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"State Perspectives on the Relationship Between Doctors and the Drug Industry: The Role of States and the Federal Government"
Senate Special Committee on Aging
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Chairman Kohl, Senator Smith, and members of the Committee. It is an honor to be here today to testify on this important issue on behalf of state legislators. I am Sharon Treat, a member of the Maine House of Representatives, and Executive Director of the National Legislative Association on Prescription Drug Prices, a nonprofit, nonpartisan organization of state legislators who network across state lines to find ways to reduce prescription drug costs and expand access to medicines.[1]

Since at least 1993, when Minnesota passed the first state law banning certain gifts and requiring disclosure of drug industry marketing activities and payments targeted to doctors and other health practitioners, states have been at the forefront of efforts to insure that the pharmaceutical industry does not unduly influence the practice of medicine and adversely affect patient health and safety.

As of June 2007 at least 30 states had enacted laws, or had legislation pending, on one or more of the following topics:

- Disclosing marketing spending and practices, including gifts and payments to doctors; banning gifts to health practitioners
- Beefing up state authority to enforce misleading advertising and marketing rules
- Protecting patient and doctor privacy by restricting the commercial use of prescriber-identifiable prescription data
- Restricting advertising in electronic prescribing software
- Regulating drug industry sale representatives or detailers
- Establishing independent academic or counter detailing programs
- Requiring disclosure and posting of clinical trials information
- Establishing conflict of interest rules, especially with regard to pharmacy benefit managers

[1] The National Legislative Association on Prescription Drug Prices is a nonpartisan, nonprofit organization of state legislators from across the country who advocate for lowering prescription drug costs and increasing access to affordable medicines. Legislators from the District of Columbia and all of the New England states plus New York, West Virginia, Oklahoma, Texas, Alaska, Arizona, Colorado and Hawaii are members.

Although the federal government has a major role regulating drug safety, advertising and marketing, states have continued to exercise their traditional authority to protect public health and safety, and fill the gaps where the federal government has failed to regulate or vigorously enforce that laws.

Without the data collected through the **Minnesota** gift disclosure law, we would not have the week-long series of front-page articles in the New York Times detailing payments to doctors and questionable or unsafe prescribing patterns linked to those doctors.

Without the public, online clinical trials databases required in the Paxil settlement - a case brought by state attorneys general, spearheaded by **New York** – the data would not have been available which formed the basis of a study linking a popular diabetes drug to increased risk of heart attacks. **Maine** law requires the results of *all* clinical trials to be published online, and other states are following suit.

State attorneys general have been in the forefront initiating consumer protection and Medicaid fraud prosecutions against pharmaceutical companies and doctors for kickbacks and misleading marketing tactics including off-label promotions and failure to accurately and completely disclose adverse effects. Examples are the multistate Neurontin litigation and Oxycontin cases, which were in part a response to criminal activity spawned by drug abuse facilitated by off-label marketing and lax or fraudulent prescribing practices.

States are concerned that marketing activities affect patient safety and provider prescribing patterns, and have enacted legislation to rein in harmful marketing practices and to promote evidence-based prescribing. **Vermont, West Virginia, California,** the **District of Columbia** and **Maine** have joined **Minnesota** in requiring disclosure of marketing and advertising spending; Maine and Vermont also grant clear authority to enforce misleading marketing standards in the courts. These states have acted in part in response to a significant reduction in the overall number of federal enforcement actions for misleading marketing, as well as FDA delay in acting to curb abuses.[2]

Vermont's law not only regulates misleading advertising, but also marketing to health care practitioners, including at educational conferences, and requires pharmaceutical sales

[2] Federal enforcement of marketing rules is lax. A 2005 report issued by Congressman Henry Waxman of the House Committee on Government Reform found that "there has been a marked decline in enforcement actions taken against drug manufacturers for illegally promoting their products" since December 2001. From 1999 to 2001, The FDA issued 250 "Notice of Violation" or "Warning" letters to drug companies, but from 2002 through 2004, the FDA sent only 70 letters. This is a reduction of more than two-thirds, despite a sharp increase in the number of drug ads and the money spent on them. The FDA does not have the resources to adequately police drug advertising. For example, in 2003, the FDA had only 18 staff assigned to review the roughly 37,000 ads and promotional pieces submitted by drug companies that year. See "*FDA Struggles to Police Print Ads for Prescription Drugs*," by Tony Pugh, January 29, 2004, Knight-Ridder.

representatives to "disclose to the prescriber evidence-based information as provided for by rule describing the specific health benefits or risks of using other pharmaceutical drugs, including drugs available over the counter; which patients would gain from the health benefits or be susceptible to the risks described; the range of prescription drug treatment options; and the cost of the treatment options."[3] **Pennsylvania** has a comprehensive academic detailing program to provide objective, evidence-based information and "unadvertisements" to physicians to counteract biased – or at least one-sided - information provided by sales representatives. Several other states have followed suit.

To the extent that marketing activities increase spending on prescription drugs, and encourage prescribing drugs that are not on a state's preferred drug list, they are also a concern for state Medicaid programs. With Medicaid costs always a significant factor in state budgets, state legislators are looking at issues of doctor and drug company conflicts of interest caused by payments for prescribing and specialty drugs which are administered in physician's offices.[4]

Data mining and targeted marketing techniques raise issues of privacy that resonate with state legislators and their constituents familiar with these issues in other policy areas. Many states passed medical records confidentiality laws predating HIPAA by many years, and some of these laws were significantly more protective of patient privacy than the federal law that followed. Over the past decade states have also dealt with privacy issues related to credit cards and credit ratings, debating between "opt in" and "opt out" approaches that mirror the debate right now over prescription data and the American Medical Association's opt out policy.

The privacy issue has taken on new currency with the recent ability of large data mining companies to purchase computerized prescription records from insurers and pharmacies, and to match that data with AMA-collected physician records and then sell that information to pharmaceutical companies to track every prescription a doctor writes. Coincident with the rise of physician identity data mining, the pharmaceutical industry has increased its spending on

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[3] According to NCSL data, as of January 2007, eight states and District of Columbia (2003), California (2004, 2005, 2006), Florida (2006) Maine (2003, 2005), New Hampshire (2006), South Carolina (2006), Vermont (2002), West Virginia (2001) and Minnesota (1993) have laws or resolutions on the books affecting pharmaceutical marketing. Maine, Vermont and New Hampshire have since amended their laws to expand oversight of marketing activities. The NCSL report is here: http://www.ncsl.org/programs/health/rxads.htm.

[4] A survey last year of 33 state Medicaid programs anticipated Medicaid prescription drug spending increases of 14.3% for 2005-06 FY, consistent with the prior year's growth of 12.9%. (Crowley & Ashner, "State Medicaid Outpatient Prescription Drug Policies: Findings of a National Survey, 2005 Update," (October 2005). Since 1990, U.S. consumer spending for prescription drugs has increased over five-fold to $251.8 billion (2005). (Kaiser Family Foundation, *Prescription Drug Trends,* 1 (June 2006); U.S. PIRG Education Fund, *Paying the Price: The High Cost of Prescription Drugs for Uninsured Americans* 6 (July 2006); Centers for Medicare and Medicaid Services, *Table 2, National Health Expenditures Aggregate Amounts and Average Annual Percent Change, by Type of Expenditure: Selected Calendar Years 1980-2004*, http://www.cms.hhs.gov/NationalHealthExpendData/downloads/tables.pdf.

direct marketing to doctors by over 275 percent[5] and doubled its sales force to over 90,000 drug reps.[6] There is now a pharmaceutical sales representative for every five office-based physicians in the U.S.[7] In 2004, the industry spent $27 billion on drug marketing (more than any other sector in the U.S. on its sales force or media advertising),[8] over 85 percent of which was targeted at doctors.[9]

It is no coincidence that states that have been vocal about privacy in other contexts (such as Real ID) have also been leading the way protecting both patient and prescriber privacy. A landmark 2006 **New Hampshire** law prohibits the use of doctor-specific prescription information for drug marketing purposes; the data can still be used for public health purposes such as tracking patient safety. At least 13 states have similar proposals, with two more signed into law so far this year. Vermont's new law creates an "opt in" system for prescribers to waive confidentiality of their data for marketing purposes; the Maine law creates a state-run system through medical licensing boards for prescribers to "opt out" of marketing use of their data.

The states' actions find legal and policy support in the traditional state role licensing doctors, pharmacists and other health care practitioners; protecting consumers from misleading advertising and unsafe products; protecting the public health; insuring that private information is protected from unwarranted invasions of privacy; and partnering with the federal government in funding and administering Medicaid and now Medicare Part D. Many of the laws enacted by the states are in fact amending the consumer protection laws or the physician or pharmacy licensing provisions.

While many of these laws have been implemented without legal challenge, others have been the subject of industry litigation, on a variety of constitutional and statutory grounds, including Commerce Clause preemption, ERISA conflicts, and First Amendment violations. While initially overturned on ERISA grounds, the Maine and D.C. pharmacy benefit manager conflict of interest and fiduciary duty laws have now been upheld.[10] The New Hampshire prescriber privacy law was recently overturned by the federal District Court on First Amendment grounds,

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[5] Kaiser, *Trends and Indicators*, exhibit 1.20.

[6] Manchanda & Hokna, *Pharmaceutical Innovation and Cost*, 5 Yale J. of Health Pol'y L. & Ethics at 788.

[7] Center for Policy Alternatives, *Prescription Drug Marketing*, www.stateaction.org/issues.cfm/issue/prescriptiondrugmarketing.xml

[8] Puneet Manchanda & Elisabeth Hokna, *Pharmaceutical Innovation and Cost: The Effects and Role of Direct-to-Physician Marketing in the Pharmaceutical Industry: An Integrative Review*, 5 Yale J. of Health Pol'y L. & Ethics 785, 785 (2005).

[9] Kaiser Family Foundation, *Trends and Indicators in the Changing Health Care Marketplace*, http://www.kff.org/insurance/7031/print-sec1.cfm, exhibit 1.20 (2005).

[10] *Pharmaceutical Care Management Association v. Rowe*, 429 F.3d 294 (1st Cir. 2005), *cert. denied*, 126 S. Ct. 2360 (2006)

and that case is being appealed.[11] States taking action to address pharmaceutical marketing do so under constant threat of litigation, whether justified or not.

There certainly is an important role for the federal government to shine a light on these marketing practices, as this Committee is today. There is also a need to have much stronger standards governing conflicts of interest, to take action to curb misleading marketing, and to require disclosure of clinical trials and other safety data. It would also be a major step forward if the federal government would start by vigorously enforcing the laws already on the books barring misleading marketing and off-label promotion, and if labeling standards and enforcement were not subject to negotiation.

That said, we have real concerns about any law which may preempt state authority to act, at least in those areas where the states act on the basis of their traditional state regulatory or enforcement function. As I have discussed, states have a traditional and effective role enforcing consumer protection and misleading advertising laws, protecting public health and regulating medical professionals, implementing Medicaid, and safeguarding the privacy of the citizenry. It would be a bad bargain to trade strong state laws - even if in place on a patchwork basis only – for weak federal laws that limit or prohibit state action.

States are passing laws because there is a regulatory and enforcement void, and major public health issues that need to be addressed. Congress should act, but it should partner with the states rather than preempt them.

SUMMARY OF STATE LAWS OF INTEREST:

- ***Regulating gifts and perks distributed to the medical community by the drug industry.*** The Minnesota law dates back to 1993 (151.461) and is an outright ban on certain gifts; it prohibits any manufacturer or wholesale drug distributor, or any agent thereof, to offer or give any gift of value to a practitioner over $50. Some exceptions apply, including payments to the sponsor of a bona fide educational purposes, honoraria for a practitioner who serves on the faculty at a professional or educational conference or meeting; compensation for consulting services of a practitioner in connection with a genuine research project; publications and educational materials; or salaries or other benefits paid to employees. Similar legislation (without some of the loopholes in the Minnesota law) is pending in several states, including **Massachusetts**.

- ***Disclosure of advertising & marketing spending:*** **Vermont, Maine, Minnesota, West Virginia, California** and the **District of Columbia** require reports disclosing spending on advertising and marketing activities. These laws have not been challenged in the courts,

[11] *IMS Health v. Ayotte*, NH District Court, No.CV-06-280-PB (April 30, 2007).

and the West Virginia Attorney General has issued a legal opinion that the state has broad powers in the area of disclosure of marketing activity.

- ***Restricting electronic marketing activities:*** In 2006 **Florida** enacted Chapter 2006-271 restricting advertising as part of electronic prescribing software including "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." Similar legislation was just passed this year in **Vermont** (S.115), **Maine** (LD 1440), and **New Hampshire** (HB 134) and is pending in **South Carolina** (S.528).

- ***Cracking down on misleading advertising and marketing***: In 2005, **Maine** passed a law adopting federal misleading advertising standards and giving its Attorney General explicit authority to go after violators. The law also requires posting data on clinical trials and a consumer education initiative by the state, funded with a fee paid by manufacturers. 2007 **Vermont** law (S.115) not only regulates misleading advertising, but also marketing to health care practitioners, including at educational conferences, and requires pharmaceutical sales representatives to "disclose to the prescriber evidence-based information as provided for by rule describing the specific health benefits or risks of using other pharmaceutical drugs, including drugs available over the counter; which patients would gain from the health benefits or be susceptible to the risks described; the range of prescription drug treatment options; and the cost of the treatment options."

  This provision addresses concerns that have prompted several states to propose bills to require drug detailer registration or qualifications. In past years, such legislation has been introduced and defeated in **New York, West Virginia** and **Maine.** Legislation filed this year in **Oklahoma**, HB 1938, would require the registration of pharmaceutical sales representatives with a commission, certain reporting and for termination procedures.

- ***Posting clinical trials results***: **Maine** law requires internet posting of all clinical trials and results, including adverse results. The law went into effect in 2005. The rules implementing this law require data to be posted through the NIH website www.clinicaltrials.gov . Unlike the NIH site, the Maine law requires results as well as registration of ongoing trials. The state also plans a public and medical provider education effort and easy-to-access web portal to communicate this information to the public. Similar legislation is pending in several states including **Minnesota** and **New York**.

- ***Prescription data confidentiality:*** A first-in-Nation 2006 **New Hampshire** law (HB 1346) prohibits the use of patient or prescriber-identified data for marketing purposes. There are exceptions for aggregated data and uses defined as non-commercial purposes such as tracking patient safety. This law is being challenged

in court *(IMS Health v. Ayotte*) on first amendment and commerce clause grounds, and the Federal District Court recently ruled in favor of the datamining company which is challenging the law. The State is appealing. **Vermont** (s.115) and **Maine** (LD 4) enacted laws in 2007 to create mechanisms for prescribers to act to either waive privacy protections or opt in to a state-run system to preserve privacy. At least 13 states have proposed similar legislation, which is still pending in **Massachusetts** and **New York**.[12]

- ***State-sponsored "academic detailing" to counter the effectiveness of targeted sales tactics.*** Some states are betting that academic detailing will save money in state pharmacy programs and lead to better health outcomes. A survey of state Medicaid programs in 2005 found that 22 states have programs to educate providers or provide "counter detailing" to promote the use of generics instead of more expensive brand name drugs.[13] The **Pennsylvania** Independent Drug Information Service (www.rxfacts.org) is the most comprehensive of the state programs. The program makes use of sophisticated "marketing" materials ("unadvertisements"), clinical information, drug information consultants, and patient education materials to help facilitate prescribing change. The academic detailers have clinical background (nursing, pharmacy). ***Vermont*** and ***Maine*** have each enacted comprehensive academic detailing legislation in 2007 ("evidence-based research education program") and ***West Virginia*** has a program through its pharmacy school.

- ***Financial disincentives***: Unsuccessful 2006 New York legislation, A 1027 would have prohibited pharmaceutical manufacturers and distributors from deducting the costs of advertising drugs to consumers from their personal or corporate income taxes. ***West Virginia's*** disclosure regulation has a link to drug pricing; the rules are intended to assist the state in negotiating drug prices that do not reflect the cost of marketing.[14]

- **Conflict of interest and fiduciary duty legislation:** A number of states now require oversight or regulation of pharmacy benefit managers, including a fiduciary relationship and conflict of interest restrictions or disclosure. **Maine's** law enacted

[12] Legislation similar to the New Hampshire law was defeated in 2006 Arizona, Hawaii, West Virginia and in California, where the California Medical Association is promoting an opt-out option for doctors, and in Washington and Nevada in 2007. See NCSL data; "Doctors Object as Drug Makers Learn Who's Prescribing What," by Stephanie Saul, New York Times, May 4, 2006, pg. A.1; "State Pharma: Regulations are Becoming Increasingly Complicated as More Watchdogs Step In," by Jonathan Vatner, Meetings & Conventions, July 2006.

[13] Crowley & Ashner, "State Medicaid Outpatient Prescription Drug Policies: Findings of a National Survey, 2005 Update," (October 2005).at 10.

[14] See also 2006 legislation **New York** S 2258 (Sen. Krueger) which would require a cost benefit analysis of pharmaceutical advertising and promotional activities associated with the provision of prescription drugs to citizens in the state, and **Pennsylvania** HR 114 Concurrent Resolution (Rep. Walko), which would direct the state Health Care Cost Containment Council to conduct a study on the impact of prescription drug advertising and promotion on drug prices in Pennsylvania.

in 2003 remains the most comprehensive; the **D.C**. law is very similar. Both the Maine and D.C. statutes have withstood legal challenge. **South Dakota** and **North Dakota** also have PBM transparency laws though without the fiduciary requirements (South Dakota requires "fair dealing") and several other states have more limited laws governing registration and/or payment provisions. 24 PBM bills were pending in at least 17 states this year, with comprehensive legislation enacted in **Iowa and Vermont**.

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