CONNECTICUT CENTER FOR PATIENT SAFETY

QUALITY HEALTHCARE IS A RIGHT.

Senator Harris, Representative Ritter and distinguished members of the Public Health Committee

I am Jean Rexford, Executive Director of the CT Center for Patient Safety and am here today to speak in strong support of Senate Bill 1049. I am providing you with a comprehensive packet of information of testimony from many individuals who support our efforts.

The Problem: My starting point here today is to remind you of the problem. Simply put, the practice of allowing pharmaceutical and device manufacturers (or anyone with a vested interest in the decisions of prescribers) to make gifts or payments of cash or goods creates an unacceptable conflict of interest that drives up costs and threatens the integrity of our health care system. Drug companies spend over $6 billion annually on marketing, and according to the New England Journal of Medicine, 94% of physicians receive some kind of payment or in-kind gratuity from drug manufacturers.

This must be understood against the all-too-familiar backdrop: The skyrocketing cost of prescription drugs in public programs continues to be a large part of the budget problem for state policymakers. Similarly, individual families without health coverage often find it an unbearable burden to afford the drugs their doctor tells them they must have.

It is ultimately Medicaid, Medicare, and other public and private health plans that pay for these gifts. Yet it is not only the millions of dollars in needless payments, meals, gratuities, and other economic benefits that trouble me and a large number of policymakers in state and federal government. It is the distorting effect that these gifts have on the relationship of trust and confidence between the patient and his health care provider. No prescriber should be forced to choose, day after day, between her own compensation and her best judgment regarding the most cost effective, medically appropriate care for her patients.

These marketing activities, and their potential to undermine appropriate medical practices, have been well documented in the literature, as well as in recent articles in *The New York Times, the Washington Post* and *The Wall Street Journal*. An article in the *Journal of the American Medical Association (JAMA),* "Health Industry Practices that Create Conflicts of Interest," summarizes the psychology and social science associated with marketing campaigns that include gifts from Pharmaceutical companies. *4* "The current influence of market incentives in the United States is posing extraordinary challenges to the principles of medical professionalism," according to the *JAMA* article. *The New England Journal of Medicine (NEJM)* recently reported that many physicians have continued to receive gifts from the industry despite voluntary guidelines discouraging the practice.5

Connecticut by supporting a gift ban can address costs and quality of care. You can solve the problem

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THE PRESCRIPTION PROJECT

Revised September 12, 2008

Fact Sheet

The Prescription Project promotes evidence-based prescribing and works to eliminate conflicts of interest in medicine due to pharmaceutical marketing.

It is promoting policy change by working with

- *State and Federal Policymakers*
- *Academic Medical Centers*
- *Professional Medical Societies*
- *Private Payers*

Created with The Pew Charitable Trusts, the Project is led by Community Catalyst in partnership with the Institute on Medicine as a Profession.

REGULATING INDUSTRY PAYMENTS TO PHYSICIANS: IDENTIFYING & MINIMIZING CONFLICTS OF INTEREST

Physicians write more than 2 billion prescriptions a year[1], an average of 7 for every American. Intensifying competition to capture these sales has doubled pharmaceutical industry marketing expenditures directed at physicians from $3.5 billion in 1996 to $7.2 billion in 2005 (excluding pharmaceutical samples).[2] An undisclosed portion of that budget is spent on direct payments to physicians in the form of gifts, food, continuing medical education, travel, and consultancy fees. It is estimated that industry spending for lunches may alone total as much as $1 billion a year.[3] A recent survey published in the *New England Journal of Medicine* indicates that 94% of physicians have received food, drug samples or other reimbursements and payments from the industry.[4]

The Problem: Payments Influence Prescribing

Though many physicians claim industry payments do not affect their behavior, social science research indicates that individuals can not accurately assess their own bias. Studies indicate that gifts, even small gifts, create reciprocal behaviors.[5] For physicians receiving industry payments, changes in prescribing may take the shape of subtle shifts in judgment outside the awareness of the recipient. According to a review published in *The Journal of the American Medical Association*, negative effects associated with industry/physician marketing and financial relationships include:

- Reduced generic prescribing
- Increased overall prescription rates
- Quick uptake of the newest, most expensive drugs including those of only marginal benefit over existing options with established safety records
- Formulary request for drugs with few if any advantages over existing drugs

Residents and physicians alike admit that without gifts and meals, their interaction with the industry would decline.[6]

Self-Regulation is Insufficient

The medical profession and the pharmaceutical industry have taken steps to regulate physician-industry interactions in the face of increased public scrutiny.

- The AMA issued guidelines on "Gifts to Physicians from Industry" in 1992.[7] These guidelines limit gifts to an unspecified "modest" value and indicate they should be for the benefit of patients.
- The Pharmaceutical Researchers and Manufacturers of America trade association (PhRMA) updated its voluntary Code in 2008 and recommends that its members end the giving of non-educational gifts and practice-related items, such as pens, and tickets to sporting events and to put some limits on the provision of meals.[8]
- The federal government also issued "Compliance Program Guidance for Pharmaceutical Manufacturers" in 2003.[9] The guidance includes a statement that specifies that companies offering gifts intended to promote prescription drug sales may be subject to anti-kickback prosecution.

These guidelines are insufficient responses to undue industry influence for several reasons.[10] They continue to allow many types of gifts and financial relationships around marketing activities. The guidelines also lack measures to monitor and ensure compliance. PhRMA has never provided any evidence, despite having been requested to do so in public hearings, that its "Code on Interactions with Healthcare Professionals" is enforced. Indeed, several state laws that do monitor industry payments to physicians indicate widespread failure to comply with self-regulation.

Evolving State Policy Solutions

Several states and the District of Columbia have enacted so-called "sunshine laws" setting limits on industry payments to physicians and/or requiring disclosure of the payments. Existing laws are important first steps toward developing policies not only to detect existing conflicts of interests, but ultimately to prevent them and end inappropriate industry influence on prescribing.

- **MINNESOTA**: Minnesota was the first state to pass such legislation, in 1993. It requires reporting of payments over $100 to physicians and bans gifts in value of $50 or more. This and the Massachusetts law are the only statutes that include restrictions and make all disclosed data, including all physician-specific data, part of the public record. Unlike other disclosure laws however, it does not require annual summary reports to the state legislature, meaning that the state is under no obligation to analyze the data it collects. Indeed, industry payment report forms had not been formally analyzed before an independent analysis was conducted in 2006.[11] In order to be licensed, all wholesale drug distributors, including pharmaceutical manufacturers operating in the state, must comply with the law.
- **VERMONT**: Vermont's law requires disclosure of payments of $25 and over. Due to a trade secret exemption, much of the data reported to the state is not made part of the public record. Annual summary reports by the Attorney General include average payment by prescriber specialty and type of service associated with payments.[12] A penalty of up to $10,000 per violation of the law may be imposed.

- **MAINE**: Maine requires disclosure of payments of $25 and over. Though physician-specific payment information is collected, it is not made publicly available. Payment information is made part of the public record only in the aggregate form. A fine of $1,000 for each violation of the law may be imposed.
- **DISTRICT OF COLUMBIA**: Requires disclosure to the District of all payments of $25 and over, including marketing, advertising and charitable contributions.
- **WEST VIRGINIA**: The weakest of these laws, West Virginia's requires disclosure only of the total number of prescribers who have received payments above $100. No individual physicians are identified. Reporting is required for all marketing expenses, in addition to physician payments. There is no enforcement mechanism and initial compliance has been poor.
- **MASSACHUSETTS**: Massachusetts law includes disclosure provisions and sets limits on certain marketing activities. The law, passed in 2008, establishes a mandatory code of marketing conduct that is "no less restrictive" than the PhRMA and Advanced Medical Technology Association (AdvaMed) codes, effectively banning the provision of non-educational and practice related items, capping the value of educational gift items to physicians at $100 and prohibiting direct industry funding for physician attendance at professional meetings. While establishing the PhRMA Code as a baseline, the law allows the Department of Public Health to go further. Several provisions of the legislation, including limits on CME funding, also go further than the industry code. The MA law also requires disclosure of all payments valued over $50 to a prescriber or health care professional by pharmaceutical and medical device companies to the Commonwealth and is reported via a publicly searchable website. [13] A penalty of up to $5,000 per violation of the law may be imposed.

Numerous other states, including New York, continue to consider similar legislation.

Disclosure Data: Shining a Light on Conflicts of Interest

State disclosure data on industry payments to physicians has shed light on the magnitude of this previously hidden practice. The FY2007 report of the Vermont AG revealed that 84 pharmaceutical manufacturers reported spending $3.1 million on fees, travel expenses, and other direct payments to Vermont physicians, hospitals, universities and others for the purpose of marketing their products. This is a 33% increase over reported expenditures for similar expenses in FY2006 and represents an average value of $1,348 of payments from pharmaceutical companies per recipient. In Minnesota, 6,946 payments totaling $31 million were disclosed over three years. This included 6,238 payments of $100 or more. These figures are likely to have significantly underestimated the actual number and amount of payments due to poor compliance by industry and the widespread use of the trade secret exemption.

In Minnesota, the first state to require industry disclosure of individual physician names, the data has allowed identification of important conflicts of interest, including:

- payments of ten of thousands of dollars to an individual on a state committee that determines which drugs are used in the Medicaid programs;[14]
- a correlation among psychiatrists between payments from drug makers and prescribing of drugs made by those companies. Psychiatrists who received at least $5,000 from drug makers wrote more prescriptions than those who received less or no money;[15] and
- a number of physicians paid by drug companies to conduct clinical trials or promote certain medicines while under sanction by the State Board of Medicine for disregarding the welfare of patients.[16]

In Vermont, annual aggregate reports have revealed that:

- the top 100 recipients received a total of $2,127,325 in FY 07, or 68% of the total payments
- among the top 100 payment recipients by prescriber specialty, psychiatrists received the most, an average of $56,944 each
- five of the ten most heavily promoted products were mental health drugs, two for ADHD and three for depression
- in 2007 Vermont began to require that companies requesting trade secret exemptions explain why the payment constitutes a trade secret. Reversing a years-long trend, there was a 22% decline in trade secret declarations in 2007

Proposed federal legislation: the Physician Payments Sunshine Act

Proposed legislation in both the U.S House and Senate would require industry to disclose "transfers of value" to physicians. For more detail, see the Prescription Project Fact Sheet: The Physician Payments Sunshine Act.[17]

Transparency laws highlight the need for change, but unlike actual marketing restrictions, disclosure itself is unlikely to completely mitigate the influence of industry marketing on prescribing. In this regard, existing laws are important first steps toward developing policies to not only detect conflicts of interests, but ultimately to prevent them. The elimination of conflicts of interest in prescribing will:

- increase the quality and safety of prescribing
- lower prescription drug costs
- repair the damaged credibility of the medical profession
- restore patient confidence

Other materials are available on the Prescription Project website (http://www.prescriptionproject.org) and http://www.reducedrugprices.org/advertising.asp

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[12] Reports accessible at: http://www.atg.state.vt.us/display.php?smod=151
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[16] Harris, G, Roberts, J. After Sanctions, Doctors Get Drug Company Payments. *The New York Times,* June 6, 2007.
[17] The Prescription Project. Fact sheet: The Physician Payments Sunshine Act. http://prescriptionproject.org/tools/solutions_factsheets/files/0008.pdf

The Truth about Pharmaceutical Payment Disclosure

Disclosure of Financial Relationships with Providers Increases Accountability

The Connecticut Coalition for Prescription Reform is calling for a ban on most gifts to providers by pharmaceutical and medical device companies; *there must be transparency -- disclosure of other financial support providers receive,* such as payments to providers for research, participation on panels and writing or coauthoring articles.

TITLE:
An Act Requiring Disclosure of Certain Gifts and Compensation to Health Care Providers

SUMMARY:
This proposal requires annual disclosure to the Department of Public Health by pharmaceutical and medical device companies of gifts and compensation provided to health care providers in excess of $1,000 per provider.

Disclosure of pharmaceutical industry gifts and payments to physicians drives transparency and accountability.

- A 2007 *New England Journal of Medicine* study found that 94% of physicians receive gifts and other payments from pharmaceutical companies.
- A wealth of evidence shows that gifts and other financial relationships between the pharmaceutical industry and health care providers influence prescribing decisions.
- Disclosure of these relationships will allow the state and the public to understand the financial relationships between physicians and companies and to monitor any undue influence created by these relationships.
- Extensive research by the *New York Times* found that "Minnesota psychiatrists who received at least $5000 from atypical [antipsychotic] makers from 2000 to 2005 appear to have written three times as many atypical prescriptions for children as psychiatrists who received less or no money."
- "We've learned that letting people see for themselves what we're doing is a good way to restore trust," Dr. John Lechleiter, CEO of Eli Lilly.

Information about financial relationships between industry and the providers they consult with for research is not private.

- Pharmaceutical companies and providers already disclose information about research to the FDA and NIH. The FDA publishes this information on a public database.
- The Connecticut law does *not* require companies to disclose the specifics of any research. Instead companies will disclose the value, nature, and recipients of payments.
- Industry analysts know what drugs a company has in pre-clinical testing and help companies track their competitors' research programs and early-stage research.
- A number of companies have announced that they will voluntarily make payment information publicly available.
- A number of other states, including Vermont, Minnesota, Massachusetts and West Virginia, require the public disclosure of financial relationships. The pharmaceutical industry endorsed a federal bill that would have required public disclosure of all payments to physicians.

THE PRESCRIPTION PROJECT

The Prescription Project

The Case for Disclosure

Reducing the Impact of Pharmaceutical Marketing to Physicians and Promoting Appropriate Prescribing and Drug Safety

The pharmaceutical industry spends nearly $30 billion annually on marketing. The majority (including samples) is spent on direct marketing to physicians (Donohue, NEJM, 2007).

Nationwide, prescription drug spending rose 500% (from $40.3 billion to 200.7 billion) between 2000 and 2005 (Kaiser Family Foundation, 2007).

"Researchers fail to reveal full drug pay," *New York Times*, June 8, 2008

A Senate Finance Committee investigation revealed that Dr. Joseph Biederman, an influential Harvard child psychiatrist whose work helped fuel a 40-fold increase of pediatric bipolar diagnoses between 1994 and 2003, failed to disclose $1.6 million in drug company payments between 2000 and 2007. Two faculty colleagues underreported their $1 million+ earnings, as well.

http://www.prescriptionproject.org/tools/solutions_reports/files/0015.pdf

"Medical device maker paid UW surgeon $19 million," *Milwaukee Journal-Sentinel*, January 16, 2009

University of Wisconsin orthopedic surgeon Dr. Thomas Zdeblick received more than $19 million from Medtronic medical device company between 2003 and 2007, a Senate Finance Committee investigation revealed, though Zdeblick only disclosed receiving "more than $20,000" per year to his university.

http://www.prescriptionproject.org/tools/solutions_reports/files/0016.pdf

"Time to disinfect research dollars," *Atlanta Journal-Constitution*, October 12, 2008

Emory psychiatry chair Dr. Charles Nemeroff's marked underreporting of drug company payments between 2000 and 2007 demonstrates that academic medical centers are not capable of policing faculty conflicts of interest themselves, says the *AJC* editorial board, and the Sunshine Act is needed.

http://www.prescriptionproject.org/tools/solutions_reports/files/0017.pdf

"Minnesota law shines light on drug companies," *Associated Press*, August 21, 2007

Minnesota disclosure data revealed that two members of Minnesota's state Medicaid panel received large speaking contracts from drug companies – $350,000 to one and $78,000 to another – during their panel tenure selecting drugs for the department's formulary.

http://www.prescriptionproject.org/tools/solutions_reports/files/0018.pdf

"Stanford doctor's stock raises ethics concerns," *San Jose Mercury News*, June 25, 2008

A Senate Finance Committee investigation revealed that Stanford researcher Dr. Alan Schatzberg owned $6 million in stock in Corcept Therapeutics, though he was conducting a clinical trial at Stanford for Corcept's own depression drug, and reported only "more than $100,000" in holdings to the University.

http://www.prescriptionproject.org/tools/solutions_reports/files/0019.pdf

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"Psychiatrists, children, and drug industry's role," *The New York Times,* May 10, 2007

Drug company payments to Minnesota psychiatrists rose six-fold between 2000-2005, while state Medicaid prescriptions for antipsychotics in children rose nine-fold in the same period. The *Times* analysis was made possible by Minnesota's first-in-nation gifts disclosure law, passed in 1993.

http://www.prescriptionproject.org/tools/solutions_reports/files/0020.pdf

"Vermont Doctors collect millions from drug firms," *Burlington Free Press,* July 10, 2008

Drug companies paid doctors in Vermont over $3.1 million in 2007, with psychiatrists receiving the most, according to the annual report by the Vermont Attorney General. Vermont's gift disclosure law, passed in 2005, requires drug companies to disclose all payments to doctors in the state over $25.

http://www.prescriptionproject.org/tools/solutions_reports/files/0021.pdf

THE PRESCRIPTION DATA MINING BAN

TITLE:
An Act Concerning Access to Prescription Information

SUMMARY:
This proposal prohibits the disclosure of patient or health care provider specific information regarding pharmaceutical drug prescriptions, otherwise known as data mining, except in very limited circumstances, such as drug recalls. The proposal is based on laws enacted in Maine, New Hampshire and Vermont.

BACKGROUND

To ensure safety and consistent recordkeeping, pharmacies are required to electronically record every prescription they fill. The record includes: the name of your prescribing doctor; the name of the medication, including whether it's a name brand or generic; the dosage; quantity; whether prior authorization is necessary; and, other notations.

WHAT IS DATA MINING?

The pharmaceutical industry buys information contained in your pharmacy records from companies known as health information organizations which purchase the record from pharmacies. The data is "mined" to target drug marketing to physicians by merging these data with a list of prescriber identification numbers purchased from the American Medical Association. Pharmaceutical manufacturers may also monitor the use of certain drugs and return to exert more pressure on a provider to prescribe a drug if the data shows that the provider is not prescribing up to their standard or expectation.

WHY WE NEED THIS BILL

Rx Data Mining negatively impacts:

Public Health: Marketing based on prescriber data often involves biased and inaccurate information about health risks, and encourages the prescribing of new drugs that might be riskier to patients than already established evidence based treatments.

Cost: Marketing based on prescriber data is a key factor in the skyrocketing costs of prescription drugs, the increased usage of expensive brand-name medicines and higher insurance premiums.

Privacy: Sales of prescriber data take place without the explicit consent, and generally without the knowledge, of prescribers. Data mining also jeopardizes the safety and confidentiality of patient records.

The Connecticut Coalition for Prescription Reform is a diverse group of local and national non-profit organizations, the Attorney General, the Healthcare Advocate, community organizations, and healthcare providers committed to promoting evidence-based, unbiased prescribing and access to appropriate and affordable prescription drugs. For more information, please contact: Jean Rexford at 203 247 5757

ISSUE BRIEF:

THE SALE OF PHYSICIAN PRESCRIBING DATA RAISES HEALTH CARE COSTS—THE NATIONAL PHYSICIANS ALLIANCE CALLS FOR A BAN

NATIONAL PHYSICIANS ALLIANCE

Databases about physicians' prescribing practices have been created, sold, and used without physicians' knowledge or consent.

- Pharmacies compile databases that show how many and which medications individual physicians prescribe; these databases are sold to Healthcare Information Organizations (HIOs). HIOs combine this information with data from the Physician Masterfile, purchased from the American Medical Association (AMA).
- The Physician Masterfile contains information on virtually every physician in the United States *including the two-thirds of physicians who are not AMA members.*
- This combined data set is then sold to pharmaceutical companies. These companies arm their drug detailers with the prescribing data of physicians in their area so they can target individual physicians with finely tuned sales pitches.
- A study from the Kaiser Family Foundation in 2001 found nearly three-quarters of physicians disapprove of this practice.[1]

This raises the cost of health care by promoting inappropriate and expensive prescribing.

- This practice is bad for public health because it raises costs to patients by promoting inappropriate prescribing of expensive drugs. Pharmaceutical representatives—who have personal relationships with many physicians and their office staff—routinely persuade physicians to prescribe newer and more expensive medications when cheaper and equally good or sometimes even better alternatives exist.
- The prescribing data allows drug detailers to tailor their marketing messages to individual physicians and use carefully selected data to convince doctors to change their prescribing to a particular company's product.
- While retail data is commonly sold in many fields, the relationship between a physician and patient is a unique one. Physicians are entrusted by society to act in their patients' best interests, yet physicians are demonstrably influenced by the marketing strategies of drug detailers.[2] The best way to ensure that physicians retain the trust of patients is to warrant it, by eliminating this commercial intrusion into the doctor-patient relationship. Medical decision-making must remain scientific and objective.

The AMA, pharmacies, and pharmaceutical companies all have a financial interest in the status quo.

- The AMA received **$44.5 million in 2005** from sales of data from the Masterfile.[3]
- Pharmacies and HIOs clearly benefit from the system. One of the leading HIOs, IMS Health, had revenues of **$1.75 billion in 2005.**[3]

Recent efforts have begun to address this problem.

- New Hampshire passed a law in 2006 that bans the sale of physician-specific prescribing data.
- The American Medical Association recently began the Prescribing Data Restriction Program (PDRP). The PDRP allows physicians to prevent their own prescribing data from being released to pharmaceutical detailers, or to "opt-out."
- The California Medical Association, working with IMS Health, is planning to start a program in 2007 that will allow physicians to access their own prescribing information but that continues to permit pharmaceutical companies to purchase prescribing data.

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BAN PHARMACEUTICAL GIFTS TO HEALTH CARE PROVIDERS

TITLE: An Act Prohibiting Certain Pharmaceutical and Medical Device Company Gifts to Health Care Providers

SUMMARY:
This proposal adopts the provisions of Massachusetts law prohibiting gifts from pharmaceutical and medical device companies to health care providers and their employees

Pharmaceutical gifts to health care providers are common.

- A 2007 study in the *New England Journal of Medicine* found that 94% of physicians receive gifts and other payments from pharmaceutical companies.
- In Vermont, where gifts and payments of over $25 are required to be disclosed, over $2 million in gifts and payments were disclosed in 2005.

Pharmaceutical companies use gifts to promote sales of the most expensive drugs.

- "Pharmaceutical companies spend billions of dollars annually to ensure that physicians most susceptible to marketing prescribe the most expensive, most promoted drugs to the most people possible. If detailing were an educational service, it would be provided to all physicians, not just those who affect market share." (Shahram Ahari, former Eli Lilly sales representative)
- Pharmaceutical representatives provide doctors with promotional information that is one-sided and biased. According to a 2006 Kaiser Family Foundation physician survey, only 9% of physicians believe that the information provided by drug reps is "very accurate."
- Prescription drug spending rose 500% between 2000 and 2005. Nearly one-third of this increase has been attributed to marketing efforts.

Industry gifts influence medical decisions.

- Studies reviewed in the *Journal of the American Medical Association* found that even small gifts influence prescribing decisions. Token gifts including company logos drive up name recognition. Regardless of their value, all gifts create demands for reciprocity.
- Studies show that payments and gifts to physicians, including promotional items, lead to higher costs, irrational prescribing, rapid prescribing of new drugs, and decreased prescribing of generics.
- A survey published in the *American Journal of Medicine* found that 84% of physicians think that their peers are influenced by pharmaceutical marketing.
- The pharmaceutical industry would not spend billions of dollars each year providing gifts if doing so didn't increase sales.

Find More Information on the other side →