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Details: Coalition of Wisconsin Aging Groups
(FORM UPDATED: 08/11/2010)

WISCONSIN STATE LEGISLATURE ...
PUBLIC HEARING - COMMITTEE RECORDS

2009-10
(session year)

Senate
(Assembly, Senate or Joint)

Committee on ... Health, Health Insurance, Privacy, Property Tax Relief, and Revenue (SC-HHIPPTRR)

COMMITTEE NOTICES ...

- Committee Reports ... **CR**
- Executive Sessions ... **ES**
- Public Hearings ... **PH**

INFORMATION COLLECTED BY COMMITTEE FOR AND AGAINST PROPOSAL

- Appointments ... **Appt** (w/Record of Comm. Proceedings)
- Clearinghouse Rules ... **CRule** (w/Record of Comm. Proceedings)
- Hearing Records ... bills and resolutions (w/Record of Comm. Proceedings)
  (**ab** = Assembly Bill) (**ar** = Assembly Resolution) (**ajr** = Assembly Joint Resolution)
  (**sb** = Senate Bill) (**sr** = Senate Resolution) (**sjr** = Senate Joint Resolution)
- Miscellaneous ... **Misc**

* Contents organized for archiving by: Stefanie Rose (LRB) (June 2012)

Wisconsin Rx
a pharmaceutical benefits purchasing coalition

Joint Informational Hearing on Prescription Drug Reform

Senate Committee on Health, Health Insurance, Privacy, Property Tax Relief and Revenue and the Assembly Committee on Aging and Long Term Care

Written Testimony of
Greg Horstman, CEO
WisconsinRx/National CooperativeRx
May 26, 2010

Chairman Erpenbach, Chairwoman Krusick and honorable members of the Senate Health Committee and Assembly Aging Committee;

Thank you for holding an informational hearing on the issue of prescription drug reform. My name is Greg Horstman, CEO of WisconsinRx/National CooperativeRx, and the goal of my testimony is simply to make you aware that our organization can be a resource to legislators when considering matters relating to prescription benefits in future legislative sessions.

WisconsinRx is a member-owned, not-for-profit cooperative that negotiates pharmacy benefits on behalf of 250 employer, labor and public health plan members. We operate in all 50 states under our National CooperativeRx division, but we were founded in Wisconsin and are headquartered here. Our members include some of this state's largest employers as well as coalitions of employers and health insurance trusts.

We exist because plan sponsors needed help navigating the complexities of prescription drug financing and administration, plus they wanted to increase their negotiating power by being part of a larger group. As much as we try to shrink the percentage for our members, prescription benefits still make up a large portion of the inflating health care dollar, and directly affect a company's capacity to hire more workers and invest in economic development.

That is why we would urge you to consider employers' perspectives when it comes to prescription drug reform. Under the new federal health care reform law, employers are expected to continue providing and paying for the majority of health benefits in the United States. Employers hope to work with government to find ways to contain costs so they can afford to continue offering quality health and prescription drug coverage to their workers.

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The concepts brought forward by the Wisconsin Coalition of Aging Groups and others are ideas we would most likely support once details become available. That said, there are many facets to the ever changing prescription drug industry that make it difficult for organizations (or businesses or physicians for that matter) to stay on top of issues that influence drug prices. Reforms should carefully weigh cost implications for both private and public purchasers before becoming law.

WisconsinRx was created to help employer plans understand these complicated issues. We are also available to help members of the legislature see how proposed legislation might fit into the bigger picture impact costs for private purchasers. Please do not hesitate to contact me at the number below or Melissa Duffy at (608) 334-0624 if we can be of assistance to you regarding these important matters.


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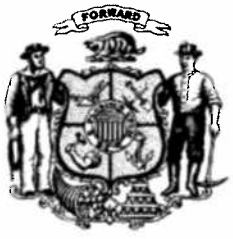
FORWARD

Statement of Senator Herb Kohl (D-WI)
State Legislative Public Hearing on Rx Reform in Wisconsin
May 26, 2010

I want to thank Chairpersons Erpenbach and Krusick and members of the Health Committees for holding this hearing on prescription drug reform in Wisconsin, and for allowing me to submit this statement.

As you know, one of the leading factors of the rapid rise of health care costs is the skyrocketing cost of prescription drugs. To address this, I have long used my various leadership and committee roles in the Senate to encourage the use of generic drugs and to promote comparative effectiveness research on drug treatments.

You may be surprised to learn that the drug and device industries spend less on research than they do on lobbying doctors with gifts, trips, and other payments to entice them to prescribe their own brand of drugs or devices. The Senate Special Committee on Aging, which I chair, has spent three years investigating the financial relationships between physicians and these industries. Our investigation has confirmed other research showing that some doctors are swayed to prescribe certain kinds of treatments that cost much more than what a patient may actually need.

I am proud to say that as part of health reform, we passed the Physician Payments Sunshine Act, a bipartisan bill I introduced with Senator Chuck Grassley, a Republican from Iowa. Now, when doctors receive any kind of gift or payment from a drug or device company, it will be publicly posted online. This will allow patients to know that their doctor is treating them without a conflict of interest and strengthen the doctor-patient relationship.

As part and parcel of this effort to get drug costs under control, I am also highly interested in providing physicians nationwide with the latest unbiased research on the full array of available treatments. Currently, drug company salesmen are one of the most common ways doctors learn about new drugs on the market, which are often the least-tested and most expensive.

Studies have shown that funding a program to determine which drugs and treatments work best would save the health care system, including the federal government, a lot of money by demonstrating that blockbuster drugs are not necessarily more beneficial than their cheaper equivalents. At my urging, the federal Agency for Healthcare Research and Quality (AHRQ) recently announced that it is directing $29.5 million in stimulus funding toward programs that will put evidence-based comparative effectiveness research in the hands of America's physicians and their patients.

Meanwhile, another ongoing battle includes our efforts to put a stop to the growing number of backroom deals between brand name drug companies and generic drug companies that keep affordable drugs out of reach for consumers. As part of these deals, brand name drug companies pay generic drug companies – their competition – to keep their generic drugs off the market. I'm working to pass legislation that would significantly reduce these pay-for-delay deals, which the U.S. Federal Trade Commission estimates cost consumers $35 billion over ten years.

As you are well aware, there is much more to do in this area, and I will continue to use my role in the Senate to push these issues forward. Thank you.

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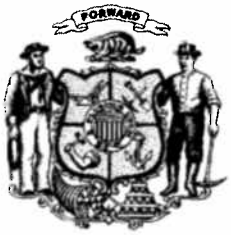

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Senate Committee on Health Insurance, Privacy, Property Tax Relief, and Revenue
Assembly Committee on Aging and Long-Term Care
Joint Committee Hearing
May 26, 2010

Prescription Drug Reform:
Suggestions for Improving Health Outcomes and Containing Costs

Statement on Restricting the Use of Prescription Information

Wolters Kluwer Pharma Solutions believes that the responsible use of anonymous prescription information promotes efficiencies in the health care system and may help lower costs. There are numerous uses for this data that serve the public's interest, further the government's mandate for greater transparency in medicine, and support initiatives intended to improve the efficacy, quality, and cost of health care. At a time when greater transparency and free flow of information that does not compromise the privacy of individual patients is being advanced at the national level to improve the quality of health care and patient safety any restriction that will impede this initiative is misguided.

Privacy: Protecting patient privacy in the digital age is not only possible but necessary to ensure confidentiality while also enabling the essential, unimpeded flow of information for quality health care, patient safety and medical research. Federal law provides strong protection of personal health information through the Health Insurance Portability and Accountability Act (HIPAA), the federal patient privacy law. We at Wolters Kluwer Pharma Solutions believe in and abide by strict federal and state laws to prohibit the improper use or disclosure of a patient's health information. We have collected, aggregated and analyzed approximately 3 billion prescription transactions annually over the past 20 years without a single HIPAA breach or violation.

Costs: There is no evidence that restricting the use of this kind of health information will reduce costs. The assertions have no basis in data or studies, and market analyses suggest exactly the opposite. For example, the state of New Hampshire restricted these data for approximately 9 months between 2006-2007 and again since February, 2009, but no evidence has been shown that restricting the use of these data has had any impact on the state's prescription drug costs or that the state has realized any savings as a result.

It is unlikely that banning the commercial use of prescriber-identifiable data would decrease marketing by sales representatives. Marketing would be less efficient, more scattered and less focused, thus increasing the cost of drugs. In the absence of this information, pharmaceutical firms will either increase the number of sales representatives to adequately deliver product messages to a larger number of physicians or market to physicians who may not have cause to prescribe particular drugs, or both, resulting in increased costs.

In addition, restricting this information can actually serve to create real costs across the system. These types of restrictions can serve to risk patient care by intentionally impeding the process that brings medical breakthroughs to physicians and patients on a timely basis. Slowing the process effectively delays treatment or the potential delivery of samples and new product information. This means that patients who could benefit from therapeutic improvement may be harmed.

Likewise, assertions that these data are used to influence physicians to prescribe only more expensive brand name drugs are unfounded. Dispensing of brand name medications has declined from 5.7% of total prescriptions in 2003 to only 1.3% in 2008. As the same time, generic medications (generally cheaper than brand name medications) grew to represent 70% of dispensed prescriptions in 2008 from 40% in 2003. Given these trends, it is difficult to make any credible argument about how the use of these data drives up costs in the system.

Jobs and competitiveness: The use of prescription information allows a more efficient process for bringing medical innovation to patients. Emerging biotechnology and life science companies doing business in the state rely on these data to educate specialists about their products and to compete with bigger companies. Restricting the use of data raises barriers to entry and cripples these companies' ability to compete.

Physicians' Choice: The notion that prescriber-identifiable information is used to persuade physicians to make inappropriate prescribing decisions is not supported by any research and defies common sense. Physicians are among the most educated and respected professionals in the country and are more than capable to make informed prescribing decisions. Physicians have access to alternative sources of information which are highly regarded and therefore heavily influence their prescribing practices, such as scientific papers, advice from colleagues and even their own training and experiences.

More importantly, physicians themselves can decide whether pharmaceutical sales representatives can have access to their prescribing history through the American Medical Association's Physician Data Restriction Program (PDRP). Wolters Kluwer Pharma Solutions has the utmost confidence that physicians will continue to make prescribing decisions based upon the needs of their patients, not based upon pharmaceutical marketing.

Public health and safety: Health information transparency is vital to promoting the quality, safety and integrity of the nation's health care system. Thorough analysis and unrestricted use of public and commercial databases containing transparent prescriber-level health data is essential to achieving a better understanding of medical practices, quality variation and patient outcomes.

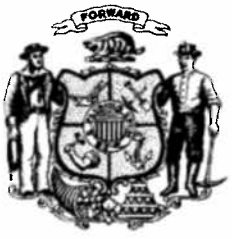
Prescribing information is used not only by pharmaceutical, biotechnology and medical device companies, but also, providers, government agencies (U.S. Food & Drug Administration, the Department of Defense, the Drug Enforcement Administration, the Centers for Disease Control and Prevention), academia and researchers. These data are used to monitor and manage the safety of medications, conduct clinical trials, implement drug recalls, rapidly communicate information to doctors about innovative new treatments and conduct public health studies.

Commercial databases developed by healthcare information companies like Wolters Kluwer Pharma Solutions offer the only comprehensive sources of prescribing information that can be used for a variety of applications that benefit our health care system and that will contribute to the health care reform debate. Use of these data for public health and safety initiatives would not be possible without the commercial use to sustain it.

Constitutionally protected speech: Two federal judges have ruled that the commercial use of prescriber-identifiable information is protected speech under the First Amendment of the United States Constitution. Over the past several years, legislation has been introduced in - and rejected by - more than two dozen states. Only New Hampshire, Vermont, and Maine have adopted these types of restrictions and those laws have been subject to constitutional challenges in federal court.

Conclusion: We firmly believe that the public good and that of the state of Wisconsin is best served by evidence-based medicine, improved transparency in the health care system, and continued responsible use of and access to prescriber-identifiable information. We appreciate the opportunity to appear before you today at this informational hearing and to submit our comments for your review and consideration.


WISCONSIN STATE LEGISLATURE


FORWARD

Written Testimony of Peter T. Wyckoff

National Consultant, Community Catalyst
Director, Minnesota Prescription Coalition

Before the Wisconsin Senate and Assembly Health Care Committees
May 26, 2010

Mr. Chairman and members of the Committees on Health, thank you for the opportunity to appear today and to submit testimony on behalf of the Community Catalyst, a national consumer advocacy organization that addresses a wide range issues, including access to and quality of care, delivery system and insurance reform as well as prescription drug reform. We collaborate with the Pew Prescription Project to address conflicts of interest created by pharmaceutical marketing and to promote an increased reliance on independent evidence of drug effectiveness.

I am Peter Wyckoff, a national consultant for Community Catalyst, and director of the Minnesota Prescription Coalition. Prior to my first "retirement", I was founder and executive director of the Minnesota and Metropolitan Senior Federations, served on the Board of Governors of a Twin Cities' hospital, founded a non-profit pharmacy, served on the Board of the National Council of Aging, and have been in ministry with the Presbyterian Church.

Background on the Problem:

Pharmaceuticals and medical devices are central to modern health care, and academic-industry collaboration is vital for their development. At the same time, it is essential that the use of these products be guided by sound evidence and good science. Every patient deserves the safest, most effective and – others things being equal – the least costly and most affordable treatment.

The pharmaceutical and medical device industries spend a great deal of money to influence a physician's choice of products. Thirty billion dollars a year for marketing just by pharma companies is a conservative estimate.[1] Most of that is focused on doctors, and a recent study in the *New England Journal of Medicine* found that 94% of U.S. physicians had some kind of financial relationship with the industry. Often it was the acceptance of free food or gifts. But 18% -- almost one in five – were being paid as consultants to one or more companies. Nearly as many again were being paid to give promotional talks for a particular product. Only around 3% of the financial relationships were for enrolling patients in clinical studies.

[1] Donohue JM, *et al. N Engl J Med.* 2007;357:673-681. For a more complete discussion of estimates of marketing spending, see Pew Prescription Project http://www.prescriptionproject.org/tools/sunshine_docs/files/0004.pdf

A doctor choosing which drug to give his patient has a conflict of interest if he is being paid by a company that markets the drug. Some financial relationships, such as gifts from a company to a health care provider, are unnecessary, do not contribute to patient care and are easily eliminated. Other relationships – such as research – are necessary and beneficial, but here greater transparency serves patients and the public good.

This is consistent with major recommendations issued by the Institute of Medicine and the Association of American Medical Colleges, and by other leaders in the medical profession.[2],[3]

There is a large body of evidence on the pervasiveness and influence of pharmaceutical marketing. One study found that medical residents received an average of 75 "giveaway" items per year.[4] Lunches, dinners and pens, coffee mugs and other branded items are all designed to open doors for industry sales reps. And social scientists have demonstrated that even small gifts create a deep sense of obligation and reciprocity—it is human nature – and such gifts do influence the judgments we make.[5],[6]

Surveys show that most physicians recognize this potential influence, even while often believing that they *personally* are not affected. In one study, only one percent of medical residents said that their own prescribing was heavily influenced by industry sales representatives. But those same doctors were much more likely to say that their *peers* were heavily influenced. In fact 84 percent said their peers were heavily or somewhat influenced by sales reps. [Similarly, most people rate themselves as above average drivers; they can't all be right.]

Patients are also more likely than physicians to believe that gifts influence prescribing and increase healthcare costs.[7] Surveys indicate that patients do not want their doctors to accept industry gifts. A survey commissioned by Pew Charitable Trusts and carried out by an independent survey firm found that 68% of Americans support legislation requiring disclosure of gifts and payments.[8]

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[2] The Institute of Medicine, the nation's most influential medical advisory group, released a report in April 2009 recommending that Congress create a national program requiring pharmaceutical and medical device companies and their foundations to publicly report payments to physicians and other prescribers, biomedical researchers and their institution. cf Institute of Medicine (2009) Policies on conflict of interest: Overview and evidence. In: Lo B, Field MJ, editors.

[3] Conflict of interest in medical research, education, and practice. Washington (D.C.): The National Academies Press. pp. 51-78

[4] Komesaroff, P.; Kerridge, I. Ethical Issues Concerning the Relationships between Medical Practitioners and the Pharmaceutical Industry. *MJA* 2002; 176(3): 118-121.

[5] Katz D, Caplan A, Merz J. All gifts large and small: Toward an understanding of the ethics of pharmaceutical industry gift giving. *The American Journal of Bioethics*. 2003;3:39-46.

[6] Wazana, A. Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift? *JAMA*. 2000;283(3):373-380.

[7] Gibbons et al. A comparison of physicians' and patients' attitudes toward pharmaceutical industry gifts. JGIM 1998; 13: 151-154.

[8] Pew Prescription Project survey conducted by ICR (June 2008) http://www.prescriptionproject.org/tools/sunshine_docs_files/0010.pdf

State Pharmaceutical Gifting Legislation

During the last seventeen years, health systems, providers, professional organizations, employers, states and the Federal government have recognized this problem and begun to take steps to limit or ban pharmaceutical and medical device manufactures gifting to prescribers.

Minnesota's Experience with a Pharmaceutical Gift Ban

Minnesota has been a pioneer in this area. Minnesota was the first to enact legislation in 1993 banning gifts above a $50 value and requiring pharmaceutical companies to report payments to health care practitioners.[9]

The information gained through Minnesota's disclosure law has been helpful in shine a light on the problems inherent in pharmaceutical gifting. For example, it allowed the discovery that an individual on the committee choosing drugs for Minnesota Medicaid patients was being paid tens of thousands of dollars by the industry.[10] The reports also led to the revelation that a number of physicians were 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.[11]

Pew has recently been analyzing reporting data in Minnesota, which show that the top ten recipients in the state received nearly $2 million in 2008. The top 100 received $7.8 million. Some of the largest payments may have been research-related, but under the current Minnesota law it is impossible to know, because companies are not required to describe payments in a useful way.

Their analysis, which will be released in more detail in the near future, was conducted in part using PharmaShine, an online service for the collection, management, and disclosure of industry payments to physicians. PharmaShine also pulls data from the few companies that are voluntarily disclosing. One interesting finding from company data from early in 2009 is that almost 90% of the fees paid were not related to research expenses or educational grants but were speaking fees paid to doctors who delivered presentations to their peers on behalf of these companies.[12]

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[9] Minnesota Statutes § 151.461 Gifts To Practitioners Prohibited and 151.47 Wholesale Drug Distributor Licensing Requirements. MN Board of Pharmacy and AG Defined "Gift" under Minnesota Statues as Gifts to Public Officials: **"Gift" means money, real or personal property, a service, a loan, a forbearance or forgiveness of indebtedness, or a promise of future employment that is given and received without the giver receiving consideration of equal or greater value in return.**

[10] Harris, G. Doctors' Ties to Drug Makers Are Put on Close View. *The New York Times*, March 21, 2007; Lohn, M. Minnesota Law Sheds Light on Drug Companies. Associated Press, August 22, 2007

[11] Harris, G. Roberts, J. After Sanctions, Doctors Get Drug Company Payments. *The New York Times*, June 6, 2007.

[12] George Dunston, Obsidian HDS PharmaShine ® (personal communication)

Other states, including Massachusetts and Vermont, have followed the lead of Minnesota, and in some respects have gone further, with more complete disclosure provisions and comprehensive limits on gifts. California, the District of Columbia, Maine, West Virginia and most recently Connecticut also now have disclosure requirements and/or regulation of gifting, albeit more limited. Change is also occurring at individual medical schools and hospitals, including the University of Minnesota and the Mayo Clinic. Systems such as Marshfield Clinic in Wisconsin have also been leaders.

National Sunshine Legislation

The Sunshine Act was initially introduced in 2009 by Senators Kohl and Grassley. Through their leadership their proposal was passed as a key part of National Health reform. **The Physician Payments Sunshine provisions** in the health care reform legislation require drug and medical device manufacturers to publicly report gifts and payments made to physicians and teaching hospitals.

While the law requires strong public disclosure, it does not limit those financial relationships. The health care reform law requires disclosure of payments whether cash or in-kind transfers to all covered recipients including: compensation; food, entertainment or gifts; travel; consulting fees; honoraria; research funding or grants; education or conference funding; stocks or stock options; ownership or investment interest; royalties or licenses; charitable contributions; and any other transfer of value as described by the secretary of Health and Human Service.

While the national legislation is a strong transparency statute, it clearly that leaves states, like Wisconsin, free to act outside its scope – for example to place limits on gifts or require of payments to other prescribers. For example, the Sunshine provisions contain very careful preemption language that ensures that companies will not face duplicative reporting requirements, but also protects the right of state legislatures to act. For example, the bill has enacted, it does not require companies to report payments to nurse practitioners who write prescriptions. Wisconsin could and Minnesota, Vermont, Massachusetts and other states can still collect that information. And, it may interest you to know that Pew analysis has found a sharp increase in payments to nurse practitioners in Minnesota in recent years, with some individuals receiving tens of thousands of dollars.

A national reporting system incorporated in the new Sunshine provisions would reduce the administrative burden to Wisconsin regulators; but also preserves the state's prerogative under state law to collect other types of information *not* captured or excluded from reporting (with the exception of *de minimis* and threshold limits), or collect any information for public health purposes or for legal proceedings.

What is the basic scope of the federal law?

All U.S. manufacturers (and entities under their common ownership) of drugs, devices, biologics, or medical supplies covered under Medicare, Medicaid, or SCHIP are required to report to HHS specified information about transfers of value they make to physicians and teaching hospitals. HHS will post this data on a public website.

Will the federal sunshine law preempt state laws?

Yes and no. The federal law is intended to preempt reporting requirements under state law that are duplicative of the *specific* categories of reporting included in the federal law. . States are *not* preempted from collecting information that is not covered in the federal reporting requirements, or that is exempted from reporting under the federal law. For example, a state may require manufacturers to report the following transactions with physicians or teaching hospitals: loans of medical devices, in-kind gifts to charities, the provision of educational materials, and other transfers of value not reported under the federal law. In addition states are not preempted from requiring other entities, such as retailers, medical schools, or medical education and communication companies (MECCs) or other CME sponsors, to make disclosures to the state.

In summary, while the new Federal Legislation, provides both a floor and uniformity for pharmaceutical and device manufacturer gifting transparency, the Federal legislation and clearly allows and the evidence clearly encourages states like Wisconsin to enact legislation to further limit and ban pharmaceutical gifting which continues to undermine the quality of health care, to undermine the prescriber/patient relationship and to increase costs for all payers.

Pharmaceutical Data Mining

First, some background on this issue.

When physicians write prescriptions, patients take them to their pharmacy of choice. Many of those pharmacies sell the information about those prescriptions, which includes the physician's name and the medication prescribed, to a company that compiles the information to sell back to the drug companies. The American Medical Association (AMA) sells a list of all physicians in the country (the Masterfile), for over $40 million annually, that is used to provide additional information about the prescriber, such as training, board certifications and states of licensure.

The drug companies have many uses for this information. Primarily, they measure the effects of their marketing campaigns to doctors, often on a weekly basis. They can identify physicians who prescribe their medications often, which can lead to offers to those doctors to serve as paid speakers. They can see when a prescriber changes from their medication to a competitors', which can prompt a visit from the drug rep to subtly inquire as to why. Former drug reps report how they are able to see the impact of the visits they make to physicians in the following week's prescribing data, yet the drug reps are trained to not make the physicians be aware that they have this information.

The Kaiser Family Foundation surveyed physicians about this practice and learned that 74% of physicians were either bothered by the practice or outright opposed it.[13] While physicians are unhappy that this practice occurs, they are not able to stop it. Because physicians are not in the position to change this practice by the drug companies, we need legislation.

Currently, the AMA offers an opt-out program for physicians. However, the opt-out is voluntary on the part of the drug companies, and it only shields the information from the lowest level people in the marketing department. In addition, the AMA is selling the information of physicians who are not members of the AMA. The Physician Masterfile includes all doctors in the United States, including the approximately 70% of physicians are not members of the AMA. Non-members are allowed to opt-out, but how are non-members supposed to know that their information is being sold, and that an opt-out program exists? And since the AMA earns over $40 million from the licensing of the Masterfile, they have a financial disincentive against promoting the opt-out option. In

[13] National Survey of Physicians Part II: Doctors and Prescription Drugs. Kaiser Family Foundation. Available at: http://www.kff.org/rxdrugs/upload/Highlights-and-Chartpack.pdf.

fact, despite the fact that over half of physicians want a ban on the sale of their prescribing information, only 5% have gone through the process to opt-out.[11]

While it is possible for a physician who doesn't want his/her information used to refuse to meet with drug reps, the drug companies continue track her prescribing information and have uses for it. For example, drug companies identify doctors with strong reputations as leaders in their field. Drug reps will often try to change other physicians' prescribing habits by telling them what those leaders prescribe. Even if a leading physician refuses to meet with reps, those reps still have their prescribing profile and they are inclined to use it for their marketing purposes.

New Hampshire passed the first Prescription Privacy Law in 2006 which prevents patient and prescriber identifying data from being sold or used for advertising, marketing, promotion or any activity intended to influence sales or market share of a pharmaceutical product.

The legislation was enacted as a consumer protection and public health measure, and seeks to maintain privacy rights of physicians and control the costs of prescription drugs in New Hampshire. The New Hampshire law prohibits only the commercial use of prescriber identity. That legislation, as the legislation before you, allows collection, non-commercial use; and allows aggregate data commercial usage.

Soon after its passage the pharmaceutical industry led by Data mining companies IMS Health and Verispan filed suit to stop the implementation of the NH legislation based primarily on economic commercial free speech arguments. While the district court initially upheld the industry, the 1st U.S. Circuit Court of Appeals in Boston in November 2008 upheld a New Hampshire law.

In its three judge panel decision Judge Bruce Marshall Selya wrote that the reselling of prescription information is "mind-boggling" in its scope, adding, "***The record contains substantial evidence that, in several instances, [drug company representatives] armed with prescribing histories encourage the overzealous prescription of more costly brand-name drugs regardless of both the public health consequences and the probable outcome of a sensible cost/benefit analysis.***" The appeals court wrote that "***the state adequately demonstrated that the Prescription Information Law is reasonably calculated to advance its substantial interest in reducing overall health care costs within New Hampshire.***"

[11] Though Most Physicians Support a Ban on Collecting Prescribing Information, Only a Fraction Have Used PDRP to Restrict Rx Data, Business Wire, February 23, 2007, Accessed at:
http://findarticles.com/p/articles/mi_m0EIN/is_2007_Feb_23/ai_n19020179

A further court appeal to stop the implementation of the New Hampshire legislation by Data-mining companies IMS Health and Verispan also failed and the NH legislation became effective in February of 2009.

The companies that gather the information claim that it is also used for health policy research, and to ban the sale of it would eliminate the incentive for gathering it. Health policy researchers who have explored this possibility and discovered that to purchase the information for purely academic purposes would costs hundreds of thousands of dollars, and the companies require that they review and approve the research protocol. Instead, currently most researchers use Medicare and Medicaid information. In addition, researchers rarely use data related to specific physicians. That level of detail is only useful in the marketing of drugs.

Lastly, the drug companies will argue that without prescription information, they will not know which doctors to target about which drugs, so they will have to spend more money blanketing all doctors with their pitches. An example they use is new therapies for HIV/AIDS. Drug companies say that without prescription information, they would not know which physicians treat such patients. This is hardly the case. In fact, physicians can be reached at medical meetings, which are often specific to narrow areas of practice. But more importantly, physicians should seek information from non-biased, peer-reviewed sources such as journal articles and independent continuing medical education (CME). We don't need salespeople to tell us about new drugs, and shouldn't become reliant upon their information.

Academic Detailing

BACKGROUND

Currently, the way Wisconsin clinicians and other prescribers often learn about prescription medications are through the drug companies who are trying to sell their products.

The industry employs over 90,000 drug representatives[15] and spends an average of about $8,800 directly marketing its products to each of the 817,500 physicians[16] practicing in the U.S. Physicians receive 60 to 70% of their pharmaceutical information from the pharmaceutical industry. The pharmaceutical industry invests most heavily in marketing the newest, most expensive brand names where profit margins are highest. The cost of industry marketing is then passed on to consumers.

These Pharmaceutical detailers make their money by promoting their company's medications by "relationship building" to increase sales and dispense favorable information about their products. 17% of the cost increase is due to switches to more expensive drugs usually promoted by the pharmaceutical detail representatives.

Doctors have too little time to get current, relevant information even though given a choice, most doctors would like to receive current, unbiased, non- compromised information in a convenient way.

WHAT IS ACADEMIC DETAILING?

Academic detailing is an innovative method of service-oriented outreach education for physicians. It provides an accurate, up-to-date synthesis of relevant drug information in a balanced format.

The goal of an academic detailing program is to provide unbiased, balanced, evidenced based information to prescribers regarding the safety and efficacy of drugs. Busy physicians and other prescribers value academic detailing programs because such unbiased, objective information about prescription drugs is not easily accessible in day-to-day practice.

However, in an academic detailing program, the professionals educating clinicians and other prescribers are not looking to make a sale. Rather, they are there to provide unbiased information on medications that are consistent with medical evidence, support patient safety and are cost-effective.

Academic detailing programs employ physicians, pharmacists, nurses and other clinical professionals to give prescribers reliable guidance on potential benefits and possible harms of specific drugs. These professionals use one-to-one interactions tailored to meet the needs of individual prescribers in their own practice settings.

While Academic Detailing Program use the same conventions established by the Pharmaceutical Industry that have worked so well for their bottom line including: Face-to-face encounters and Between-encounter support services there are critical differences from industry detailing:

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[15] Sales Makeover. *Medical Marketing & Media*. Nov, 2003.

[16] U.S. Department of Health and Human Resources. *Physician Supply and Demand: Projections to 2020*. Available at: http://bhpr.hrsa.gov/healthworkforce/reports/physiciansupplydemand/currentphysicianworkforce.htm.

- Independence from biasing influences
- Training of academic detailers
- Print materials supporting communication
- No primary pursuit of dichotomous outcomes – buy / no-buy

In the U.S., academic detailing programs already exist in Maine, Vermont, Massachusetts, New York, Pennsylvania, South Carolina and in D.C. Pilot programs are underway in Idaho and Oregon.

Do Academic Detailing Programs Work? – Yes!

In addition to helping manage drug costs, academic detailing has been shown repeatedly to be effective in promoting safe and appropriate drug use over a 25-year period.

A recent summary of the evidence about improving physician clinical care and patient health through educational programs concluded that interactive techniques like academic detailing are the most effective means to improve physician practices and patient outcomes. National reviews from other countries with academic detailing programs like Australia[17] and Canada[18] have concluded that academic detailing positively influences physician practices and promotes safe and appropriate drug use.

Are Independent Prescriber Education Programs cost effective? – Yes!

- **Harvard Study**: *For **every dollar spent** on an academic detailing program. **Returns two dollars** in reduced cost*
- **Australia**- Study of mature program – 1996
    - **Between $5 and $6.50 of direct health expenditure was saved for each $1 spent delivering the program.**
- **PACE Study:** Focused on just one class of drugs – the so called "little purple pill" or acid-reflux and its cheaper equally effective cousins. Data from economic analyses of the Pennsylvania program show that it pays for itself with reduced drug costs and better outcomes from improved utilization of medications.[19,20]
    - ***Showed reduced cost of $120 per doctor per month***
        - $378 for heaviest prescribers
        - If the changes persisted it would equate to a ***$572 thousand savings against program cost of $1 million***

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[17] May, Avorn, Silagy et al.. An overview of current practices of academic detailing in Australia and internationally - Part II. Canberra: Australian Commonwealth Department of Health.; December 1997. Report: Part II:. pps.193. Available at: http://pdfserve.pharmacy.uq.edu.au/qumdatabase/PDFs/ID565_Report_1.4MB.pdf

[18] Maclure, Allen, Bacovsky, et al. Show me the evidence: Best practices for using educational visits to promote evidence-based prescribing. Victoria: Canadian Academic Detailing Collaboration and Drug Policy Futures; June 2006. pp.102. http://www.rxfiles.ca/CADC.htm

[19] Soumerai, Avorn. Economic and policy analysis of university-based drug "detailing". Med Care 1986;24(4):313-31

[20] Mason, Freemantle, Nazareth, et al. When is it cost-effective to change the behavior of health professionals? JAMA 2001;286(23):2988-92

As more states launch academic detailing programs, it is possible to achieve economies of scale by sharing the production and use of educational materials, training programs and data management systems. There is great potential for states to come together on this issue.

A Case Example of Academic Detailing – the Pennsylvania PACE Program

- Tom Snedden, Director of the Pennsylvania Academic Detailing Program testified in Minnesota a couple of months ago before a joint interim legislative hearing. He said in part:
- Pennsylvania as Minnesota (*and Wisconsin*) faces the burdens of:
  - Rising pharmaceutical expenditures and the need to
  - Support use of medications to provide the greatest clinical benefit
  - and to contain their cost.
- There is ample evidence nationally that physicians often make prescribing decisions that are ***not the most cost-effective or evidence-based.***
- Rather than limit eligibility or increase the co-payments, the Department of Aging determined that it would be better to enable physicians to make more appropriate, evidence-based prescribing decisions.
- A study released in December 2009, which you have a copy of showed, Compared the prescribing practices and costs among doctors offered academic detailing visits compared to comparable doctors in other parts of the state where the program did not exist.
  - Showed reductions in excessive or unnecessary prescribing that have yielded substantial savings,
  - Improving the appropriateness of drug use.
- The study also showed great acceptance by physicians - Physician surveys in Pennsylvania found response to the program to be uniformly high.
  - Nearly all physicians surveyed responded "strongly agree" or "agree" to statements such as:
    - *"The program provides me with useful information about commonly used medications"*
    - *"The program provides a perspective on prescribing that is different from what I get from other sources."*
    - *"My Drug Information Consultant is a well-informed source of evidence-based information about drugs I prescribe."*
    - *"I find the patient materials useful in my practice"*
    - *"It makes sense for Pennsylvania to devote resources to this activity; and I would like to see this program continue."*

The draft legislation before you would direct the Wisconsin Department of Health Services to develop and operate an independent prescriber education program. Such a program as described would serve your state well. Beyond a number of funding options which could be budget neutral, there is increased interest and funding from the Federal Government to use American Recovery and Reinvestment Act Funding for states to establish Academic Detailing programs.[21]

A former Merck Sales representative spoke recently on a proposed MN Academic detailing legislation. He said

"Academic detailing that is geared towards a comprehensive, unbiased education would be an outstanding service for the public. Many physicians are bombarded on a daily basis by conflicting marketing messages that are often contradictory. Elaborate graphs and carefully constructed statistics are used by pharmaceutical representatives to exaggerate the features and benefits of their products. Physicians are left to sort through the conflicting and convoluted information from opposing companies in order to make the best possible decisions for their patients.

An organized program that objectively organizes evidence based information would provide a streamlined process for physicians to access important and new information relative to their practice. There is a clear difference between information exchanges which are primarily "marketing", and information exchanges which are intended as "education." The difference is intent. Organized, objective, and unbiased academic detailing would offer a form of education physicians can trust with no strings attached."

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[21] Agency for Healthcare Research and Quality (part of the U.S. Department of Health and Human Services) about a solicitation that was posted on May 17 in *Federal Business Opportunities* https://www.fbo.gov/index?s=opportunity&mode=form&id=8aed8d6582561033a8ff49a17ee32e1f2&tab=core&_view=1 AHRQ is soliciting proposals on a full and open basis, for an Academic Detailing Initiative to be funded with American Recovery and Reinvestment Act. (ARRA) funds. This is a new requirement and there is no incumbent

Specifically, this contract will conduct **academic detailing** to specific target audiences, especially clinicians in both large and small group practices, nurses, health plan formularies, benefits managers, and others who may use information generated by AHRQ's comparative effective research activities

Conclusion

Dr. Stephen Schondelmeyer, Director of the PRIME Institute of the University Of Minnesota College Of Pharmacy, reminds all of us that prescription drugs and medical devices bring great value to us as a society.

- Drug Therapy Has Been Beneficial.
  - Improved health care options & outcomes
  - Improved quality of life & length of life
- Not All Drug Use is Beneficial
  - Inappropriate Drug Use Adds Cost
  - Limited Info. on Drug Effectiveness & Safety
  - Key Research Questions Not Studied
  - Price Information is Not Known or Considered
  - Costs Sometimes Exceed Marginal Value

All of us bear the costs of the conflicts of interest that influence the prescribing of medications:

- *Failure to, or delay in, publishing negative results*
- *Failure to study adverse consequences*
- *Ghost-written articles*
- **One-Sided Marketing Influence**
- **Inappropriate Prescribing**

  (*e.g., Antidepressant Medications → wasted expense*)
- **Inflated Prices & Unnecessary Expenditures**
- **Prescription Drug Abuse**[22]

We all bear the cost of the abuse by pharmaceutical companies in their undue influence on Wisconsin prescribers.

- January 2004, Pfizer's maker of the epilepsy drug called Neurontin pleaded guilty of two felony counts for marketing the drug for unapproved uses. Pfizer paid **$430 million** in criminal fines and civil penalties and assured prosecutors that Pfizer and its units would stop promoting drugs for unauthorized purposes.

[22] Dr Stephen Schondelmeyer in prepared remarks before the Minnesota Legislature, January 26, 2010

- Since May 2004, Pfizer, Eli Lilly & Co., Bristol-Myers Squibb Co. and four other drug companies have paid a total of $7 billion in fines and penalties. Six of the companies admitted in court that they marketed medicines for unapproved uses.
    - September 2007, New York-based Bristol-Myers paid $515 million — without admitting or denying wrongdoing — to federal and state governments in a civil lawsuit brought by the Justice Department. The six other companies pleaded guilty in criminal cases.
    - January 2009, Indianapolis-based Lilly, the largest U.S. psychiatric drug maker, pleaded guilty and paid $1.42 billion in fines and penalties to settle charges that it had for at least four years illegally marketed Zyprexa, a drug approved for the treatment of schizophrenia, as a remedy for dementia in elderly patients.
- September 2, 2009, another Pfizer unit, Pharmacia & Upjohn, plead guilty to the same crime. This time, Pfizer executives had been instructing more than 100 salespeople to promote Bextra, a drug approved only for the relief of arthritis and menstrual discomfort, for treatment of acute pains of all kinds.
    - Pfizer paid the largest criminal fine in U.S. history: $1.19 billion.
    - Pfizer also paid on the same day $1 billion to settle civil cases involving the off- label promotion of Bextra and three other drugs with the U.S. and 49 states.

US Prosecutor Michael Locks said at last fall's announcement, "At the very same time Pfizer was in our office negotiating and resolving the allegations of criminal conduct in 2004, Pfizer was itself in its other operations violating those very same laws," Loucks, 54, says. "They've repeatedly marketed drugs for things they knew they couldn't demonstrate efficacy for. That's clearly criminal."

"Marketing departments of many drug companies don't respect any boundaries of professionalism or the law," says Jerry Avorn, a professor at Harvard Medical School in Boston and author of "Powerful Medicines: The Benefits, Risks, and Costs of Prescription Drugs" (Random House, 2004). "The Pfizer and Lilly cases involved the illegal promotion of drugs that have been shown to cause substantial harm and death to patients."

About 15 percent of all drug sales in the U.S. are for unapproved uses without adequate evidence the medicines work, according to a study by Randall Stafford, a medical professor at Stanford University in Palo Alto, California.[23]

By addressing these issues today and in the next session of your legislature, Wisconsin is part of a broad national trend towards restoring trust in the medical profession and protecting public programs and patients.

Thank you. I welcome any questions you may have.

5/25/10 - 9:15 am

[23] "Pfizer unit Pharmacia & Upjohn plead guilty to promoting Bextra for non-FDA approved purposes"; Bloomberg, Monday, November 9, 2009


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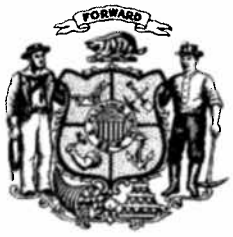

FORWARD

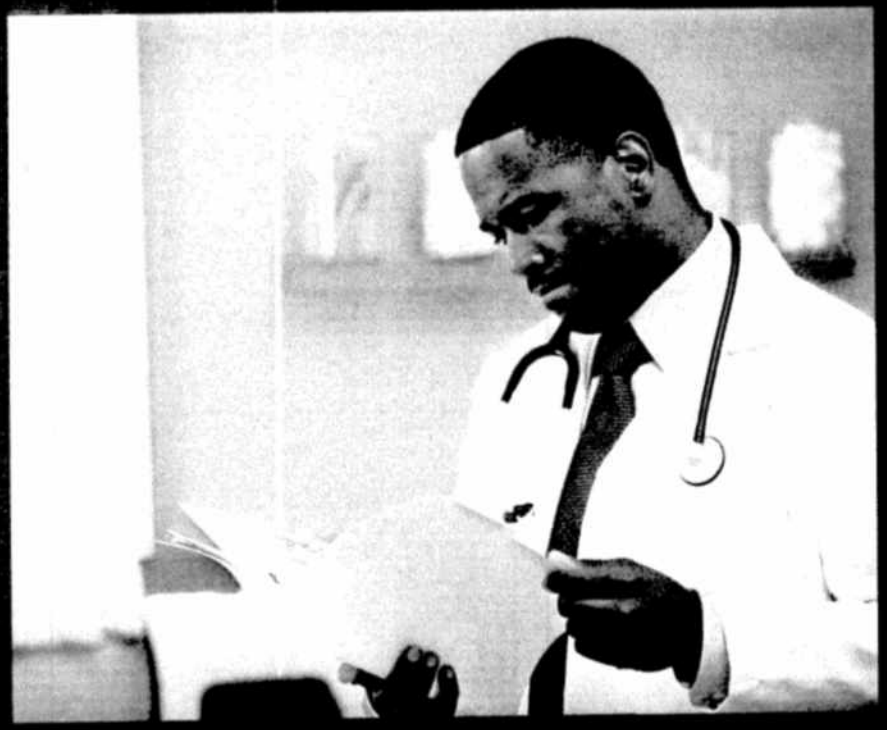
PhRMA

Understanding the **Value** & **Regulation** of Prescription Drug Samples

PhRMA

New Medicines. New Hope.

Audits and Record Keeping

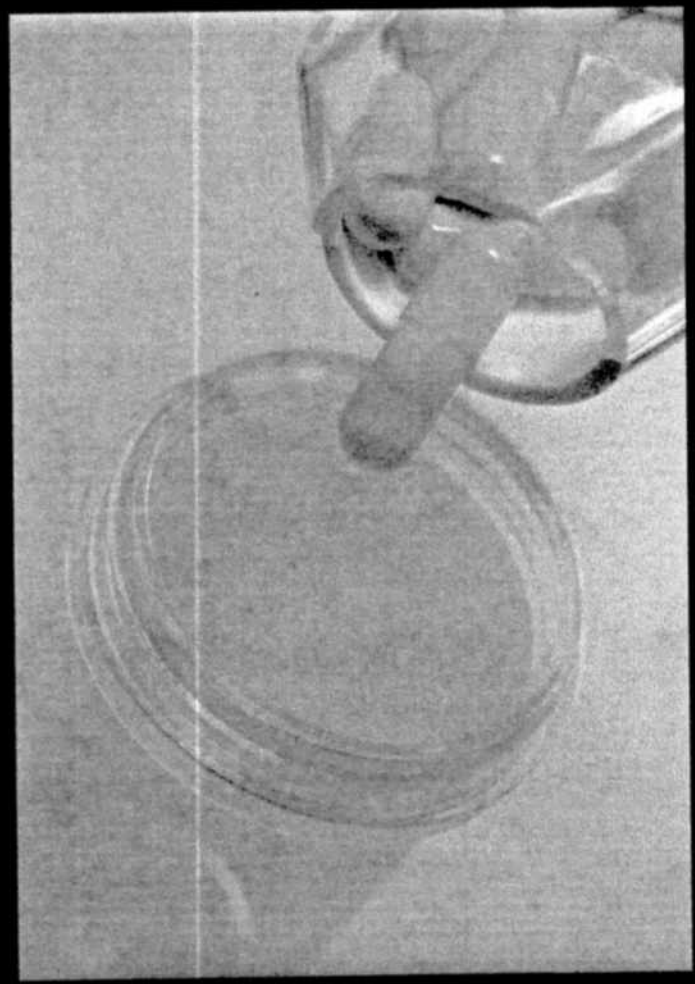


Some critics want to limit or ban the availability of free pharmaceutical samples to healthcare providers, who utilize them to assess the tolerability and effectiveness of the medication with individual patients. The critics neglect to account for the positive impact samples have on patients and their treatment.

1. Samples improve the process of finding the right medication for patients.
   - » Samples allow providers to evaluate how a patient responds to a particular drug therapy before the patient fills a prescription.
   - » Since a patient could experience a side effect with any medication, a provider can optimize the dosage and choice of medication before committing to a full course of the drug therapy. This can be especially important for patients taking several medications.

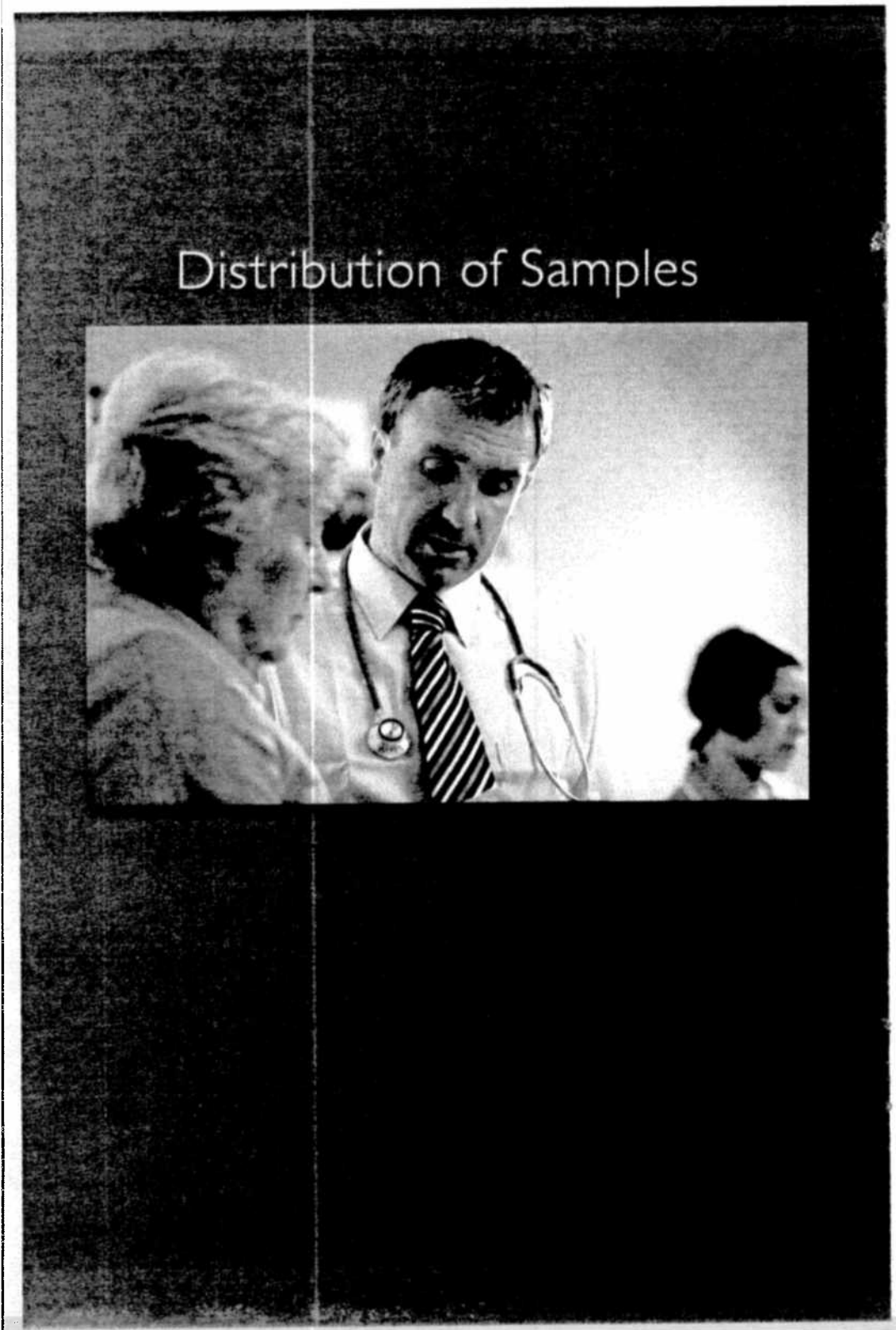
2. Pharmaceutical samples are beneficial because a healthcare provider can dispense them directly to the patient during an office or clinic visit.
   - » Samples allow patients to start therapy immediately.
   - » Starting therapy immediately is especially important when time is of the essence, such as when a patient is experiencing pain or is diagnosed with a chronic illness.

Labeling and Storage



3. Pharmaceutical samples are valuable to patients and provide no economic benefit to healthcare providers.
   - » It is illegal under federal law to sell, purchase, or trade a drug sample. 21 U.S.C. § 353(c). This federal law requires that samples be distributed free of charge for use by patients.
   - » The Department of Health and Human Services Office of Inspector General has recognized that samples provided to healthcare practitioners for their patients, when done so consistent with the Prescription Drug Marketing Act of 1987 (PDMA), do not constitute either direct or indirect remuneration to the healthcare professionals.

4. Physicians report that samples are useful to patients and healthcare providers. A 2008 KRC Research survey found that, of physicians surveyed:
   - » 69% believe free drug samples are either always useful (52%) or often useful (17%).
   - » 95% agreed that samples allow patients to start treatment immediately.
   - » 92% say that samples allow patients to see if a medicine works for them before filling a full prescription.
   - » 84% said that samples provide them with useful first-hand experience.



Role in Prescribing?

Prescription drug samples play an important role in helping physicians determine which medicine is right for individual patients, but they are only one factor among many in the healthcare system. A variety of other resources shape physicians' opinions and many factors weight more heavily on each prescribing decision.

1. Samples are just one of many factors that physicians consider when making prescribing decisions.
   - » U.S. generic prescribing rates are high. 72% of all prescriptions dispensed in the U.S. in 2008 were for generic drugs, up from 49% in 2000.
   - » The U.S. has one of the largest generic market shares of any developed country. In July of 2009, IMS Health reported that 72% of scripts filled by Medicare Part D beneficiaries and 70% filled by enrollees of other payers were filled with generics.

2. Payers and other factors strongly influence prescribing decisions.
   - » A recent KRC Research survey sponsored by PhRMA found that by far the most important factors in prescribing are a physician's clinical knowledge and experience and the patient's unique situation. Journal articles, clinical guidelines, and formularies are all factors that physicians consider.
   - » A survey by the Tufts Center for the Study of Drug Development echoed the KRC findings.

Prescription Drug Marketing Act of 1987 (PDMA)

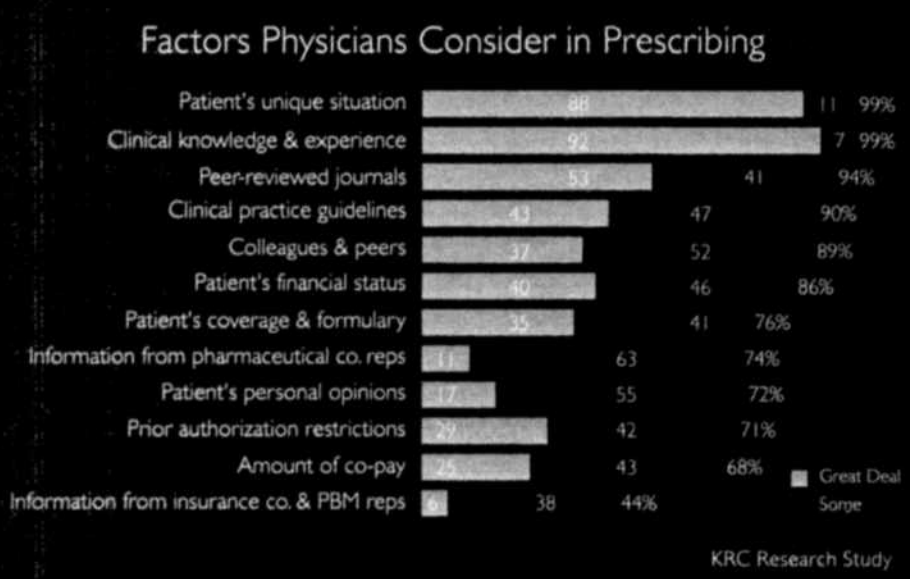
Regulation

Federal law extensively regulates all aspects of the use of prescription drug samples. There are detailed rules in place governing the distribution, labeling, and storage of samples to ensure that they are used appropriately and safely.

- The practitioner must complete, in advance, a written request form for the drug sample. The request must:
  1. Include the practitioner's name, professional title, and address.
  2. Identify the sample requested, the quantity and strength of the drug requested, and the name of the manufacturer; and it must include a signature and date.

- Any manufacturer or authorized distributor that distributes drug samples must maintain policies and procedures describing the systems in place for:
  1. Distributing drug samples by mail, by common carrier, or by representative;
  2. Conducting the annual physical inventory for a reconciliation report;
  3. Implementing its sample distribution security and audit system, including conducting random and for-cause audits of sales representatives by personnel independent of the sales force;
  4. Storage of drug samples by representatives; and
  5. Monitoring and reporting to FDA and local police any loss or theft of drug samples.

Do Samples Play a



- Only the manufacturer of a prescription drug and its authorized distributor may distribute drug samples. They may:

  1. Distribute the samples only to practitioners licensed to prescribe that drug.

  2. Distribute drug samples by mail, common carrier, or through a sales representative.

- The recipient must execute a receipt form upon delivery of the sample and the receipt form must be returned to the manufacturer or distributor.

- A licensed practitioner may provide donated drug samples to a charitable institution if delivered in original packaging in a sealed carton by mail or common carrier.

- Any authorized agent of the recipient institution may accept the donation.

- Prior to dispensing a drug sample that has been donated, a licensed practitioner or staff member designated by a licensed practitioner must determine that:

  1. The drug is not out of date;

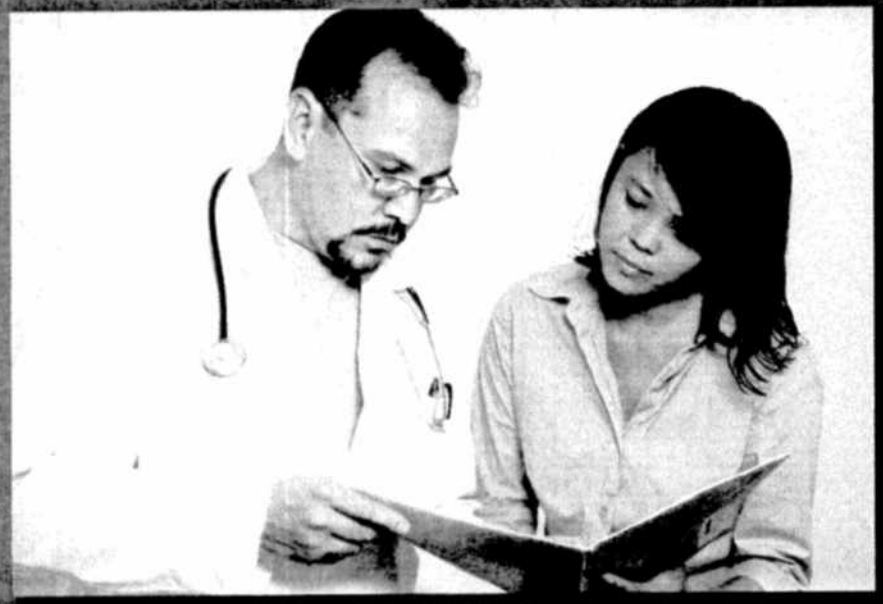
  2. Its labeling has not been mutilated, obscured, or detached from its packaging;

  3. It has not been recalled or is no longer marketed; and

  4. It does not show evidence of having been stored or shipped under conditions that might adversely affect its stability, integrity, or effectiveness.

- If the donated sample turns out unsuitable, the recipient institution must dispose of it.

Value of Samples



- The label and the outside container or packaging of every sample unit must include a lot control number to enable tracking of the sample unit.

- Each manufacturer and authorized distributor must maintain records of lot or control numbers sufficient to permit tracking of sample units to the point of the licensed practitioner.

- The label of a sample unit must also clearly denote the sample unit's status as a drug sample.

- Manufacturers, authorized distributors, and their representatives must "store and handle all drug samples under conditions that will maintain their stability, integrity, and effectiveness, and ensure that the drug samples are free of contamination, deterioration, and adulteration."

Value of Samples

- Manufacturers and distributors must maintain distribution request and receipt forms for three years.

- Recipients of donated drugs must maintain donation records and conduct annual inventories of prescription drug sample stocks.

- Manufacturers and authorized distributors of drug samples by means of sales representatives must conduct annual physical inventories of drug samples.

- Prescription drug samples reporting and record keeping obligations for manufacturers and their authorized distributors:

  1. To use and maintain request and receipt forms
  2. To investigate falsified drug sample records
  3. To investigate significant loss and known theft of drug samples
  4. To notify FDA if a sales representative has been convicted of certain offenses
  5. To verify that a person requesting a drug sample is licensed or authorized by the appropriate state authority to prescribe the product
  6. To maintain inventory records and reconciliation reports for drug samples distributed by representatives
  7. To maintain records of drug sample distributions by lot number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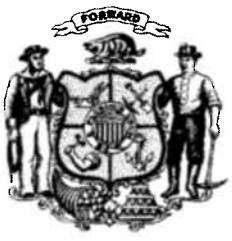

FORWARD

TRUTHFUL PRESCRIPTION DRUG ADVERTISING AND PROMOTION:

THE PRESCRIBER'S ROLE -- RECOGNIZE AND REPORT

The prescriber can play an important role in ensuring that prescription drug advertising and promotion is truthful by recognizing and reporting misleading drug advertising and promotion.

DDMAC's Mission

FDA's Division of Drug Marketing, Advertising, and Communications is responsible for ensuring truthful advertising and promotion of prescription drugs. Our mission is to...

- Protect the public health by assuring prescription drug information is truthful, balanced, and accurately communicated.
- Guard against false and misleading advertising and promotion through comprehensive surveillance, enforcement, and educational programs.

Prescription drug advertising must:

- Be accurate
- Balance the risk and benefit information
- Be consistent with the prescribing information approved by FDA
- Only include information that is supported by strong evidence from clinical studies

What types of promotion does DDMAC regulate?

- Sales representative presentations
- Speaker program presentations
- TV and radio advertisements
- All written or printed drug promotional materials

DDMAC does not regulate promotion of:

- Over-the-Counter Drugs
- Dietary Supplements
- Medical Devices

Common Violations:

- Omitting or downplaying of risk
- Overstating the effectiveness
- Promoting off-label, or unapproved, uses
- Misleading drug comparisons

EXAMPLES OF VIOLATIONS

Example of Omission of Risk

You attend a speaker program which features a slide show that presents efficacy information about Drug X, but no risk information.

This presentation would be misleading because it fails to include a fair balance of benefit and risk information for Drug X.

Example of Unapproved Use

You are in a commercial exhibit hall and a company representative tells you that a drug is effective for a use that is not in the FDA-approved product labeling.

This presentation would be illegal because it promotes an off-label use.

Example of Overstating the Effectiveness

"Doctor Smith, Drug X delivers rapid results in as little as 3 days."

This presentation is misleading because the majority of patients studied in the clinical trials for Drug X showed results at 12 weeks, with only very few showing results in 3 days.

FREQUENTLY ASKED QUESTIONS

Can I report anonymously?

Yes, anonymous complaints often alert FDA to potential problems. However, complaints accompanied by names and contact information are helpful in cases for which FDA needs to follow-up for more information.

Will DDMAC be able to stop the misleading promotion?

In many cases, yes, especially if evidence is provided. Evidence can include the actual promotional materials or documentation of oral statements made by company representatives.

What will happen to my complaint once I have contacted DDMAC?

The information you provide will be sent to a Regulatory Review Officer in DDMAC responsible for this class of drugs. The reviewer will evaluate it and determine if it may serve as the basis for a potential enforcement action or as valuable information for our ongoing surveillance activities.

How do I learn more?

To learn more about DDMAC in-service training for large medical group/hospitals or to speak directly with a DDMAC Reviewer, call 301-796-1200.

WHAT YOU CAN DO: RECOGNIZE & REPORT

RECOGNIZE

Be aware of the many advertisements and promotions that you see every day.

REPORT

Help FDA stop violations by reporting activities and messages that you consider false or misleading.

Phone: 877-RX-DDMAC
(877-793-3622)

E-Mail: BadAd@fda.gov

Write: FDA/CDER/DDMAC
5901-B Ammendale Rd.
Beltsville, MD 20705-1266

Fax: 301-847-8444

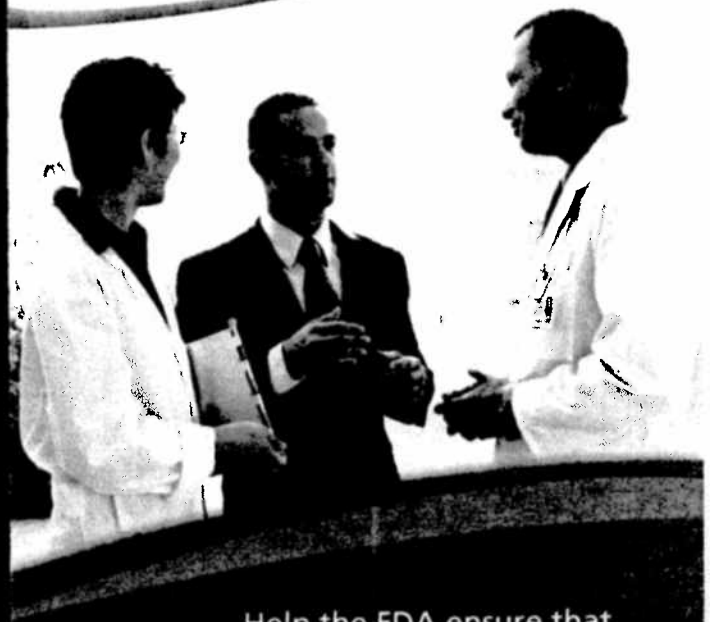
April 2010

DDMAC

A message from the U.S. Food and Drug Administration's Division of Drug Marketing, Advertising, and Communications

TRUTHFUL PRESCRIPTION DRUG ADVERTISING AND PROMOTION:

THE PRESCRIBER'S ROLE



Help the FDA ensure that prescription drug advertising and promotion is truthful and not misleading.

U.S. Department of Health and Human Services

FDA
U.S. Food and Drug Administration

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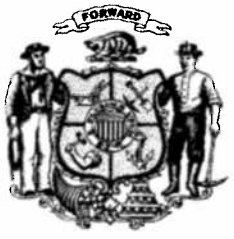

Wisconsin Alliance for Retired Americans

AARP

The Truth about Banning Pharmaceutical Gifts and Entertainment Legislation

Leon Burzynski - President, Wisconsin Alliance of Retired Americans

Opening Remarks:

According to the New England Journal of Medicine, more than 90% of physicians have some financial relationship with the pharmaceutical and medical device industries. Last year, the Rx Drug industry spent approximately $30 Billion on advertising, marketing, education and on pharmaceutical sales representatives. Contrary to what the Rx Drug Industry reports, they in fact spend more money on advertising, sales, marketing, sales reps. and educational seminars than they do on research and development for new prescription drugs.

So let me begin by talking about the Rx Drug Industry's "Myths" and why they opposed a ban on gifts and entertainment to health care prescribers.

MYTH: The gift ban will hurt Wisconsin's biotech and pharmaceutical research industries.

TRUTH: Despite the industry's claims, laws limiting the marketing influence of pharmaceutical companies on prescribers will not hurt business in Wisconsin. A bill would not impact any research or clinical trial engagements with prescribers. Bio-tech organizations may still utilize the expertise of clinical specialists for purposes of drug development provided that the compensation offered is reasonable for the services provided. In Massachusetts, where similar gift ban legislation was enacted in 2008, several areas within its life sciences sector expanded after enactment. There have been no reports of companies reducing their presence in Massachusetts, and neither the number of scientists nor the research dollars decreased because of the disclosure requirements.[1]

MYTH: Federal "sunshine" legislation replaces the need for state gift legislation.

TRUTH: Both current national proposals, Senator Kohl and Grassley's Sunshine Act and President Obama's proposal, support the states' ability to go beyond transparency. The need for action on these proposed bills in Wisconsin is still strong. Gifting to prescribers introduces bias into prescribing habits, and we must go beyond transparency to effectively curb the undue influence of pharmaceutical companies. Minnesota has led the nation on reform and its landmark 1993 gift ban legislation became a catalyst for national sunshine legislation. **Wisconsin needs to demonstrate similar leadership in this area.**

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[1] Allan Coukell, Pew Charitable Trusts, Testimony, MN Legislature, February 16, 2010 http://www.minnesotaprescriptioncoalition.org/sites/default/files/5484105_Coukell%20Testimony%20MN%202-16-10%20impact%20of%20MA%20FINAL.pdf

MYTH: The gift ban greatly increases paperwork for manufacturers.

TRUTH: Being prudent business organizations, all manufacturers are already tracking expenses and categorizing these for budgetary and 'Return On Investment' reasons. The proposed legislation may add a small, incremental change to the manufacturers existing processes, but it is not a new or overly burdensome procedure.

MYTH: Jobs will be lost if this legislation is implemented.

TRUTH: Legislation would likely create new jobs as new entities develop to track and interpret both the financial disclosures and the clinical health improvements recognized through transparent industry initiatives. Pharmaceutical sales and marketing will continue by all manufacturers. The proposed bills do not ban marketing of products - just the inappropriate offering of incentives to providers. **Massachusetts saw no evidence of job loss after enacting similar legislation. In fact, Massachusetts' biopharmaceutical industry has stood out in research growth, capital investment, and job creation since passage of its legislation.**

MYTH: Doctors will be prohibited from partnering with pharmaceutical companies and medical device manufacturers and open disclosure will negatively impact providers.

TRUTH: Disclosure will not prevent prescribers from partnering with medical device or pharmaceutical firms to develop new products -- **it will simply make that interaction transparent and honest for all to see.**

MYTH: Voluntary disclosure by the drug and medical device industry is effective enough.

TRUTH: The existing voluntary disclosures are self-policing and cannot be enforced. If the current voluntary disclosures kept these manufacturers in check, then adding a regulatory requirement should not introduce any additional burden, nor should it have any impact on jobs/employment. **It is apparent that the industry's opposition to the legislation is in fact an acknowledgement by manufacturers that self-policing is not effective.**

MYTH: Gifts from pharmaceutical and medical device companies to providers have decreased.

TRUTH: PhRMA and medical device companies continue to distribute substantial and influential incentives to prescribers. While offers of reminder items and trinkets by pharmaceutical and medical device companies may have decreased, gifting and entertainment still occurs through costly and biased "educational" programs and industry sponsored seminars. Moreover, regardless of their value, all gifts, speaker fees and industry sponsored research create an atmosphere of quid pro quo. Prescription drug and medical device manufacturers are funding educational seminars, private dinners and speakers with manufacturer-biased content. These events claim to "educate" prescribers on diseases for which their drugs or medical devices are used. Often, they share "preliminary clinical data" at these educational programs on alleged benefits of a drug beyond FDA labeled indications -- including off-label uses. These events routinely cost hundreds or thousands of dollars per attendee.

***See NY Times Article - "For $520 Million, AstraZeneca Will Settle Case Over Marketing of a Drug"*

MYTH: The gift ban prohibits pharmaceutical companies from marketing their products.

TRUTH: The proposed legislation would still allow pharmaceutical companies to offer drug samples and their sales reps to visit providers' offices to provide information about their products. The proposed legislation would simply ban gifts and entertainment and create an environment where transparency and evidence-based prescription drug information would improve patient health outcomes and lower drug costs.

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[1] See current unofficial engrossment at: http://www.minnesotaprescriptioncoalition.org/updates-status-gift-law-legislation


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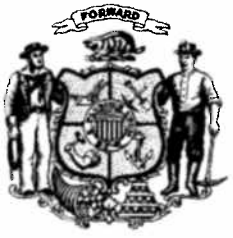

FORWARD

STATEMENT OF
KIM WITCZAK
JOINT INTERIM HEARING
ON
PRESCRIPTION DRG REFORM BILLS

On August 6, 2003, my husband of almost 10 years, Woody died of a Zoloft-induced suicide at age 37. He was not depressed, nor did he have any history of depression or any other mental illness. He died after taking the drug a total of 5 weeks with the dosage being doubled shortly before his death. He was given the antidepressant from his general physician for "insomnia."

Woody loved life. He was a compassionate, loyal husband, son, brother, uncle, godfather and friend. He had endless energy, a constant smile and a laugh that could be heard a mile away. But to me, Woody was simply my best friend who always greeted me with "Hello Sunshine". He was the guy that I was supposed to have a family and grow old with.

Woody had a successful sales career and had just started his dream job as VP of sales with a start up company. He was excited about this new opportunity and along with this excitement came difficulty sleeping which is not uncommon for entrepreneurs starting their own business. So on June 30th, 2003 Woody went to see his family doctor and after a 5-minute consultation, he was given Zoloft for an insomnia diagnosis. This was the first time he'd ever gone to a doctor for this sort of issue.

The 3-week Pfizer-supplied sample pack that Woody came home with automatically doubled the dose unbeknownst to him after week one. No cautionary warning was given to him or me about the need to be closely

monitored when first going on drug or dosage changes. In fact, I was out of the country on business for the first 3 weeks he was on the drug. Within days, Woody experienced every known side effect of Zoloft, including depersonalization and akathisia (a neurological condition that causes sever internal restlessness and agitation).

Shortly before his death, Woody came home crying after driving around all day. He sat in a fetal position on the kitchen floor with his hands pressing around his head like a vice saying, "Help me. Help me. I don't know what's happening to me. I am losing my mind. It's like my head is outside my body looking in." Two weeks later, a total of 5 weeks on the drug, Woody was found hanging from the rafters in our garage by my dad.

We tried many things during this period trying to figure out why Woody suddenly changed from sleeplessness to having all of these new problems. We were unaware and unwarned that Zoloft, the drug that is touted and sold to help, was actually causing Woody harm.

We only wish we knew then what we know now. It wasn't Woody's head. It was the drug.

For the right person, being prescribed by the right doctor for the right diagnosis with the right warnings and monitoring, these drugs may help. But without nonbiased information and warnings, these drugs, in fact, all drugs can be deadly.

While still struggling to cope with this loss I have chosen to use my experience to try and make a difference.

So how does Woody's story relate to what you are considering today?

Since Woody died, I have spent countless hours trying to determine what happened to Woody and how our current system failed him.

Woody was given a 3-week **sample** of Zoloft by his general practitioner. Insomnia is an "off-label" use for Zoloft. Samples are a marketing technique used to promote drugs.

I now know that a great deal of the information doctors get about the drugs they prescribe come from the drug companies' representatives. Drug reps visit the office to discuss the attributes of the drugs and to leave samples.

Between 60-80 percent of all antidepressant prescriptions are written after about a 5 to 10 minute consultation by general practice or family doctors who may or may not know the significance of all the side effects.

In my research, I learned that the FDA and the pharmaceutical industry have long been aware of the suicide risk in antidepressants since before the FDA held hearing on Prozac suicides in 1991. Somehow, the issue was swept under the rug. The drug companies instructed their sales reps not to tell general practitioners about these risks.

I have worked in advertising and marketing for years -- and I understand marketing. Drug reps are marketers. Drug companies hire the very best MBAs from the best schools to sell their goods. They use marketing tactics that work. That's their job. But prescription drugs should not treated the same as cars, cereal, and soft drinks.

From a consumer's perspective, educating doctors about new drugs should not be left to marketers. Doctors need **nonbiased** information and they need **all** the

research available to know the risks of what they are prescribing. The academic detailing program proposed by this legislation before you would help deliver nonbiased, research-based information into the hands of doctors and clinics.

From my work on this issue here and in Washington, I have also learned about the many, many financial ties between doctors, health care providers and pharmaceutical companies. Financial incentives influence decisions.

Patients deserve more. Families deserve more. We need to trust that our health care providers are giving us the best health care. Nothing should come between you and your doctor - certainly not the pharmaceutical company.

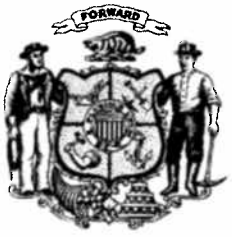
I don't blame Woody's doctor for what happened. Rather, I believe he was a victim of a system that is too heavily influenced by the pharmaceutical companies and the millions of dollars they spend to promote their drugs.

I urge you to do whatever you can to reduce the conflicts of interest that exist between doctors and pharmaceutical companies in Minnesota. These bills before you are a step in the right direction.

I believe Woody's death was preventable. I don't want what happened to our family to happen to yours.

Thank you for your time.


WISCONSIN STATE LEGISLATURE


FORWARD

THE PRESCRIPTION PROJECT

November 19, 2008

Fact Sheet

Prescription Data Mining

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

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.

The Problem

Pharmaceutical companies buy doctors' prescribing records from pharmacies and use the information to target their marketing to physicians. This practice negatively affects:

- **Public Health**: Marketing based on prescriber data often involves biased and inaccurate information about health risks, and encourages the prescription of new drugs that might be riskier to patients than already established treatments.
- **Cost**: Marketing based on prescriber data is a key factor in the skyrocketing costs of prescription drugs and the increased usage of expensive brand-name medicines.
- **Privacy**: Sales of prescriber data take place without the consent, and generally without the knowledge, of physicians. Patient records may also be inadequately protected, particularly in small communities with few physicians or few patients with particular diagnoses.

The pharmaceutical industry spent $29 billion on promoting and marketing prescription drugs in 2005, with $7.2 billion spent on marketing directly to physicians.[1] ($29 billion includes detailing, advertisements in medical journals, direct-to-consumer advertising and drug samples.) The industry employs over 90,000 drug representatives and spends up to about $8,800 per doctor, per year marketing its products directly to physicians."

New and expensive drugs are often promoted over less expensive drugs that are equally or more effective. According to the data mining industry itself, "research has shown that winning just one more prescription per week from each prescriber yields an annual gain of $52 million in sales."[3]

How Does Data Mining Work?

When a patient fills a prescription at a major pharmacy, a record of that prescription (minus patient name) is sold to companies – so-called *health information organizations* – that pool information from multiple pharmacies. The bundled information is combined with individual physician identities purchased from the American Medical Association to create prescriber profiles (name, specialty, practice site, which and how many prescriptions written, etc.) that are sold to the drug companies.

Drug companies then give the information to their salespeople, who use it to tailor marketing strategies, messages, gifts and other inducements for individual physicians.[iii] As a result, many patients are prescribed expensive medicines that are no better, and may be worse, than other available medicines or non-pharmacological therapies.[iv]

For example, Dendrite International touts its data mining product as follows: "[N]ow, pharmaceutical manufacturers who partner with Dendrite can gain a level of insight that allows them to predict and influence physician prescribing behavior like never before."[v]

Addressing the Problem

Physician organizations, patient advocacy groups, and legislators have highlighted problems associated with data mining and have taken steps to minimize its use for commercial marketing purposes in the following states:

New Hampshire: The Prescription Privacy Law (2006) prevents patient and prescriber identifying data from being sold or used for advertising, marketing, promotion or any activity intended to influence sales or market share of a pharmaceutical product (http://www.gencourt.state.nh.us/rsa/html/XXX/318/318-47-f.htm). The law was passed as a consumer protection and public health measure, and seeks to ensure privacy in prescribing.

Vermont: As part of a comprehensive package to control the costs of prescription drugs and regulate inappropriate marketing tactics, Vermont recently passed legislation that provides strong privacy protections by limiting the use of personally identifiable prescription information for marketing purposes unless doctors and other health care providers explicitly agree to waive the protections. The law includes a physician *opt-in* provision at the time of licensure or renewal.

This provision, managed by the state's professional licensing board, allows a prescriber to choose to have his or her identifying information used for marketing and promotion of prescription drugs. The Vermont Medical Society supports the measure.[vi]

Maine: Maine also passed legislation requiring its Board of Licensure to include confidentiality protection of prescribing data as part of its licensure and license

renewal process."[v] The Board must inform applicants that their prescription drug information is used for marketing purposes and how the prescribers may "opt out," a weaker alternative to the prescribing data protection systems in Vermont and New Hampshire.

Other states, including Hawaii, Maryland, Massachusetts, Nevada, New York, Washington, and the District of Columbia, have introduced legislation to limit data-mining.

All existing or proposed legislation restricts only the sale and use of patient or prescriber data specifically for marketing or commercial purposes. They do not restrict the sale and use of such identifiable data for other purposes, including for insurance reimbursement, dispensing prescriptions, utilization review, public health research, law enforcement purposes, controlled substances monitoring, adverse effects reporting, or compliance with Medicaid or private insurance formularies and rules.

The AMA's inadequate response

The response of the American Medical Association (AMA) to concerns about data-mining has been weak. The AMA plays a key role in enabling the data-mining industry by selling its physician database to data-mining companies. The AMA "Physician Masterfile" contains the name, identity, practice location, training site, licensure and disciplinary history for nearly every U.S. physician[vi] – even the two-thirds of doctors who are not AMA members. Sale of Masterfile data brought the AMA $44.5 million in 2005. Although the AMA initiated an option in 2006 to allow physicians to "opt out" of this program, the process is cumbersome and few physicians are aware of the option. Moreover, even when a doctor "opts out," the AMA continues to sell that doctor's personally identifiable prescribing information. Pharmaceutical companies may still use the information to target their marketing efforts, as long as they pledge not to provide that individual prescriber's data directly to salespeople. Furthermore, the collection of prescribing data and identities through pharmacies is not affected by the AMA policies.

Industry Challenges

The data mining industry has challenged the New Hampshire, Maine, and Vermont statutes. The Federal District Court of New Hampshire overturned the law on constitutional free speech grounds. The State of New Hampshire appealed the decision, asserting that the state has a substantial interest in protecting the confidentiality of prescriber data from use for drug marketing purposes. On November 19, 2008, the Court of Appeals for the First Circuit overturned the ruling of the district court, and unanimously upheld the New Hampshire law. The Court found that the law regulates conduct, rather than protected speech, and that it is further justified by the state's substantial interest in promoting containment of prescription drugs costs.

"There is a second basis for our decision. Even if the Prescription Information Law amounts to a regulation of protected speech — a proposition with which we disagree

— it passes constitutional muster. In combating this novel threat to the cost-effective delivery of health care, New Hampshire has acted with as much forethought and precision as the circumstances permit and the Constitution demands."[ix]

The challenge in Maine is covered by the First Circuit's ruling and it is therefore very likely that the Maine law will be upheld. The Vermont lawsuit is governed by the law of the Second Circuit Court of Appeals, which has not yet ruled on this issue. That lawsuit will continue, although it is likely to be affected by the forceful reasoning of the First Circuit panel in the New Hampshire case.

The data mining and pharmaceutical industries have also opposed these initiatives in state legislatures. They argue that allowing companies like IMS and Verispan to profit from collecting and analyzing individual prescriber data for marketing purposes serves a public interest because it is then available (at a price) for research and to track drug safety problems.[x] However, all state legislation passed or proposed explicitly allows for the collection of this data for non-marketing purposes, and the data are available for such purposes through other sources, such as pharmacies, Medicare and Medicaid.

Other materials on data mining, including a legal analysis, model policy, policy brief, and a myths and rebuttals piece are available on the Prescription Project website and http://www.reducedrugprices.org/advertising.asp

[i] Donohue, J., Cevasco, M., Rosenthal, M. A Decade of Direct-to-Consumer Advertising of Prescription Drugs. *New England Journal of Medicine*. 2007; 357: 673-681.

[ii] U.S. Department of Health and Human Resources. Physician Supply and Demand: Projections to 2020. Available at: http://bhpr.hrsa.gov/healthworkforce/reports/physiciansupplydemand/currentphysicianworkforce.htm. Accessed August 22, 2007.

[iii] National Physicians Alliance, Issue Brief: The Sale of Physician Prescribing Data Raises Health Care Costs - the National Physicians Alliance Calls for a Ban

[iv] Schaefer, B. Restuccia, R. Mining Our Own Business. *Kennebec Journal*. April 13, 2007. Available at: http://kennebecjournal.mainetoday.com/view/columns/3795317.html Accessed August 15, 2007.

[v] Defendant's Memorandum of Law in Support of its Objection to Plaintiff's Motion for Preliminary Injunction, IMS v. Ayotte, No. 06-CV-280-PB, at 13 (D.N.H. filed April 30, 2007). (Memorandum filed September 1, 2006).

[vi] Vermont Medical Society Statement on Governor Douglas' Signing of S.115. Vermont Medical Society Website. 2007. Available at: http://www.nlarx.com/policy/pdfs/VMSStatement_Gov_Signing_S115_RxBill.pdf. Accessed August 15, 2007.

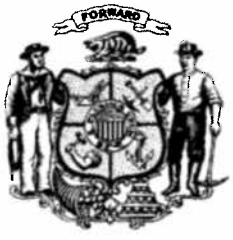
[vii] Maine Public Law, Chapter 460. Available at: http://janus.state.me.us/legis/LawMakerWeb/externalsiteframe.asp?ID=280022219&LD=4&Type=1&SessionID=7. Accessed August 27, 2007.

[viii] American Medical Association. Description of AMA Physician Masterfile Data Elements. 2004. Available at: https://profiles.ama-assn.org/amaprofiles/info/pdf/mfile_elements.pdf Accessed: August 25, 2007.

[ix] IMS Health Inc. and Verispan, LLC v. Kelly A. Ayote, New Hampshire Attorney General, (1st Cir. 2008). Available at: http://www.ca1.uscourts.gov/pdf.opinions/07-1945P-01A.pdf

[x] Turner, M., Duncan, J, Varghese, R., Walker, P. The impact of provider-identifiable data on healthcare quality and cost. April, 2007; 29-35

WISCONSIN STATE LEGISLATURE



THE INDEPENDENT DRUG INFORMATION SERVICE

Balanced data about medications for Pennsylvania physicians

The Commonwealth of Pennsylvania spends about ten percent, $2.5 billion, of its annual budget reimbursing prescription medications for over two million of its state residents. These individuals, many of whom are in frail health with multiple chronic conditions and requiring daily maintenance medication, are enrolled in a dozen different programs, most of which provide comprehensive prescription drug coverage with nominal cost sharing by the beneficiary.

Three programs carry over 80% of the state's annual prescription drug spending: Medicaid, state employee and retiree drug benefits, and the senior pharmacy assistance program, PACE. In the past, these programs have noticed a persistent and disturbing problem involving inappropriate prescribing and the misutilization of prescription medications among enrollment, particularly in the PACE program. To address this problem, programs adopted effective interventions, drug utilization reviews and mandatory point-of-sale edits, which achieved measurable success.

As a complement to these interventions, the PACE Program decided in 2005 to test a program of proactive educational outreach targeted at improving the clinical appropriateness of physicians' prescribing. The Independent Drug Information Service, sponsored by the PACE Program of the Pennsylvania Department of Aging, has no ties to any pharmaceutical company. Its clinical content is created by an independent group of physicians and researchers on the faculty of Harvard Medical School.

WHAT IS ACADEMIC DETAILING?

Academic detailing is an innovative method of service-oriented outreach education for physicians. It provides an accurate, up-to-date synthesis of relevant drug information in a balanced format.

Doctors need an accurate source of current data about the comparative effectiveness, safety, and costs of prescription drugs. This information can be time-consuming to assemble from the research literature, and due to time constraints and competing demands for their time, physicians often rely on more convenient sources of information.

Pharmaceutical sales representatives, called drug detailers because they provide detailed information about their products, visit physicians in their offices and deliver marketing materials about the products they promote. While the method of delivery is effective, the information is designed with commercial objectives in mind, regardless of whether more effective, safer or less expensive therapies exist.

Academic detailing is outreach education that combines the interactive, one-on-one communication approach of industry drug detailers with the evidence-based, noncommercial information of academia. Academic detailing has been utilized in Australia, Canada, the United Kingdom, and the Netherlands to assist prescribers in making optimal prescribing decisions. In 2005, the Pennsylvania Department of Aging's PACE Program launched the first large-scale state academic detailing program in the United States.

WHAT IS iDiS?

The Independent Drug Information Service (iDiS) is the academic detailing service currently underway in Pennsylvania. An independent group of physicians and drug researchers on

the faculty of Harvard Medical School comprehensively evaluate medical journals and other data sources to pull together the best available, objective information about drugs used commonly in primary care practice.

They then synthesize it into concise, clinically relevant summary documents, decision-making tools, and patient education materials. Trained pharmacists, nurses, and allied health professionals visit with physicians in their offices to discuss therapeutic choices and patient care practices. Rather than promote particular products, academic detailers provide summaries of the evidence to help physicians prescribe the safest, most effective medications for their patients.

In many cases, the most appropriate therapeutic options are tried and true drugs with safety-risk profiles that demonstrate benefit at relatively lower risk, and because they have been on the market longer, they are often available as affordable generics. This is particularly true in the case of heavily marketed drug classes such as acid-suppressing therapy. But academic detailing is not simply about prescribing generics.

Academic detailing is a quality-driven endeavor that helps physicians make appropriate clinical decisions based on the best available safety, efficacy, and cost-effectiveness data. Because aggressive marketing of high-priced drugs increasingly strains public and private health care budgets, academic detailing has the potential to help control costs while improving patient care and health outcomes, thus aligning the interests of physicians, payers and patients.

In mid-2008, the approach expanded to include education about medications and interventions designed to give primary care physicians information they need to help prevent unnecessary institutionalization of frail elderly living in the community.

WHAT IS THE PENNSYLVANIA EXPERIENCE?

The Department of Aging funds academic detailing for about $1 million per year, a small fraction of the PACE prescription benefits of $726 million in 2008. This funding allows eleven independent drug consultants to work in the 28 most populous counties. Four drug classes that present special contemporary concerns in relation to quality of care or cost are chosen per year as topics. Classes to date include non-steroidal anti-inflammatory drugs, cox-2 inhibitors, gastrointestinal medications, anti-platelet therapy, cholesterol-lowering drugs, antihypertensives, type 2 diabetes management, antidepressants, falls and mobility problems, and cognitive impairment.

Initial dissemination will address other state sponsored drug programs, beginning with the retired state employee population. With additional signs of success, the number of covered programs will increase and funding is likely to be shared by the agencies whose constituents receive the benefit of improved prescribing practices. Inquiries about academic detailing have been numerous given the media coverage within Pennsylvania and in national news outlets. Some organizations are looking to collaborate to add value to the project or to cover additional populations. Other states have inquired about how the program could work for them. Massachusetts and Washington, DC, began similar academic detailing programs.

Pennsylvania's academic detailing initiative has helped physicians decide which medications to prescribe by arming them with information to select the most effective drug, not necessarily the one with the biggest advertising budget. In Pennsylvania, this has been a good investment that will continue in the PACE.

All iDiS clinical materials are made freely available for non-commercial use at www.RxFacts.org.