195
2002	\$17,852,096	\$12,278,684	\$11,036,126
2003	\$23,094,939	\$16,437,138	\$12,370,713
2004	\$28,757,009	\$20,537,284	\$14,572,225

\* Reimbursement amounts do not reflect federally required rebates from drug manufacturers.

When drugs are considered by group rather than by therapeutic category, the top five drug groups were antiviral, antipsychotic, antihypertensive, antidiabetic, and antidepressant. The growth in expenditures for antivirals and antipsychotics was particularly rapid; antiviral expenditures more than doubled, from \$9.9 million in 1999 to \$24.9 million in 2004, and antipsychotic expenditures more than tripled, from \$4.5 million to \$16.1 million. (See Figure 2 and Table 2.) Given high rates of childhood obesity in the District (22.8% compared to a national average of 14.8%)<sup>4</sup>, rates of diabetes are likely to increase in the future and require greater spending on antidiabetic prescriptions.

<sup>11</sup> Compiled with data from Mathematica Policy Research Inc. for the Centers for Medicare and Medicaid Services. *Statistical Compendium: Medicaid Pharmacy Benefit Use and Reimbursement* (DC Versions for 1999, 2001-2004).

**Figure 2: DC Medicaid Reimbursement\* by Drug Group<sup>11</sup>**



\* Reimbursement amounts do not reflect federally required rebates from drug manufacturers.

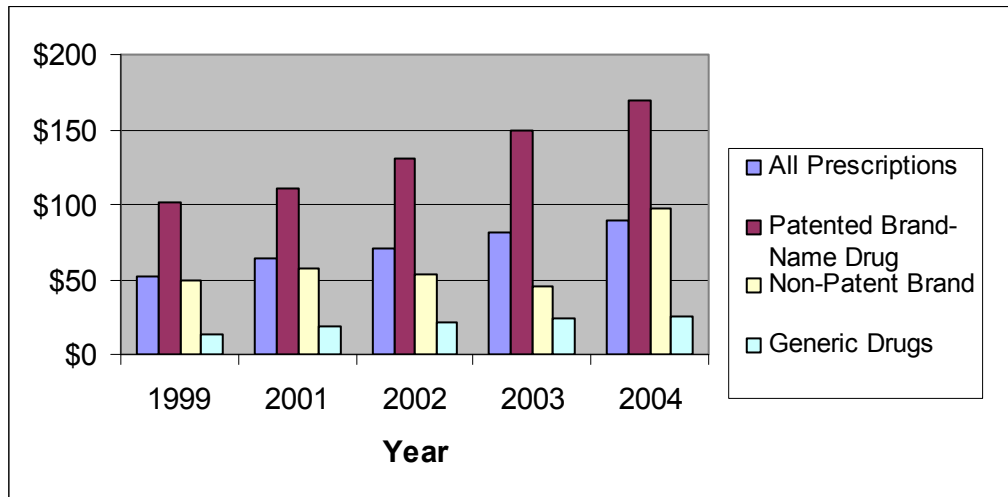
**Table 2: DC Medicaid Reimbursement\* by Drug Group**

	Antiviral	Antipsychotic	Antihypertensive	Antidiabetic	Antidepressant
1999	\$9,880,369	\$4,523,143	\$2,108,425	\$1,791,324	\$1,590,707
2001	\$12,145,666	\$7,351,288	\$2,805,578	\$2,798,815	\$2,255,471
2002	\$14,715,115	\$8,878,192	\$3,257,980	\$3,178,156	\$2,592,514
2003	\$19,644,670	\$12,612,868	\$3,422,093	\$3,636,791	\$2,955,728
2004	\$24,893,416	\$16,116,240	\$3,860,763	\$4,006,492	\$3,390,420

\* Reimbursement amounts do not reflect federally required rebates from drug manufacturers.

The mean Medicaid reimbursements for drugs by brand status bear out the assumption that patented brand-name drugs are the most costly for the District's Medicaid program. Patented brand-name drugs cost an average of \$101 per prescription in 1999 and \$143 per prescription in 2004; in contrast, generic drugs cost an average of \$14 in 1999 and \$26 in 2004. (See Figure 3 and Table 3.)

**Figure 3: DC Medicaid Mean Reimbursement\* per Prescription by Brand Status<sup>11</sup>**



\* Reimbursement amounts do not reflect federally required rebates from drug manufacturers.

**Table 3: DC Medicaid Mean Reimbursement\* per Prescription by Brand Status**

Year	All Prescriptions	Patented Brand-Name Drug	Non-Patent Brand-Name Drug	Generic Drug
1999	\$52	\$101	\$50	\$14
2001	\$64	\$111	\$58	\$19
2002	\$71	\$131	\$53	\$22
2003	\$81	\$149	\$45	\$24
2004	\$89	\$169	\$97	\$26

\* Reimbursement amounts do not reflect federally required rebates from drug manufacturers.

Beginning in 2006, responsibility for prescription-drug benefits for dual eligibles (recipients enrolled in both Medicare and Medicaid) was transferred from Medicaid agencies to Medicare. Like all of the states, the District must still finance the majority of dual-eligibles' prescription-drug costs through "clawback" payments to the federal government, but it no longer has the opportunity for cost savings on this population's prescription-drug costs via prescription-drug policies.<sup>12</sup> In the District, these policies include Drug Utilization Review and a Preferred Drug List "managed through restrictions on use, prior authorization, therapeutic substitution, preferred products, and physician profiling."<sup>13</sup> In 2003, dual eligibles accounted for more than half of the District's total Medicaid pharmacy reimbursement (\$17.9 million out of \$33.5 million total).<sup>14</sup>

<sup>12</sup> The Kaiser Commission on Medicaid and the Uninsured. *Few Options for States to Control Medicaid Spending in a Declining Economy*. April 2008. Accessed 5/28/09. <http://www.kff.org/medicaid/upload/7769.pdf>

<sup>13</sup> National Pharmaceutical Council. *Pharmaceutical Benefits under State Medical Assistance Programs*. 2007.

<sup>14</sup> Mathematica Policy Research, Inc. for the Centers for Medicare and Medicaid Services. *Statistical Compendium: Medicaid Pharmacy Benefit Use and Reimbursement in 2003 DC*. Accessed 5/28/09. [http://www.cms.hhs.gov/MedicaidDataSourcesGenInfo/downloads/2003AllBenes\\_DC.pdf](http://www.cms.hhs.gov/MedicaidDataSourcesGenInfo/downloads/2003AllBenes_DC.pdf).

### III. Concerns About Pharmaceutical Marketing

There are three main concerns about the effects of pharmaceutical marketing on healthcare: higher-than-necessary expenditures, leaving less money for other healthcare needs; the use of prescription of drugs that are less effective or have more problematic side effects than alternatives; and inappropriate off-label prescribing. The use of drugs that are less effective, have more side effects, or are inappropriate for the patients taking them can lead to adverse health outcomes that increase utilization of care.

#### ***Prescription-drug Expenditures***

Since pharmaceutical companies profit more from sales of drugs still under patent, these are the drugs that they market most heavily. (Aggressive marketing once a patent has expired can also slow the erosion in market share.)<sup>15</sup> Many new drugs do represent substantial improvements over older generic drugs that treat the same conditions, proving to be more clinically effective and/or to have fewer side effects. In these cases, increased spending on newer drugs is justifiable considering the greater value. For instance, one group of researchers found that care of patients with AIDS, which relies heavily on antiretroviral drug therapy, has saved at least three million years of life in the United States alone.<sup>16</sup> Other researchers estimate that antihypertensive therapy treatment has generated a benefit-to-cost ratio of at least 6:1, and that without antihypertensive therapy, 86,000 premature deaths from cardiovascular disease would have occurred in 2001 alone.<sup>17</sup>

However, pharmaceutical companies sometimes make minor changes to a drug whose patent has or will soon expire in order to obtain a new patent. For example, when facing the expiration of the patent for its blockbuster drug Prilosec, AstraZeneca applied for a patent on Nexium; both drugs consist of isomers of the generic drug omeprazole, but Nexium was different enough to receive a new patent. The antidepressant Prozac is now available as a generic, but Prozac Sarafem is patented as a weekly dosage for severe premenstrual syndrome.<sup>18</sup>

Researchers from the University of British Columbia noted that Canada's drug spending doubled between 1996 and 2003 and investigated whether the drugs prescribed in British Columbia during that time period were considered "breakthrough" drugs. (Canada's Patented Medicine Prices Review Board appraises the therapeutic novelty of newly patented drugs and notes which constitute breakthroughs.) They found that 80% of the increase in drug expenditures in British Columbia during the seven-year period "was explained by the use of new, patented drug

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<sup>15</sup> Santerre R and S Neun. *Health Economics: Theories, Insights, and Industry Studies*. 4th edition, South-Western College Publishing, 2006.

<sup>16</sup> Walensky R, Paltiel D, Losina E, et al. The Survival Benefits of AIDS Treatment in the United States. *Journal of Infectious Diseases* 2006; 194: 11-9.

<sup>17</sup> Cutler D, Long G, Berndt E, et al. The Value of Antihypertensive Drugs: A Perspective on Medical Innovation. *Health Affairs* 2007, 26(1): 97-110.

<sup>18</sup> Michaels D. *Doubt is Their Product: How Industry's Assault on Science Threatens Your Health*. Oxford University Press, Inc., 2008.

products that did not offer substantial improvements on less expensive alternatives available before 1990.”<sup>19</sup>

In these cases, marketing efforts may lead to prescriptions for a new drug in cases where an older one will be just as clinically effective, and patients and payers will spend more money than is necessary to achieve essentially the same results.

Within the District, residents with private insurance often face higher co-payments for branded drugs; low-income residents may struggle to afford these co-payments and face a choice between paying for their medications and meeting other important needs. Residents on Medicaid do not face this choice, but the District’s Medicaid budget is likely to be strained if prescription-drug costs continue to grow at their current pace. Common state responses to Medicaid budget problems are cutting benefits and eligibility, which will leave some residents without services they need, and reducing provider payments, which can cause providers to see fewer Medicaid patients and exacerbate existing problems with access to healthcare.

## ***Effectiveness and Side Effects***

Pharmaceutical marketing efforts are also problematic if they influence health professionals to prescribe drugs that are not the best choices for their patients. Of course, prescribers often do not know what the best choice will ultimately be for each patient and must try different therapies. Problems arise when health professionals prescribe drugs with incomplete knowledge of identified risks, a situation that can arise when pharmaceutical marketing efforts fail to adequately disclose side effects or potential drug interactions. (Busy healthcare providers’ lack of time to keep up with the latest medical literature also contributes to this problem, and academic detailing efforts – discussed in Section V – can help address this.) Marketing efforts can also contribute to excessive enthusiasm for new drugs that leads some prescribers to stop prescribing older products, even though older drugs may have a better balance of risks and benefits for some patients.

There are many troubling examples of pharmaceutical companies using marketing efforts that downplay or altogether fail to mention the risks associated with the drug being promoted. For instance, manufacturer Merck knew that its anti-inflammatory drug Vioxx increased the risk of heart attacks as much as five-fold, but as US Representative Henry Waxman noted after reviewing over 20,000 pages of internal company documents, Merck used its “highly trained [marketing] force to present a misleading picture to physicians about the drug’s cardiovascular risk.”<sup>20</sup> Merck finally withdrew the drug in 2004 after results of another clinical trial solidified the evidence of Vioxx’s role in heart attacks and strokes – but that was after the drug had been on the market for four years and caused an estimated 88,000 – 139,000 heart attacks.<sup>18</sup>

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<sup>19</sup> Morgan S, Bassett K, Wright J, et al. “Breakthrough” drugs and growth in expenditure on prescription drugs in Canada. *British Medical Journal* 2005 October 8; 331(7520): 815–816.

<sup>20</sup> Waxman H. *Memorandum to Democratic members of Congress. Re: the marketing of Vioxx to physicians.* May 5, 2005. Accessed 5/28/09. <http://oversight.house.gov/documents/20050505114932-41272.pdf>.

While the evidence against Vioxx was mounting, concerns were also growing about the role of serotonin-reuptake inhibitor (SSRI) antidepressants in patient suicides, particularly when the patients were children. It turned out that some of the companies manufacturing SSRIs funded multiple clinical trials of their products, and only reported the favorable results.<sup>21</sup> In 2004, FDA finally required manufacturers to add a “black box” warning to the labeling of antidepressants to warn about the increased risk of suicidal thoughts and behaviors in children and adolescents taking the drug and to emphasize the need for close monitoring of patients starting on them.<sup>22</sup>

Even when risks of drugs are disclosed appropriately, enthusiasm for new products – generated not only by marketing, but by reports of successful treatments – can cause some prescribers to turn away from tried-and-true drugs that may be preferable for some patients. In a recent *New York Times* op-ed, psychiatry professor Richard Friedman writes that new medical treatments “have an allure that is hard to resist,” and provides examples of older psychiatric drugs that have been overshadowed by newer ones, even though the older drugs are still effective. He notes that lithium, while it must be administered carefully to avoid toxicity, has been used successfully to treat bipolar disorder for decades and is “the only psychotropic drug that has ever been shown to have specific antisuicidal effects”; however, drug companies can’t make much money from it, so they are promoting a new generation of mood stabilizers, “some more tolerable than lithium, but none more effective.”

## **Off-Label Prescribing**

Off-label prescribing includes the prescription of drugs for both conditions and populations for which they are not specifically approved. The practice is legal and generally embraced by healthcare providers; the FDA itself has also noted that many unapproved uses may be appropriate, and off-label uses may later result in labeling revisions. The lack of FDA approval for a particular use may be due to a lack of manufacturer interest in pursuing approval for that use due to commercial or financial reasons.<sup>23</sup> Physicians treating special populations, such as children and pregnant women, often must prescribe drugs off-label, because manufacturers often do not seek approval for the use of their products for these populations.

Off-label uses do not receive the same degree of scientific scrutiny as approved uses,<sup>24</sup> but information to help guide physician decisions may be available from compendia relying on expert committees and from professional organizations that produce guidelines for off-label prescribing for specific indications, diseases, or populations.<sup>23</sup> One study by David Radley et al analyzed prescriptions of commonly used medications that accounted for more than half of all estimated prescription drug use in 2001 and assessed whether the prescriptions were for an FDA

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<sup>21</sup> Avorn J. Dangerous Deception - Hiding the Evidence of Adverse Drug Effects. *New England Journal of Medicine* 2006 November 23; 355 (21): 2169-2171.

<sup>22</sup> U.S. Food and Drug Administration. *FDA Launches a Multi-Pronged Strategy to Strengthen Safeguards for Children Treated With Antidepressant Medications*. October 15, 2004. Accessed 5/28/09. <http://www.fda.gov/bbs/topics/news/2004/new01124.html>.

<sup>23</sup> Nightingale S. Off-Label Use of Prescription Drugs. *American Family Physician* 2003 August; 68(3): 425-427.

<sup>24</sup> Radley, D, Finkelstein S, Stafford R. Off-label Prescribing Among Office-Based Physicians. *Archives of Internal Medicine* 2006 May 8; 166:1021-1026.

approved use, for an off-label use that had strong scientific support, or for an off-label use with limited or no scientific support. They found that “about 21% of all estimated uses for commonly prescribed medications were off-label, and that 15% of all estimated uses lacked scientific evidence of therapeutic efficacy.” Off-label prescribing was found to be most common among cardiac medications (46%) , anticonvulsants (46%), and anti-asthmatics (42%), and off-label prescriptions with limited or no scientific support were most common among psychiatric drugs (96% limited or no support vs. 4% strong support) and allergy therapies (89% vs. 11%).<sup>24</sup>

The Food and Drug Administration (FDA) prohibits pharmaceutical companies from promoting their products for off-label uses, but the agency is unable to review all of the promotional materials that companies submit to it, and its monitoring and surveillance activities to identify violations (such as a detailer’s discussion of off-label uses with a doctor) are also limited.<sup>25</sup> Recent new guidance from FDA allows pharmaceutical companies to distribute reprints of peer-reviewed research from scientific journals (though not material that is written or influenced by drug companies) without requiring that FDA preview the publications beforehand.<sup>26</sup> FDA policy prohibits direct-to-consumer promotion of drugs for off-label uses.<sup>24</sup>

In a study on FDA and Department of Justice (DOJ) actions taken between 2003 and 2007, the Government Accountability Office found that FDA issued 42 regulatory letters requesting that companies stop promotions that violated the law on promoting off-label uses; it took an average of seven months between the agency’s drafting of the letters and sending them, and an average of four months for companies cited for more serious violations to take the requested corrective actions. During the same time period, the DOJ settled 11 cases involving off-label promotion (and, in some cases, additional allegations).<sup>25</sup> Three examples of these cases are:

- Pfizer, Inc. reached a \$430 million settlement with DOJ in May 2004 regarding Neurontin, which is approved as an anti-seizure medication for epilepsy patients. DOJ alleged that Pfizer promoted the drug for various pain disorders, attention deficit disorders, migraines, and other conditions, and that it encouraged sales representatives to give sales pitches to physicians about off-label uses.
- The Purdue Frederick Company reached a \$635.5 million settlement with DOJ in May 2007 regarding Oxycontin, which is approved for management of moderate to severe pain in specific instances. DOJ alleged that the company promoted the drug as being “less addictive, less subject to abuse, and less likely to cause withdrawal symptoms” and for use for a wider pool of patients and conditions than those for which it was approved.
- Bristol-Myers Squibb Company reached a \$515 million settlement with DOJ in September 2007 regarding Abilify, which is approved for treatment of adult schizophrenia and bipolar disorder. DOJ alleged that the company also promoted the drug for use with children and for dementia-related psychosis.<sup>25</sup>

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<sup>25</sup> United States Government Accountability Office. *Prescription Drugs: FDA’s Oversight of the Promotion of Drugs for Off-Label Uses*. (GAO-08-835). July 2008.

<sup>26</sup> U.S. Food and Drug Administration. *Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices*. January 2009. <http://www.fda.gov/RegulatoryInformation/Guidances/ucm125126.htm>.



In recent years, use of psychiatric drugs in children has risen and has attracted concern. Many of these drugs are not approved for use in children, and therefore are prescribed off-label; of six atypical antipsychotics, only one (risperidone, to treat irritability associated with autism) is indicated for use by children under age 10.<sup>27</sup> More than half a million U.S. children are now being prescribed atypical antipsychotics, whose side effects can include rapid weight gain and blood sugar problems, both of which are risk factors for diabetes, and disfiguring tics and dystonia. Reporting of adverse events related to drugs – which is mostly voluntary and therefore likely to represent only a fraction of actual cases – indicates that antipsychotics were the primary suspect in the deaths of at least 29 children and serious side effects in at least 165 others in 2006 alone.<sup>28</sup>

State-level actions provide insight into the rapid growth of the use of antipsychotics for children and into the more-recent decline in some states that are responding to the issue. A New York Times analysis of Minnesota’s marketing data documents that financial relationships between prescribers and manufacturers corresponds to the rise in prescriptions of atypical antipsychotics for children. From 2000 to 2005, manufacturers’ payments to Minnesota psychiatrists more than tripled (to \$1.6 million), and at the same time antipsychotic prescriptions for children enrolled in Minnesota’s Medicaid program increased more than ninefold. The psychiatrists who received \$5,000 or more from the companies manufacturing these drugs “appear to have written three times as many atypical prescriptions for children as psychiatrists who received less or no money.”<sup>28</sup>

By one estimate, prescriptions for psychiatric drugs for children under 10 increased 44.6% between 2002 and 2007, but rose only 3.5% in the year following that period. “Litigation, reaction to improper marketing tactics, and concern about side effects” may be affecting sales, and California and Florida have seen the rates of these prescriptions drop after their state Medicaid agencies tightened requirements for their use in children. In 2006, California put in place a prior-authorization plan for the use of psychiatric medicines in children under six; these prescriptions have since fallen from 5,686 to 4,200. Florida started a program in 2008 under which state-hired psychiatric consultants review prescriptions for children under six before Medicaid will cover them; the number of atypical antipsychotic prescriptions written for this group has fallen from 3,167 to 1,137.<sup>27</sup>

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<sup>27</sup> Armstrong D. Children’s Use of Psychiatric Drugs Begins to Decelerate. *The Wall Street Journal*, May 18, 2009.

<sup>28</sup> Harris G, Carey B, Roberts J. Psychiatrists, Children and the Drug Industry’s Role. *The New York Times*, May 10, 2007.

## IV. Effects of Marketing

Overall, pharmaceutical advertising expenditures have grown from \$9 billion in 1996 to \$21 billion in 2002.<sup>29</sup> In the District of Columbia, pharmaceutical companies reported total marketing expenditures of almost \$158.2 million in 2007. This included:

- \$116.6 million in expenses associated with employees and contractors engaged in marketing
- \$31.3 million in gifts and payments (not including free samples or expenses related to clinical trials or attendance at a conference or seminar); this included:
  - \$11.3 million to individuals (doctors, nurses, etc.)
  - \$19.9 million to non-individual recipients (clinical organizations, professional medical organizations, disease-specific organizations)
- \$10.3 million in advertising

### ***Marketing to Physicians***

In the U.S. between 1996 and 2007, pharmaceutical advertising expenses aimed at physicians doubled in value from \$3.5 billion to \$6.7 billion.<sup>30</sup> With the number of pharmaceutical detailers reaching 90,000 and the advertising costs reaching \$7 billion, the pharmaceutical industry spends approximately \$15,000 per U.S. physician per year.<sup>31</sup> Concerns have arisen that the large amount of pharmaceutical advertising money spent on physicians is unduly influencing their prescribing habits and creating bias in their medical decision making. Pharmaceutical reps provide free food to doctors and staff; distribute free drug samples; compensate doctors for their travel and lodging expenses; hire doctors as consultants and speakers; and finance clinical trials. These types of physician-industry relationships have the potential to make doctors feel the need to reciprocate by prescribing the companies' products. As Jennifer Niebyl puts it, "Gifts create an obligation, a need to reciprocate, which is what creates a conflict of interest. Gifts create a sense of entitlement, unlike advertising, and may erode professional values, unlike advertising."<sup>29</sup>

Qualitative focus groups and surveys with physicians indicate that many physicians recognize the potential for interactions with detailers to create bias, but justify these interactions as being educational. Physicians acknowledge that the potential for undue influence exists, but often think they themselves are "personally invulnerable" while their colleagues are susceptible to industry influence.<sup>31</sup>

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<sup>29</sup> Niebyl J. The pharmaceutical industry: friend or foe? *American Journal of Obstetrics & Gynecology*. 2008 April; 199(2): 435-439.

<sup>30</sup> Kaiser Family Foundation. *Prescription Drug Trends*. September 2008. Accessed 5/21/09. [http://www.kff.org/rxdrugs/upload/3057\\_07.pdf](http://www.kff.org/rxdrugs/upload/3057_07.pdf)

<sup>31</sup> Chimonas S, Brennan T, Rothman D. Physicians and Drug Representatives: Exploring the Dynamics of the Relationship. *Journal of General Internal Medicine* 2007; 22: 184-190.

The potential for pharmaceutical-company influence exists as early as medical school, and attitudes about personal invulnerability appear to already be taking shape at that stage. Pharmaceutical detailing has become such a pervasive factor in the medical community that a large majority of medical students report having received gifts from pharmaceutical companies and attended grand rounds or other events sponsored by pharmaceutical companies. In a survey of ten medical schools around the country, approximately 69% of students believed that receiving food or gifts would not increase the likelihood of them prescribing the drug company's product in the future, but an almost equal amount, 67%, agreed that drug company-sponsored rounds are often biased in favor of the company's products.<sup>32</sup> Similar to what has been demonstrated by physician attitudes, a larger percentage of students felt their colleagues would be influenced by company-sponsored events compared to themselves.

Research suggests that prescribers may not be as skillful as they believe in absorbing companies' educational content without being unduly influenced by it. A survey of physicians in Kentucky found a positive correlation between physician cost of prescribing and perceived credibility, availability, and applicability of information from pharmaceutical-company representatives; in particular, frequency of use of information from these representatives was a positive predictor of cost.<sup>33</sup> A more recent controlled experiment by David Grande et al on the effects of promotional-item distribution concluded, "Subtle exposure to small pharmaceutical promotional items influences implicit attitudes toward marketed products among medical students." The experiment was conducted on third- and fourth-year medical students at University of Pennsylvania School of Medicine (Penn State), which has restrictive policies in place prohibiting gifts, meals, and samples, and the University of Miami Miller School of Medicine (Miami), which has no such policies. Researchers found that Penn State fourth-year students exhibited a negative response towards a certain drug after receiving branded items, while fourth-year students from Miami responded much more positively towards the branded drug. Researchers suggest that because Penn State has a restrictive policy in place, its students are generally more aware of promotional items and act negatively towards them, while students at Miami have no such policies and are therefore more open to pharmaceutical promotional items and less aware of their effects.<sup>34</sup> This study adds significantly to the body of knowledge that suggests even small promotional gifts can exert influence on prescribing behavior.

Prescribers receive information not only from pharmaceutical detailers, but from medical colleagues, many of whom receive fees or research funding from pharmaceutical companies. Drug manufacturers seek to identify "key opinion leaders" or "thought leaders" from the medical field who can influence their colleagues; companies then pay many of these individuals to speak to their colleagues about the benefits of the manufacturer's products. Ray Moynihan, an Australian investigative journalist who has written extensively about the role of pharmaceutical companies in medicine, has suggested that many of these key opinion leaders are drug marketing reps in disguise. Pharmaceutical companies recognize the broad influence thought leaders have

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<sup>32</sup> Sierles F, Brodkey A, Cleary L, et al. Medical Students' Exposure to and Attitudes about Drug Company Interactions: A National Survey. *Journal of the American Medical Association* 2005; 294(9): 1034-1042.

<sup>33</sup> Caudill T, Johnson M, Rich E, McKinney W. Physicians, Pharmaceutical Sales Representatives, and the Cost of Prescribing. *Archives of Family Medicine* 1996; 5: 201-206.

<sup>34</sup> Grande D. et al. Effects of Exposure to Small Pharmaceutical Items on Treatment Preferences. *Archives of Internal Medicine* 2009 May 11; 169(9): 887-893.

on many other physicians and “routinely measure the return on our investment, by tracking prescriptions before and after their presentations.”<sup>35</sup>

A recent article by Adriane Fugh-Berman, a Georgetown University Medical Center professor, and Shahram Ahari, a former drug rep for Eli Lilly, points out that these “thought leaders” are not just helping to market pharmaceutical products – they themselves are a target of marketing efforts. “Physicians invited and paid by a rep to speak to their peers may express their gratitude in increased prescriptions,” they explain.<sup>36</sup> A press release from a company that works closely with drug executives suggests that doctors can earn an average of \$3,000 for a “scientific speech.”<sup>35</sup>

## Free Samples

Pharmaceutical companies’ practice of providing clinics and hospitals with free samples for distribution has also raised concerns. Proponents of this practice argue that free samples provide patients with easy access to the newest and most effective products and assist patients who might otherwise struggle to afford the medications. However, opponents argue that free samples accustom patients to relying on more-expensive drugs when generic or over-the-counter alternatives are available. In one study, medical residents at an inner-city primary care clinic were followed over a six-month period. Physicians were split into two groups, with one group having access to drug samples and the other not. Researchers found that residents with access to drug samples prescribed more heavily advertised drugs than those without access and exhibited a trend towards a decreased use of inexpensive medications.<sup>37</sup> A study examining the characteristics of free-sample recipients, published in the *American Journal of Public Health*, concluded, “Poor and uninsured Americans are less likely than wealthy or insured Americans to receive free drug samples”<sup>38</sup>; this suggests that the samples’ role is not primarily to assist patients who would have difficulty affording prescription medication.

## Research Participation and Results

A literature review of original manuscripts in the *Journal of the American Medical Association* (JAMA) and the *New England Journal of Medicine* (NEJM) conducted by Lee Friedman and Elihu Richter found that approximately one-third of the original manuscripts published in the two largest general medicine journals in the U.S. were funded by private corporations. The study sponsors reported most often were pharmaceutical companies, and the authors note that pharmaceutical companies spent approximately \$23 billion on clinical research in 2001 (by

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<sup>35</sup> Moynihan R. Key Opinion Leaders; Independent experts or drug representatives in disguise? *British Medical Journal* 2008 June 21; 336: 1402-1403.

<sup>36</sup> Fugh-Berman A and S Ahari. Following the Script: How Drug Reps Make Friends and Influence Doctors. *PLoS Medicine* 2007 April; 4(4): 621-625.

<sup>37</sup> Adair R and L Holmgren. Do drug samples influence resident prescribing behavior? A randomized trial. *The American Journal of Medicine* 2005; 118: 881-884.

<sup>38</sup> Cutrona S, Woolhandler S, Lasser K, et al. Characteristics of Recipients of Free Prescription Drug Samples: A Nationally Representative Analysis. *American Journal of Public Health* 2008 February; 98(2): p. 284-289.

contrast, the National Institute of Health spent only \$18 billion).<sup>39</sup> Industry sponsorship of clinical trials and research has drawn public scrutiny due to the increased likelihood of positive results based on the funding source. In reviewing the clinical trial literature in JAMA and NEJM, Friedman and Richter found a strong association between studies whose authors had conflicts of interest and reported positive findings. An even stronger association was found between researchers who did not have any conflicts of interest and reporting negative results.<sup>39</sup>

A report by the United Kingdom's House of Commons Health Committee examines extensively how the drug industry funds a large proportion of the clinical trials reported in medical journals and states, "Inevitably the industry not only has a major effect on what gets researched, but also how it is researched and how results are interpreted and reported." The report highlights the lack of transparency in clinical trials sponsored by drug companies, which makes it difficult for physicians to effectively interpret and assess the findings of research. It also notes that five out of six systematic reviews of research have found industry-sponsored research is much more likely to produce positive results, while trials producing negative results are deemed failed trials rather than failed drugs.<sup>40</sup>

## Physicians in the District

In 2007, pharmaceutical companies reported spending \$158.2 million on marketing in the District, and \$166.6 million of that was for "aggregate costs" – expenses for employees and contractors engaged in advertising and marketing activities. This is by far the largest of the expenditure categories, and its size suggests that pharmaceutical companies are dedicating large amounts of resources to pharmaceutical detailing visits to prescribers in the District.

Companies also reported giving \$10.2 million to District providers with MD credentials. The majority of that amount, over \$6.7 million, was described as being for speaker fees. Seventeen physicians received over \$100,000 in payments from pharmaceutical companies in 2007. Given recent high-profile concerns over psychiatrists' potential conflicts of interest, it is worth noting that three of these 17 are psychiatrists. For the ten physician recipients who received the most money from pharmaceutical companies, speaker fees accounted for the overwhelming majority of their totals – 75% or more in nine out of the ten cases. These figures suggest relationships that have the potential for serious conflicts of interest.

Because the District's Medicaid prescription-drug expenditures play such an important role in the overall cost, utilization, and delivery of healthcare services in the city, it is worth investigating the extent to which Medicaid providers might be acting as consultants or "key opinion leaders" for pharmaceutical companies. We selected \$1,000 as an amount that might signal pharmaceutical companies' interest in a particular physician, and prepared a list of physicians who received gifts or payments valued at \$1,000 or more from these companies in 2007. We identified a total of 193 physicians who met these criteria.

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<sup>39</sup> Friedman L and E Richter. *Relationship Between Conflicts of Interest and Research Results*. Journal of General Internal Medicine 2004; 19:51-56.

<sup>40</sup> House of Commons Health Committee. *The Influence of the Pharmaceutical Industry; Fourth Report of Session 2004-5*. Volume 1. 5 April 2005.

We compared the list of 193 physicians who received more than \$1,000 in speaking or consulting fees to lists of District Medicaid prescribers based on 2007-2008 Medicaid claims. Medicaid provider data was split into two databases: providers who saw Medicaid patients on a fee-for-service basis and providers who saw Medicaid patients who are enrolled in a managed care program. Of the 193 physicians who received over \$1,000 for speaking and consulting, 31 appeared in the fee-for-service Medicaid provider list. Eight of those 31 were also identified as Medicaid managed care providers. In addition to those eight physicians who saw both fee-for-service and managed care beneficiaries, another 29 doctors from our list of 193 were identified in the Medicaid managed care list. So, a total of 60 doctors out of the 193 who received more than a \$1,000 from the drug industry for speaking and consulting fees alone were identified as Medicaid providers. It is likely that the actual total is higher than 193, since the pharmaceutical-company reports named individual physicians while the Medicaid provider lists gave practice names in some cases and individual practitioners' names in others.

We identified the 200 Medicaid fee-for-service providers with the highest number of Medicaid claims, and found that 11 physicians from our list of 193 receiving \$1,000 or more in speaking or consulting fees were among these top Medicaid fee-for-service providers. The number of claims for these 11 physicians ranged from 132 to 2,191, the number of unique patients ranged from 31 to 598, and the amount of money received from pharmaceutical companies ranged from \$1,000 to \$39,508. There was no obvious correlation between the amount of money received from drug companies and the number of Medicaid claims.

We then identified the 200 Medicaid managed care providers with the highest number of Medicaid patients seen, and found that six physicians from our list of 193 receiving \$1,000 or more in speaking or consultation fees were among these top Medicaid managed care providers. One of these physicians was also among the top 200 fee-for-service Medicaid providers. The number of patients seen by these six providers ranged from 71 to 144, and the amounts they received from pharmaceutical companies ranged from \$1,500 to \$23,710.

In all, 60 District Medicaid providers identified in the databases we used received \$1,000 or more in speaking or consulting payments from pharmaceutical companies in 2007, and 16 of those 60 were among the top Medicaid providers.

The AccessRx Act does not require pharmaceutical companies to report expenses related to clinical trials or the distribution of samples that will be given to patients at no cost, so it was not possible to determine the extent to which these practices occur in the District.

### ***Direct-to-Consumer Advertising***

In 1997, the U.S. Food and Drug Administration released broadcasting guidelines that allowed direct-to-consumer (DTC) advertising “into broadcast and electronic media” for the first time, radically altering the playing field for pharmaceutical advertising. DTC advertising is only legal in the United States and New Zealand. Since 1997, pharmaceutical companies have directed growing amounts of advertising resources to DTC: between 1997 and 2003, DTC expenditures

increased from \$791 million to \$3.2 billion, an increase of almost 400%. In 2004, DTC advertising increased to \$4 billion.<sup>41</sup>

The growth in DTC advertising appears to have paid off for pharmaceutical companies. Between 1998 and 1999, retail spending on prescription drugs grew by \$17.7 billion, and 34% of that increase was attributable to the 24 most heavily advertised drugs. In 2000, “doctors wrote 25% more prescriptions for the 50 most heavily DTC advertised drugs compared to 4.3% more scripts for all other drugs combined.”<sup>42</sup> Pharmaceutical advertisements have become pervasive on television; one study found that “based on average television viewing in the United States, an adult is exposed to 100 minutes of direct-to-consumer advertising for each minute they spend with their doctor each year.”<sup>41</sup>

Direct-to-consumer advertising has affected the relationships between physicians and their patients. Surveys from physicians suggest that DTC advertising, rather than promoting beneficial dialogue, tends to confuse patients and create a perception that there “is a pill for every ill.” Many of those surveyed felt DTC should be discontinued. Physicians have also expressed concerns over the pressure they feel to prescribe medications patients request after seeing them on television; they fear that if they refuse, patients may transfer to a different provider. Based on a study comparing prescription habits of doctors in Sacramento, California and Canada, researchers found patients from the U.S. who had been exposed to DTC were more likely to request or ask about a medication they saw on TV, and were also more likely to receive a prescription for the medication.<sup>43</sup> As Dr. Jerry Avorn states in his book *Powerful Medicines: The Benefits Risks and Costs of Prescription Drugs*, “Direct-to-consumer ads can also have adverse effects on the doctor-patient relationship by turning the prescription into a kind of zero-sum negotiation between conflicting parties.”<sup>44</sup>

The large increase in allergy-related visits to physicians and prescriptions is one striking example of how DTC influences patients. Before the 1997 FDA decision that allowed for DTC advertising, the rate of allergy-related visits to healthcare providers remained steady throughout the 1990s. Then, the amount jumped from about 13-14 million a year to 18 million in 1999. In 1998 and 1999, allergy medications were among the top 50 most heavily marketed drugs. In 1999, the oral antihistamine Loratidine, otherwise known as Claritin, ranked number one as the most heavily marketed drug, with Schering-Plough, the drug’s producer, spending \$137.1 million in DTC advertising.<sup>42</sup> In fact, only 12 medications accounted for nearly half of all advertising spending, while the top 50 marketed drugs accounted for 95% of the spending.<sup>41</sup>

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<sup>41</sup> Gellad Z and K Lyles. Direct-to-Consumer Advertising of Pharmaceuticals. *The American Journal of Medicine* 2007; 120: 475-480.

<sup>42</sup> Findlay S. Direct-to-Consumer Promotion of Prescription Drugs. *Pharmacoeconomics* 2001; 19(2): 109-119.

<sup>43</sup> Mintzes B, Barer M, Kravitz R, et al. How does direct-to-consumer advertising (DTCA) affect prescribing? A survey in primary care environments with and without legal DTCA. *Canadian Medical Association Journal* 2003 September 2; 169(5): 405-412.

<sup>44</sup> Avorn J. *Powerful Medicines; The Benefits, Risks, and Costs of Prescription Drugs*. Alfred A. Knopf, 2004.

## **Direct-to-Consumer Advertising in the District**

Pharmaceutical companies spent over \$10 million in advertising in the District of Columbia in 2007. Television advertisements had the largest share of all advertising expenses, accounting for 42% of the total amount. Advertising expenses represented the smallest proportion of overall marketing costs, when compared to the categories of gift expenses and costs associated with marketing personnel. However, it is important to note that some companies reported spending \$0 in advertising costs because District-specific advertising could not be differentiated from their overall national advertising expenses. In fact, six of the twenty-six companies who spent over \$1 million in total marketing costs reported spending zero dollars on advertising. This suggests that the actual 2007 District advertising expense figure is far higher than the reported amount.

## **Funding of Organizations Producing Continuing Medical Education and Patient Information**

A recent New York Times article, *Psychiatric Group Faces Scrutiny Over Drug Industry Ties*, highlights another aspect of pharmaceutical marketing often overlooked: the direct sponsorship of professional organizations and continuing medical education by pharmaceutical companies. The article reveals that in 2006, 30% of the American Psychiatric Association's (APA) \$62.5 million in financing came from the drug industry. The organization spent half of that money on advertisements in psychiatric journals and exhibits at annual meetings, and the other half to "sponsor fellowships, conferences and industry symposiums at the annual meeting."<sup>45</sup> The scrutiny of the APA evidently had an effect: In March of 2009, the organization announced that it would phase out industry-supported symposia and industry-supplied meals at its annual meetings.<sup>46</sup> But APA is hardly alone among professional organizations in receiving large sums from the pharmaceutical industry, and the ties go beyond conference-related events.

In a JAMA article entitled "Professional Medical Associations and Their Relationships With Industry: A Proposal for Controlling Conflict of Interest," authors note that industry funding of professional medical association activities is pervasive. Pharmaceutical and medical device companies subsidize annual meetings by purchasing booths and underwriting physician attendance; providing honoraria; purchasing advertising space; supporting publications of practice guidelines and other materials; and funding continuing medical education. The authors call for professional medical organizations to adopt uniform guidelines on conflict of interest, including a requirement that presidents and officers of these organizations be conflict-free during their tenure.<sup>47</sup> In a report by the Association of American Medical Colleges' task force on industry funding, authors explain that organizations' reliance on drug-industry funding "raises

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<sup>45</sup> Carey B and G Harris. *Psychiatric Group Faces Scrutiny over Drug Industry Ties*. *The New York Times*. July 12, 2008.

<sup>46</sup> American Psychiatric Association. News Release: The American Psychiatric Association Phases Out Industry-Supported Symposia. March 25, 2009.

<sup>47</sup> Rothman D, McDonald W, Berkowitz C, et al. Professional medical associations and their relationships with industry: a proposal for controlling conflict of interest. *Journal of the American Medical Association* 2009 Apr 1; 301(13):1367-72.



concerns because such support, including gifts, can influence the objectivity and integrity of academic teaching, learning, and practice.”<sup>48</sup>

Industry funding of continuing medical education (CME) is of particular concern, because prescribers are generally required to complete CME regularly in order to maintain their licenses. In 2006, the 729 accredited CME providers earned \$2.38 billion; physician member organizations that provide CME received roughly one-third of that. As recently as 1998, most of CME providers’ income came from registration fees of participants or sponsoring organizations, but since 2003, most of that money has come from industry.<sup>49</sup> In a JAMA commentary on industry funding for CME, Robert Steinbrook writes:

Continuing medical education has become so heavily dependent on support from pharmaceutical and medical device companies that the medical profession may have lost control over its own continuing education. Commercial funding may inherently distort education and practice to the detriment of physicians and patients, regardless of the various safeguards to protect the integrity of the enterprise.<sup>49</sup>

The Accreditation Council for Continuing Medical Education (ACCME) will not accredit commercial interests, and it requires that CME planners, speakers, and authors disclose relevant financial relationships from the past five years. In 2007, ACCME announced new policies and an intention to consider a new monitoring system and alternative funding models; Steinbrook notes, “The effect of these initiatives – and the sufficiency of the council’s standards – remains to be seen.”

Due to the large amount of money being spent by pharmaceutical companies on CME, Des Spence, who works with the organization No Free Lunch,<sup>50</sup> has actually referred to drug-sponsored educational events as “marketing masquerading as education.” Although not entirely conclusive, research on the effect of corporate sponsorship of educational events points to a trend in increased prescriptions after events, which pharmaceutical companies monitor closely. Concerns over the industry’s control over the information presented by speakers and lack of disclosure of industry ties are the primary activities indicative of a conflict of interest between physicians, professional organizations that host symposiums and meetings, and the drug industry. Based on conversations with drug company representatives in Australia, Roy Moynihan suggests drug companies, as sponsors of an educational meeting, are allowed to suggest certain speakers and topics.<sup>51</sup>

Pharmaceutical-industry funding of professional medical organizations is also of concern because these organizations often issue practice guidelines that set standards for patient care. The

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<sup>48</sup> Association of American Medical Colleges. *Industry Funding of Medical Education: Report of an AAMC Task Force*. June 2008. Accessed 6/1/09.

[https://services.aamc.org/Publications/showfile.cfm?file=version114.pdf&prd\\_id=232&prv\\_id=281&pdf\\_id=114](https://services.aamc.org/Publications/showfile.cfm?file=version114.pdf&prd_id=232&prv_id=281&pdf_id=114)

<sup>49</sup> Steinbrook R. Financial Support of Continuing Medical Education. *Journal of the American Medical Association* 2008 March 5; 229(9): 1060-2.

<sup>50</sup> *No Free Lunch* is a non-profit organization of health care providers who aim to better inform the health care profession about industry sponsorship and provide resources for providers to free themselves from promotional activities.

<sup>51</sup> Moynihan R. *The Invisible Influence*. *British Medical Journal* 2008 February 23; 336: 416-417.

group of JAMA authors who proposed ways to control conflicts of interest between medical associations and pharmaceutical companies recommends:

Under no circumstances should PMAs [professional medical associations] accept funding from industry to develop practice guidelines or outcome measures ... PMAs must hold the individuals who write guidelines and outcome measures to the most stringent conflict-of interest standards ... At minimum, PMAs must exclude from such committees persons with any conflict of interest (\$0 threshold) involving direct salary support, research support, or additional income from a company whose product sales could be affected by the guidelines.<sup>47</sup>

Less recognized and not as well researched or understood is the relationship between drug companies and disease-specific organizations, also called patient organizations. In a survey of patient organization websites that assessed indicators of transparency, advertising, and disclosure of pharmaceutical sponsorships, researchers found that only about half of the websites provided links to financial reports, and disclosures of funding varied dramatically. In addition, a third of the websites featured company logos or links to drug company websites. From their survey of these patient organization websites, researchers concluded that patients were not provided with adequate information to assess possible conflicts of interest that may exist between organizations and drug companies.<sup>52</sup>

Of particular concern is patient organizations' lack of information concerning potential risks and side effects of medications mentioned on their websites. A 2006 Washington Post article highlighted two examples of this: The American Diabetic Association failed to mention safety concerns about the experimental diabetes drug *muraglitazar*, which research has linked to possible increased risk of fatal heart problems, and the National Osteoporosis Foundation neglected to describe the scientific debate about the long-term effects of popular osteoporosis drug *Fosamax* – and neither organization disclosed its financial ties with the drug manufacturers of these medications.<sup>53</sup> Since many patients rely on disease-specific organizations for information about treatments, such a lack of disclosure is troubling.

## **Funding of Organizations in the District**

Organizations (non-individual recipients) in the District received close to \$20 million in gifts from pharmaceutical companies in 2007; this constituted approximately two-thirds of all gift expenses in the District. A little over 75% of that, or roughly \$15.2 million, was reported to be for the purpose of “education”; although many of the pharmaceutical-company reports did not provide additional details, \$2.3 million was specifically described as being for the purpose of CME.

The analysis of non-individual recipients divided organizations into three categories: Professional Organizations, Disease-Specific Organizations, and Clinical Organizations. Of

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<sup>52</sup> Ball D, Tisocki K, Herzheimer A. Advertising and disclosure of funding on patient organization websites: a cross-sectional survey. *BMC Public Health* 2006; 6: 201-213.

<sup>53</sup> Ready T. Divided Loyalties? *The Washington Post*. February 7, 2006.

these three categories, Professional Organizations received the most from the drug industry. The top ten Professional Organization recipients alone received about \$9.4 million in 2007, which represents almost half of all gift expenditures for non-individual recipients. Of these ten professional organizations, seven state on their websites that they offer CME or educational meetings. Out of the seven, only two disclose financial support from the pharmaceutical industry, and they describe the amount only in relative terms (e.g., differentiating Diamond Level Supporters from Bronze Level Supporters). Due to the influence that professional organizations have over physicians and clinical practices, it is important these entities ensure their educational activities remain free of bias and undue influence from corporate sponsors.

The top ten disease-specific organization recipients in DC received approximately \$2 million in 2007 from pharmaceutical companies. Of these ten organizations, only four clearly name corporate sponsors on their websites, and none of them disclose the amounts of funding received from these sponsors.

## V. Efforts to Control Pharmaceutical Marketing's Influence

Efforts to stem the tide of increasing drug costs are currently being seen on all levels of government and within medical institutions. These efforts focus on minimizing the influence of pharmaceutical marketing through transparency and disclosure of financial relationships that pharmaceutical companies have with healthcare providers, institutions, and organizations.

The Pharmaceutical Research and Manufacturers Group of America (PhRMA), an association that represents research-based pharmaceutical and biotechnology companies, released their revised voluntary "Code on Interactions with Healthcare Professionals" in January 2009.<sup>54</sup> These recent standards are noteworthy because they propose a voluntary discontinuation of the practice of providing branded products (mugs, pens, t-shirts, etc.) to healthcare providers. The updated code also reinforces guidelines established in 2002 that prohibit more-lavish gifts and expensive goods "like tickets to professional sports games and junkets to resorts."<sup>55</sup> Although PhRMA's code represents a significant step, its voluntary nature makes it less forceful than many of the requirements by states and institutions to limit gifts and payments to prescribers and improve transparency.

### **State-level Efforts**

Minnesota, Vermont, the District of Columbia, and Massachusetts have led the way in progressive legislation requiring financial disclosure and transparency. Most recently, Vermont and Massachusetts have passed legislation or adopted regulations that will ban many types of gifts and require public disclosure of payments from pharmaceutical companies to healthcare providers. Minnesota has long made information about pharmaceutical manufacturer's payments to practitioners available to the public. In the District, pharmaceutical companies have been required to report payments since 2006, and new legislation creates new standards for detailers and establishes an academic detailing program.

### **Minnesota**

In 1993, the Minnesota Legislature enacted a law limiting the amount of gifts and payments that pharmaceutical companies and manufacturers could give to physicians. The law also required drug companies and manufacturers to report payments to practitioners and specified that these reports would be made publicly available.<sup>56</sup> Only gifts and payments valued at \$100 or more are

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<sup>54</sup> The Pharmaceutical Research and Manufacturers of America. *Code on Interactions with Healthcare Professionals*. January 2009. Accessed 6/4/09.

<http://www.phrma.org/files/PhRMA%20Marketing%20Code%202008.pdf>

<sup>55</sup> Singer N. No Mug? Drug Makers Cut Out Goodies for Doctors. *The New York Times*, December 31, 2008.

<sup>56</sup> Minnesota Board of Pharmacy. Payments to Practitioners Documents. Accessed 6/1/09.  
[http://www.phcybrd.state.mn.us/main\\_pay.htm](http://www.phcybrd.state.mn.us/main_pay.htm)

required to be reported.<sup>57</sup> Payment reports for each drug company marketing in Minnesota are available from the year 1997 and are publicly available online.<sup>56</sup> Any interested party has the ability to go online and check to see if his or her physician or practitioner has received money from pharmaceutical companies.

Because Minnesota's information is available as multiple individual documents (submitted by the companies) rather than in a single annual report, casual readers may not find it user-friendly. Researchers and reporters, on the other hand, have made use of the data and drawn attention to the large sums that some providers receive from pharmaceutical companies.<sup>28, 57</sup>

## Vermont

Vermont enacted the Pharmaceutical Marketing Disclosure Law in 2002. The law requires pharmaceutical companies to disclose all gifts and payments made to any persons in Vermont who are authorized to prescribe, dispense, or purchase pharmaceutical products. Vermont has been utilizing this data to create annual reports, since 2003, which describe total marketing expenditures in Vermont by pharmaceutical companies, marketing expenditures by recipient type, a specialty profile of top 100 recipients, a description of marketing expenditures for particular products and indications, and the primary purpose and nature of marketing expenditures. In a statement by the Vermont Attorney General's office regarding the 2008 disclosure report, it was revealed that total marketing expenditures have decreased by 30% in the five years the state has required reporting. The Attorney General admits that it is hard to distinguish if the decrease is based on financial decisions by the industry or results from increased public scrutiny from the reports.<sup>58</sup>

On June 8, 2009, Vermont's governor signed a strict new law<sup>59</sup> that will ban all free meals from pharmaceutical companies to prescribers; publicly disclose all money given to providers, including names and dollar amounts; and close a loophole in the previous regulation under which companies had kept some expenses private by designating them as trade secrets.<sup>60</sup> Free drug samples intended for distribution to patients and expenses connected to bona fide clinical trials are exempt from disclosure requirements.<sup>61</sup>

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<sup>57</sup> Ross J, Lackner J, Lurie P, et al. Pharmaceutical Company Payments to Physicians. Early Experience with Disclosure Laws in Vermont and Minnesota. *Journal of the American Medical Association* 2007 March 21; 297(11): 1216-23.

<sup>58</sup> Vermont Attorney General's Office. Pharmaceutical Marketing Disclosures. Accessed 5/28/09. [http://www.atg.state.vt.us/upload/1239813108\\_2009\\_Pharam\\_Report.pdf](http://www.atg.state.vt.us/upload/1239813108_2009_Pharam_Report.pdf).

<sup>59</sup> Barlow D. New law curbs marketing of pharmaceuticals. *Times Argus*. June 9, 2009.

<sup>60</sup> Singer N. Vermont Acts to Make Drug Makers' Gifts Public. *The New York Times*, May 20, 2009.

<sup>61</sup> Vermont Office of the Attorney General. Pharmaceutical Marketing Disclosure Law. Accessed 6/1/09. [http://www.atg.state.vt.us/upload/1206473447\\_18\\_VSA\\_4632\\_-\\_Statute.pdf](http://www.atg.state.vt.us/upload/1206473447_18_VSA_4632_-_Statute.pdf).

## **District of Columbia**

In 2004, the District of Columbia passed the AccesRx Act, which requires pharmaceutical companies to report gifts and payments made to healthcare providers. In 2008, the District addressed practices of pharmaceutical detailers with the SafeRx Act, which requires that pharmaceutical detailers working in the District be licensed by the Board of Pharmacy. To apply for a license, each detailer must establish that he or she is a graduate of a recognized institute of higher learning; pay a licensing fee; and submit a notarized statement agreeing to abide by a code of ethics and other requirements for the practice of detailing. Detailers must not engage in deceptive or misleading marketing of a pharmaceutical product or use a title or designation that would falsely suggest that he or she has a license to practice medicine. Fines for practicing without a license can be as much as \$10,000.<sup>62</sup>

Another important component of the District's SafeRx Act is the establishment of the Pharmaceutical Education Program. This is an academic detailing (or educational outreach) program tasked with educating prescribers who participate in the District's Medicaid program and other publicly funded or subsidized healthcare programs about the "therapeutic and cost-effective utilization of pharmaceutical products." The program will use independent educational resources that promote "high-quality, evidence-based, cost-effective information regarding the effectiveness and safety of pharmaceutical products" and will inform prescribers about pharmaceutical-company marketing practices intended to "circumvent competition from generic, other therapeutically-equivalent alternatives, or other evidence-based treatment options."<sup>62</sup>

## **Massachusetts**

In March of 2009, the Massachusetts Public Health Council passed sweeping new regulations that ban pharmaceutical and medical-device companies from giving gifts to physicians and require public disclosure of payments over \$50. Meals are still allowed if they are modest and provided at trainings or educational events; payments for "genuine research projects and clinical trials" and prescription drugs provided for patients' use are exempt from disclosure. Massachusetts is the only state so far to require disclosure by device makers as well as drug companies.

## **Other states**

Maine and West Virginia also require that pharmaceutical manufacturers submit reports listing their advertising and marketing expenditures. Maine requires reporting gifts or payments of \$25 or more, while West Virginia's limit is \$100. Both states exempt free samples for patients and clinical trial or research expenses from disclosure, and neither one exempts payments for

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<sup>62</sup> The Council of the District of Columbia. SafeRx Amendment Act of 2008. Accessed 5/28/09. Available at: [http://hrla.doh.dc.gov/hrla/frames.asp?doc=/hrla/lib/hrla/pharmacy\\_control/saferx\\_act.pdf](http://hrla.doh.dc.gov/hrla/frames.asp?doc=/hrla/lib/hrla/pharmacy_control/saferx_act.pdf).

continuing medical education. Neither Maine nor West Virginia requires that disclosures be made public.<sup>63</sup>

In 2008, a total of 20 different states proposed legislation requiring marketing disclosure by drug manufacturers, regulating direct-to-consumer advertising, or prohibiting the sale of prescription information for commercial purpose.<sup>64</sup>

## **Hospitals and Medical Schools**

Some hospitals and medical schools (which are often affiliated with one another) have taken steps to bar or limit marketing activities by pharmaceutical companies. Many of these changes have taken place over the past year, and are likely due, at least in part, to growing scrutiny of potential conflicts of interest between pharmaceutical companies and doctors, researchers, and faculty members.

In April 2009, two widely respected health systems announced sweeping changes to their policies around pharmaceutical marketing. The Johns Hopkins system in Maryland (a medical school, hospital, and clinics) announced a new policy that prohibits gifts, entertainment, or food from drug and medical-device companies, and restricts those companies' representatives from visiting unless invited by doctors or other staff. Individual doctors may no longer receive industry donations, although companies may still donate to Hopkins.<sup>65</sup> In Massachusetts, Partners HealthCare (which includes Mass General and Brigham and Women's hospitals, as well as outpatient clinics) will bar its doctors from accepting meals from pharmaceutical companies and serving on companies' speakers bureaus. Pharmaceutical representatives will need "written invitations defining the purpose and terms of visits" in order to see prescribers, and they may provide samples only through a central mechanism, rather than distributing them to individual doctors.<sup>66</sup>

Several major medical schools – Stanford University and the universities of Massachusetts, Pittsburgh, Colorado, Kansas, and California-Davis – have established school-wide pools for funding continuing medical education; companies may contribute to these pools, but may not specify which courses they wish to finance. The Association of American Medical Colleges has recommended that medical schools use such a mechanism in order to shield instructors from commercial influences. The Memorial Sloan-Kettering Cancer Center has gone even further and prohibited all industry support for its classes for doctors.<sup>67</sup>

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<sup>63</sup> Lurie P, Ross J, Rosenbaum A, Krigel J. Testimony on State Laws Requiring Disclosure of Pharmaceutical Company Payments to Physicians. Testimony before the Senate Special Committee on Aging, June 27, 2007.

<sup>64</sup> National Conference of State Legislatures. 2008 Prescription Drug Legislation. March 2009. Accessed 6/1/09. <http://www.ncsl.org/default.aspx?tabid=14418>.

<sup>65</sup> Rubenstein S. Johns Hopkins Bans Free Drug Samples, Gifts from Industry. *The Wall Street Journal Health Blog*, April 8, 2009.

<sup>66</sup> Goldstein J. Harvard-Affiliated Hospitals to Limit Docs' Industry Ties. *The Wall Street Journal Health Blog*, April 10, 2009.

<sup>67</sup> Harris G. Stanford to Limit Drug Maker Financing. *The New York Times*, August 26, 2008.

Other medical schools and hospitals have taken steps to increase transparency around industry funding that their faculty members and doctors receive. In December 2008, the University of Pennsylvania School of Medicine and its health system unveiled plans to create a website with searchable information on its doctors' and scientists' outside activities,<sup>68</sup> and the Cleveland Clinic announced that its online directory of physicians and scientists had been expanded to include in each individual's biography "a list of the names of companies with which they have collaborations, further identifying whether they have equity, the right to royalties, a fiduciary position or a consulting relationship that pays \$5,000 or more per year."<sup>69</sup> Earlier this year, the University of Minnesota Medical School released a new conflict-of-interest policy that requires faculty and staff to report external funding exceeding \$500 from any single source and recommends creation of a public website documenting all industry payments faculty receive.<sup>70</sup> Stanford University announced that it will begin identifying doctors and other faculty members who receive more than \$5,000 from pharmaceutical or device companies, although they will not disclose exact figures.<sup>71</sup>

Pharmaceutical companies are also taking steps toward transparency. Eli Lilly, GlaxoSmithKline, Merck, and Pfizer have all announced that they will begin disclosing their payments to doctors.<sup>72</sup>

Medical students are playing an important role in advancing stricter conflict-of-interest policies. Harvard students raised objections to professors delivering lectures on drugs' benefits without mentioning their ties to the drugs' manufacturers, and now the school is alone among leading medical schools in requiring that all professors and lecturers disclose their industry connections to their classes.<sup>73</sup> The American Medical Student Association runs a PharmFree campaign, and in collaboration with the Prescription Project, they issue an annual scorecard that grades schools based on their "restrictions on gifts, paid speaking for products, acceptance of drug samples, interaction with sales representatives, and industry funded education, among other criteria." Their 2008 scorecard awarded A or B grades, which signify that the schools have strong policies, to only 21 schools out of 150 surveyed.<sup>74</sup>

## District Hospitals and Medical Schools

The Accreditation Council for Continuing Medical Education (ACCME) provides standards for Commercial Support in order to ensure independence of CME activities, and any medical school,

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<sup>68</sup> Goldstein J. Penn Medicine to disclose doctors' drug ties. *Philadelphia Inquirer*, December 5, 2008.

<sup>69</sup> Cleveland Clinic. News Release: Cleveland Clinic Makes Physician Disclosures Available Online. December 3, 2008. Accessed 5/28/09. Available at: [http://my.clevelandclinic.org/news/2008/cleveland\\_clinic\\_physician\\_disclosures.aspx](http://my.clevelandclinic.org/news/2008/cleveland_clinic_physician_disclosures.aspx).

<sup>70</sup> Moore J. Med school pares rules on conflict of interest. *StarTribune*, March 3, 2009.

<sup>71</sup> Rockoff J. Stanford Medical School to Disclose More About Industry Comp. *The Wall Street Journal Health Blog*, April 1, 2009.

<sup>72</sup> Goldstein J. How Pfizer's Doctor-Payment Disclosure Compares to Grassley Plan. *The Wall Street Journal Health Blog*, February 10, 2009.

<sup>73</sup> Wilson, D. Harvard Medical School in Ethics Quandary. *The New York Times*, March 3, 2009.

<sup>74</sup> American Medical Student Association. AMSA PharmFree Scorecard Grades U.S. Medical Schools on Conflict-of-Interest Policies. June 3, 2008. Accessed 5/28/09. <http://www.amsa.org/news/release2.cfx?id=345>.



hospital, or other facility offering CME courses must abide by these standards in order to have their courses accredited. The ACCME standards include the following requirements:

- All providers of CME must fully disclose all relevant financial relationships with commercial interests;
- Providers cannot be required by a commercial interest to accept advice on content of a presentation or the service of certain participants as part of the conditions of the contributing funds, and written agreements must document terms of financial support from commercial interests; and
- Presentations may not include any type of advertising or product name.<sup>75</sup>

Both the George Washington University School of Medicine and Health Sciences and the Georgetown University School of Medicine are accredited through the ACCME and follow these guidelines.

We contacted medical schools located in the District to determine whether they, or the hospitals with which they are affiliated, have adopted policies regarding contact or gift-giving between pharmaceutical marketing representatives and the institution's medical students, faculty members, or healthcare providers.

According to a spokesperson from the CME office at Georgetown University Hospital, the medical school is currently drafting a strict policy that will severely limit interaction with medical students/staff and the pharmaceutical industry and be similar to the American Medical Association guidelines.<sup>76</sup>

Representatives from the public affairs and media office of the George Washington University Hospital and School of Medicine and Health Services were unaware of any policies regarding restrictions on gifts or interactions between physicians or medical students and pharmaceutical representatives.

Howard University Medical School and Hospital did not respond to multiple requests for this information. The only information available is from Howard University's Code of Ethics, where there is a small section regarding "Relationship with Vendors." This section states:

No member of the University Community may approve, recommend, or promote a business transaction in which that person has a direct personal interest, or otherwise cause the University to do business with a firm in which that person an officer or senior management employee or in which that person own more than a 5 percent equity interest,

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<sup>75</sup> Accreditation Council for Continuing Medical Education. *ACCME Standards for Commercial Support*. 2007. Accessed 5/28/09. [http://www.accme.org/dir\\_docs/doc\\_upload/68b2902a-fb73-44d1-8725-80a1504e520c\\_uploaddocument.pdf](http://www.accme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-8725-80a1504e520c_uploaddocument.pdf).

<sup>76</sup> Personal communication with Janet Owens, Senior Coordinator of Continuing Medical Education at Georgetown Hospital. May 7, 2009.

unless such person first discloses his/her relationship and the relevant circumstances of the contemplated activity, in writing, to the President and the Compliance Officer.<sup>77</sup>

Georgetown University Hospital is owned by MedStar Health, a non-profit, community-based health care system that owns several hospitals in the District of Columbia and Maryland (including Washington Hospital Center), and Georgetown's media representative referred questions about pharmaceutical marketing policies to MedStar. MedStar Health has a vendor access badge system for all sales and service vendor representatives who want to enter MedStar facilities. There are three levels of access for vendor badges: Level I allows access to non-patient care areas, Level II allows access to patient care areas and Level III allows access to restricted patient care areas, with an increasing amount of documentation needed for each level of access. For all three levels vendors must:

- (1) Read and sign MedStar Health's vendor Code of Conduct,
- (2) Provide documentation of substance abuse testing,
- (3) Complete a vendor profile record,
- (4) Provide documentation of criminal background check,
- (5) Provide documentation of non-exclusion from participation in federal programs,
- (6) Provide documentation of education/certification on service or equipment being provided,
- (7) Read and sign a confidentiality statement, and
- (8) Read and sign a gift disclosure statement.<sup>78</sup>

The Senior Coordinator at the Continuing Medical Education Office at Georgetown University Hospital stated that the MedStar badge policy is so comprehensive that it tends to dissuade many pharmaceutical representatives from entering the hospital. In addition, the Senior Coordinator believed there was a policy prohibiting the distribution of free drug samples at MedStar Hospitals, but this could not be verified.

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<sup>77</sup>Howard University Board of Trustees. Howard University Code of Ethics and Conduct. August 1998. Accessed 5/28/09. <http://www.howard.edu/policy/codeofethics.pdf>.

<sup>78</sup>Hardy C. MedStar health vendor access program: one system's story. *AORN Journal* 2007 Nov; 86(5):815-23.

## VI. Recommendations

Research limitations make it difficult to pinpoint specific problematic behaviors related to prescribing practices in the District, but certain steps involving prescription drugs can nonetheless be taken by the District to improve the cost, quality, and utilization of healthcare for its residents.

### ***Research Options and Limitations***

Under our nation's current healthcare system, an array of payers and tracking systems makes it difficult to gather reliable and complete information about prescription-drug use in the District. Data available at the national level, however, can provide important insights into trends in prescription-drug use. Major pharmacy benefit management companies, such as Medco<sup>79</sup> and ExpressScripts<sup>80</sup>, publish annual drug trend reports based on their clients' use of drugs; these contain information about changes in prescribing in different classes of drugs, trends in generic substitution, and other useful information. Because the Medicare Part D pharmaceutical benefit is delivered through private plans, those expenditures also show up in the data on private expenditures.<sup>15</sup> For national-level information on Medicaid pharmaceutical spending, Medicaid Pharmacy Benefit Use and Reimbursement Chartbooks prepared by Mathematica Policy Research, Inc. using Medicaid Analytic eXtract files are currently available for 1999, 2001, 2002, and 2003.<sup>81</sup>

At the District level, it is possible to obtain data about prescription-drug use for the Medicaid population (although dual eligibles' prescriptions are included in Medicare Part D beginning with 2006). Existing information sources of District-specific Medicaid data include:

- **Statistical Compendium to the Medicaid Pharmacy Benefit Use and Reimbursement** – These are available for the District for 1999, 2001, 2002, 2003, and 2004.<sup>82</sup> These include expenditure amounts reported by therapeutic class and drug group, and information about spending per prescription and average benefit use per month.
- **State Drug Utilization Data** – These data files, available from the Centers for Medicare and Medicaid Services, consist of raw data for prescription drugs that are part of the Medicaid Drug Rebate Program.<sup>83</sup> Each file includes data on the total units reimbursed

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<sup>79</sup> Medco Annual Drug Trend Reports available at <http://medco.mediaroom.com/index.php?s=64&cat=5>.

<sup>80</sup> Express Scripts' Drug Trend Reports available at <http://www.express-scripts.com/industryresearch/industryreports/>.

<sup>81</sup> Mathematica Policy Research, Inc. *Chartbook: Medicaid Pharmacy Benefit Use and Reimbursement*. Accessed 5/28/09. [http://www.cms.hhs.gov/MedicaidDataSourcesGenInfo/08\\_MedicaidPharmacy.asp](http://www.cms.hhs.gov/MedicaidDataSourcesGenInfo/08_MedicaidPharmacy.asp).

<sup>82</sup> Mathematica Policy Research, Inc. *Statistical Compendium: Medicaid Pharmacy Benefit Use and Reimbursement in 2004: DC*. Accessed 5/28/09.

[http://www.cms.hhs.gov/MedicaidDataSourcesGenInfo/downloads/2004AllBenes\\_DC.pdf](http://www.cms.hhs.gov/MedicaidDataSourcesGenInfo/downloads/2004AllBenes_DC.pdf)

<sup>83</sup> Centers for Medicare and Medicaid Services. *State Drug Utilization Data*. Accessed 6/1/09.

<http://www.cms.hhs.gov/MedicaidDrugRebateProgram/SDUD/list.asp>

per quarter for each of these drugs; files are available for all years from 1991-2007. These files may be useful for investigations into the use of specific drugs by Medicaid beneficiaries.

- **Medicaid Claims Data** – For a fee (which varies by requested variables), researchers can obtain Medicaid claims data, which includes information on individual prescriptions. In these data, the link between prescriptions filled and the prescriber is too confounded to be used to determine which physicians write the most prescriptions or which physicians prescribe the most of a particular drug; however, this source may be useful in determining the overall number of prescriptions. This is already being evaluated by Harvard researchers engaged in academic detailing efforts to identify physicians with the most Medicaid patients and claims.

Given the limitations of these data sources, it is not currently possible to use them to identify healthcare providers who may be prescribing inappropriately. These data sources can provide information about trends in the prescription of particular drugs or classes of drugs in the District, which can in turn guide academic detailing and health promotion efforts.

## ***Strengthening AccessRx***

The AccessRx Act of 2004 took an important step in requiring pharmaceutical manufacturers to report their marketing expenditures, and it has provided useful information to the District's Department of Health. However, since the Act requires the Department to keep that marketing information confidential, it limits the ability of the media and the public to identify worrisome trends and make more-informed choices about their healthcare providers. Because Minnesota makes its pharmaceutical-marketing data public, New York Times reporters were able to detect and report on correlations between doctors' receipt of large total payments from the makers of atypical antipsychotics and high rates of prescribing those companies' products to children; reports of such correlations can prompt prescribers to question whether they might be influenced by pharmaceutical-company payments and scrutinize their own prescribing habits more closely. If such information were available in an easily searchable format, individuals concerned about the effects of pharmaceutical marketing could use it to guide their choices when selecting a new provider, or to apply an appropriate level of skepticism to a current provider's drug recommendations. Amending the AccessRx Act to allow for public reporting of pharmaceutical companies' marketing-expenditure reports would allow prescribers and patients to realize greater benefits.

The pharmaceutical marketing reports would also be more informative if the Act were amended to eliminate the reporting exceptions for samples that will be given free to patients and for expenses related to clinical trials or to attendance at a conference or seminar; require unique identifiers (e.g., the National Provider Identifier for gift recipients); and require that reports of individual expenditures include information about the product being marketed.

There is a possibility of passage of national legislation, the Physician Payment Sunshine Act, that would require national-level reporting and pre-empt state reporting requirements. If that occurs,

the District will instead have to turn its attention to gathering useful data from national pharmaceutical-marketing reports.

## ***Educating Prescribers***

Educational outreach visits, also known as academic detailing, can offset some of the negative effects of pharmaceutical marketing (such as a lack of sufficient awareness about side effects) and can help busy health professionals stay up-to-date on the current scientific evidence. Academic detailers can present unbiased information about treatment options for particular conditions and allow prescribers to make well-informed decisions about which product is best for a particular patient. A Cochrane Collaboration review on educational outreach visits concluded, “This review found 69 studies that evaluated educational outreach visits. Educational outreach visits appear to improve the care delivered to patients. When trying to change how health care professionals prescribe medications, outreach visits consistently provide small changes in prescribing, which might be potentially important when hundreds of patients are affected.”<sup>84</sup>

Under the SafeRx Act, which passed in 2008, the District has already established an academic detailing program that is conducting outreach visits to District Medicaid providers. This is an important step toward evidence-based prescribing in the District.

The District could also partner with the organization PharmedOut, an independent physician-run project that offers lectures and online CME courses that educate prescribers (and other interested individuals) about how pharmaceutical companies seek to influence prescribing behavior. (PharmedOut is funded through the Attorney General Consumer and Prescriber Education grant program, created as part of a 2004 settlement between Warner-Lambert, a division of Pfizer, Inc., and the Attorneys General of 50 States and the District of Columbia, to settle allegations that Warner-Lambert conducted an unlawful marketing campaign for the drug Neurontin®.)<sup>85</sup> The District could support efforts to bring PharmedOut presentations to hospitals and medical schools, where the organization’s message could reach prescribers and medical students not receiving academic detailer visits.

## ***Focusing on Top Expenditure Categories***

As noted above, the five drug groups responsible for the greatest expenditures in the District’s Medicaid program in recent years were antivirals, antipsychotics, antihypertensives, antidiabetics, and antidepressants. These expenditures are likely high due to a combination of high drug prices and high rates of conditions that these drugs are used to treat. As the District builds its academic detailing program, it may wish to emphasize educational efforts around these

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<sup>84</sup> O’Brien M, Rogers S, Jamtvedt G, et al. *Educational outreach visits: effects on professional practice and health care outcomes* (Review). The Cochrane Library, 2009, Issue 2.

<sup>85</sup> PharmedOut. About Us. Accessed 5/28/09. <http://pharmedout.org/aboutus.htm>.

groups of drugs, and consider conducting outreach to specialists who tend to prescribe these drugs.

Although this report focuses on the effects of pharmaceutical marketing, it would be remiss for public-health researchers to fail to note that the success or failure of disease-prevention efforts influences the need for prescription drugs. In particular, the District should consider the future costs of prescription drugs for HIV/AIDS, hypertension, and diabetes when it makes decisions about increasing or reducing funding for programs designed to reduce HIV transmission and to encourage lifestyles (proper nutrition, regular exercise, etc.) that can help prevent hypertension and diabetes. The District's high rate of childhood obesity is particularly worrisome, and suggests that rates of diabetes, hypertension, and other obesity-related diseases are likely to grow rapidly over the coming years.

## VII. Conclusion

Pharmaceutical marketing activities can influence the cost, utilization, and delivery of healthcare services in the District by leading to the use of expensive brand-name drugs that may be inappropriate, or even dangerous, for some patients. Individuals who are prescribed expensive drugs may struggle to pay for them and as a result may fail to take prescriptions as directed; this is of particular concern for the District's uninsured and low-income residents. Prescription-drug expenditures for the District's Medicaid program have grown quickly, and the shift of dual eligibles to Medicare Part D limits the impact that the District's prescription cost-control policies can have. If Medicaid prescription-drug costs continue to grow as they have in recent years, pressure will increase to reduce benefits and provider payments, both of which will affect utilization and delivery of healthcare services for the Medicaid population.

It is more difficult to quantify the existence of inappropriate prescribing – that is, prescribing of drugs whose profile of benefits and risks does not compare favorably to those of alternatives – which can lead to adverse outcomes and thereby cause excessive utilization of healthcare services. Because prescribing decisions must be made on the basis of each patient's conditions and needs, it is extremely difficult to detect individual cases of inappropriate prescribing. Research demonstrates, however, that pharmaceutical marketing practices can influence doctors to have inflated views of the benefits and insufficient awareness of the risks of heavily marketed drugs.

Information about pharmaceutical companies' marketing activities in 2007 provides insight into the ways that these companies seek to influence both prescribers and patients in the District. Given the large share of reported expenditures devoted to employees and contractors engaged in marketing (\$116.6 million out of \$158.2 million), it is likely that companies are devoting many of their marketing resources toward detailer visits with physicians. The District's new detailer regulations may help strengthen ethical practices by detailers, and knowing the number of detailers licensed in the District may allow for a better understanding of the scope of this practice. Restrictions and requirements by medical schools and hospitals can also affect detailers' access to physicians, faculty, and students.

Gifts to physicians (including speaker fees and honoraria) are another avenue by which pharmaceutical companies can influence prescribers, and payments of speaker fees to doctors suggest that those doctors may be considered "key opinion leaders" and are touting the company's products to medical colleagues. In the District, we have identified 193 physicians who received over \$1,000 in consulting or speaker fees alone. (Many other physicians received more than \$1,000 in other forms of payments.) This is a relatively small percentage of the thousands of physicians practicing in the District, but it is still a sizeable number.

Because the District's Medicaid prescription-drug expenditures play such an important role in the overall cost, utilization, and delivery of healthcare services in the city, it is worth investigating whether Medicaid providers are among those receiving speaking fees or other large gifts from pharmaceutical companies. Sixty Medicaid providers appeared on the list of 193 physicians receiving \$1,000 or more in consulting or speaker fees, and 16 of those providers

were among the top 200 Medicaid providers in the District in either the fee-for-service or managed care category.

Determining the influence of pharmaceutical-company sponsorship of continuing medical education on District prescribers is difficult, but gift-payment figures for some of the professional medical organizations located in the District provide an indication of the scope of sponsorship. These organizations provide education that is available to health professionals from across the country, and District providers may be educated by organizations located elsewhere, but the numbers help substantiate existing estimates of pharmaceutical-company contributions to CME providers. Approximately \$15.2 million of the nearly \$20 million in payments given to non-individual recipients was designated as having the purpose of “education”; approximately \$2.3 million of that was specifically identified as “continuing medical education,” but most reports did not provide that level of detail. Professional organizations, the type of organization most likely to offer CME, received much of the money given to non-individuals. In fact, ten professional organizations alone received \$9.4 million from pharmaceutical manufacturers and labelers in 2007.

The AccessRx Act does not require pharmaceutical companies to report expenses related to clinical trials or the distribution of samples that will be given to patients at no cost, so it was not possible to determine the extent to which these practices occur in the District. Concerns have mounted in recent years about the potential conflicts of interest that arise when pharmaceutical companies sponsor clinical trials that contribute to the salaries or careers of prescribers. The distribution of free samples may cause both prescribers and patients to rely on drugs that may not be the most appropriate or cost-effective options. Amending the AccessRx Act to require reporting of expenses related to clinical trials and distribution of free samples would allow for a better understanding of the scope of these practices.

Because there are many avenues by which pharmaceutical companies can influence prescribing patterns, educational outreach is a good choice for addressing concerns about this influence. The District’s program of academic detailing for Medicaid providers is an important step toward ensuring evidence-based, appropriate prescribing. Additional educational efforts, such as presentations to medical students or provider groups about pharmaceutical marketing strategies and evidence-based prescribing, could help reach a wider audience with this valuable information.

Finally, greater transparency about pharmaceutical-marketing expenditures would enable researchers to identify worrisome trends and allow the public to make more-informed decisions about which providers to see and whether to view their prescription advice with skepticism. Amending the AccessRx Act to make the contents of pharmaceutical companies’ reports public would allow this to happen.