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**Implementing Titles II & III of Access Rx
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**Hearing on the Implementation of Access Rx, Titles II and III
Council of the District of Columbia, Committee on Health
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Council Member Catania and members of the District of Columbia Public Health Committee, thank you for inviting me to testify this morning. My name is Sean Flynn. I am the Associate Director of the Program for Information Justice and Intellectual Property and an Adjunct Professor of Law at the Washington College of Law. I am also a legal adviser to the Prescription Project, a new national initiative funded by the Pew Charitable Trusts, and am submitting this testimony for the Project.¹

Background

Prescription drugs comprise the most rapidly increasing component of health care, with retail prescription drug expenditures exceeding \$221 billion in the United States for fiscal year 2005.² The rising prices of prescription drugs have attracted national scrutiny to all aspects of the marketing and distribution of pharmaceuticals. The District of Columbia

¹ The goal of the Prescription Project is to eliminate conflicts of interest created by pharmaceutical industry marketing, increase public trust in the medical profession, and expand the use of evidence-based prescribing through both institutional and public policy reform. The Project is led by Community Catalyst, a national non-profit consumer organization dedicated to reforming the U.S. health care system to ensure quality, affordable health care for all; in partnership with the Institute on Medicine as a Profession, based at the Columbia University College of Physicians and Surgeons, which aims to promote the ideals of professionalism among physicians and medical institutions. (www.prescriptionproject.org).

² Frederick James. Drug Store News. "Beset by Challenges, Pharmacy Faces Better Times." 8/22/2005.

took the initiative to develop legislation to contain the cost medications for consumers, health coverage providers, and public assistance programs through the enactment of Access Rx. Vigorous implementation and enforcement of the Act and the active involvement of health coverage groups and health care providers are the next steps to reducing prescription drug prices for residents of the District.

The regulations implemented under Access Rx Title II and Title III establish two different approaches to reducing the price of prescription drugs in the District. Access Rx Title II eliminates the ability of the middlemen of pharmacy benefit management, Pharmacy Benefit Managers (PBMs), from profiteering by increasing prescription drug prices for their clients and covered individuals. Moreover, Title II increases transparency into the PBM industry in the District and imposes fiduciary duties onto PBMs, requiring them to act in the best interest of their clients for the purpose of defraying costs. Title III requires full disclosure of all expenditures on marketing pharmaceuticals to residents and health care professionals in the District. The data obtained from Title III provides the Department of Health with information necessary to develop appropriate objective clinical programs to educate residents and health care professionals about less expensive prescription medicines, which are less heavily marketed but equally efficacious.

PBM Background

Since the mid-1980's, Pharmacy Benefit Managers (PBMs) have become a prominent part of the American health care system. PBMs now manage pharmacy benefits for nearly 200 million Americans, amounting to nearly 95% of all Americans with medical coverage. PBMs are active in all aspects of prescription drug coverage, including processing claims to pharmacies, developing and managing formularies, negotiating with prescription drug manufacturers for rebates, and operating mail-order pharmacies to fill prescriptions directly.

As the role of PBMs expanded in the American health care system, national legislation failed to develop accordingly. Consequently, PBMs had ample opportunity to develop numerous practices that increased their own profits while raising prescription drug prices for their clients and covered individuals.

PBMs are hired by employers and other health coverage organizations to provide a comprehensive array of pharmaceutical-related services and to use their expertise to reduce the cost of pharmaceutical benefits. Major tasks performed by PBMs include formulary management and development, drug utilization review (DUR), claims processing, therapeutic interchange, and reimbursement of providers and patients. In the performance of these administrative duties, PBMs independently negotiate with three separate entities: pharmaceutical manufacturers, pharmacies, and health coverage providers. Consequently, the terms of all contracts are known only by the PBMs, creating informational asymmetry and the opportunity for arbitrage.

By being at the heart of so many different and competing negotiations, PBMs found that they could game nearly every transaction to their advantage.

Firstly, PBMs have been known to accept rebates from manufacturers in return for placing higher priced medications on the formulary. Rather than disclosing these rebates to the clients, PBMs have kept them secret and retained some or all of the rebates while charging clients higher prices. Moreover, PBMs are often paid higher rebates to include “single-source” brand name drugs without generic equivalents on their formularies. Higher priced brand name drugs often account for over 50% of prescription drugs dispensed to plan members.

Secondly, PBMs have been known to “play the spread” between the prices paid by clients and the price paid at the pharmacy. Since PBMs negotiate contracts with employers

and pharmacies separately, asymmetric information permits them to charge their employers more than the PBM actually pays to the pharmacy. For example, one investigation found that a PBM charged an employer \$215 for a generic prescription but paid the pharmacy only \$15. The PBM pocketed the \$200 spread at the expense of the employer.

Thirdly, PBMs often favor higher priced drugs that provide them with greater incentives and switch customers from low-cost to the higher-cost medication. PBMs may ask a health professional to permit them to switch medications, knowing that the switch serves the sole purpose of earning a higher rebate for the PBM. Drug-switching became the cause of action in the 20-state lawsuit against Medco when the PBM persuaded more than 71,000 doctors to switch patients from lower priced Lipitor, made by Pfizer, to more expensive Zocor, made by Merck. Similar allegations of drug-switching were made against Advance PCS, for encouraging doctors to switch patients from a generic ulcer drugs to Celebrex, which cost over ten times more. A drug-switching lawsuit also commenced against Express Scripts for accepting \$500,000 from AstraZeneca to call 22,000 doctors to switch patients from Prilosec to Nexium. These lawsuits illustrate the prevalence of drug-switching when PBMs are left unmonitored.

In the absence of transparency into PBM practices, PBM clients are powerless to monitor self-interested PBM practices or to confidently choose a competing PBM that offers better terms. Legislation such as Access Rx Title II corrects this market failure in the PBM industry by increasing transparency into PBM practices and imposing a fiduciary duty onto PBMs, requiring them to act in the best interest of clients for the purpose of defraying costs for covered individuals. Moreover, Access Rx Title II authorizes PBM clients to monitor the prices that PBMs pay for drugs and the rebates they receive from manufacturers. Increases in transparency also increase competition among PBMs and can effectively to push down

overall prescription drug prices. Consequently, success in the PBM industry in Washington D.C. will hinge on the cost-savings and expertise that PBMs provide to their clients.

Some of over 50 of America's largest employers, including Caterpillar, Ford Motor, Starbucks, and IBM, formed a purchasing coalition and used its purchasing power to demand full-disclosure and transparency into all PBM practices. The largest three PBMs of the time, (Medco, Caremark, and Express Scripts) dropped out of the bidding process, declining to serve over 5 million employees. By 2006, when more states considered legislation to regulate PBMs and more lawsuits settled against the "Big Three," Medco and Caremark agreed to the full-disclosure purchasing model of the coalition.³ Smaller employers and those unwilling to be locked-in to multi-year contracts or to pay the administrative fees of the model, however, have been unable to obtain transparency into PBM practices. Consequently, many employers, pharmacies, and health coverage organizations have maintained a general distrust of the PBM industry.

Access Rx Title II

Access Rx Title II provides transparency into PBM practices for all covered entities in the District. The Act confers upon covered entities the right to retain manufacturer rebates and to audit the prices that PBMs pay to pharmaceutical manufacturers and pharmacies on a per drug basis. This reduces the high costs of litigation and investigations through discovery, which are ultimately passed on as higher prices for the PBM's clients and covered individuals. Moreover, PBM clients that utilize the provisions of Access RX Title II and diligently oversee PBMs can expedite savings from rebates, develop the most cost-effective and medically beneficial formularies, and eliminate delays from investigations and litigation.

³ American Health Line. "Two Large Companies Agree to New Purchasing Model." July 24, 2006.

Title II of Access Rx operates to defray prescription drug prices by imposing a fiduciary duty on virtually all middlemen working in pharmacy benefit management. Entities subject to the fiduciary duties imposed onto PBMs under Access Rx Title II include all organizations that process claims and payments to pharmacies, that develop and manage clinical formularies, or that work in patient compliance, generic substitution, and disease management programs. Moreover, the broad scope of organizations protected as “covered entities” under Title II serves to constrain prescription drug prices for virtually all insured residents and PBM clients that are organized or licensed in the District. PBM clients qualifying as “covered entities” include public health programs administered by the D.C. Department of Health, hospitals, medical service organizations, insurers, health coverage plans, and HMOs that are licensed in the District. Employers, labor unions, and other groups organized in the District and contracting with PBMs also qualify as covered entities and are protected under Title II of the Act.

The general imposition of a fiduciary duty under Access Rx Title II is a catch-all provision that requires PBMs to always discharge their duties to the client for the primary purpose of providing benefits to covered individuals and defraying costs. Like all other fiduciaries, PBMs contracting with covered entities in the District must exercise care, skill, prudence, and diligence in discharging their duties, and they must notify clients of any circumstance creating a conflict of interest with duties toward the client. This duty includes disclosing any rebates from manufacturers or benefits gained from drug-switching or from including medications on the formulary. The covered entity retains the right to agree by contract to compensate the PBM for rebates or other benefits that the PBM passes on from the manufacturers. Title II also mandates that PBMs can only substitute less expensive equivalent drugs for more expensive ones, and not vice versa. Substitutions to more

expensive medications can only be made for their medical benefits, and such substitutions require the approval of the prescribing professional.

The overall scheme of Title II alters the incentive system that lead to the devious tactics that grew rampant in the PBM industry. Because Title II requires PBMs to transfer to the client any benefits gained from drug switching, the PBM no longer has an incentive to switch drugs for reasons contrary to public health or contrary to the client's benefit. Moreover, since PBMs must disclose conflicts of interest, they have a stronger incentive to accurately disclose up-front the costs and benefits of including medications on the formulary. These regulations provide the appropriate incentive for developing formularies for the sole purposes of improving public health and defraying costs for the covered individuals.

Access Rx Title III- Full Disclosure of Prescription Drug Marketing Costs

Title III of Access Rx requires full disclosure of all prescription drug marketing expenditures in the District of Columbia. The purpose of Title III is to promote wiser prescription drug decisions and contain prescription drug prices for residents. Drug manufacturers are estimated to spend about \$25,000 per physician per year on detailers that promote the latest most expensive drugs to health care professionals.

The industry spends \$7.2 billion each year in direct marketing to physicians. Around the country, an estimated 90,000 pharmaceutical representatives promote specific drugs, often those that are newer, less tested and more expensive. These marketing practices lessen the quality of health care and substantially drive up medical costs for patients and for public and private payers.

Marketing to the medical profession takes many forms: free lunches provided to doctors, free sample medications, marketing efforts disguised as continuing medical

education, and gifts and financial incentives. The pharmaceutical industry's access to physicians is strategic, targeted and comprehensive. It has developed methods to permeate all aspects of a physician's and medical student's schedule and education.

Gift-giving by pharmaceutical representatives ("detailers") includes the seemingly trivial (e.g. pens, coffee mugs, prescription pads and "modest" meals) to substantial meals and costly items such as handheld computers. Lavish meals, entertainment and trips are commonly provided. The detailers routinely found in physician waiting rooms often serve as a major source of information on the newest drugs, despite their lack of professional training and their goal, which is to aggressively sell product.

Physicians are also paid to be on speakers bureaus, which are merely an extension of manufacturer's marketing apparatus. Some are paid for publishing articles that are ghostwritten by industry employees.

Continuing medical education (CME) is another way that the industry influences physicians. Physician "thought leaders" are paid by the industry as speakers and the sponsor may provide the CME educational materials. Today drug companies sponsor 60% of all CME events, and studies show that industry sponsorship is associated with preferential highlighting of the sponsor's projects and increased prescribing of the sponsor's drugs, even when competitor drugs were more effective. (Huang et al, Dec. 2005). Travel funds, fellowships and scholarships are "awarded" to physicians and medical students to entice them to attend industry sponsored conferences where companies market their latest products. Medical students with limited incomes often find themselves dependent on pharmaceutical dollars for educational opportunities.

Doctors themselves may not fully understand the weight of their interactions with the pharmaceutical industry. A recent article in the Journal of General Internal Medicine

found that physicians hold contradictory views of the situation: They recognize that conflicts of interest exist but often believe that they are personally immune to them. In fact, they believe that it is possible for them to sort out the facts amid the marketing and, therefore, rely upon the information presented as a basis for decision making about prescriptions for their patients.

Physician-group attempts at self-regulation have not produced sufficient results; a recent study in the New England Journal of Medicine indicated that 94% of physicians continued to have interactions or relationships with drug companies. The quality of medical decision making is undermined by these relationships.

Studies have consistently proven that detailing influences physicians' decisions to prescribe the most expensive medications, even when substantial evidence indicates that less expensive drugs with longer histories of safety are equally effective. Prescriptions for higher priced medicines especially burden those living on a fixed budget and those who are not aware of less expensive alternatives or generic equivalents.

Major scandals due to widespread and inappropriate prescribing of drugs such as Vioxx, Neurontin, Paxil, Ketec and Avandia, have brought into stark relief the influence of industry marketing on drug safety and quality of care.

Title III of Access Rx provides the D.C. Department of Health with the information and opportunity to monitor and to reverse the adverse influence of marketing on prescription drug choices in the District. Virtually all marketing expenses for prescription drugs must be disclosed under Title III of Access Rx. Any prescription drug manufacturer or labeler that utilizes marketing representatives in the District must disclose marketing expenditures made to consumers and prescribing professionals. This includes all expenditures for advertisements via television, radio, newspapers, telemarketing, and other

media. It also includes marketing to health care professionals through educational programs and seminars, gifts exceeding \$25, or travel expenses. Manufacturers and labelers must also disclose the aggregate cost of all employees and contractors paid to market prescription drugs in the District.

Under the reporting rules for Title III, expenses must be reported by individual prescriber to the District. This data will provide an important means by which the District can evaluate the impact of marketing on the utilization of pharmaceuticals by its public programs. For example, the state of Minnesota passed a gifts ban and marketing disclosure law in 1993, and in that state, the records are also public. In a recent analysis of the impact of marketing on the prescribing of atypical antipsychotics to children, the New York Times (Gardiner Harris, 5-10-2007) found that Minnesota Medicaid records and gifts disclosures records showed that “on average, Minnesota psychiatrists who received at least \$5000 from atypical makers from 200 to 2005 appear to have written three times as many atypical prescriptions for children as psychiatrists who received less or no money” Title III will allow the District to conduct analyses of such patterns that affect residents in publicly funded programs and to better devise solutions to address the identified problems.

Marketing disclosures also provide the D.C. Department of Health with information valuable for developing counter-detailing (also known as academic detailing) programs and other evidence-based medicine programs that further the goals of cost containment and a higher standard of pharmaceutical health care. Academic-detailing programs utilize pharmacists, physicians or nurse practitioners to bring unbiased, evidence based information directly to physicians in their offices to assist them in making prescribing decisions. The information serves to debunk impressions created by advertisements, such as beliefs that the latest most expensive medications confer greater benefits on patients, and most importantly

helps the physician to identify the most effective and safest drugs, which are often less expensive. Evidence-based medicine educational programs in general provide health care professionals with a way of evaluating medicines in terms of costs, safety, and efficacy.

Information gained through Access Rx Title III can also improve the quality of formularies developed for D.C. residents. Marketing by the pharmaceutical industry is directed not only at individual prescribers, but at those responsible for designing formularies at health care institutions and in health care programs and plans. As in the case of PBMs, if such formularies are influenced by industry inducements to those responsible for their design, therapeutic benefits are undermined and costs are increased.

Finally marketing disclosures required under Title III provide information pivotal to assessing the reasonableness of manufacturer rebates for the low-income elderly and the uninsured as required by Access Rx Title I.

Conclusion

Insight into PBM practices and pharmaceutical marketing is essential to ensuring that decisions regarding prescription drug purchases are based on sound medical and financial principles. Efficiently functioning markets depend on symmetrical reliable information by all parties to a transaction. The provisions of Access Rx Title II and Title III can illuminate hidden costs and undisclosed practices that are highly relevant to making the most informed health care decisions in the interests of patients and covered entities. Disclosure of the expenses associated with industry marketing to prescribers and health care institutions and organizations is a powerful tool for understanding the dynamics of industry influence and for combating its impact.