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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)

AARP

December 2009

Rx Watchdog Report

Shining a light on the cost and quality of prescription drugs

Academic Detailing: An Interview with Jerry Avorn, M.D.

Jerry Avorn, M.D., is a professor of medicine at Harvard Medical School and chief of the Division of Pharmacoepidemiology and Pharmacoeconomics at Brigham and Women's Hospital, and author of *Powerful Medicines: The Benefits, Risks, and Cost of Prescription Drugs*. An internist, he has worked as a primary care physician and geriatrician and has been studying drug use and its outcomes for over 25 years.

Dr. Avorn, known as the "father of academic detailing," devised the approach when he and his colleagues showed that such programs could improve prescribing decisions and reduce costs by correcting improper medication expenditures. Today, programs based on his work are in place in the U.S., Canada, Europe, Australia and the developing world.

Where and how do you see academic detailing fitting into the overall health care reform debate?

The way things are shaping up at the national level will leave a larger role for academic detailing because two big ingredients missing now, which will emerge later on, are ensuring that doctors know what works best, and addressing physician incentives. The current plans in Congress do not seem to take on these issues effectively as we have seen in Massachusetts. Just guaranteeing access to health insurance, without managing the cost of care being delivered, is just asking for a bigger problem down the road. Making sure that physicians have the information they need to make the best and most cost-effective decisions will be necessary if we are to have quality, affordable care.

"Just guaranteeing access to health insurance, without managing the cost of care being delivered, is asking for a bigger problem down the road. Making sure that physicians have the information they need to make the best and most cost-effective decisions will be necessary if we are to have quality, affordable care."

Academic detailing can't fix the incentives problem of fee-for-service reimbursement. But academic detailing can help address what doctors know. If we could combine that increased base of knowledge about prescribing with the proper incentives, this would be an even better way to improve quality and contain costs. But even in the current system, equipping doctors with better knowledge about drugs has been shown to change our

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Academic Detailing in Practice: A Tale of Four States

Frustration has reached a boiling point with governments, the public and lawmakers over the negative effects of the pharmaceutical industry's marketing practices. Spending on marketing and promotional goods, including drug samples, is estimated at nearly $30 billion (according to the *New England Journal of Medicine* article, "A Decade of Direct-to-Consumer Advertising of Prescription Drugs," Donohue, 2007), with $7.2 billion targeting physicians. The industry employs approximately 90,000 pharmaceutical sales representatives, which average out to about one for every five doctors. With scores of conflict of interest issues abounding between the industry and physicians, and the number

What Is Academic Detailing?

Academic detailing is a service offered to prescribers that sends trained clinicians to the prescribers' offices to present the best available, objective scientific evidence on prescription drugs (prescribers include physicians, nurse practitioners, physician assistants–those authorized in the respective state to prescribe). The clinicians–often pharmacists, physicians and nurses–have face-to-face discussions and answer any questions prescribers may have on the topic presented. Many times, and at the prescriber's request, the clinicians make follow-up visits to discuss the overall patient practices and the use of those drugs, and/or make another presentation to discuss another class of drugs.

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An Interview with Jerry Avorn, M.D. continued from page 1

prescribing for the better.

We understand academic detailing is much more than saving dollars, but can you speak to saving the states money, especially because they are currently in such financial distress? And also how do states get funding for academic detailing programs?

Fortunately, three of the programs we're working with were up and running before the economic meltdown. The grand-daddy program—in Pennsylvania—was started in 2005 because Governor Rendell and Tom Snedden, director of the state's Pharmaceutical Assistance Contract for the Elderly (PACE) program, reasoned that it would be plausible to spend 1/20th of 1% of their drug expenditures in order to improve the way doctors use those drugs. They spent a tiny fraction to help doctors make smarter prescribing decisions.

But even in this current economic climate, Massachusetts as well as the District of Columbia found modest amounts of money to fund their programs in 2009. Massachusetts is contemplating a tax on drug companies associated with the state's new gift ban legislation, in order to help fund the academic detailing program they already have in place. D.C. has proposed a fee on drug company sales reps to fund their academic detailing program.

States are having a hard time funding their prescription programs, but if they can get an academic detailing program in place, it could help contain those medication costs. Several programs have found that if you can educate a doctor to use a $50 per year generic medication to treat hypertension or diabetes instead of a $1,000 per year brand-name medication that may be no better, or not even as good, that can improve care as well as saving costs.

There is also some "poetic justice funding" that has been made available for this work. When Pfizer had to pay $430 million to settle litigation over off-label marketing of Neurotin, the attorney generals managing the case decided to take on the problem of misleading marketing by using some of the settlement funds to fund programs that teach physicians and medical students about evidence-based prescribing. I hope this recent settlement with Pfizer (regarding Bextra and other drugs for non-approved off-label use) does the same.

The poster child for what NOT to do with the settlement money from the pharmaceutical companies is the tobacco settlement. Much of that went to general state revenues or to repair state highways instead of to deterring smoking. Similarly, I hope the settlement dollars from the pharmaceutical manufacturers don't get poured into general funds, but instead are used to undo the problem that gave rise to the settlements and for academic detailing programs. Doctors often rely on pharmaceutical sales reps to shape their drug choices, so the more we hear about intentional misinforming of physicians, the more we understand the need to get them evidence-based and objective information.

Several programs have found that if you can educate a doctor to use a $50 per year generic medication to treat hypertension or diabetes instead of a $1,000 per year brand-name medication that may be no better, or not even as good, that can improve care as well as saving costs.

So, are there studies about evidence-based research resulting in better outcomes for patients, in addition to cutting costs?

In the early 1980s, after conceiving the idea of academic detailing, I wanted to test the concept, so conducted a large multi-state randomized trial involving over 400 doctors in four state Medicaid programs. As Steve Soumerai and I reported in the *New England Journal of Medicine*, 92% of the doctors who were offered this service accepted it, and those who were randomized to the academic detailing group significantly improved their prescribing. In a formal cost-benefit analysis, we found that such a program could save $2 for every $1 it cost to run. This was not a surprise; it is how the drug companies move prescribing in the direction they want. They know exactly what they are doing.

And evidence-based recommendations do save money. My Harvard colleague Michael Fischer, M.D., and I studied 133,634 patients treated for hypertension in a state pharmaceutical assistance program who filled 2.05 million prescriptions. In a paper we published in the *Journal of the American Medical Association*, ("Implications of Evidence-Based Prescribing for Hypertension") we found 815,316 prescriptions (40%) for which an alternative regimen appeared more appropriate, according to evidence-based recommendations. Such changes would have reduced the costs to payers in 2001 by $11.6 million (nearly a quarter of the program spending was on antihypertensive medications), as well as being more clinically appropriate overall. Nationally, that would come to over $1 billion. Use of pricing limits, similar to those in the Medicaid program, would have resulted in even larger potential savings of $20.5 million in just that one state (42% of program costs).

So, we found if you could get doctors to treat hypertension using evidence-based recommendations, it would not only improve outcomes, but it would save costs. If doctors prescribe according to the very best available evidence, it will bring about the best outcomes and also reduce costs—we can have both, and we don't have to choose.

Since the academic detailing program in Pennsylvania got started in 2005 and has been so successful, have other states moved the dial on similar programs?

There is now a critical mass of academic detailing programs around the world and growing in the U.S. The non-profit Alosa foundation is the group that funds some of these programs and allows us to provide the clinical content to states including Massachusetts and Pennsylvania, as well as D.C.

There are also academic programs

in South Carolina, New Hampshire, Vermont, Maine and a large program in New York. Alosa provides training and the educational materials to these states as well. In the U.S. some integrated health care systems—particularly Kaiser—have mounted their own academic detailing services. Several Canadian Providences run academic detailing programs; Ontario soon plans to launch the largest academic detailing program in North America. Additionally, European countries, the Netherlands and Australia have some excellent academic detailing programs. Some of our colleagues from Australia have worked with us here in the U.S. My hope in the next calendar year is to continue building a critical mass and have a world-wide meeting so we can share programmatic and clinical experiences and learn from each other.

Why is it so challenging for physicians to get the best information on which medicines to prescribe?

I practiced for many years on the front lines, and I know how hard it is to get this information without spending hours reading journals. Getting information from a pharmaceutical representative is problematic, since you know darn well it's just a sales line. But academic detailers can provide a concise, 20-minute, boiled down discussion that reviews all the latest data on managing diabetes or depression, for example. Doctors find that to be terribly useful information.

Now the doctors ask the academic detailers, "When can you come back? Can you give grand rounds at our hospital?" Once they know the valuable information is out there—that is evidence-based and that we are not just pushing products—they all want more of it.

Why is the approach to academic detailing more effective than say, a Web cast or a taped lecture?

We academics tend to stay up in our ivory towers and lecture from there—that is, we talk at physicians, not with them. There is good evidence this method does not change behavior.

By contrast, academic detailing is based on the same idea that drug companies take advantage of to change behavior; that is, they know how to engage you, interact with you, and learn about your beliefs and attitudes, and have a very clear objective: "Dr. Avorn, I want you to put your patients on xyz medication." Plus, the drug companies have the additional advantage of having access to what the doctors are already prescribing—since they buy that data.

If doctors prescribe according to the very best available evidence, it will bring about the best outcomes and also reduce costs–we can have both, and we don't have to choose.

So then I wondered what would happen if we could take this interactive adult learning exchange and use it in the context of conveying evidence based on rational prescribing. This explains how we do academic detailing. Avorn also added the academic detailers are physicians, nurses, pharmacists – they are health care professionals that are not out to make a profit, versus the drug company sales representatives that are solely there to sell their company's drugs and make a profit, which dictates what kind of subjective information they will present to the physicians.

I noticed at my doctor's office at Johns Hopkins they no longer allow pharmaceutical sales representatives. They do allow for academic detailers, right?

Yes, that is interesting and I believe you are correct. Academic detailing is not just a "say no to drugs" program. It begins with the assumption that prescribing is one of the most useful and challenging things we doctors do, and we crave accessible, unbiased data about the drugs we prescribe. If war is too important to be left to the generals, then drug information is too important to be left primarily to the pharmaceutical industry. I think of getting good, current, non-commercial, evidence-based information to doctors as an important public good—like good roads, primary-school education and clean air.

For more on academic detailing visit the website **www.rxfacts.org/**. ■

State Advocacy Update

States are facing dramatic fiscal pressures as revenues decline and the demand for state services remains high. Policy makers are not expected to have much appetite for expanded funding of state programs, and will be looking to cut state expenditures wherever possible.

In this environment, AARP needs to combat short-sighted efforts to reduce or eliminate state-funded State Pharmaceutical Assistance Programs, which often supplement the coverage available under Medicare Part D. While these dollars can be cut without sacrificing federal funds, this risks incurring the much higher cost of treating unmanaged chronic conditions.

For more information on threats to State Pharmaceutical Assistance Programs, read the March 2009, Issue 2 of *Rx Watchdog*: www.aarp.org/health/conditions/rx_watchdog/

We are also expecting AARP offices in a number of states to promote academic detailing programs. While the purpose of these programs is not to decrease costs, it is a likely "side effect" of providing physicians and other prescribers independent, unbiased information about prescription options in order to counter the efforts of brand pharmaceutical manufacturers who encourage the use of their products, which are many times the latest, least tested, and most expensive drug therapies. ■

Pharmaceutical Giant Pfizer Off-Label Marketing Settlements

Is It Enough to Deter Others?

The world's largest pharmaceutical company—which just got even larger due to a recent approval to buy Wyeth in a $68 billion deal—recently settled a criminal case with the Department of Justice (DOJ) by agreeing to pay the government $2.3 billion in fines, which is the largest single fine ever extracted by the DOJ from a single defendant.

This is not the first time, nor the second, that Pfizer, Inc., has paid millions of dollars in fines paid out for the same allegations. They have been found marketing off-label uses of prescription drugs, which is illegal.

"Although it is legal for physicians to prescribe off-label uses of drugs that are not approved by the U.S. Food and Drug Administration (FDA), it is illegal for drug manufacturers to market such usages without the approval of the FDA."

Although it is legal for physicians to prescribe off-label uses of drugs that are not approved by the U.S. Food and Drug Administration (FDA), it is illegal for drug manufacturers to market such usages without the approval of the FDA. The rationale for this distinction is that physicians may become aware of the beneficial therapeutic effects. An example would be aspirin: physicians many prescribe it for reducing the onset of heart disease.

Pfizer is racking up significant fines due to the illegal use of off-label promotion for several prescription products. In September 2009, they settled a criminal case with the DOJ by agreeing to pay the government $1.3 billion in fines for marketing off-label uses for Bextra-Vioxx "cousin" pain reliever (both were removed from the market due to safety concerns). As part of the same settlement, Pfizer paid another $1 billion to settle whistleblower cases alleging marketing off-label use of Zyvox (an antibiotic), Geodon (anti-schizophrenia and anti-mania), and Lyrica (fibromyalgia and nerve pain). Combined, the fines totaled the historical $2.3 billion dollars.

In another settlement involving marketing of Geodon, Pfizer agreed to pay $33 million to 42 states and the District of Columbia to resolve civil consumer protection claims.

In 2004, Pfizer paid $430 million to settle allegations of marketing off-label uses of Neurotin, originally approved for anti-seizure use in patients with epilepsy. A portion of this settlement helped to fund over two dozen prescriber education grants to help increase professional awareness of pharmaceutical influences, including off-label prescribing. Last year, Consumers Union received a $4.4 million grant from the same settlement to raise consumer awareness about similar issues. Details can be found at **www.consumersunion.org/pub/core_health_care/005581.html**.

As always with legal actions against drug makers, it is unclear whether even such a massive fine will deter similar behaviors from other drug makers, given the economic power of the drug industry. ■

AARP Federal Advocacy

Right now Congress is grappling with how to overhaul our nation's health care system. AARP is fighting to guarantee all Americans have access to affordable, quality health coverage. For our members with Medicare coverage, the doughnut hole stands out as a major affordability concern and a real barrier to access. That's why AARP is fighting to ensure that Congress closes the doughnut hole.

More than 3 million people fall into the doughnut hole each year, and millions more live in fear of reaching this dangerous gap in coverage. Research shows that people who have trouble paying for their prescription drugs are more likely to skip doses or stop taking medications altogether, which can lead to more serious health problems and higher long-term costs for both them and for our health care system.

In addition to closing the doughnut hole, AARP is also working on several other prescription drug issues, including:

- Fighting to bring less costly generic versions of biologic drugs (typically very expensive drugs made out of living organisms and tissue, and that treat diseases such as cancer, multiple sclerosis and rheumatoid arthritis) to market in a safe and timely way;
- Pushing for measures that allow for the safe and legal importation of lower cost prescription drugs from abroad;
- Advocating that the Secretary of the Department of Health and Human Services be given the power to negotiate with the pharmaceutical companies for lower prescription drug prices.

For more information on AARP's health care reform effort, please visit **www.aarp.org/health/articles_health_reform_get_the_facts.html**. ■

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of lawsuits and safety issues with some drugs—the Vioxx debacle, for example—the momentum is growing for objective, evidence-based methods of getting accurate information into the hands of physicians and other prescribers. One strategy that has shown particular promise is academic detailing.

Cost-Savings for States

The good news for state policy makers is that academic detailing is not only good for prescribers and their patient's health outcomes but it is cost effective too. While not originally designed to do so, these programs may produce substantial savings for Medicaid programs and other large purchasers, such as Kaiser Permanente, which has its own academic detailing program.

By one estimate, every dollar spent on an academic detailing program returns two dollars in reduced drug costs. This estimate, reported by the Pew Prescription Project, was developed from an economic model by researchers at the Harvard Medical School and Brigham and Women's Hospital, and published in the *New England Journal of Medicine*.

Another analysis was done in Pennsylvania's academic detailing program, within their Pharmaceutical Assistance Contract for the Elderly Program (PACE). The analysis was done by the Independent Drug Information Service, which is affiliated with Harvard Medical School, on the information on several classes of drugs. One preliminary economic analysis—for just one drug class—focused solely on an acid-reflux medication and its cheaper equivalent. They found reduced drug costs of approximately $120 per doctor per month.

According the Pew Prescription Project's report, *Cost-Effectiveness of Prescriber Education ("Academic Detailing" Programs)*, the heaviest prescribers showed a reduction of $378 per month. Worth noting is that the savings shown is just for one single class of drugs and only for those in the PACE program, who make up just a fraction of the caseload of any physician.

Other savings in using academic detailing include the increased use of generics (underuse of generics cost the U.S. health system an estimated $8.8 billion each year). In looking at hypertension, for example, the evidence shows that for most patients the first drug of prescribers' choice would be inexpensive thiazide diuretic instead of one of the several new more expensive, heavily marketed drugs. The estimated savings is $433 million a year, according to a study cited by the Pew Prescription Project.

States' Experiences

Pennsylvania

Not everyone likes to boast about cost savings. Tom Snedden, director of Pennsylvania's PACE and academic detailing program, doesn't want to even know how much money the state saves, he says. "Once you start putting a lot of numbers out there, and you measure your success that way and publicize it, you just end up alienating the physician community. Then docs think it is all about saving money," Snedden said.

> **"What I find is many states don't optimize the use of their resources to control the misutilization of drugs. They need to be more assertive and take a closer look at their processes."**

Snedden said it was never about the money when he developed both the academic detailing and the PACE program. "Never in the 18 years did we look back to see what it saved. Did it save us money? Undoubtedly yes. But if they are taking medications that are going to kill people or harm them, who is thinking about the money? And if it is keeping people out of hospitals and I know it is, then I know we are saving Medicare and Medicaid money. I bet the savings is astronomical," Snedden said.

Snedden's advice to other states, as he often gives regarding academic detailing, is to complement academic detailing with other approaches. "You can't expect academic detailing to be a panacea as the biggest cost saver—it needs to be coupled with other strategies," Snedden said. He recommends strategies like drug utilization and using an online real-time adjudication process. "What I find is many states don't optimize the use of their resources to control the misutilization of drugs. They need to be more assertive and take a closer look at their processes."

South Carolina

"I wasn't sure about their goals when they first approached me, maybe a little reticent about it, but I liked their approach towards education and utilization of a given topic of the class of drugs," said Internist Irwin Linton, M.D., of Charleston, South Carolina. And now I find it extremely helpful and convenient for my schedule."

Dr. Linton is referring the academic detailers who have visited him to present evidence-based research and useful information on mental health drugs. "The primary difference between these pharmacists/academic detailers and pharmaceutical sales representatives is that the academic detailers pose questions, help resolve problems and have a scope of knowledge that is broader and more in-depth. They discuss the pros and cons to each of the drugs and bend over backwards to make sure we know they were not promoting any agent in a drug class," Linton said. "The more education we physicians can receive, the better. Our belief that we can master the intricacies of all the pharmaceutical agents is just not possible. I also have problems with computerized programs that spit out interactions and information—it may be pertinent to some of my patients, but not others. And I can't ask it questions and it doesn't help me problem solve. And I

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don't have time to do all this because I'm so busy seeing patients."

South Carolina is unique in that most of the academic detailing programs originated and are located in the northeast part of the U.S. "Kudos to Medicaid for their forward thinking," said Sarah Ball, director of the South Carolina Academic Detailing Program, and assistant professor at the South Carolina College of Pharmacy.

"Medicaid, in looking at their data, saw there was a need to improve the mental health of the beneficiaries and heard about academic detailing. "It is a research and operationally validated tool for achieving better outcomes and value from medical care, as a way to make that happen. The South Carolina Department of Health and Human Services subsequently entered into a contract with the College of Pharmacy to develop and implement academic detailing services," Ball said.

It is too early into the program to decisively tell whether the program has saved Medicaid any money, but Ball said "the focus is on making the best choices for the patients and what we know is if you get someone mentally well, the cost savings is tremendous."

Ball is hoping that supplemental funding can be found to continue and expand the academic detailing program. There are currently federal grants and other sources available and she said she is "anxiously confident and remains optimistic."

Idaho

There is a lot of territory to cover in Idaho, but in the academic detailing pilot project, it is getting done by just three people covering two large regions of the state. Tami Eide, Idaho's Medicaid Pharmacy Unit supervisor, and a pharmacist all said they wanted to concentrate on mental health drugs. Their program is unique in that they only meet with nurse practitioners—who in Idaho, are licensed to prescribe drugs without the oversight of a physician, and who see the majority of patients on Medicaid.

"We felt mental health drugs were not being used as appropriately as they could be—we were not looking to save money so much as we were to find ways to approach prescribers and get them to change their prescribing behavior versus having them use a preferred drug list. With mental health drugs, prescribing issues are not as clean cut as they are with other drugs. There is a lot of patient variability. Examples include using some of the drugs off label despite lack of good evidence suggesting it, using higher doses than recommended, etc. Our feeling is if we get the prescribers to use the best evidence-based drugs more effectively, we will save money," Eide said.

"We heard about academic detailing at a conference about drug utilization sponsored by the Community Catalyst and we read the Drug Effectiveness Review Project (DERP) guidelines and it seemed like a good way to approach this group of drugs," Eide continued. (see links below for more information on Community Catalyst and DERP).

Eide said after each visit, like most academic detailers, they do an evaluation and gain feedback from the prescribers to learn how they can improve their presentation or materials, find out if the physicians found it helpful and so forth.

It is too early into the program to decisively tell whether the program has saved Medicaid any money, but Ball said "the focus is on making the best choices for the patients and what we know is if you get someone mentally well, the cost savings is tremendous."

The feedback, Eide said, has been very positive. Idaho's program includes plans to finish these modules, measure the effort to see if they have changed prescribing behavior, and then possibly look at DERP's reviews on diabetes and asthma drug classes for future work.

Maine

Maine's academic detailing program is unique primarily because the Maine Medical Association (MMA) manages the program. Gordon Smith, the executive director of the MMA, said the association really embraced the program. "I think the state could have done a competitive contract, but because academic detailing was so new [state officials] wanted us [to manage the program] because they assumed physicians will take the information better from other physicians—they were worried otherwise they wouldn't get through the door," Smith said.

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Resources and Information on Academic Detailing

Independent Drug and Information Service
www.rxfacts.org/

Prescription Policy Choices
www.policychoices.org

Prescription Policy Choices Academic Detailing Toolkit
www.policychoices.org/AcademicDetailingToolkit_000.shtml

Drug Effectiveness Review Project
www.ohsu.edu/ohsuedu/research/policycenter/DERP/

Community Catalyst
www.communitycatalyst.org/about_us/

Community Catalyst: The Pew Prescription Project
www.prescriptionproject.org/

Prescriber Education Program

Maine (since 2009)

Structure: 2007 legislation mandated DHHS establish a program; DHHS has contracted with the Maine Medical Association and GHS Data Management; the MMA is subcontracting with the Independent Drug Information Service (iDiS) for training and materials; 2 detailers (both PAs)

Topics: Type 2 diabetes, anti-platelet therapy

Budget: The budget for 2009 is approximately $150,000, raised from fees of $1000 assessed on pharmaceutical manufacturers and labelers who market their products in the state of Maine (small, one-product companies are excluded from fee).

www.mainemed.com/academic/index.php

Vermont (since 1999)

Structure: The Dept. of Health directs the program in collaboration with the AG, the Univ. of VT AHEC program and Office of Vermont Health Access; recently expanded from 2 to 4 detailers (PharmD and MD)

Topics: Insomnia, depression, hypertension, cholesterol, heartburn

Budget: 2007 legislation enables Vermont to assess a 0.5 % fee on what the Office of Vermont Health Access spends on each manufacturer's or labeler's products. $200,000 of these fees is directed toward academic detailing. (PhRMA filed an unsuccessful challenge to this fee in 2007. In 2009, a Vermont District Court upheld the law enabling Vermont to collect the fee.)

www.med.uvm.edu/ahec/TB1+BL.asp?SiteAreaID=290

Massachusetts (since 2009)

Structure: The Dept. of Public Health directs the program in cooperation with Commonwealth Medicine; contracts with the Independent Drug Information Service (iDiS); 2 detailers (BSN/MPH, MD/MPH)

Topics: Type 2 diabetes

Budget: Massachusetts passed legislation on academic detailing in 2008, appropriating $500,000 from its general fund that was later cut to $200,000 due to budget constraints.

New York (since 2008)

Structure: Department of Health directs the program in cooperation with the State University of New York (SUNY) and the Univ. of Massachusetts Medical School; contracts with the Independent Drug Information Service; 20 detailers/8 FTEs (PharmDs)

Topics: Antibiotics, antipsychotics, hypertension

Budget: Supported by general funds offset by booked savings

www.nyhealth.gov/health_care/medicaid/program/prescriber_education/presceducationprog

Washington, DC (since 2009)

Structure: Department of Health is contracting with the Independent Drug Information Service; 2 detailers (RN/BSN, MD/MPH)

Topics: Type 2 diabetes

Budget: 2008 legislation allocated $500,000 from the general fund for implementation of SafeRx of which approximately $450,000 is dedicated for academic detailing.

Pennsylvania (since 2005)

Structure: Pennsylvania's drug assistance program (PACE) contracts with the Independent Drug Information Service (this is the original state contract for academic detailing with iDiS); 11 detailers/6.5 FTEs (RN, BSN, PharmD, MS, MBA)

Topics: Pain management, upper GI symptom treatments, anticoagulants, lipid-lowering therapies and blood pressure medication.

Budget: Pennsylvania's drug assistance program (PACE) supports its academic detailing program with a budget of $1 million a year financed through state lottery funds (not statutory). The development of the program was supported in part with funds from a multi-state settlement with a pharmaceutical manufacturer (Neurontin Consumer and Prescriber grant program).

www.rxfacts.org

South Carolina (since 2007)

Structure: South Carolina Medicaid program contracts with Univ. of South Carolina School of Pharmacy; 5 detailers/3 FTEs (PharmD and RPh)

Topics: Mental health focused (antipsychotics, antidepressants, and mood stabilizers)

Budget: Supported by a Medicaid grant of approximately $1 million a year.

Idaho (since 2009)

Structure: Focus is on clinicians serving large proportions of Medicaid patients; 3 detailers (PharmD, RPh)

Topics: Mental health drugs

Budget: This grant-funded pilot operates on a budget of $50,000, which includes funding through Medicaid match. Court upheld the law enabling Vermont to collect the fee.)

Oregon (since 2009)

Structure: Focus is on clinicians serving large proportions of Medicaid patients; 3 detailers (PharmD, RPh)

Topics: Mental health drugs

Budget: This grant-funded pilot operates on a budget of 50,000 which includes funding through Medicaid match.

New Hampshire

Structure: 2008 enabling legislation empowered the New Hampshire Medical Society to spearhead the program in conjunction with the AHECs under the direction of DHHS; no state funds were allocated to support the program; NHMS is exploring potential funding mechanisms.

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The MMA negotiated a contract with the state after legislation was passed and the funding was made available, set up an advisory committee, and worked with Prescription Policy Choices (PPC), a nonprofit organization with expertise in prescription drug policy. The detailers/clinicians received their training from the Independent Drug Information Service (IDIS) and use IDIS modules. The program began in August of 2009, according to Smith.

Other states have called on Smith seeking his advice on how to set up similar academic programs, and he tells them if it were not for the PPC, he doubts he would have done it. "Most medical societies don't have the resources to put together a robust program like this," said Smith, adding "now health plans, which also benefit from academic detailing, should also be big supporters of these programs."

Federal Action

There is federal legislation pending—The Independent Drug Education and Outreach Act of 2008 (IDEA Outreach Act of 2008)—that would establish federal funding in the form of grants for academic detailing programs offered to states. It is sponsored by Senator Kohl in the Senate and Representative Pallone in the House. If Congress took action on this legislation and it was passed into law, it would not affect existing or new state-based programs. ■

AARP

Rx Watchdog Report

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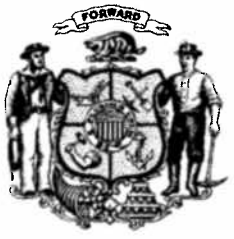
www.aarp.org/issues/rx_watchdog

WISCONSIN STATE LEGISLATURE



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention

April 2, 2010

To Whom It May Concern:

In 2009, the World Health Organization declared antimicrobial resistance one of the world's most pressing public health threats, a problem responsible for growing numbers of infections that are increasingly difficult to treat. Antimicrobial resistance has been shown to be directly correlated to antimicrobial use. Each year more than ten million courses of antibiotics are prescribed inappropriately for respiratory viral conditions. As a result, there is a public health need for provider-level antimicrobial prescribing data to identify prescribing patterns that can be used to focus and leverage public health interventions. Because CDC does not have a monitoring system designed to measure antimicrobial prescribing or sales, information from commercial sources is critical for supporting research and guiding public health efforts.

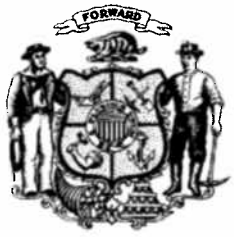
Antimicrobial prescribing and sales data gathered by commercial sources are used to determine areas of the country where prescribing is high and also offer insight into the provider specialties with the highest prescribing rates. By understanding where inappropriate antimicrobial use is occurring, interventions can be introduced to reduce the spread of antimicrobial resistance. The data can also be used to assess the impact of the interventions.

Monitoring antimicrobial prescribing is just one example of how provider-level data can be used for public health purposes. The recent H1N1 influenza pandemic provides another example of how commercial prescribing data can be used to respond to public health threats. Antiviral prescribing and sales data were used to identify areas of the country where antivirals were in short supply. Attempts to regulate access to provider-specific antimicrobial prescribing data should take into account the potential negative impact on public health.

Sincerely,

Lauri A. Hicks, DO
Medical Director, Get Smart: Know When Antibiotics Work
Centers for Disease Control and Prevention


WISCONSIN STATE LEGISLATURE


FORWARD

AARP

May 2010

Rx Watchdog Report

Shining a light on the cost and quality of prescription drugs

Brand Name And Specialty Drug Prices Continue To Climb

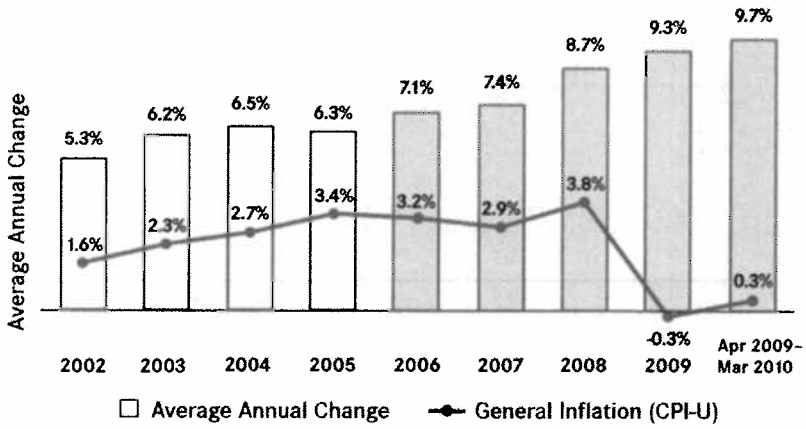
At the same time that Congress was putting the final touches on health care reform, manufacturers of brand-name and specialty prescription drugs were raising their prices at record rates. Despite a near-zero rate of inflation for all consumer goods and services, manufacturer prices for widely used brand name and specialty drugs rose by more than 9 percent, on average, in the twelve month period ending with March 2010, according to the AARP Public Policy Institute's most recent *Rx Watchdog Report*. In contrast, manufacturer prices for widely used generic drugs fell by an average of over 9 percent during the same time period. The report showed findings through the first quarter of 2010 on the pattern of manufacturer price changes for brand name, specialty, and generic drugs widely used by Medicare Part D beneficiaries.

Brand Name Drugs

Manufacturer prices for brand name drugs are clearly on an upward trend—the report found the highest percentage increase for brand name prescription drugs since the AARP Public Policy Institute began publishing the *Rx Watchdog* reports (see Figure 1). More specifically, the manufacturer prices of the brand name prescription drugs most widely used by Medicare beneficiaries increased by an average of 9.7 percent in the 12 months ending with March 2010. This far exceeded the rate of increase observed during any of the prior eight years, which ranged from 5.3 percent to 9.3 percent, and would be even higher if the analysis had excluded brand name drugs that are off patent. For the consumer, this is not good news. An older

continued on page 2

Figure 1. Average Annual Percentage Change in Manufacturer Prices for Widely Used Brand Name Prescription Drugs Continues to Increase in 2010



Note: Analyses for 2008, 2009, and 2010 exclude Zyrtec 10 mg tablets, which began to be sold over the counter, without a prescription in January 2008. Shaded bars indicate years when Medicare Part D was operational.

Health Reform To Reduce Drug Costs For Many Americans

Attention to the new health care reform legislation has largely focused on coverage and rather than cost control. But a vital part of the new law involves reducing the cost of prescription drugs for American consumers. Advocates working to lower drug costs achieved a number of victories: the Medicare Part D doughnut hole will be phased out; cost sharing on prescription drugs will be eliminated for chronically ill low-income Medicare beneficiaries; and the U.S. Food and Drug Administration (FDA) will now be allowed to approve lower-priced generic versions of biological drugs.

However, some goals were not achieved. Even after health reform legislation was signed into law, Medicare is still banned from directly negotiating with drug manufacturers for lower prescription drug prices in Part D; Americans still cannot legally import prescription drugs from other countries; and biologic drugs will not face competition for a longer period of time than many feel is necessary.

Good News: Closing the Part D Doughnut Hole

Each year millions of those covered by Medicare's Part D prescription drug program have medication costs so high that they hit the infamous **gap in coverage known as the** "doughnut hole." The doughnut hole is a gap in Medicare Part D coverage where enrollees are responsible for 100 percent of their prescription drug costs. In 2010, once an enrollee's total spending on prescription drugs reaches $2,830, the gap begins—Part D benefits are suspended and enrollees bear the full cost of their medications. After spending a total of $4,550 out-of-pocket for prescription drugs (including the deductible and cost sharing during the initial coverage period), the enrollee emerges from the gap and their Medicare benefits start again.

Under the new Health Care and Education Affordability Reconciliation Act of 2010, the

continued on last page

Table 1: All of the Top 25 Brand Name Prescription Drug Products Experienced a Manufacturer Price Change in The Past Year

Rank by Sales among Study Market basket*	Product Name, Strength, and Dosage Form	Package Size	Manufacturer	Therapeutic Class	% Change in WAC, Apr 2009–Mar 2010
1	Nexium 40 mg capsule	30	AstraZeneca	Ulcer Drugs (PPIs)	7.4%
2	Plavix 75 mg tablet	90	Bristol-Myers Squibb	Anticoagulants	10.5%
3	Prevacid 30 mg DR capsule	100	Takeda Pharmaceuticals	Ulcer Drugs (PPIs)	8.1%
4	Protonix 40 mg tablet	90	Wyeth	Ulcer Drugs (PPIs)	9.3%
5	Lipitor 20 mg tablet	90	Pfizer	Cholesterol Agents (HMG CoA)	5.5%
6	Lipitor 10 mg tablet	90	Pfizer	Cholesterol Agents (HMG CoA)	5.5%
7	Aricept 10 mg tablet	30	Eisai	Antidementia Agents	13.9%
8	Fosamax 70 mg tablet	4	Merck	Osteoporosis Agents	6.7%
9	Norvasc 10 mg tablet	90	Pfizer	Antihypertensives (CCBs)	5.0%
10	Advair Diskus 250-50 mist	60	GlaxoSmithKline	Respiratory Agents	7.0%
11	Lipitor 40 mg tablet	90	Pfizer	Cholesterol Agents (HMG CoA)	5.5%
12	Actonel 35 mg tablet	4	Warner Chilcott Pharm	Osteoporosis Agents	9.3%
13	Norvasc 5 mg tablet	90	Pfizer	Antihypertensives (CCBs)	5.0%
14	Celebrex 200 mg capsule	100	Pfizer	Anti-Inflammatory Agents	5.0%
15	Namenda 10 mg tablet	60	Forest	Antidementia Agents	7.6%
16	Singulair 10 mg tablet	30	Merck	Respiratory Agents	9.7%
17	Flomax 0.4 mg capsule	100	Boehringer Ingelheim	Prostatic Hypertrophy Agents	27.6%
18	Zetia 10 mg tablet	30	Merck/Schering-Plough	Cholesterol Agents (HMG CoA)	10.8%
19	Lexapro 10 mg tablet	100	Forest	Antidepressants (SSRIs)	6.4%
20	Lantus 100/ml inj	10	Sanofi-Aventis	Antidiabetics (Insulins)	7.5%
21	Zocor 20 mg tablet	30	Merck	Cholesterol Agents (HMG CoA)	6.3%
22	Ambien 10 mg tablet	100	Sanofi-Aventis	Sedatives	13.9%
23	Seroquel 200 mg tablet	100	AstraZeneca	Antipsychotics	15.6%
24	Zocor 40 mg tablet	30	Merck	Cholesterol Agents (HMG CoA)	6.3%
25	Avandia 4 mg tablet	30	GlaxoSmithKline	Antidiabetics (Oral)	11.6%
General rate of inflation (as measured by growth in CPI-U)					**0.3%**

**Ranking based on prescriptions processed by the Medicare Part D plan provider during 2006.*

American who takes three brand name medications on a chronic basis is likely to have experienced an average increase in the cost of therapy of more than $700 during the 12 months ending in March 2010, assuming that the manufacturers' price increases were passed along in the form of higher prices.

The report also found that 192 of the 219 brand name drugs (88%) in the market basket experienced a manufacturer price increase in the 12-month period. Twenty-seven (12%) of the 219 brand name drugs products had no change in price during the same period; only two of these products were still under patent (see Table 1). All of the 25 most widely used brand name drug products had price increases of at least 5 percent, including 7 that had double-digit price increases. This indicates that manufacturer price increases for brand name drugs tend to slow or stop once they face generic competition.

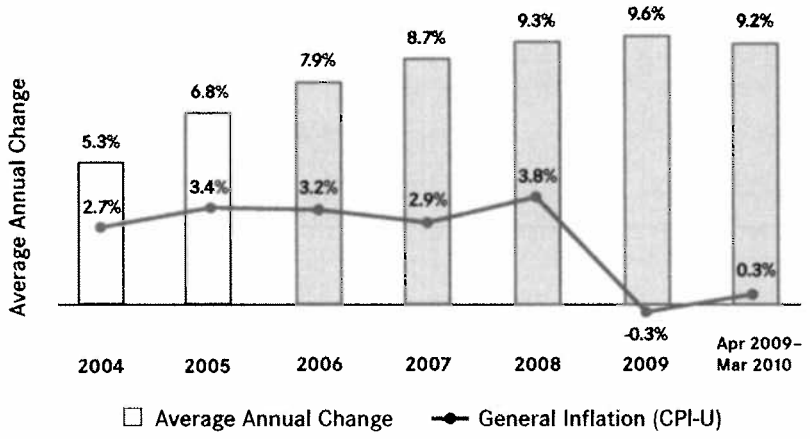
Specialty Drugs

The manufacturer prices of 144 specialty prescriptions most widely used by Medicare beneficiaries increased by an average of 9.2% in the 12 months ending with March 2010 (see Figure 2). If the 52 drug products in the specialty market basket that are off-patent are excluded from the analysis, the average manufacturer price change is actually 9.8% over

continued on page 3

Brand Name And Specialty Drug Prices Continue To Climb continued

Figure 2: Average Annual Percent Change in Manufacturer Prices for Widely Used Specialty Prescription Drugs Remain High in 2010



Note: Shaded bars indicate years when Medicare Part D was operational

this time period. A specialty drug is one that is often used to treat chronic illness, such as multiple sclerosis or cancer, and is typically very expensive.

An example of a specialty drug is the newly approved Provenge, which is used to treat prostate cancer. Each infusion of Provenge will cost $31,000, bringing the full cost of treatment for three infusions to $93,000. According to experts, the drug will cost an average of about $23,000 per month of life extension, based on the Phase II study that found the drug extended life by 4.1 months. Additionally, Dendreon, the drug's manufacturer, said that initially the demand will outpace the supply as they build their out their manufacturing sites.

90 of the 144 (about two-thirds) drug products in the specialty market basket experienced a manufacturer price increase in the 12-month period ending with the first quarter of 2010. Two of the 144 specialty drug products had a decrease in price; both of these were generics. One-third (52 of 144) of the specialty drug products had no change in price in the same period; most of the drug products with no price change were generics or off-patent brands.

Generic Drugs

The good news is that the manufacturer prices of generic prescription drugs widely used by Medicare beneficiaries decreased by an average of 9.7 percent in the 12 months ending with March 2010. For an individual who takes three generic prescriptions on a chronic basis, the average cost of therapy decreased by $51

"The good news is that the manufacturer prices of generic prescription drugs widely used by Medicare beneficiaries decreased by an average of 9.7 percent in the 12 months ending with March 2010."

in the 12 months ending with the first quarter of 2010, assuming that the price decreases were passed along in the form of lower prices.

Combined Market Basket

When combined, the average annual rate of increase for all of the drugs analyzed —brand, specialty and generic—was 5.3 percent in the 12 months ending with the first quarter of 2010. This combined rate of growth for drug prices is attributable to continuing high levels of manufacturer price growth among brand name and specialty drugs that more than offset the substantial price decreases among generic drugs.

The Impact Of Higher Drug Pricing

Higher drug prices can raise Medicare beneficiaries' costs, particularly for those beneficiaries who pay a percentage of drug costs, referred to as a coinsurance, rather than a fixed amount, known as a copayment.

Higher drug prices also push more Part D enrollees into the dreaded "doughnut hole"—the gap in coverage when enrollees have to pay 100 percent of their prescription drug costs every year. And, once in the doughnut hole, enrollees pay for the full effects of the higher manufacturer prices. Furthermore, if escalating drug prices are not addressed, the substantial value of closing the doughnut hole could be eroded over the years.

Also, higher prices to retail pharmacies are generally passed on as higher costs to consumers and drug plans. Higher drug costs to plans may also result in reduced benefits and higher premiums for enrollees.

The impact of manufacturer price increases will be substantial for those persons taking brand name medications which have grown in price by an average of 9.7 percent in the 12 months ending with the first quarter of 2010. Even more challenging will be affording the price of high-cost specialty drugs which have grown in price by an average of 9.2 percent over the same period. And even though generic drug prices have decreased by an average of 9.7 percent, it is not sufficient to offset price increases of brand and specialty medications.

For the full AARP Public Policy Institute *Rx Watchdog Report* "Brand Name Drug Prices Continue to Climb Despite Low General Inflation Rate" go to: **www.aarp.org/research/ppi/health-care/medicare/articles/rx_watchdog.html** ■

Health Reform To Reduce Drug Costs For Many Americans continued

doughnut hole will gradually be eliminated. As the first step, Part D enrollees who hit the doughnut hole in 2010 will receive a $250 rebate check.

This $250 payment could be made to about 4 million Medicare beneficiaries this year. While the Centers for Medicare and Medicaid Services (CMS) have not finalized the process, it is anticipated that checks will be issued automatically after an individual enters the doughnut hole.

Low-income Medicare Part D enrollees who receive the Low-Income Subsidy (also known as "Extra Help") will **not** receive the $250 rebate since their costs are already covered by the federal government. However, while CMS has not issued final rules, it is expected that Part D enrollees whose cost-sharing is paid for by State Pharmaceutical Assistance Programs (SPAPs) will receive the $250 payment after they enter the doughnut hole, even if the SPAP pays some or all of their prescription drug costs while they are in it.

The real action on closing the doughnut hole, however, starts in 2011. Beginning that year, drug manufacturers will be required to provide 50 percent discounts to Part D enrollees while they are in the doughnut hole. In addition, the Medicare program will provide a 7 percent discount on generic prescription drugs for Part D enrollees while they are in the doughnut hole. Starting in 2013, Medicare will also begin providing a discount on brand-name drugs. Medicare will gradually increase its discounts on generic and brand-name drugs each year, so that by 2020 Part D enrollees will only be responsible for 25 percent of their prescription drug costs while they are in the doughnut hole. Thus, enrollees will have the same level of coverage from the time they meet their deductible to the time they reach catastrophic coverage.

Another change in Medicare Part D is the elimination of out-of-pocket drug costs for chronically ill Part D enrollees who are also enrolled in Medicare and who receive home and community based services rather than going into a nursing home. If these enrollees were in a nursing home, they would pay nothing for Part D drugs. This new provision gives the same protection to beneficiaries who are similarly sick or incapacitated but are able to remain in their own homes.

More Good News: Cheaper Biologics—in the Long Run

Another health reform victory for consumers is a provision that finally creates a system for the FDA to approve generic versions of biologic drugs, or "biosimilars". Biologic drugs differ from conventional pharmaceuticals in that they are derived from living organisms, rather than from chemical compounds. Once prescribed to treat only rare genetic diseases, biologics have rapidly become a more common treatment option for people with conditions such as multiple sclerosis, diabetes, cancer, and rheumatoid arthritis. They are also typically expensive: some treatments can cost tens to hundreds of thousands of dollars per year. Although European countries have successfully been using biosimilars for several years, in the U.S. there was virtually no legal mechanism for the FDA to approve similar drugs. But thanks to the new law, the FDA will be able to approve them. However, brand name biologic manufacturers will be protected from competition with 12 years of market exclusivity, during which no lower-priced biosimilars may be sold. It will take a while to get the approval process started, and experts don't expect the first biosimilar drugs to be on the market for several years. (For more information about the issue of market exclusivity for biologic drugs, see the May 2009 and August 2009 issues of AARP's *Rx Watchdog Report* at **www.aarp.org/watchdog**.)

The Bad News: Some Savings Were Left on the Table

Even with these victories, the health reform bill doesn't contain everything that consumers wanted. For example, although drug manufacturers will be providing discounts to Medicare beneficiaries who fall into the doughnut hole, there won't be any constraints on far much manufacturers can raise their prices. During the 12 months ending March 31, 2010, manufacturers raised prices on brand-name drugs by an average of 9.7 percent (see lead article), continuing an upward trend in drug price increases. Across Part D plans, even enrollees who do not fall into the coverage gap still face cost-sharing for brand-name drugs of $40 to $95 per prescription, excluding "specialty tier" drugs which have cost-sharing of 30 to 40 percent or more.

The health reform law did not include two tools that could have been used as leverage to get lower prices from manufacturers. First, the law keeps in place a provision that prohibits Medicare from negotiating directly with drug manufacturers to achieve lower prices for Medicare Part D enrollees. Second, the law does not include a provision to allow safe importation of prescription drugs from countries such as Canada and European Union members.

In addition, some observers believe that the law gives excessive protections to manufacturers of brand name biologic drugs. While many advocates, including AARP, sought to limit market exclusivity, the drug industry was still able to obtain 12 years of market exclusivity. Such a long period of exclusivity also contradicted the findings of the Federal Trade Commission, which concluded that brand name biologic manufacturers did not need any market exclusivity, and that 12 years actually negatively impacts innovation. "This means extra years that consumers, insurers, and Medicare will be paying incredibly high prices for these drugs," said AARP Executive Vice President John Rother.

"Health reform clearly means lower drug costs for consumer," Rother continued, "but our work isn't over. There is still a lot of room to improve the market even more, and that's why AARP will continue to fight for Medicare negotiating authority and safe drug importation." ■

Ed Dale contributed to this article

AARP

Rx Watchdog Report

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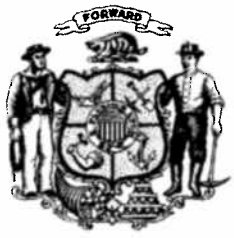
FORWARD

Milwaukee Journal Sentinel: Your Opinions

Posted: May 3, 2010

HEALTH CARE

Sunshine provision will help patients

In addition to providing Americans with access to quality affordable health care, the new health reform law will also bring much needed transparency to the financial relationships between the pharmaceutical industry and physicians.

The law includes provisions from the Physician Payments Sunshine Act, co-sponsored by Sens. Chuck Grassley (R-Iowa) and Herb Kohl (D-Wis.), that would require drug and device companies to publicly report the gifts and payments they make to doctors.

According to the New England Journal of Medicine, more than 90% of physicians have some financial relationship with the pharmaceutical industry. Pharmaceutical companies spend at least $25 billion each year marketing to doctors, which can create potential conflicts of interest that unduly influence prescribing and drive up costs.

Patients deserve to know if their doctors are receiving money from drug companies, and now they will. The new reporting requirements will enhance the safety of consumers and help restore trust in our health care system.

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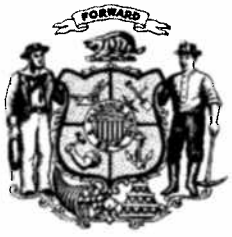
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May 21, 2010

The Honorable Jon Erpenbach
Chair, Senate Committee on Health,
Health Insurance, Privacy, Property Tax Relief, and Revenue

Representative Peggy Krusick
Chair, Assembly Committee on Aging and Long-Term Care

Testimony regarding the issue of provider level data.

Senator Erpenbach and Representative Krusick:

IMS Health appreciates the opportunity to participate in this informational hearing and applauds your efforts to gather information prior to the introduction of legislation. Often this has not been the case, and the result can be unintended consequences arise that are quite different from legislative intent. While I will make my oral remarks short and focused on the discussion of the day, the issue of medical data, their uses (both commercial and non-commercial) is complex and full of mutual inter-relationships. Unfortunately, the assertions of those advocating banning commercial use apply straight one-on-one relationships that ignore the downstream impact of denying properly anonymous information to flow freely. I request that my complete statement be entered into the record so that Members can more fully examine our perspective before judging their merits.

IMS Health is an international health information company with its headquarters in Norwalk, Connecticut. We employ over 1500 employees in the United States, many of whom have advanced degrees in data management, statistics and other quantitative skills. IMS Health provides information and consulting services to a diverse range of healthcare stakeholders in the public and private sectors in over 100 countries around the world. Our primary interest is to preserve critical data assets and the flow of anonymous data that our nation will need to face the serious healthcare challenges ahead, and to inform efforts to improve quality and longevity for our population at an affordable price. We support efforts to protect the privacy of personal health information for patients and applaud efforts to establish and disseminate best practices. Our own policies and practices to protect patient privacy currently include multiple encryption techniques and many overlapping safeguards so that the data we provide to assist healthcare stakeholders in no way allow identification of individual patients. We fully expect these

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practices to change in response to new risks and technology to maintain patient trust and secure critical data assets for future use.

IMS understands the need to manage healthcare costs. Collectively, our quality of life depends upon it. We applaud your efforts to manage utilization and to increase the appropriate use of generics, which now represents well over 70% of all prescription products dispensed in this country. Many healthcare reform initiatives are being proposed at the state and federal levels, and there is a complex and interdependent set of alternatives and possible solutions under consideration. Successful implementation, quality improvement, safety and appropriate outcomes will depend upon local care and systems to provide accurately and timely evidence-based information to enable reform while protecting patients from unintended consequences. It is well recognized by this as well as the past four administrations of both political parties as well as the Institute of Medicine that such an effort will require the public and private sectors to work together toward common goals and incentives.

That fact is at the core of our efforts to participate in a broad effort to advance the knowledge drawn from proper, anonymous health data. Today, IMS data support hundreds of health research studies annually. Further, these data are utilized by the medical community, states/territories and government agencies to monitor and inform decisions about patient care.

> *In one important example, the CDC used IMS data to monitor utilization of antiviral drugs as a surrogate for the advance of H1N1 flu. Analyses showed populations affected and rates of change on a timely basis that alternative government databases do not reveal, thus providing a more powerful tool to the CDC in pursuit of patient care. Our experience strongly suggests that IMS (private sector) data affords a differential advantage in terms of its granularity and timeliness, two factors that apply similarly to the national challenges ahead.*
> *It is also of great importance to us that the principles that will guide healthcare reform going forward are protected and preserved today.*

That is why IMS supports legislation that recognizes the value and utility of health data that does not compromise the privacy of individual patients, and is against data restriction laws which impede the free flow of important information. These legislative proposals undermine the principle of transparency, which is an underlying tenet in healthcare reform. Health care experts, agencies and thought-leaders of political parties as well as AARP, SEIU, and a host of consumer advocacy organizations have repeatedly stated the importance of maintaining transparency. Without such transparency, professional accountability is lost.

Legislative efforts to restrict data to specific stakeholders in the healthcare system have been justified over time by a shifting set of rationales, with little if any substance in facts.

Initially, they were framed by their proponents in the context of patient and physician privacy…

- "They interfere with the physician/patient relationship."
- Of course, these aspersions are intended to garner support and raise the level of fear around this issue when, in fact, no such risk exists. Of particular importance, two federal judges examined the matter through actual testimony and decided there is no inherent privacy issue, supporting our contention that there was intentional exaggeration by some of the proponents of these bills in the first place.
- In addition, HHS is currently seeking providers to test current practices to protect patient privacy as a means to improve these practices, not to undermine access to the data.

It seems that privacy advocates at times are willing to mislead and work against national efforts to secure anonymous data for the healthcare system.

When these privacy arguments failed, it was suggested that these laws would reduce costs. This is a popular theme, but to date no information has been provided by proponents of these laws to support such a conclusion; and there is significant information to the contrary that suggests marketplace practices already exist to manage cost, without the need for data restrictions that may compromise patient care:

- New Hampshire restricted these data for approximately 9 months in 2006-2007; with no reported impact on costs. If the availability of these data drives costs, how does one account for that?
- In Vermont, witnesses for the state indicated that the measurement of any impact from a data restriction law would take years. This would only be the case if these data have only a minimal (if any) impact on costs, requiring sufficient time and numbers to measure?
- The dispensing of new brand medications (products with a market presence of 3 or less years) has declined from 5.7% of total prescriptions dispensed in 2003 to only 1.3% in 2008. At the same time, generic medication grew to represent over 70% of dispensed prescriptions in 2008. How would that lead one to conclude that these data were causing physicians to prescribe brand medications inappropriately?

- From 1999 to 2007, the use of prescriber-level data by pharmaceutical research company representatives increased by nearly 56% while the annual rate of prescription drug spend growth plummeted from over 15% to only 1.6%. In 2008, there was a negative growth rate recorded for drug spend.

- Of particular importance, managed prescription programs and practices are much more influential in determining what is dispensed and offer powerful alternatives to data restrictions. Based on clinical and cost considerations, using active formulary management, patient education, tiered co-pays, and offering patients lower-cost equivalents (generic or brand) when appropriate, managed prescription programs continue to lower costs. And they have done so in spite of price increases and a 31% increase in the overall number of prescriptions dispensed from 2003 to 2008.

- Managed prescription programs are well established and effective in managing utilization and costs. Today, generic prescribing uptake and share have achieved a national average of more than 70% of dispensed prescriptions. Once again, how would one conclude that payers in the public or private sectors were being over-run by rampant or irrational prescribing practices?

In essence, the intent by proponents of banning commercial use of these data is intended to work by slowing the use of all commercially marketed medications, whether their use is desirable or not! Such efforts do not discriminate between desirable or undesirable drugs as is the case in the context of formulary management. These efforts provide no appeal process for breakthrough drugs or improvements that extend life or improve quality of care...not even for drugs that reduce overall healthcare costs. As a result, they risk patient care by intentionally impeding the process that brings medical breakthroughs to patients on a timely basis.

- Slowing this process effectively delays treatment. That means patients who can benefit from newer medications may be harmed.

- This law affects all products regardless of patient benefit. Life-saving medications and documented advances will be impacted the same as marginal improvements. The lives and safety of patients in need of breakthrough treatments for devastating diseases such as cancer, HIV, Epilepsy and "orphan" ailments would be jeopardized by the passage of this bill.

- Data restriction would undermine efforts to support risk management programs, without which important medicines may not reach patients.

Proponents assert that the medical marketplace will disseminate all the information required for patient care when in fact studies published in the New England Journal of Medicine showed that patients are not routinely treated according to best practices. Further, the Institute of Medicine indicated that dissemination of proven practices throughout the healthcare system can take as long as 17 years, even with these data available!

In light of these fundamental and harmful flaws, IMS suggests that legislation banning this information would remove one of the tools that support timely dissemination of product information, quality improvement, patient safety and continuous education.

- Furthermore, banning this information risks the health of a robust biotechnology industry as members of the bioscience industry attest; these data allow a more efficient process for bringing medical innovation to patients. Without these data, marketing costs will increase and there will be a need for a relatively larger sales force. It is clear this information allows small companies to compete with large companies and fuels the emergent biotech companies that employ small sales forces to reach few physicians...who treat the small populations who may benefit (The proverbial needle in a haystack).

- "In one documented case study, the Massachusetts Biotechnology Council illustrates the potential harm to patients. Massachusetts Biotechnology Council Case Study re: Banzel, for the treatment of Lennox-Gastaut Syndrome. The attached case study "Treatment Delayed is Treatment Denied" shows the impact of data restrictions in New Hampshire on the care process as it relates to a new drug for Lennox-Gastaut Syndrome (LGS). LGS is a rare and catastrophic form of epilepsy in children 4 years and older and adults. The case study points out how a data restriction law in New Hampshire "may increase the time it takes to get new drugs to patients, and certainly reduce effectiveness and efficiency in the dissemination of information that impact patient care...potentially delaying access to an effective product for a catastrophic illness."

Finally, we object to the idea that government should decide who has access to and the use of information. Government deciding to block the flow of information because it wants to control market behavior represents a very dangerous precedent. Moreover, this type of ill-advised blockade of information has been considered and rejected in more than 20 states over the last several years. To those who assert that this is "settled law", it is not. The U.S. Supreme Court has turned down a petition for certiorari on the First Circuit Court of Appeals opinion without comment either way. At the time of that decision, there were two other active cases at the Circuit Court of Appeals level. Those cases are still pending as are the further appeals from either side when those decisions are rendered. This is anything but "settled law".

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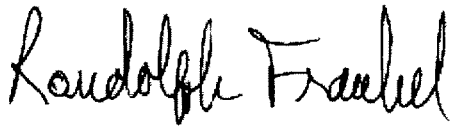
In conclusion, IMS welcomes further inquiry into the uses of these data, and holds to its belief that the inter-relationship and inter dependency of both commercial and non-commercial use of these data is a valuable national asset that should not be compromised. We urge you and your committee to move carefully when denying the public access to such valuable information.

Respectfully submitted,



Randolph Frankel
Vice President, IMS Health

c.c.:
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Senator Julie Lassa
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Senator Ted Kanavas

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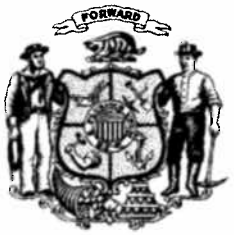
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CWAG

"Advocating for All Generations"

The Coalition of Wisconsin Aging Groups is a nonprofit, nonpartisan, statewide membership organization that was founded in 1978.

Coalition of Wisconsin Aging Groups
Intergenerational Leadership Development • Education • Advocacy • Elder Law Center

For Immediate Release:

Contact:
A.J. Nino Amato
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Wisconsin Prescription Drug Reform Coalition to Fight Influence of the Pharmaceutical Industry

State Legislative Public Hearing on Rx Reform in Wisconsin – May 25, 2010

(Madison, WI) - On the morning of Wednesday, May 26th (10:00 am to 12:30PM), the Wisconsin Prescription Drug Reform Coalition consisting of: Coalition of Wisconsin Aging Groups (CWAG), AARP Wisconsin, Wisconsin Alliance of Retired Americans (WIARA), Citizen Action Coalition, Wisconsin's Nurses Association, Pew Prescription Project, Community Catalyst and other consumer health care advocates and medical health care professionals, will propose four separate pieces of prescription drug reform legislation that will be heard at a joint public hearing of the Wisconsin Senate and Assembly Health Care Committees. National experts and consumers will also testify about how prescription drug reform legislation has successfully worked in other states and lowered prescription drug costs.

"Frustration about the pharmaceutical industry sales, advertising and marketing practices is at an all-time high," said Nino Amato, President of the Coalition of Wisconsin Aging Groups, who directs the work and advocacy of the coalition. "Wisconsin's consumers, doctors, health care providers and policymakers believe that there must be something done to curb the influence of the pharmaceutical companies and their lobbyists on health care decision in Wisconsin and the United States," said Amato.

According to the New England Journal of Medicine, more than 90% of physicians have some financial relationship with the pharmaceutical industry. "Pharmaceutical companies spend more money on sales and marketing than they do on research and development," said Billy Feitlinger, Executive Director of the Wisconsin Alliance of Retired Americans.

Spending on direct TV advertising, sales and marketing, promotional gifts, entertainment and education seminars by the pharmaceutical industry is estimated at nearly $30 billion - much of it directed at consumers who prescribe medications. The Wisconsin Prescription Drug Reform Coalition is working to reduce the current conflicts of interest between the pharmaceutical industry and health care prescribers and, at the same time, we want to make sure that Wisconsin patients and consumers get the highest quality prescriptions available by giving doctors nonbiased prescription drug research information.

"Based on national research and investigative journalism, too many conflicts of interest exist between the pharmaceutical industry and physicians/prescribers are undermining evidence based health care decisions and contributing to the skyrocketing costs of prescription drugs." said D'Anna Bowman, State Director of AARP Wisconsin.

The Wisconsin Prescription Drug Reform Coalition believe that no one should come between health care decisions made between doctors and patients - certainly not the pharmaceutical lobbyists and their public relation and advertising firms.

The four separate pieces of prescription drug reform legislation that will be proposed at the May 26th legislative hearing are:

- Legislation that will ban gifts and entertainment to health care providers from pharmaceutical manufacturers and improve transparency and reporting laws that more clearly define relationships between health care providers and the pharmaceutical industry.

- Public transparency for all pharmaceutical educational and financial research grants that are given to University of Wisconsin facility and researchers. The University of Wisconsin System would be required to publish all education and financial grant information from pharmaceutical companies.

- Legislation to establish an "academic detailing" program to give physicians nonbiased information to make the best and most cost-effective decision about prescriptions, using an evidence-based prescription drug research. Health care providers and doctors would be able to access this information, which would improve their health care decision, made between them and their patients.

- Legislation that will prohibit pharmaceutical companies from buying doctors' prescribing records and using the information to target their sales and marketing strategies to individual doctors. This would prohibit Pharmaceutical Data Mining in Wisconsin.

In summary, there are too many conflicts of interest that exist between the pharmaceutical industry and physicians and prescribers which undermine health care and contribute to the skyrocketing costs of prescription drugs. Now is the time for Wisconsin leaders to follow the legislation that has passed in Minnesota and Pennsylvania.

For more information, please contact one of the following coalition members:

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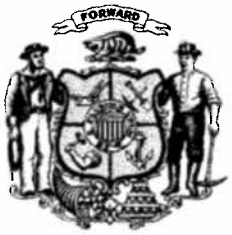
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Wisconsin Medical Society

Your Doctor. Your Health.

TO: Senate Committee on Health, Health Insurance, Privacy, Property Tax Relief and Revenue
Senator Jon Erpenbach, Chair
Assembly Committee on Aging and Long-Term Care
Representative Peggy Krusick, Chair

FROM: Tim Bartholow, MD – Senior Vice President

DATE: May 26, 2010

RE: Information on Transparency and Conflicts of Interest

On behalf of the nearly 12,500 members of the Wisconsin Medical Society, thank you for this opportunity to address the Committees on matters involving improving health outcomes and containing costs. The Society is proud to note that our conversation today happens against the backdrop of the federal Agency for Healthcare Research and Quality (AHRQ) in 2009 ranking Wisconsin as having the best overall health quality score in the nation. Physicians are pleased with this status, of course, but Wisconsin's physicians seek to do ever better.

The Society is on the record when it comes to transparency and we have provided the Committees a copy of our Transparency Principles. We believe the complex health care environment requires information for consumers and purchasers, as well as doctors, to know what is the next wisest investigation or treatment. While we will provide each patient with the care they need, gone are the days when doctors simply write the prescription, or order the test or treatment, without regard to the cost impact to the patient or the system. We have undertaken study of the some of the most expensive areas of health care delivery and have identified areas for investigation that we are confident will only further enhance the high quality, low cost status among states. But because care is still not affordable for so many, we cannot rest.

The Society also has made specific statements about conflict of interest which we also share today. Wisconsin residents need to know that when they go into that exam room with their doctor, only the patient's interests are being served, and that the partnership in care between the patient and physician does not have any invisible partners with other goals. We will all be patients, including all doctors, at one time or another; this absence of conflict is the only proper way to act.

The path toward transparency and clarification of potential conflict of interest has made significant gains, yet has a distance to go. We are hesitant to endorse legislative mandates in these areas, however, due to the potential for unintended consequences impacting these very complex areas. In order to protect the patient's relationship with their doctor, we must continue the efforts we have already initiated while striving for further improvements.

Thank you again for this opportunity. The Society looks forward to continued partnership with the State Legislature as we work to maintain our status as the nation's top source for high-quality health care.

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Wisconsin Medical Society Transparency Principles

Approved by the Board of Directors October 11, 2008

- The Society believes the relationship between the Patient and Physician is critical to positive health outcomes. Transparency efforts should not supersede or unnecessarily impact the patient-physician trust.
- The Society believes there is benefit to using a common database of health care information that is aggregated across key stakeholder groups for multiple uses, including quality improvement, population health research, public reporting, financial risk-sharing models and product development.
- The Society believes the value associated with the database is based on the credibility of the data, which results from the collaborative process and methodological rigor applied to these data products. The credibility must be preserved and enhanced as the scope, sources and uses of the data expand.
- The Society believes it is critical to deploy a collaborative system to measure error rates and gaps in the data, as well as performance variations. Stakeholders must commit to correct/improve these conditions over time and thus make fair and reasonable decision on public reporting of information.
- The Society believes that the use of nationally vetted and endorsed measures will serve to decrease variation and allow for improvements in health care delivery.
- The Society believes that Quality and Cost Measurement should be evidence-based and reported together whenever possible for stakeholder decision-making.
- The Society believes that it is essential, for the public good, that the measures derived from the database are reliable, valid and can favorably influence the outcome of patient care.
- The Society believes that a disciplined, neutrally operated appeals/dispute resolution policy, that audits data results and processes used to reach results, must accommodate the database. Further, if an appeal is significant and pervasive in the data, a moratorium on access to and use of the data must be activated until the data is remedied.
- The Society expects that users of the data would commit to the following:
    - o Users will use data in a way that is accurate, meaningful and statistically valid.
    - o Users will openly disclose to the physician community the objectives, measures and methods related to any use of performance data.
    - o Users will work to include the most effective risk adjustment as possible, and any adjustment methods included in the users analysis will be fully described including the limitations of such adjustments.
    - o Users will reference the source of the data and display its imprimatur.
    - o Users will develop and implement strategies for monitoring the impact of the implied uses of performance data that are not unduly burdensome.

Note: These principles do not replace Society Policy DHC-004. They are intended to provide a more general, yet succinct description of the Society's position on Transparency.

Wisconsin Medical Society

Your Doctor. Your Health.

Society Policy ETH-004: The Relationship of the Profession to the Health Product Industry

The Wisconsin Medical (Society) supports the following policy on accepting gifts from those who provide health products prescribed by physicians, including the pharmaceutical and device industries. Physicians shall accept no gifts from any provider of products that they prescribe to their patients such as personal items, office supplies, food, travel and time costs, or payment for participation in online CME. A complete ban eases the burdens of compliance, biased decision making, and patient distrust.

Medical philosophers from ancient to modern affirm the priority of patient interest as the cornerstone of medical professionalism and the first principle in resolving conflict of interest (COI) questions. High quality patient care and health outcomes depend on patient trust in physician advice. COI is ubiquitous in human relationships, including the patient-physician relationship, therefore, the profession and each physician every day must strive to acknowledge and manage COI in order to prevent avoidable bias in medical decision making. A physician's prescribing decision should be based on the best evidence available.

The reciprocal giving of gifts is an ancient human practice and likely has survival value by reinforcing social bonds. Health product companies have long offered gifts to physicians and the profession has long denied being influenced by these gifts. By distinguishing among possible gifts according to monetary value or value to patient care, ethicists have attempted to estimate the risk that specific gifts could bias medical decision making -- no doubt these distinctions have reduced the frequency of outrageous gifts, however, it is becoming apparent that any gift from a product provider to a product prescriber risks biased decision making, and at least, risks loss of patient trust in physician advice. Some conflicts can't be avoided, but avoidance of unnecessary conflicts is the cornerstone strategy of professional conflict management.

An article found in *JAMA* 2006: 295: 429-433 has renewed the western world's conversation about the commercial relationship between health product industries and the profession of medicine. Following their recommendations, the Society affirms the following examples of ethical professional behavior.

- The direct provision of drug samples to patients should be limited and, when possible, should be replaced by a system of vouchers for evidence-based drug choices.
- Physicians serving on formulary committees who have any kind of commercial relationship with a health product company shall disclose any such relationship and recuse themselves from the formulary process, as necessary to avoid bias.
- CME providers should not accept support from health product companies directly. A CME provider may create a fund for medical education that may accept unrestricted donations from health product companies that is then dispersed according to institutional policy; this policy, financial contributors and the amount of their contributions shall be disclosed as public information on an easily accessible Web site.
- Physicians should not serve as members of speaker bureaus for health product companies or their contractees.
- Physicians should not allow their names to be listed as authors for articles written by health product company employees, a practice called "ghostwriting."
- Since ethical collaboration between the profession and the health product industry is essential for the continued development of health products, high-integrity consulting and research relationships shall be strongly encouraged. However, to avoid such relationships being tantamount to a gift, such relationships shall be based in contracts for specific "deliverables" in return for just compensation.

Note: This policy was adopted by the Board of Directors October 11, 2008.

Wisconsin Medical Society
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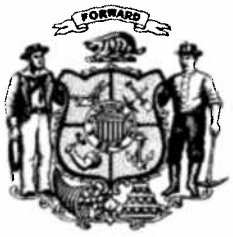
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PHARMACY
SOCIETY OF
WISCONSIN

"Leading Our Profession in a Changing Health Care Environment"

Date: May 26, 2010

To: **Senate Committee on Health, Health Insurance, Privacy, Property Tax Relief, and Revenue**

Assembly Committee on Aging and Long-Term Care

From: Erika Horstmann Pharm.D. for the Pharmacy Society of Wisconsin

Hello. My name is Erika Horstmann and I am a community pharmacist working for Hometown Pharmacy Group in the greater Madison Area. I reside in Middleton and my state legislators are Senator Erpenbach and Representative Roys. I would like to thank both the Senate Committee and the Assembly Committee for the opportunity to comment on items pharmacists in Wisconsin believe are important points of consideration related to the subject of prescription drug reform. The Pharmacy Society of Wisconsin has more than 2,500 members who practice in all types of pharmacies and other health care institutions. I happen to be a member who is a community pharmacist and I am actively involved in projects that help control health care costs on the prescription side of things.

Prescription drugs are perhaps the most important form of medical treatment in the United States and it is certainly the most prevalent form of treatment. Nearly 7 million prescriptions are dispensed in Wisconsin each month…more than one prescription for every Wisconsin resident.

Prescription medications have cured some illnesses altogether, they are used to treat conditions without cure, relieve symptoms of diseases that are otherwise intolerable, and they generally improve the quality of life for the persons who take them. However, these valued medical improvements come at a cost, both literally and figuratively. Some prescription medications are expensive, especially those used to treat uncommon illnesses. In addition, some medications have untoward effects associated with their use and some cause unanticipated harm when they are used or combined with other medications. None-the-less, medications are usually the most convenient and least expensive form of medical treatment available today. When used properly, medications keep people well and away from more expensive forms of treatment.

However, many problems exist with prescription drug use. These problems are associated with suboptimal and unnecessary medication use. Estimates indicate that there is more money spent to address the consequences of suboptimal medication use than is actually spent on prescription drugs themselves. Said another way, we are spending more money in the U.S. health care system to fix the problems with medications…more than $250 billion annually…than we are on the medications themselves

It is this area of improving medication use where we believe greater emphasis and innovative solutions must be placed. And, because seniors use more medications

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The over 65 demographic is where attention and support should be waged. Seniors represent only 15% of the population but they use nearly 50% of the prescription drugs in this country.

The attached paper from the American Society of Consultant Pharmacists (ASCP) outlines the problems associated with medication use in the elderly and it describes how seniors are at greatest risk for medication-related problems. Pharmacists help Wisconsin's seniors every day understand how to use their medications properly but more needs to be done. The health care system and often the focus of consumers has been on how to purchase prescription drugs as inexpensively as possible rather that determining how to obtain the greatest value from the medication treatment. It is precisely this shift in thinking that will lead to a reduction in health care costs and the improvement of health care quality.

If you have had to help an aging parent or grandparent figure out how to manage their medications, especially after a hospitalization or after a major change in their health status, you understand the difficulty of this situation. Add formularies, prior authorization policies, and other insurance management tactics and it is easy to see how a person, any person, would become overwhelmed with the complexity of their care. We should immediately consider how to help the people who need the most help. Wisconsin's pharmacists are prepared to provide the necessary information and monitoring to ensure that medications are used optimally but the system must be changed such that they are looked to provide this needed service, in addition to dispensing the medications.

The Wisconsin Pharmacy Quality Collaborative (WPQC) is a combined effort of health care purchasers (insurers and employers) and pharmacy providers with the singular focus of improving medication use in the state of Wisconsin. We encourage the Committee's consideration of WPQC as a solution to meaningful prescription drug reform in Wisconsin. The people who use medications need the assistance and the people who pay for the prescription drug therapies deserve the value in what they are purchasing. The Pharmacy Society of Wisconsin (PSW) has led the creation of WPQC and PSW is committed to leading a call for improvement in medication use in Wisconsin. Until health policies are changed and until a focus on quality emerges, rather than merely trying to buy drugs cheap, we are doomed to continue to encounter the problems we have had in the past. Reform is needed but in order to improve, it is imperative that we focus on the real problems.

If you would like to hear some specific examples of how the WPQC program has helped reduce costs and improve care, I'd be eager to share those with you at your request.

Thank you for your time.

SENIORS AT RISK:

DESIGNING THE SYSTEM TO PROTECT AMERICA'S MOST VULNERABLE CITIZENS FROM MEDICATION-RELATED PROBLEMS

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SENIORS AT RISK:

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MILLIONS OF SENIORS ARE UNKNOWINGLY AT HIGH RISK FOR ILLNESS, DISABILITY, AND DEATH. THE CAUSE?

Medication-Related Problems

Medications are probably the single most important technology in preventing illness, disability, and death in the senior population. Appropriate use of a medication saves more than it costs in terms of reduced overall health care expenditures, lower incidence of disease, and greater productivity and functionality. However, if not properly dispensed and monitored medicines can hurt instead of help.

Today there are more than 38 million individuals aged 65 and older in the United States. By 2030, that number will nearly double to 75 million. Among seniors, who take more medications than any other age group, the risks of medication-related problems are greatly magnified. More than 200,000 people die each year from medication-related problems. Adverse drug reactions alone are between the fourth and sixth leading cause of death (Ernst and Grizzle 2001; Lazarou et al. 1998).

Senior Care Pharmacy Facts

- Seniors have more chronic diseases and multiple conditions, so they use more prescription and over-the-counter drugs. More than 77% of seniors between the ages of 65 and 79 suffer from one or more chronic diseases. The number rises to 85% for those over age 80. (Hwang et al., Health Affairs 2001)
- Seniors represent just over 13% of the population, but consume 40% of prescription drugs and 35% of all over the counter drugs
- On average, individuals 65 to 69 years old take nearly 14 prescriptions per year, individuals aged 80 to 84 take an average of 18 prescriptions per year
- 15% to 25% of drug use in seniors is considered unnecessary or otherwise inappropriate
- Adverse drug reactions and noncompliance are responsible for 28% of hospitalizations of the elderly
- 36% of all reported adverse drug reactions involve an elderly individual
- Each year 32,000 seniors suffer hip fractures caused by medication-related problems (FDA, 1996)

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Millions of seniors are unknowingly at risk for illness, disability, and death.

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SENIORS AT RISK:

DESIGNING THE SYSTEM TO PROTECT AMERICA'S MOST VULNERABLE CITIZENS FROM MEDICATION-RELATED PROBLEMS

WHAT IS A MEDICATION-RELATED PROBLEM?

An event or situation involving drug therapy that actually or potentially interferes with an optimum outcome for a specific patient.

Medication-related problems can be categorized EIGHT ways:

1. **Untreated conditions**
   The patient has a medical condition that requires drug therapy but is not receiving a drug for that condition.

2. **Drug use without indication**
   The patient is taking a medication for no medically valid condition or reason.

3. **Improper drug selection**
   The patient's medical condition is being treated with the wrong drug or a drug that is not the most appropriate for the special needs of the patient.

4. **Subtherapeutic dosage**
   The patient has a medical condition that is being treated with too little of the correct medication.

5. **Overdosage**
   The patient has a medical problem that is being treated with too much of the correct medication.

6. **Adverse drug reactions (ADRs)**
   The patient has a medical condition that is the result of an adverse drug reaction or adverse effect. In the case of older adults, ADRs contribute to already existing geriatric problems such as falls, urinary incontinence, constipation, and weight loss.

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7. **Drug interactions**
   The patient has a medical condition that is the result of a drug interacting negatively with another drug, a food, or a laboratory.

8. **Failure to receive medication**
   The patient has a medical condition that is the result of not receiving a medication due to economic, psychological, sociological, or pharmaceutical reasons.

Consultant Pharmacists Taking Care of Older Adults Have a Positive Effect.

- Mrs. GT is an 85-year old white widowed female who lives alone in her home in a small town in North Carolina. Her daughter, who felt that she had become lethargic, belligerent, verbally abusive, and overweight from eating junk food and lying in bed all day, referred her mother to a consultant pharmacist. Mrs. GT recently had back surgery, but refused to participate in physical therapy because she was in pain and had no energy. She was unkempt, very uncooperative, and did not want to be bothered. Her medication, which she had taken for many years, included pain medicine, blood pressure/heart medicine, and a "nerve" pill. She felt that her physician knew what was best for her, so she was not interested in having anything changed.

  The consultant pharmacist referred the daughter to a geriatrician and recommended to the physician that all of the above medications be discontinued gradually. The consultant pharmacist suggested replacing them with a routine pain medication/anti-inflammatory for her back pain, adding a narcotic one hour prior to physical therapy, an ACE-Inhibitor for her blood pressure, and an SSRI for her depression. The geriatrician agreed with these recommendations, and within two to three weeks, Mrs. GT was a different person. She was now getting up in the mornings to attend physical therapy. She began a walking program and soon lost weight. Best of all, her mood and demeanor changed dramatically. Instead of her sullen and abusive statements to her daughter, she was now talking quite pleasantly and was much happier with her life's circumstances.

- Betsy M., an 80-year-old female resident of a skilled nursing facility, has had four urinary tract infections (UTIs) over four consecutive months. She was treated with four different, progressively more expensive antibiotics and was at significant risk for a serious blood infection (urosepsis) and hospitalization. After reviewing her medical record, the pharmacist recognized that she was taking four drugs that could lead to urinary retention and increase the risk of UTIs. The physician was consulted about this risk resulting in discontinuation of two of these medications and dose reduction for the other two medications. Over the next 12 months, she experienced only one UTI, which was easily treated. Potential savings were approximately $300-$500 in avoided antibiotic costs and $3,000-$5,000 in avoided hospitalization costs.

SENIORS AT RISK:

DESIGNING THE SYSTEM TO PROTECT AMERICA'S MOST VULNERABLE CITIZENS FROM MEDICATION-RELATED PROBLEMS

THE HUMAN TOLL

How are seniors affected by medication-related problems?

Medication-related problems (MPRs) can cause, aggravate, or contribute to common and costly geriatric problems, including:

- Confusion
- Delirium/hallucinations
- Depression
- Dizziness
- Drowsiness
- Falls
- Incontinence
- Insomnia
- Loss of coordination
- Malnutrition/dehydration
- Memory loss
- Other psychiatric problems

> "Any symptom in an elderly patient should be considered a drug side effect until proved otherwise."
>
> (Gurwitz et al. 1995)

Which can lead to:

- Decreased quality of life
- Emergency room visits
- Hip fractures and other physical disabilities
- Hospitalization
- Loss of functional ability
- Loss of independence
- Nursing facility placement
- Physician visits
- Death

> "Too often, illness in older people is misdiagnosed, overlooked, or dismissed as the normal process of aging, simply because health professionals are not trained to recognize how diseases and drugs affect older people."
>
> (Murphy 1999)

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The human toll

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SENIORS AT RISK:

DESIGNING THE SYSTEM TO PROTECT AMERICA'S MOST VULNERABLE CITIZENS FROM MEDICATION-RELATED PROBLEMS

WHAT WILL ONE OF EVERY THREE SENIORS SUFFER THIS YEAR?

A Fall

- More than 11 million seniors—one of every three—will fall this year (Sattin 1992; Tinetti, Speechley, and Ginter 1988), and approximately one in 10 of those falls will result in a serious injury such as hip fracture or head injury (Tinnetti 2003). More than 500,000 seniors will suffer hip fractures annually by 2040 (Cummings, Rubin, and Black 1990).

- Each year, 35% to 40% of generally healthy seniors living in the community fall (Campbell, Spears, and Borrie 1990). Because nursing facility residents are older, more frail, and more cognitively impaired, approximately 50% fall each year (Rubinstein, Josephson, and Robbins 1994).

- About 20% of hip fracture patients will die within five years of the fracture (Cooper 1997), yet thousands of those deaths are **PREVENTABLE.**

- Most people do not realize that falls can be a medication-related problem.

"No risk factor for falls is as potentially preventable or reversible as medication use."

(Leipzig, Cumming, and Tinetti 1999)

- Risk factors for falls include medication use, advanced age, decreased mobility and strength, balance impairment, neurological disease, cardiovascular disease, incontinence, visual impairment, and cognitive impairment.

- Certain medications—such as high blood pressure medications, antidepressants, sleep aids, antiseizure medications, and heart antiarrhythmic medications—can contribute to falls in the elderly for a variety of different reasons. Perhaps a drug causes dizziness in an elderly patient, and that patient has not been properly instructed on how to rise and walk while on the medication. Standing up too quickly could result in a fall. Or, perhaps a drug causes frequent urination, and a patient constantly gets up during the night. One of those bathroom trips could cause a fall, and possibly a hip fracture.

Medication-related falls and hip fractures are preventable

- Consultant pharmacists can assess seniors' drug regimens for exposure to risks that may contribute to falls, recommend drug therapy changes, and educate the patient and caregiver on how to avoid dangerous situations. Medication management is an effective fall prevention measure (Cooper 1997).

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What will one of every three seniors suffer this year?—A FALL

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SENIORS AT RISK:

DESIGNING THE SYSTEM TO PROTECT AMERICA'S MOST VULNERABLE CITIZENS FROM MEDICATION-RELATED PROBLEMS

A PUBLIC HEALTH PROBLEM

More than 200,000 people die and another 2.2 million are injured each year because of medication-related problems—and seniors are the most susceptible.

(Ernst and Grizzle 2001; Lazarou, Pomeranz, and Corey 1998).

WHY?

- **Seniors take more medications than any other age group.** In 2000, seniors filled an average of 28.5 prescriptions per year, and it is projected they will fill an average of 38.5 prescriptions per year in 2010. (Families USA 2000).

- **The physiological changes of aging can alter how a body processes and reacts to a certain medication.** In the aging body, the liver and kidneys may not as easily metabolize medications. In addition, changes in the distribution of fat and muscle can make seniors more susceptible to adverse drug events.

In 1998, Medicare beneficiaries who did not have drug coverage filled 31% fewer prescriptions than those with drug coverage.

(Murphy 1999)

- **Seniors have more chronic diseases and multiple conditions, so they use more prescription and over-the-counter drugs.** More than 77% of seniors between the ages of 65 and 79 suffer from one or more chronic diseases. The number rises to 85% for those over age 80 (Hwang et al. 2001).

- Compounding the public health problem, **seniors may not be taking the medications they need because they cannot afford them.** The elderly account for 42% of total annual drug spending in the U.S.: $43 billion of the $102 billion total (Families USA, 2000). Millions of seniors cannot afford the medicines they need to stay healthy. Seniors spend nearly four times as much on prescription medications than those under age 65 (Cohen et al. 2000).

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A public health problem

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SENIORS AT RISK:

DESIGNING THE SYSTEM TO PROTECT AMERICA'S MOST VULNERABLE CITIZENS FROM MEDICATION-RELATED PROBLEMS

THE NATION'S $200 BILLION "DISEASE"

More money is spent to treat medication-related problems than is spent on the cost of medications.

The $200 Billion Price Tag:

- In the community population, medication-related problems cost $177.4 billion a year, a 57% increase in only five years (Ernst and Grizzle 2001):
  - Hospital admissions cost $121.5 billion (69%)
  - Long-term care admissions cost $32.8 billion (18%)
  - Physician visits cost $13.8 billion (8%)
  - Emergency department visits cost $5.8 billion (3%)
  - Additional treatments cost $3.5 billion (2%)

- An additional $24 billion is spent on medication-related problems in other settings:
  - $20 billion in acute care facilities, such as hospitals (Bates et al. 1997)
  - $4 billion in nursing homes (Bootman, Harrison, and Cox 1997)

How do these costs compare to the amount spent on prescription drugs?

Outpatient prescription drugs cost more than $154 billion a year, and that number is rising fast. (NIHCM 2002).

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The nation's $200 billion "disease"

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SENIORS AT RISK:

DESIGNING THE SYSTEM TO PROTECT AMERICA'S MOST VULNERABLE CITIZENS FROM MEDICATION-RELATED PROBLEMS

HOW DO WE PREVENT MEDICATION-RELATED PROBLEMS?

Consultant and Senior Care Pharmacists are the answer.

Consultant and senior care pharmacists are specialists in geriatrics, geriatric pharmacotherapy, and the unique medication-related needs of the geriatric population. These experts are uniquely qualified to identify individuals who are at high risk for medication-related problems that interfere with the goals of therapy. By applying expert knowledge to seniors wherever they reside, consultant and senior care pharmacists can identify, resolve, and prevent more medication-related problems. As many as 50% of medication-related problems are preventable (Gurwitz JH et al., Am J Med, 2000).

The most important and fastest growing component of consultant pharmacy practice is **senior care pharmacy**—the delivery of high quality pharmaceutical care to at-risk seniors in home and community settings.

Consultant pharmacists identify and prevent medication-related problems through evaluation of patients' drug regimens, increasing the frequency of optimal therapeutic outcomes by 43%, and saving $3.6 billion annually in costs from avoided medication-related problems.

(Bootman et al. 1997)

Consultant and Senior Care Pharmacists:

- Ensure that a patient's drug therapy is appropriate, effective, safe, and used correctly
- Determine whether a sign, symptom, syndrome, or decline in function is medication-related
- Identify medications that may cause or aggravate common geriatric problem areas
- Serve as essential members of the interdisciplinary team

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Consultant and senior care pharmacists save lives and money—and they can save more.

Unless America's seniors have regular access to a consultant or senior pharmacist to manage their medications, they will continue to suffer from medication-related problems. The current system does not provide incentives to gain positive health outcomes. As a first step, however, medication management, including pharmacists' drug therapy monitoring, has been marked as a national priority in a report by the National Institute of Medicine (Frey D., Rahman A. 2003).

Today, more than 10,000 consultant pharmacists provide services to more than 1.45 million skilled nursing facility residents, 800,000 assisted living residents, and hundreds of thousands of others in a wide variety of care environments such as community-based care, adult day care, correctional facilities, and individuals living in their own homes.

(Poisal and Murray, 2001; NCAL Data, 2001)

Although federal legislation requires that consultant pharmacists review the drug regimens of nursing facility residents at least once a month, **no such federally mandated medication management regulations exist for assisted living facilities.** Yet both the average nursing facility resident and average assisted living facility resident take approximately eight medications each day, so each faces the same risks for suffering from medication-related problems (Briesacher et al. http:// aspe.hhs.gov/daltcp/home.htm).

How do we prevent medication-related problems?

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SENIORS AT RISK:

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THE AMERICAN SOCIETY OF CONSULTANT PHARMACISTS

Protecting Older Adults From Medication-Related Problems

Who Are America's Consultant and Senior Care Pharmacists?

The American Society of Consultant Pharmacists (ASCP) was founded in 1969 to represent the interests of its members who ensure safe and effective medication therapy for the residents of nursing facilities, mostly frail elderly patients. The term "consultant pharmacist" is rooted in federal regulations that require the services of such a pharmacist for nursing facility residents.

The over-65 age group is the fastest-growing segment of the United States population. While medications are probably the single most important factor in improving the quality of life for older Americans, the nation's seniors are especially at risk for medication-related problems due to physiological changes of aging, higher incidence of multiple chronic diseases and conditions, and greater consumption of prescription and over-the-counter medications.

Over the past 30 years, ASCP has grown dramatically, and its members have diversified and expanded their services to people who need them most—today's seniors. ASCP's members have specialized knowledge in geriatrics, geriatric pharmacotherapy, and the unique medication-related needs of the senior population. And today, ASCP members—America's Senior Care Pharmacists®—are patient advocates for all of our nation's seniors, wherever they reside.

Consultant and Senior Care Pharmacist's Creed

- I hold my patients' interests above all others.
- I take responsibility for my patients' medication-related needs.
- I ensure that my patients' medications are the most appropriate, the most effective available, the safest possible, and are used correctly.
- I identify, resolve, and prevent medication-related problems that may interfere with the goals of therapy.

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