

**STATE ATTORNEYS GENERAL AND PHARMACEUTICALS:
WRITING A NEW PRESCRIPTION TO
CURTAIL DRUG COSTS**

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I. Executive Summary

Spending on prescription drugs in the United States totaled \$275 billion in 2006. These expenditures are predicted to continue to grow about 8% per year for the foreseeable future. While some of this increase results from public health demands of caring for a population that is aging and facing increased diagnoses of chronic diseases, the actions of the pharmaceutical industry also play a significant role. Industry pricing and marketing strategies seeking to expand utilization of all drugs and to shift utilization towards more costly, though not necessarily more effective, drugs have contributed to an increase in the average retail price of individual drugs over three times the rate of inflation. Ballooning costs at the pharmacy counter is a growing concern not only for those who need medicines, but also for states struggling to provide prescription drug coverage to their employees and to residents who are uninsured or under-insured.

Over the past decade, states have employed strategies to introduce some rationality to the pharmaceutical marketplace. States are using a combination of market forces and policy approaches to realize significant savings of pharmaceutical dollars by:

- Joining together in multi-state bulk purchasing agreements to negotiate bulk rate discounts;
- Putting cost-effective drugs on preferred drug lists to encourage sensible prescribing;
- Countering the effects of marketing by increasing price transparency, educating prescribers, and regulating marketing;
- Ensuring that companies that manage pharmaceutical coverage benefits exercise their duties with sufficient care; and
- Attempting to develop rational pricing systems that more closely resemble the “real” dollar value of medicine.

Legal tactics are also being employed. As the chief law enforcement officers for their states, Attorneys General have focused their attention on initiatives that seek to:

- Fight Medicaid fraud by uncovering price manipulation that costs states millions of dollars in overpayments on Medicaid reimbursements;
- Protect consumers by requiring pharmaceutical manufacturers to publicize undisclosed drug risks, and cease inappropriate off-label marketing practices; and
- Enforce antitrust laws that are violated when manufacturers pay-off potential generic competitors or otherwise collude to keep generics off the market or manipulate market entrance.

It is outside the realm of law enforcement and State Attorneys General to constrain state drug spending by improving the health of the populations they serve. However, there is a clear role for Attorneys General to focus on legal and policy solutions that can help curtail current unwarranted spending on pharmaceuticals. This report outlines the principle solutions that states have pursued in these efforts, as well as some of the savings they have realized.

II. Introduction: Prescription for Spending

Spending on prescription drugs has been increasing significantly in the United States, reaching \$275 billion in 2006.¹ This spending growth is forecast to continue for the foreseeable future at an annual rate of 8.2 percent², fueled by increases in overall drug utilization, especially the use of high-priced, specialty pharmaceuticals,³ and overall increases in drug prices.⁴ An analysis by the Kaiser Family Foundation found that between 1994 and 2005 the average number of prescriptions per capita increased from 8 to 12, the total number of prescriptions grew 71% (compared to a 9% growth in population), and the average retail price of each prescription rose 8.3% per year, more than triple the average inflation rate of 2.5%.⁵ A report by the consumer advocacy group AARP shows that brand name drugs are fueling this price surge. AARP found that, in 2006, the price of ten common branded drugs increased up to 9 times the rate of inflation. In comparison, the prices for 75 common generics fell by 2 percent.⁶

High utilization of a few heavily marketed, expensive drugs and drug classes continues to contribute disproportionately to overall prescription drug spending. In 2006, \$21.6 billion, or 7.9% of all prescription drug spending in the United States, was for cholesterol-reducing drugs.⁷ Two individual “statin” cholesterol-reducers—Lipitor and Zocor—accounted for \$11.7 billion in sales, or 4.3% of all U.S. prescription drug spending.⁸ Table 1 lists the top ten drug products and the top ten therapeutic classes for 2006.

¹ IMS Health Inc., *Top 10 Products by U.S. Sales* (March 2007). Accessed at

http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_80408845_80411835,00.html

² J.M. Hoffman, N.D. Shaw, L.C. Vermeulen et al, *Projecting future drug expenditures—2007*, Am J Health-Syst Pharm. (February 1, 2007).

³ C. Borger, S. Smith, C Truffer et al, *Health Spending Projections Through 2015: Changes on the Horizon*, Health Aff. (February 22, 2006).

⁴ J.M. Hoffman, N.D. Shaw, L.C. Vermeulen et al, *Projecting future drug expenditures—2007*, Am J Health-Syst Pharm. (February 1, 2007).

⁵ Kaiser Family Foundation, *Prescription Drug Trends* (June 2006).

⁶ AARP, *Trends in Manufacturer Prices of Prescription Drugs Used by Older Americans, Research Report 2006*. Accessed at <http://www.aarp.org/research/health/drugs/aresearch-import-869-2004-06--IB69.html>

⁷ IMS Health Inc., *Top 10 Therapeutic Classes by U.S. Sales* (March 2007). Accessed at http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_80408845_80411835,00.html

⁸ IMS Health Inc., *Top 10 Products by U.S. Sales* (March 2007). Accessed at http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_80408845_80411835,00.html

Table 1.

Top 10 Products by U.S. Sales, 2006						
Rank	Product	2006 Total Dollars (Billions)	2005 Total Dollars (Billions)	2004 Total Dollars (Billions)	2003 Total Dollars (Billions)	2002 Total Dollars (Billions)
1	LIPITOR	\$8.6	\$8.3	\$7.7	\$6.8	\$6.1
2	NEXIUM	\$5.1	\$4.3	\$3.8	\$3.0	\$1.9
3	ADVAIR DISKUS	\$3.9	\$3.5	\$2.9	\$2.3	\$1.5
4	ARANESP	\$3.9	\$2.7	\$1.9	\$1.0	\$0.2
5	PREVACID	\$3.5	\$3.8	\$3.8	\$4.0	\$3.5
6	EPOGEN	\$3.2	\$2.9	\$2.9	\$3.1	\$2.9
7	ZOCOR	\$3.1	\$4.4	\$4.6	\$4.3	\$4.0
8	ENBREL	\$3.0	\$2.7	\$2.0	\$1.3	\$0.8
9	SEROQUEL	\$3.0	\$2.6	\$2.0	\$1.5	\$1.0
10	SINGULAIR	\$3.0	\$2.5	\$2.2	\$1.7	\$1.2
	All	\$274.8	\$253.7	\$239.8	\$219.5	\$195.1
Top 10 Therapeutic Classes by U.S. Sales, 2006						
Rank	Therapeutic Class	2006 Total Dollars (Billions)	2005 Total Dollars (Billions)	2004 Total Dollars (Billions)	2003 Total Dollars (Billions)	2002 Total Dollars (Billions)
1	LIPID REGULATORS	\$21.6	\$19.7	\$18.0	\$15.3	\$13.3
2	PROTON PUMP INHIB	\$13.6	\$12.9	\$12.8	\$13.0	\$11.4
3	ANTI-DEPRESSANTS	\$13.5	\$12.8	\$13.8	\$13.8	\$12.3
4	ANTIPSYCHOTICS,OTH	\$11.5	\$10.5	\$9.5	\$8.4	\$6.6
5	ERYTHROPOIETINS	\$10.0	\$8.7	\$8.1	\$7.5	\$6.4
6	SEIZURE DISORDERS	\$8.9	\$8.0	\$8.4	\$7.0	\$5.5
7	ANTINEO MONOCLONAL ANTIB	\$5.8	\$4.0	\$2.6	\$1.7	\$1.4
8	ANGIOTENSIN II ANTAG	\$5.7	\$5.0	\$4.4	\$3.5	\$2.7
9	INSULIN SENSITIZER	\$4.8	\$4.0	\$3.4	\$3.0	\$2.6
10	CALCIUM BLOCKERS	\$4.7	\$4.6	\$4.5	\$4.4	\$4.3
	All	\$274.8	\$253.7	\$239.8	\$219.5	\$195.1

Source: IMS Health Inc.⁹

Pharmaceutical manufacturers have developed a two-pronged marketing approach to increase utilization and sales of certain prescription drugs. They advertise directly to patients

⁹ IMS Health Inc., *Top 10 Products by U.S. Sales* (March 2007). Accessed at http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_80408845_80411835,00.html

with direct-to-consumer (DTC) ads, and appeal to prescribers with direct-to-doctor (DTD) marketing. The industry's expenditures on both types of marketing are quite large, and are growing: they reached an estimated \$11.4 billion in 2005, up from \$10.7 billion in 2003, and \$5.9 billion five years earlier.¹⁰ These figures do not include the estimated value of free samples, which was \$15.9 billion in 2004.¹¹ Pharmaceutical marketing has deeply penetrated the medical community. A recent survey found that 94% of doctors report some type of relationship with the drug industry: 83% receive food, 78% receive free samples, 35% receive reimbursement for attending professional meetings or trainings, and 28% receive payments for consulting, enrolling patients in trials, or lectures.¹²

Despite the forecast for increased overall spending on pharmaceuticals, the rate of this spending growth has actually decelerated compared to the previous decade, a trend attributed to three major factors:

- The availability of lower cost generic forms of a few widely-used, high-priced drugs that recently lost patent exclusivity -- fluoxetine, gabapentin, metformin, omeprazole, and tramadol;
- Decreased usage of certain costly drugs due to safety concerns -- Vioxx, Celebrex, hormone replacement for women, and SSRI antidepressants for children; and
- Increased cost sharing among employer-provided prescription-drug benefits in the form of rising or percentage co-payments and higher deductibles.¹³

III. Burden on States

Bearing the brunt of prescription drug costs are the two largest individual payers, the state Medicaid programs and, starting in 2006 with the new Part D prescription drug benefit, the federal Medicare program. While private health insurance covered nearly 73% of prescription drug spending in 2005, two-thirds of the remaining portion was covered by state Medicaid programs, to the tune of \$40 billion.¹⁴ In 2006, the 14% of Medicaid recipients who were considered "dual-eligibles" had their coverage shifted over to Medicare, and the Part D drug benefit reduced Medicaid drug spending by 45%.¹⁵ Reductions in federal Medicaid funding, however, are dampening the impact of this beneficial relief, and forcing states to dip into their general funds to make up for dwindling federal funding. As the federal government pledges to slash an additional \$10 billion from its support to state Medicaid programs over the next five

¹⁰ U.S. Government Accountability Office, *Prescription Drugs: Improvements Needed in FDA's Oversight of Direct-to-Consumer Advertising*, (November 2006). Accessed at <http://www.gao.gov/new.items/d0754.pdf>

¹¹ U.S. Government Accountability Office, *Prescription Drugs: Improvements Needed in FDA's Oversight of Direct-to-Consumer Advertising*, (November 2006).

¹² EG Campbell et al, *A National Survey of Physician-Industry Relationships*, April 26, 2007, NEJM.

¹³ J.M. Hoffman, N.D. Shaw, L.C. Vermeulen et al, *Projecting future drug expenditures—2007*, Am J Health-Syst Pharm. (February 1, 2007).

¹⁴ A. Catlin, C. Cowan, S. Heffler et al, *National Health Spending in 2005: The Slowdown Continues*, Health Aff. (January/February 2007).

¹⁵ Kaiser Family Foundation. *Prescription Drug Trends*. (May 2007). Accessed at http://www.kff.org/rxdrugs/upload/3057_06.pdf

years,¹⁶ the search for innovative cost reduction strategies is assuming greater urgency, especially through the use of multi-state purchasing pools and formularies. Emerging evidence indicates that such measures are having the desired effect. In 2005 growth in Medicaid drug spending slowed to 2.8 %, compared to 11.6% the previous year, and an average annual rate of 15.4% for the preceding decade.¹⁷

There is no question that prescription medications are critically important to the healthcare system, contributing greatly to saving lives and reducing the burdens of chronic disease. Appropriately used, they are among the most cost effective forms of medical intervention¹⁸. But it has also become clear that certain market forces encourage inappropriate prescribing, overuse of costly drugs, and excessive spending, without commensurate improvements in health outcomes. Such behavior threatens the health care system by adding to an increasing financial burden and, in some cases, by eroding the quality of health care that patients receive.

IV. State Responses

1. Formularies and Bulk Purchasing

Formularies, Prior Authorization and Supplemental Rebates. In the context of the Medicaid program, preferred drug lists (PDLs)—also known as formularies—are generally used to indicate the drugs that health care providers can prescribe without seeking prior authorization or approval. At the end of 2006, 27 states reported using PDLs in their Medicaid programs.

The state Medicaid programs will provide payment for any federally-approved drug, including drugs not on a preferred list. However, in states with prior authorization requirements, drugs that are not on the preferred list require special, or “prior,” authorization from the state before Medicaid will pay for these drugs. PDLs and prior authorization programs result in a market shift in favor of the preferred drugs. Manufacturers generally seek to have their drugs added to the preferred drug list by negotiating better discounts, and by providing supplemental rebates to states with such programs. Supplemental rebates are rebates that are in addition to those required under federal law.¹⁹

The principle argument against the use of PDLs is that they effectively limit the range of drug choices available to prescribers to those drugs on the list. The concerns about reduced access to effective treatments can be addressed in a number of ways, including:

¹⁶ Kaiser Family Foundation, *Medicaid Budgets, Spending and Policy Initiatives in State Fiscal Years 2005 and 2006*, (October 2005). Accessed at <http://www.kff.org/medicaid/7392.cfm>

¹⁷ J.M. Hoffman, N.D. Shaw, L.C. Vermeulen et al, *Projecting future drug expenditures—2007*, Am J Health-Syst Pharm. (February 1, 2007).

¹⁸ N.E. Morden & S.D. Sullivan, *States’ Control of Prescription Drug Spending: A Heterogeneous Approach*, Health Aff. (July/August 2005).

¹⁹ Congressional Budget Office, *Prices for Brand-Name Drugs Under Selected Federal Programs*, (June 2005). Accessed at <http://www.cbo.gov/ftpdocs/64xx/doc6481/06-16-PrescriptDrug.pdf>

- Utilize open formularies that provide a wide range of drug choices within each therapeutic category;
- Provide overrides for the use of non-preferred drugs when they are clinically essential; and
- Ensure that drug lists are evidenced-based and cover treatments proven to be most effective.

The use of PDLs, coupled with prior authorization and supplemental rebates, allows a state to negotiate better discounts for prescription drugs from the drug manufacturers. These practices also have the added benefit of allowing the state to become a better benefit and care manager for the people covered under the Medicaid program.

- **Litigation Over PDLs and Prior Authorization Requirements.** Courts have generally upheld the ability of the states to use PDLs, prior authorization and supplemental rebates, finding that the programs are within the states' authority and do not represent impermissible limitations under federal Medicaid law. However, it should be noted that states do not have unfettered ability to use the Medicaid program as leverage to reduce costs for all state drug programs. For instance, the Centers for Medicare and Medicaid Services (CMS) will not approve bundling non-Medicaid drug programs with Medicaid for enhancing a state's negotiating position over costs.

Drug Purchasing Pools. Drug purchasing pools are another mechanism states employ to leverage their purchasing power. Most states pool purchases for their state Medicaid programs across state lines with other state Medicaid programs. Inter-state Medicaid purchasing pools must be approved by CMS. Multi-state purchasing pools use a single pharmaceutical benefits manager or administrator to negotiate manufacturer rebates and to manage patient benefits. There are five inter-state drug purchasing pools currently in operation: The Michigan Multi-State Pooling Agreement; the Top Dollar Program (TOP\$); Sovereign States Drug Consortium (SSDC); the Minnesota Multi-State Contracting Alliance for Pharmacy (MMCAP); and the Northwest Prescription Drug Consortium.²⁰

- **The Michigan Multi-State Pooling Agreement (National Medicaid Pooling Initiative).** The Michigan Multi-State Pooling Agreement, formerly known as the National Medicaid Pooling Initiative, was the first Medicaid multi-state purchasing pool to receive CMS approval, in April 2004. Ten states – Alaska, Hawaii, Kentucky, Michigan, Minnesota, Montana, Nevada, New Hampshire, New York and Tennessee – are members of this pool, which uses PDLs, prior authorization and supplemental rebates to achieve cost savings. States use their individual pharmacy and therapeutic committees to develop their own PDLs. Overlap in the states' lists and the volume of utilization per state population determines the level of discounts available for each particular drug for each state.

²⁰ National Conference of State Legislatures, "*Pharmaceutical Bulk Purchasing: Multi-state and Inter-agency Plans, 2007 edition.*" Accessed at <http://www.ncsl.org/programs/health/bulkrx.htm>

Savings examples: In 2004 the State of Michigan estimated that it saved \$8 million by participating in the pool, and Nevada estimated its 2005 savings at \$4.5 million.

- **TOP\$.** In May 2005, the Top Dollar Program became the second multi-state Medicaid purchasing pool to receive CMS approval. Originally organized by three states—Louisiana, Maryland and West Virginia—there are currently seven states taking part: Delaware, Idaho, Pennsylvania and Wisconsin have joined the three founding states. Each participating state retains its own PDL, and overlap between those lists allows for enhanced discounts in certain cases.

Savings examples: The pharmaceutical benefit administrator for TOP\$ claims that a state joining the pool with its own PDL typically saves an additional 10%, and the three founding states anticipated 2006 savings to their Medicaid programs of \$27 million, \$19 million, and \$16 million, respectively.

- **Sovereign States Drug Consortium.** In July 2006, the Sovereign States Drug Consortium (SSDC), consisting of Maine, Iowa and Vermont, received CMS approval to negotiate supplemental drug rebates from manufacturers. The SSDC also employs PDLs and prior authorization to reduce costs. All drug purchasing and rebate negotiations are completely transparent to participating states, which retain complete control of the consortium.

Savings examples: In 2006, Maine received an estimated \$12.2 million in supplemental rebates, and is anticipating an additional \$2.6 million in savings in 2007.

- **Minnesota Multi-State Contracting Alliance for Pharmacy (MMCAP).** MMCAP was created in the mid-1990's and is operated and managed by the Materials Management Division of the State of Minnesota's Department of Administration for government-run hospitals and other health care facilities. The MMCAP participating entities (43 states and several cities) service more than 3,000 government-operated health care facilities. The MMCAP annually issues a Request for Proposal (RFP) to drug companies to provide bids on more than 6,000 products. The MMCAP does not use a formulary, but member facilities are encouraged to exclusively purchase their products through MMCAP to produce the greatest volume discounts. Average savings for brand name pharmaceuticals are reportedly the average wholesale price (AWP) minus 23% and generic savings are reportedly AWP minus 65%. The program does not serve Medicaid or public employee programs.

Savings example: In fiscal year 2005, participating states saved an average of \$27 million.

- **Northwest Prescription Drug Consortium.** In 2006, Washington and Oregon created the Northwest Prescription Drug Consortium, the first multi-state purchasing pool aimed at benefiting uninsured and underinsured state residents rather than

government programs. A prescription card discount program affiliated with this program allows residents in both states to save up to 60% on their prescriptions.

Savings examples: All savings from this program are passed on to residents in the form of lower prescription costs. In 2007 this totaled \$3.26 million for Oregonians and \$2.86 million for residents of Washington.

2. Pharmacy Benefit Management Reform

Private corporations and governmental entities use pharmacy benefit managers (PBMs) to help lower costs of prescription drug plans. PBMs manage the procurement of prescription drugs at a negotiated rate, often including discounts and rebates, from pharmaceutical manufacturers. PBMs pass some or all of those rebates on to their clients. PBMs may also administer or manage prescription drug benefits, including any of the following services:

- Mail order;
- Claims processing;
- Clinical management and formulary development and management;
- Patient compliance, therapeutic intervention and generic substitution programs; and
- Disease management programs.²¹

PBMs have become controversial because of a concern that they have failed to adequately disclose the existence of all rebates and have failed to pass through to their clients rebates as required under plan contracts.

Several states have enacted legislation designed to regulate PBMs, including Maine, South Dakota, North Dakota, the District of Columbia and Vermont. Maine's experience with its PBM legislation is instructive, in that it was the first PBM law in the nation, and it also resulted in litigation that helped define the contours of state authority in this area.

Maine's PBM Law. Maine's Act to Protect Against Unfair Prescription Drug Practices ("UPDPA")²² created in all PBMs operating in the state a fiduciary duty to their clients in accordance with the provisions of state and federal law. The law provides that a PBM must perform its duties with care, skill, prudence and diligence, and in accordance with the standards of conduct applicable to a fiduciary.

The Maine law also requires PBMs to make financial disclosures to insurers, health plans, employers and others who form their client base. At a client's request, the PBM must disclose financial and utilization information relating to the client's contract, including the provision of benefits to the client's covered individuals and other services performed for the

²¹ 22 M.R.S.A. § 2699.

²² 22 M.R.S.A. § 2699.

client. The PBM must disclose to its client all financial terms between the PBM and prescription drug manufacturers, including formulary management and drug-switch programs, educational support programs and sale of data programs. The law also requires PBMs to disclose to their clients any activity or policy that presents a “conflict of interest with the duties imposed” by the law. The PBM may elect to make these disclosures in confidence, with certain limited exceptions.

Maine’s law mandates disclosure of information when the PBM initiates a drug switch, or “therapeutic interchange.” These switches are often initiated to increase market share of a particular drug, thereby increasing rebates to the PBM and clients. If the PBM substitutes a more expensive drug for the prescribed drug, it must disclose to the client the cost of both drugs and any benefit accruing to the PBM as a result of the substitution.

In addition to requiring disclosures, Maine’s law requires certain fund transfers from the PBM to its clients. In the drug-switch situation, the PBM must remit to its client any benefit or payment received by the PBM as a result of the switch. Even in the event that the switch is from a more expensive drug to a less expensive drug – which is often the case when a brand name drug is replaced by a generic – the PBM must transfer any benefit or payment it receives as a result of the switch to the client. And when the PBM has an agreement with a drug manufacturer to receive payments based on the volume of sales of a particular drug, or class or brand of drugs, within Maine, those payments are to be passed on to the client. Compliance with the law is required in “all contracts for pharmacy benefits management entered into in [Maine] or by a covered entity in [Maine].”²³

A PBM trade association, PCMA, challenged Maine’s law, claiming it violated the Commerce Clause, violated the Takings Clause, and was preempted under federal law. The courts upheld the Maine law, finding it to be constitutional in all respects. *Pharm. Care Mgmt. Ass’n v. Rowe*, 429 F.3d 294 (1st Cir. 2005), *cert. denied*, 126 S.Ct. 2360 (U.S. June 6, 2006) (No. 05-1297).

Medco. State Attorneys General have also engaged in law enforcement efforts involving the activities of PBMs. In 2004, the pharmaceutical benefits manager Medco Health Solutions Inc. paid \$26.5 million to 20 states, and \$2.5 million to patients affected by inappropriate drug-switching practices. While Medco denied wrongdoing, the State Attorneys General investigation found that the company routinely pressured physicians to change patients’ medications by providing misleading information, including the failure to disclose the increased monetary incentives Medco garnered by switching drugs.

3. Marketing Restrictions, Disclosures and Standards

Pharmaceutical manufacturers’ marketing dollars are well spent, with the number of prescriptions written for heavily advertised drugs growing over 6 times faster than prescriptions for drugs that are not heavily advertised.²⁴ While the extent and nature of drug marketing’s

²³ 22 M.R.S.A. § 2699(3).

²⁴ U.S. Government Accountability Office, *Prescription Drugs: FDA Oversight of Direct-to-Consumer Advertising has Limitations*, (October 2002). Accessed at <http://www.gao.gov/new.items/d03177.pdf>

effect on prescribing and health outcomes is difficult to establish with any scientific certainty, there is evidence that it increases spending on pharmaceuticals by increasing utilization of all drugs, and steering patients towards higher priced drugs and away from lower cost alternatives, including non-drug measures.^{25, 26} Pharmaceutical manufacturers engage in marketing to doctors, as well as marketing directly to consumers.

Marketing to Doctors. The pharmaceutical industry does not disclose precise figures for how much it spends on marketing, but it is clear that physicians receive the majority of the companies' attention and money.

A recent GAO report found the industry spent \$7.2 billion marketing to physicians in 2005, which was slightly less than the \$7.4 billion spent in 2003, but considerably more than the \$4.6 billion spent five years earlier.²⁷ Those figures do not include the retail price of free samples, estimated at \$15.9 billion in 2004, up from \$13.5 billion in 2003, and \$6.6 billion five years earlier.²⁸ Marketing to physicians includes the following activities:

- Medical journal advertising;
- Educational materials provided to doctors;
- Product samples;
- Drug company representatives' visits to doctors' offices (known as "detailing");
- Consultant agreements with physicians;
- Continuing medical education (CME) seminars;
- Promotional (non-CME) seminars and presentations; and
- Entertainment, dinners, and gifts.

The pharmaceutical industry claims that marketing to physicians has informational and educational value, and that free samples offer valuable therapeutic charity to consumers who cannot afford to pay for their products.²⁹ Studies suggest, however, that marketing materials may not provide reliable, unbiased information. One study of pharmaceutical promotional brochures aimed at physicians, for example, found that only 40% of marketed drugs were compared to alternative treatments (the rest were compared to placebo, or no treatment), 15% presented data that was at odds with the findings of the underlying study, and 80% of studies cited were funded by the pharmaceutical industry.³⁰ Another study found that 11% of statements

²⁵ U.S. Government Accountability Office, *Prescription Drugs: Improvements Needed in FDA's Oversight of Direct-to-Consumer Advertising*, (November 2006). Accessed at www.gao.gov/new.items/d0754.pdf

²⁶ D.A. Kessler, D.A. Levy, *Direct-to-Consumer Advertising: Is it Too Late to Manage the Risks?* (January/February 2007). *Ann Fam Med*.

²⁷ U.S. Government Accountability Office, *Prescription Drugs: Improvements Needed in FDA's Oversight of Direct-to-Consumer Advertising*, (November 2006). Accessed at <http://www.gao.gov/new.items/d0754.pdf>

²⁸ U.S. Government Accountability Office, *Prescription Drugs: Improvements Needed in FDA's Oversight of Direct-to-Consumer Advertising*, (November 2006). Accessed at <http://www.gao.gov/new.items/d0754.pdf>

²⁹ Pharmaceutical Researchers and Manufacturers of America, *Pharmaceutical Marketing and Promotion: Tough Questions, Straight Answers* (Fall 2004). Accessed at http://www.phrma.org/files/Tough_Questions.pdf

³⁰ R. Cardarelli, J.C. Licciardone, L.G. Taylor, *A Cross-Sectional Evidence-Based Review of Pharmaceutical Promotional Marketing Brochures and their Underlying Studies: Is What They Tell Us Important and True?* *BMC Family Practice* (March 3, 2006).

made by pharmaceutical sales representatives to physicians about a marketed pharmaceutical were scientifically incorrect, and physicians generally failed to recognize the inaccuracies.³¹ Other research suggests that free samples may influence physicians to prescribe medications that are neither their first choice nor the choice recommended by clinical guidelines.³² While dispensing free samples is motivated by a desire to save patients money, it may lead to an overall increase in cost when the physician subsequently writes a prescription for the higher priced sampled drug.³³ Evidence indicates that, overall, clinics that dispense free samples prescribe a lower percentage of formulary-preferred medications, and account for significantly higher monthly prescription costs than comparable clinics that do not dispense the samples.³⁴

Unlike television or print advertising targeting consumers, much of the marketing efforts leveled at physicians takes place behind closed doors. This obscurity creates a heightened concern about the potential for questionable and even illegal practices, such as inappropriate off-label promotion.

Marketing to Consumers. The amount spent on Direct-to-Consumer (DTC) advertising is less than the amount spent on physicians, but still impressive: \$4.2 billion in 2005, up from \$3.3 billion in 2003, and \$1.3 billion five years earlier.³⁵ The GAO reports that every \$1 of DTC advertising generates a \$2.20 return, as about one-third of patients who see an ad will discuss it with their doctor, about a one-quarter of them will request a prescription for the drugs, and half of those requests will be given a prescription for the drug.³⁶ A few pharmaceutical manufacturers have instituted voluntary waiting period after a new drug has been approved before advertising it directly to consumers. Bristol-Myers Squibb has pledged to wait at least a year, and Pfizer at least 6 months. On average, a drug is advertised directly to consumers 15 months after it has been approved.³⁷

The pharmaceutical industry argues that DTC ads educate consumers about the latest treatment options, encourage participation in care decisions, and motivate consumers to seek medical help for conditions that may otherwise remain undiagnosed.³⁸ Some evidence supports these claims: studies have found an association between DTC advertising and subsequent increases in diagnosis of high cholesterol and depression, and treatment with drugs.³⁹

³¹ M.G. Ziegler, P. Lew, B.C. Singer, *The Accuracy of Drug Information From Pharmaceutical Sales Representatives*, JAMA (April 26, 1995)

³² L.D. Chew, T.S. O'Young, T.K. Hazlet, K.A. Bradley, C. Maynard, D.S. Lessler, *A Physician Survey of the Effect of Drug Sample Availability on Physicians' Behavior*, J Gen Intern Med (July, 2000).

³³ L.D. Chew, T.S. O'Young, T.K. Hazlet, K.A. Bradley, C. Maynard, D.S. Lessler, *A Physician Survey of the Effect of Drug Sample Availability on Physicians' Behavior*, J Gen Intern Med (July, 2000).

³⁴ B. Symm, M. Averitt, S.N. Forjuoh, C. Preece, *Effects of Using Free Sample Medications on the Prescribing Practice of Family Physicians*, J Am Board Fam Med (September/October 2006).

³⁵ U.S. Government Accountability Office, *Prescription Drugs: Improvements Needed in FDA's Oversight of Direct-to-Consumer Advertising*, (November 2006). Accessed at <http://www.gao.gov/new.items/d0754.pdf>

³⁶ U.S. Government Accountability Office, *Prescription Drugs: Improvements Needed in FDA's Oversight of Direct-to-Consumer Advertising*, (November 2006). Accessed at <http://www.gao.gov/new.items/d0754.pdf>

³⁷ M. Shuchman, *Drug Risks and Free Speech—Can Congress Ban Consumer Drug Ads?* NEJM (May 2007)

³⁸ Pharmaceutical Researchers and Manufacturers of America, *Pharmaceutical Marketing and Promotion: Tough Questions, Straight Answers* (Fall 2004). Accessed at http://www.phrma.org/files/Tough_Questions.pdf

³⁹ U.S. Government Accountability Office, *Prescription Drugs: Improvements Needed in FDA's Oversight of Direct-to-Consumer Advertising*, (November 2006). Accessed at <http://www.gao.gov/new.items/d0754.pdf>

Opponents of DTC advertising counter that the practice can overstate a drug's benefits and understate its risks,⁴⁰ promote drugs to consumers before side effect profiles are fully understood,^{41, 42} drive up costs through increased utilization of medicines in general and more expensive advertised drugs in particular,⁴³ and undermine the patient-doctor relationship.⁴⁴ As to the educational potential for consumers, an increasing body of evidence supports the assertion of former FDA commissioner David Kessler that “[I]n general, the ads that consumers see do not contain the right balance of information to provide any meaningful health education.”⁴⁵ A recent content analysis found that only a quarter of primetime television ads described causes, risk factors or the prevalence of a condition, and none mentioned lifestyle changes as a possible alternative to the advertised drug.⁴⁶ Instead, over 80% of the ads analyzed relied on rational arguments and factual claims, 78% claimed that drug-taking would engender social approval, and 95% made emotional appeals to encourage use of the promoted drug. Further, advertised drug benefits are overwhelmingly described in qualitative, unquantifiable terms, and generally omit meaningful comparisons with alternative treatments.^{47,48} Risks are similarly sparse, oversimplified or obfuscated, with discussions generally leaving consumers confused and misinformed.^{49,50}

The states have adopted laws to require pharmaceutical manufacturers to better disclose their marketing practices and, to a lesser extent, to restrict some of these practices. States have also developed their own marketing programs designed to counter the effects of company marketing. Here is a description of some of these state efforts.

Florida’s Electronic Prescription Information. The use of computerized prescription programs has been shown to reduce medication errors by up to 60%, primarily by ensuring that prescriptions are legible, complete, and do not interact with other medications concurrently being taken by a patient.^{51, 52} Evidence of the effectiveness of computerized prescription programs led

⁴⁰ K.C. Stange, *Time to Ban Direct-to-Consumer Drug Marketing*, *Annals of Family Medicine* (March/April 2007)

⁴¹ M. Shuchman, *Drug Risks and Free Speech—Can Congress Ban Consumer Drug Ads?* *NEJM* (May 2007)

⁴² J.M. Donohue, M. Cevasco, M.B. Rosenthal, *A Decade of Direct-to-Consumer Advertising of Prescription Drugs*, *NEJM* (August 2007)

⁴³ U.S. Government Accountability Office, *Prescription Drugs: FDA Oversight of Direct-to-Consumer Advertising has Limitations*, (October, 2002). Accessed at <http://www.gao.gov/new.items/d03177.pdf>

⁴⁴ K.C. Stange, *Time to Ban Direct-to-Consumer Drug Marketing*, *Annals of Family Medicine* (March/April 2007)

⁴⁵ D.A. Kessler & D.A. Levy, *Direct-to-Consumer Advertising: Is it Too Late to Manage the Risk?* *Annals of Family Medicine* (January/February 2007)

⁴⁶ D.L. Frosch, P.M. Krueger, R.C. Hornik, P.F. Cronholm, F.K. Barg, *Creating Demand for Prescription Drugs: A Content Analysis of Television Direct-to-Consumer Advertising*, *Annals of Family Medicine* (January/February 2007).

⁴⁷ S. Woloshin, L.M. Schwartz, H.G. Welch, *The Value of Benefit Data in Direct-to-Consumer Drug Ads*, *Health Affairs* (April 28, 2004).

⁴⁸ M.F. Hollon, *Direct-to-Consumer Advertising: A Haphazard Approach to Health Promotion*, *Journal of the American Medical Association* (April 27, 2005).

⁴⁹ S. Woloshin, L.M. Schwartz, H.G. Welch, *The Value of Benefit Data in Direct-to-Consumer Drugs Ads*, *Health Affairs* (April 28, 2004).

⁵⁰ M.M. Mello, M Rosenthal, P.J. Neumann, *Direct-to-Consumer Advertising and Shared Liability for Pharmaceutical Manufacturers*, *Journal of the American Medical Association* (January 22/29, 2003)

⁵¹ R.E. Ferner, *Computer Aided Prescribing Leaves Holes in the Safety Net*, *BMJ* (May 15, 2004).

Congress, through the Medicare Prescription Drug, Improvement, and Modernization Act (MMA), to begin funding the implementation of electronic prescribing systems in 2007. The MMA specifically allows third parties, including those with potential conflicts of interest such as pharmaceutical companies, to fund these systems on behalf of providers.⁵³ While these steps will likely accelerate the adoption of electronic prescription systems, one unintended consequence of this innovation has been to allow the pharmaceutical industry another avenue to influence prescribing patterns. Some e-prescribing software developed by commercially interested third parties attempts to steer physicians towards specific choices at the moment he or she is writing a prescription, by flagging certain drugs within a therapeutic category, altering the order in which drugs appear, using certain symbols, or displaying “pop-up” advertisements.⁵⁴

Florida led the charge to preempt this marketing venue through laws restricting a company's ability to advertise to doctors on the electronic prescribing systems. Florida's law establishes explicit standards for electronic prescriptions. The law specifically states:

“Electronic prescribing software shall not use any means or permit any other person to use any means, including, but not limited to, advertising, instant messaging, and pop-up ads, to influence or attempt to influence, through economic incentives or otherwise, the prescribing decision of a prescribing practitioner at the point of care. Such means shall not be triggered or in specific response to the input, selection, or act of a prescribing practitioner or his or her agent in prescribing a certain pharmaceutical or directing a patient to a certain pharmacy.”⁵⁵

Other states have adopted Florida's law, including Vermont and New Hampshire.⁵⁶

New Hampshire's prescription privacy law. The current practice of electronically storing and transmitting prescription data has dramatically facilitated another aggressive pharmaceutical marketing tactic. Pharmaceutical companies “data-mine” prescription records using physician-identifying information to facilitate targeted marketing, or “detailing,” of physicians.⁵⁷ New Hampshire became the first state in the nation to outlaw the commercial use of such information with the passage of its Prescription Privacy law. The New Hampshire law outlawed the sale, transfer or use of an individual prescriber's prescription information for any commercial purpose, including advertising, marketing, promotion, or any activity that could

⁵² D.S. Bell, R.S. Marken, R.C. Meili, C.J. Wang, M. Rosen, R.H. Brook, and the RAND Electronic Prescribing expert Advisory Panel, *Recommendations for Comparing Electronic Prescribing Systems: Results of an Expert Consensus Process*, Health Affairs (May 25, 2004)

⁵³ D.S. Bell, R.S. Marken, R.C. Meili, C.J. Wang, M. Rosen, R.H. Brook, and the RAND Electronic Prescribing expert Advisory Panel, *Recommendations for Comparing Electronic Prescribing Systems: Results of an Expert Consensus Process*, Health Affairs (May 25, 2004)

⁵⁴ D.S. Bell, R.S. Marken, R.C. Meili, C.J. Wang, M. Rosen, R.H. Brook, and the RAND Electronic Prescribing expert Advisory Panel, *Recommendations for Comparing Electronic Prescribing Systems: Results of an Expert Consensus Process*, Health Affairs (May 25, 2004)

⁵⁵ [F.S.A.](#) § 456.43

⁵⁶ 9 V.S.A. § 2466a; RSA 318:47-c

⁵⁷ Program on Information Justice and Intellectual Property, Washington College of Law, *Brief Amicus Curiae the National Legislative Association on Prescription Drug Prices, The New Hampshire Medical Society, and Prescription Policy Choices in Support of Defendant's Objection to Plaintiff's Motion for Preliminary Injunction*, (December 15, 2006). Accessed at www.wcl.american.edu/pijip/documents/IMSNLARxBrief.pdf

influence sales or market share of a pharmaceutical product.⁵⁸ Such data may be used for reimbursement, research, utilization review, compliance, education, or for other uses provided by law.

A federal district court overturned the law, siding with two leading health information companies, IMS Health and Verispan LLC, who challenged the law on the grounds that it violates the First Amendment by improperly restricting commercial speech.⁵⁹ The New Hampshire Attorney General has appealed the district court decision to the First Circuit.⁶⁰

Vermont and Maine have enacted similar laws, which are also being challenged in the courts.⁶¹

California's Fair Drug Marketing Law. In September 2004, California Governor Arnold Schwarzenegger signed SB 1765 into law, creating the first state law to require pharmaceutical manufacturers to comply with marketing guidelines set by the Office of Inspector General (OIG) at the U.S. Department of Health and Human Services. California's Fair Drug Marketing Law requires manufacturers to comply with the previously-voluntary code on proper marketing practices created by the industry's trade association, Pharmaceutical Research and Manufacturers Association ("PhRMA"). The intent of California's law is to ensure compliance with the OIG guidelines and PhRMA code, thereby limiting marketing practices by pharmaceutical manufacturers to marketing activities deemed legitimate under the guidelines and code.⁶²

California's law requires every pharmaceutical company active in California to adopt a Comprehensive Compliance Program that:

- Complies with the April 2003 "Compliance Program Guidance for Pharmaceutical Manufacturers" developed by the OIG, including: ensuring the integrity of data used to establish government reimbursement; prohibiting kickbacks and other illegal remuneration; and complying with regulations relating to drug samples;
- Complies with the PhRMA July 2002 "Code on Interactions with Health Care Professionals," including provisions relating to such marketing practices as gifts, meals and entertainment, hiring and payment of consultants, and participation in speaker training and educational conferences;
- Establishes limits on gifts and incentives provided to medical and health care professionals; and

⁵⁸ HB 1346-Final Version, (May 4, 2006). Accessed at <http://www.gencourt.state.nh.us/legislation/2006/hb1346.html>

⁵⁹ IMS Health Incorporated, et al. v. Ayotte, 490 F. Supp.2d 163 (D.N.H. 2007)

⁷³ IMS Health Incorporated, et al. v. Ayotte, No. 07 1945 (1st Cir. June 20, 2007)

⁶¹ See: http://www.imshealth.com/ims/portal/front/indexC/0,2773,6599_82199038_0,00.html

⁶² Foley & Lardner LLP, *New California Laws Focus on Marketing of Prescription Drugs and Use and Disclosure of Medical Information*, Law Watch, 04-08, Oct. 21, 2004.

- Creates specific annual dollar limits on gifts, promotional materials or items or activities that are given or provided to medical or health care professionals by pharmaceutical companies.⁶³

As long as the companies' actions conform to the OIG guidelines and the PhRMA code, certain activities are exempt from the requirements of the California law, including:

- Drug samples given for free distribution to patients;
- Financial support for medical education forums and scholarships; and
- Legitimate payments for professional services (*i.e.*, consulting), as long as the payments do not exceed fair market value for services rendered.⁶⁴

California's law does not contain its own penalty or enforcement provision. A violation of the California law is an unfair business practice under California's Business and Professions Code section 17200.⁶⁵

Vermont's Pharmaceutical Payment Disclosure Law. In 2002, Vermont enacted its Pharmaceutical Marketing Disclosure Law, also called the "Payment Disclosure Law," which requires pharmaceutical companies to disclose certain expenditures on marketing within the state.⁶⁶ Vermont's Gift Disclosure Law requires disclosures of "the value, nature, and purpose of any gift, fee, payment, subsidy or other economic benefit" provided in connection with marketing activity to any doctor, hospital, nursing home, pharmacists, health benefit plan administrator, or any other person authorized to prescribe, dispense or purchase prescription drugs in Vermont. The disclosures must also include the name of the recipient of the economic benefit.

Exempt from disclosure are:

- Free samples of prescription drugs intended to be distributed to patients;
- Payment of reasonable compensation and reimbursement of expenses in connection with bona fide clinical trials;
- Gifts, fees, payments or other economic benefits with a value less than \$25.00;
- Scholarships or other support for medical students, residents and fellows to attend significant medical conferences; and
- Drug rebates and discounts.⁶⁷

⁶³ Cal. Health & Safety Code § 119400 *et seq.*; see Hogan & Hartson LLP, *New California Law Affects Pharmaceutical Manufacturer Compliance Plans and Reporting Obligations*, Update, Feb. 2005.

⁶⁴ Cal. Health & Safety Code § 119400 *et seq.*; see Hogan & Hartson LLP, *New California Law Affects Pharmaceutical Manufacturer Compliance Plans and Reporting Obligations*, Update, Feb. 2005.

⁶⁵ Arnold & Porter LLP, *New California Law on Gifts to Health Care Providers: Interpretation Challenges and Liability Risks*, Client Advisory. Nov. 2004.

⁶⁶ 33 V.S.A. § 2005.

⁶⁷ 33 V.S.A. § 2005(a)(4).

Pharmaceutical companies are allowed to designate all or part of their information as trade secret, as long as the designation conforms to Vermont law. Vermont law defines “trade secret” quite broadly, so this trade secret provision was included to prevent a legal challenge to the law based on the claim that the law’s reporting requirements amounted to an unconstitutional “takings” of proprietary marketing strategy. The trade secret provision has been criticized for hindering transparency, and has been the subject of a lawsuit seeking public disclosure of information deemed trade secret.⁶⁸ Whether other states should include such a provision depends largely on the breadth of their state definition of trade secret.

The Vermont law requires the Attorney General’s Office to aggregate the information and publish an annual report.⁶⁹ Starting in January 1, 2004, the law required pharmaceutical companies to report the names of the recipients along with the amount of reportable gifts. Total expenditures on reportable gifts amounted to \$2,196,592 in FY 05 and \$2,247,769 in FY 06. In addition to increasing the transparency of pharmaceutical marketing practices, information from reports could be helpful in guiding counter-detailing programs towards targeted medical specialties. For example, disclosures from FY 2004 through FY 2006 show that among medical specialties, psychiatrists are the largest recipients of drug manufacturer payments. In FY 2006, out of the \$2,247,769 that drug manufacturers paid in fees, travel expenses, and other direct payments to all Vermont prescribers, 11 psychiatrists received a total of just over \$502,000, or approximately 22% of the total. The average direct payment received by these psychiatrists was \$45,692.

Other states have since adopted payment disclosure laws, including Maine,⁷⁰ Minnesota,⁷¹ West Virginia,⁷² and the District of Columbia.⁷³

Maine’s State Enforcement of Federal False Advertising Standards. While the federal Food, Drug and Cosmetics Act regulates direct-to-consumer advertising, enforcement by the FDA has been lax.⁷⁴ States have shown an interest in stricter enforcement of false advertising as a result. A Maine law adopts federal misleading advertising standards and gives its Attorney General explicit authority to prosecute violators.⁷⁵ Vermont recently enacted a similar provision.⁷⁶

Washington D.C.’s Unconscionable Pricing Law. Prices for prescription drugs are approximately 50% lower in Canada, France and the UK than in the United States.⁷⁷ Washington D.C.’s unconscionable pricing law sets a benchmark price of 30% above the price of the same

⁶⁸ J.S. Ross, J.E. Lackner, P. Lurie et al, *Pharmaceutical Payments to Physicians: Early Experiences with Disclosure Laws in Vermont and Minnesota*, JAMA (March 27, 2007).

⁶⁹ Reports are available at <http://www.atg.state.vt.us/display.php?smod=151>.

⁷⁰ 22 M.R.S.A § 2699

⁷¹ M.S. Ann. § 151.461

⁷² W.Va. Code §5A-3C-13

⁷³ D.C. Code § 48-831.01

⁷⁴ U.S. Government Accountability Office, *Prescription Drugs: Improvements Needed in FDA’s Oversight of Direct-to-Consumer Advertising*, (November 2006). Accessed at <http://www.gao.gov/new.items/d0754.pdf>

⁷⁵ 22 M.R.S.A. § 2700-A

⁷⁶ 18 V.S.A. § 4631

⁷⁷ GF Anderson, et al. *Doughnut Holes and Price Controls*, July 21, 2004, Health Affairs.

drug in 4 industrialized "high income" countries. The law provides a legal remedy to those affected by excessive prices, and gives the drug makers an opportunity to justify pricing decisions by showing that prices reflect legitimate costs, such as research and development.

The D.C. law has been struck down by a federal district court.⁷⁸ The drug industry trade organization PhRMA and the Biotechnology Industry Organization (BIO) claimed, successfully, that the law was preempted by federal patent laws, and violated the Commerce Clause. Subsequently the District of Columbia appealed this decision to the Court of Appeals. The appeals court affirmed the district court's injunction against enforcement of the District's law, stating that federal patent laws preempted it. As the patent-law preemption invalidated the District's price unconscionability law in its entirety, the appeals court declined to consider the Commerce Clause argument.⁷⁹ On October 30, 2007 the District of Columbia's Petition for Panel Rehearing or Rehearing en banc was denied.⁸⁰

Pennsylvania's Academic-Detailing Program. Pennsylvania's PACE (Pharmaceutical Assistance Contract for the Elderly) program provides comprehensive prescription coverage to older Pennsylvanians, including most medications that require prescriptions, including insulin, syringes, and insulin needles. These programs are administered by the Pennsylvania Department of Aging and funded by the Pennsylvania Lottery. PACE has launched an academic detailing program that aims to:

- Provide prescribers with accurate, unbiased information about drug efficacy;
- Lower drug expenditures by encouraging the use of lower cost, equally effective generics; and
- Counter the effects of pharmaceutical industry marketing.

Academic detailers working with PACE conduct office visits with Pennsylvania prescribers to provide trainings, and offer continuing medical education credits as an incentive.

The PACE academic detailing program utilizes comprehensive reviews of clinical evidence by drug researchers at Harvard University and elsewhere to create evidence reports and teaching modules about the most effective choices in some of the most widely prescribed drug classes. To date, five drug classes have been reviewed: NSAID and Cox-2 pain relievers, stomach acid suppressors, anti-coagulation drugs, cholesterol-lowering drugs, and high-blood pressure treatments. These evidence reports are available free of charge at www.RxFacts.org.

Generic Drug Sampling. A newly enacted Vermont law calls for the creation of a first in the nation generic sampling program.⁸¹ Providing samples or vouchers for free prescription drugs has long been used as an industry marketing strategy to steer prescriptions towards more expensive brand-name drugs. The Vermont law recognizes the effectiveness of free samples, and seeks to utilize the practice to steer prescriptions towards lower cost, equally effective generics. The program will be administered as part of an academic detailing program, funded by yearly fees collected from pharmaceutical manufacturers who are reimbursed by the state Medicaid

⁷⁸ *PhRMA v. District of Columbia*, 406 F.Supp.2d 56 (D.D.C. 2005).

⁷⁹ *Biotechnology Industry Organization, et al. v. District of Columbia*, 496 F.3d 1362 (D.C. Cir. 2007)

⁸⁰ *Biotechnology Industry Organization, et al. v. District of Columbia*, - F.3d- , 2007 WL 314634 (D.C. Cir. 2007)

program. Though it has yet to be launched, the program will begin with a single drug class, such as cholesterol-lowering statins, and offer vouchers for free samples of lower cost, equally effective generics.

4. Consumer-Oriented Purchasing Aids

A number of states and organizations are attempting to promote more economical pharmaceutical purchasing decisions by educating patients directly. Two approaches that are growing in popularity are websites that compare prices for specific drugs at different local pharmacies, and websites that evaluate drugs' cost-effectiveness.

Price Comparison Websites. Price comparison websites are generally created and managed by State Attorneys General, or other state agencies, to report the “usual and customary” prices for the most commonly prescribed drugs. Since those prices are regularly reported to state Medicaid regulators, and are comparable to the full-retail price that a customer would pay if they lacked prescription-drug coverage, they can allow comparison shopping among pharmacies for consumers who are uninsured, underinsured, or have reached the Medicare Part D “donut hole.” States with such websites include Florida (www.myfloridarx.com), Maryland (www.oag.state.md.us/drugprices/), Missouri (www.morxcompare.mo.gov/), and Vermont (<http://www.atg.state.vt.us/display.php?smod=185>). The New York Attorney General developed an alternative method of gathering drug prices for their site (www.nyagr.org), relying on surveys performed by volunteers visiting pharmacies.

Websites are generally searchable either by county or drug name, and provide prices for a typical 30-day supply. While it is unclear how much, if anything, these websites might be saving consumers, a recent analysis of the New York site found that the average search could potentially save a customer \$17.36, or 24% per prescription.⁸² Variations in price among the most commonly searched drugs ranged from 14% for sildenafil (a male impotence drug) to 53% for atenolol (a heart drug).

Traffic figures indicate that retail-price comparison websites are frequently used: Vermont's site recorded over 5,000 hits in its first 6 months of operation, Florida's saw 220,000 visitors its first year, and New York's received over 643,000 visits in 2007.

5. Litigation

Federal oversight and enforcement in the area of pharmaceutical marketing and pricing has been viewed as spotty and weak, leaving State Attorneys General among the “most potent regulators of all in this arena.”⁸³ The three principle litigation approaches to managing pharmaceutical costs are in the areas of Medicaid fraud, antitrust, and consumer protection.

⁸⁹ 18 V.S.A. § 4622

⁹⁰ Office of New York State Attorney General, *The Benefits of Comparison Shopping for Prescription Drugs: A Report on Consumers' Potential Savings*, (February 2006). Accessed at www.oag.state.ny.us/press/2006/feb/NYAGR%20savings%20report.pdf

State Attorneys General have accelerated their enforcement efforts in these areas in an attempt to stop illegal practices that can lead to higher pharmaceutical expenditures.

Medicaid Fraud. Medicaid fraud cases primarily involve, in the pharmaceutical arena, false claims in the reporting of drug prices by the manufacturers. The Omnibus Budget Reconciliation Act of 1990 mandates that the price of a drug sold to Medicaid has to be lower than the “best price” paid by any private-sector purchaser.⁸⁴ “Best price” is reported by manufacturers, who stand to profit by manipulating those figures upwards. In addition, in 16 states and the District of Columbia, False Claims Act statutes contain *qui tam* provisions, which allow, among other things, private individuals to bring to the states’ attention improper activities affecting state expenditures for pharmaceuticals. These provisions have proven to be an especially helpful tool against Medicaid fraud.^{85, 86}

- **Claritin:** In 2004, Schering-Plough agreed to pay 49 states \$140.7 million to settle allegations that it had failed to report the “best price” charged for its widely marketed allergy drug Claritin.⁸⁷ In an effort to increase market share in the private health insurance market, Schering-Plough had provided discounts, concessions and incentives to certain HMOs to encourage preferential coverage of Claritin. Incentives included a \$2.5 million “data processing” fee for reports that an HMO was already required to provide to Schering-Plough. These marketing strategies resulted in a price that was lower than the “best price” for Claritin reported to the Centers for Medicare and Medicaid Services, and resulted in significant overpayments by state Medicaid programs to cover Claritin.
- **Albuterol:** In 2000, the Attorney General of Texas filed a *qui tam* suit against two subsidiaries of the drug manufacturer Schering-Plough and Dey Inc., a subsidiary of Merck Pharmaceuticals. The Texas Attorney General accused these companies of overcharging Medicaid by falsely inflating the average wholesale price (AWP) paid for the asthma drug albuterol (AWP is the reference used to calculate the price that Medicaid reimburses for a drug, so increasing AWP increases the cost to Medicaid). The case was

⁸³ A. Friede, *Pharmaceutical Advertising: “May You Live in Interesting Times,”* (February 9, 2007) Washington Legal Foundation Working Paper

⁸⁴ Congressional Budget Office, *Prices for Brand-Name Drugs Under Selected Federal Programs*, (June 2005). Accessed at <http://www.cbo.gov/ftpdocs/64xx/doc6481/06-16-PrescriptDrug.pdf>

⁸⁵ Text of each state’s False Claims Act with *qui tam* provisions is available from Taxpayers Against Fraud. See <http://www.taf.org/statefca.htm>

⁸⁶ A provision of the Federal Civil False Claims Act, *qui tam* allows a private citizen (a “relator”) to file a lawsuit on behalf of state or federal government charging fraud by government contractors or others receiving or using government funds. Relators also receive any where from 15 to 30% of any money recovered, as well as reimbursement for legal expenses if the case is won. In effect, *qui tam* allows private citizens—frequently whistle blowers—to act as individual attorneys general, filing complaints in court and providing all available material evidence to state investigators who investigate the claim. If the state joins the case, it defines the level of involvement by the relator; if it chooses not to join, the relator can continue to investigate and prosecute the case on its own.

⁸⁷ “Pharmaceutical Company to Reimburse State \$204,000 in Medicaid Fraud Settlement,” (July 30, 2004). Accessed at <http://www.doj.mt.gov/news/releases2004/07302004.asp>

settled in 2004 for \$45.5 million, which was shared by Texas, the federal government, and the *qui tam* relator⁸⁸.

Antitrust Enforcement. State antitrust activities in the pharmaceutical arena typically involve an attempt by a manufacturer of a branded drug to keep a lower-cost generic off the market by paying the generic manufacturer, either through settlement of litigation or as part of a contractual agreement. State antitrust enforcement also examines agreements not to compete with certain products, or agreements on mutually beneficial pricing schemes. Antitrust enforcers also examine manufacturers that file false information to register additional patents with the FDA, thereby extending their patent-exclusivity under federal law, or file baseless patent infringement suits against generic manufacturers.⁸⁹

- **Hytrin.** In 2001, several State Attorneys General filed suit charging that Abbott Laboratories wrongly paid Geneva Pharmaceuticals to delay introduction of its generic version of Hytrin, prescribed for hypertension and enlarged prostate, alleging this illegal activity harmed consumers. According to the complaint, Abbott and Geneva entered into a contract in April 1998 that called for Abbott to pay Geneva \$4.5 million a month to keep its generic version of Hytrin off the market until a resolution was reached in the parties' patent infringement dispute. The antitrust litigation was resolved in 2005 through a settlement requiring Abbott and Geneva to pay refunds from a \$30.7 million pool to consumers and third-party payers in 18 states.⁹⁰
- **Cardizem.** Also in 2001, Michigan and New York led a coalition of 29 states that filed an antitrust suit against the drug manufacturer Hoechst Marion Roussel, which has since merged into Aventis Pharmaceuticals. The states alleged that Aventis had paid the generic pharmaceutical maker Andrx \$89 million not to produce a generic version of Aventis' blockbuster, \$750 million-a-year heart-disease drug Cardizem CD. As the first manufacturer to gain FDA approval to manufacture a generic version of Cardizem CD, Andrx was granted a 180-day exclusivity period that would start once it had launched its generic product.⁹¹ By paying Andrx not to produce a generic, Aventis effectively extended its own exclusivity by blocking all other generics from entering the marketplace. The result was that consumers, and state Medicaid programs, were forced to continue paying the significantly higher brand-name price of \$73 a month instead of the lower generic price of \$32 a month. A 2005 settlement required the manufacturers to refund overcharges of \$24 million to consumers, and \$4.5 million to state agencies.⁹²
- **Ovcon.** In 2005, 21 states and the District of Columbia filed suit against Warner Chilcott and Barr Pharmaceuticals, alleging that the companies had entered into an agreement that

⁸⁸ "Attorney General Reaps \$27 Million Medicaid Fraud Settlement with Major Drug Maker," (May 3, 2004). Accessed at <http://www.oag.state.tx.us/oagnews//release.php?id=453>

⁸⁹ Federal Trade Commission. *Overview of FTC Antitrust Actions in Pharmaceutical Services and Products*. (October 2005). Accessed at <http://www.ftc.gov/bc/0510rxupdate.pdf>

⁹⁰ Available at: <http://myfloridalegal.com/newsrel.nsf/newsreleases/E4208EAF672805C85256FD50068E8C1>

⁹¹ "Consent Agreement Resolves Complaint Against Pharmaceutical Companies Hoechst Marion Roussel, Inc. and Andrx Corp." April 2, 2001. Accessed at <http://www.ftc.gov/opa/201/04/hoechst.htm>

⁹² "Distribution of \$28.5 Million in Cardizem Settlement Begins," July 20, 2007. Accessed at http://www.oag.state.ny.us/press/2005/jul/jul20b_05.html

prevented entry of Barr's lower-priced generic version of Warner Chilcott's oral contraceptive Ovcon. In exchange for keeping Barr's generic off the market, the complaint alleged that Warner Chilcott paid Barr \$20 million dollars. In 2007, a settlement agreement was reached between Warner Chilcott and the states, requiring Warner Chilcott to pay \$5.5 million dollars and providing for other injunctive relief. The case against Barr proceeds.⁹³

Consumer Protection Enforcement. State Attorneys General have, in recent years, brought numerous consumer protection suits involving inappropriate marketing by pharmaceutical manufacturers. These suits focus on curtailing wrongdoing that may both undermine the quality of medical care a patient receives, and lead to unnecessary costs for patients and payers. In most circumstances, it is illegal for pharmaceutical companies to engage in off-label marketing, or market drugs for conditions that have not been approved by the FDA. States have a number of ways of addressing off-label marketing. Some states use food and drug laws that mirror federal laws prohibiting the practice. Most states attack the practice as a form of unfair or deceptive promotion. In addition to off-label promotion cases, the State Attorneys General use consumer protection laws to pursue pharmaceutical manufacturers which fail to disclose important information about their products to consumers and prescribers.

- **Neurontin.** In 2004, State Attorneys General entered into a global settlement with Pfizer relating to the marketing practices of its subsidiary, Warner-Lambert, for its epilepsy drug Neurontin. The case centered on Warner-Lambert's criminal indictment and guilty plea for marketing Neurontin off-label. In addition to potentially putting patients at risk from the unapproved use of a powerful medicine, this practice resulted in increased costs to state Medicaid programs paying for inappropriate treatment. The \$430 million global settlement included the federal government and State Attorneys General representing Medicaid programs and consumers.⁹⁴ The consumer protection component included an innovative provision allowing the State Attorneys General to use \$21 million to establish the Attorney General Consumer and Prescriber Education Grant Program, which funds programs around the country designed to educate physicians and patients about prescription drug marketing and other related issues.⁹⁵ To date, 28 grantees in 19 states and the District of Columbia have been awarded a total of \$10.5 million.
- **Oxycontin.** Earlier this year, Purdue Pharma settled claims that it had engaged in off-label marketing of its opioid pain reliever Oxycontin, and had failed to adequately disclose the drug's abuse and diversion risks. In a consent agreement signed by 26

⁹³ *Federal Trade Commission, Plaintiff, v. Warner Chilcott Holdings Company III, Ltd.; Warner Chilcott Corporation; Warner Chilcott (US) Inc.; Galen (Chemicals) Ltd.; and Barr Pharmaceuticals, Inc.* Accessed at <http://www.ftc.gov/os/caselist/0410034/0410034.shtm>. See also: "Attorney General Sorrell Announces \$5.5 Million Settlement In Oral Contraceptive Lawsuit." June 13, 2007. Accessed at <http://www.atg.state.vt.us/display.php?pubsec=4&curdoc=1326>

⁹⁴ "AG Announces \$430 Million Global Settlement Against Warner-Lambert, a Subsidiary of Pfizer," (May 13, 2004). Accessed at <http://www.doj.state.or.us/releases/2004/re1051704.shtml>.

⁹⁵ More information on this program can be found at www.ohsu.edu/cpgp.

states and the District of Columbia, Purdue Pharma agreed to pay \$19.5 million to the states, as well as to significantly reform its practices. The settlement requires Purdue to maintain an abuse and diversion-detection program to detect problem prescribing, and requires all sales representatives to undergo training on the program before being allowed to promote OxyContin. Other restrictions contained in the Consent Judgment include requirements that Purdue Pharma cease engaging in off-label promotion and other improper marketing of OxyContin.

- **Baycol.** Also earlier this year, Bayer Corporation settled claims that it withheld information about the increased risk of life-threatening side effects posed by its cholesterol lowering statin-drug Baycol (cerivastatin). State Attorneys General from 30 states alleged that post-marketing surveillance of Baycol showed that it caused myopathy (muscle weakness) and rhabdomyolysis (muscle breakdown) at a much higher rate than other statins. While Bayer informed the FDA, the State Attorneys General alleged that Bayer failed to adequately warn prescribers and consumers about these problems. Ultimately, Baycol was withdrawn from the market due to these adverse side effects. In a consent agreement Bayer did not admit any wrong doing, but agreed to pay participating states a total of \$8 million. The settlement also requires that Bayer register clinical trials of its prescription products, and post all results, not just those with positive outcomes.

V. Conclusion

This report represents the latest effort by the National State Attorneys General Program at Columbia Law School to focus on the role that State Attorneys General can play in reducing the current level of spending on prescription pharmaceuticals by states, consumers, private insurers and employers. At a conference held at Columbia Law School in May 2007, State Attorneys General, academics, advocates, and state and federal regulators all gathered to discuss the policy options that states can pursue in their efforts to save pharmaceutical dollars, while continuing to improve healthcare quality, access, and cost-effectiveness. The insightful participation of conference presenters has significantly shaped this report.

As the 2008 legislative season opens, we believe that the policy and program initiatives profiled in this report will provide practical examples of potential solutions for State Attorneys General, legislators, regulators, and others to consider, emulate, or improve upon for their own states. And further, as ongoing legal actions by State Attorneys General continue to serve the public, we trust that the discussions of legal strategies contained in this report will assist the discussion about the role that state litigation can play.