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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)

The Prescription Project

The Case for Disclosure

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

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

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

This fact sheet was created in collaboration with

COMMUNITY CATALYST

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Medical device maker paid UW surgeon $19 million

School didn't share in payments

By John Fauber of the Journal Sentinel
Posted: Jan. 16, 2009

Thomas Zdeblick, an orthopedic surgeon at the University of Wisconsin-Madison, raised eyebrows three years ago when it was learned that he had been receiving $400,000 yearly from the medical device company Medtronic.

But a document obtained Friday indicates the actual yearly payments averaged about 10 times that figure.

Zdeblick, a professor and chairman of the department of orthopedics at UW, received more than $19 million in payments from Medtronic from 2003 through 2007, according to a letter that Sen. Charles Grassley (R-Iowa) sent Monday to UW System President Kevin Reilly.

The letter is part of an investigation of payments to doctors from medical companies that Grassley, ranking member of the Senate Finance Committee, is conducting.

The issue involves a policy at the UW School of Medicine and Public Health that allows doctors and other personnel to disclose imprecise amounts of income received from drug, medical device companies and other organizations in their field.

Doctors have to disclose only ranges of income, and the top category is $20,000 or more. So the medical school has no way of knowing whether a doctor received $20,000 from a drug company or $200,000 or $2 million.

For instance, disclosure forms that Zdeblick filed with the university for outside income during 2005, 2006 and 2007 indicate he received $20,000 or more in consulting and royalty payments.

The Grassley letter says he actually received $3.9 million, $3.6 million and $2.6 million from Medtronic in those years. He also received $4.6 million in 2003 and $4.6 million in 2004.

Critics have said the UW policy, which the medical school is thinking of changing, allows doctors to shield large payments that might pose more substantial conflicts of interest.

Doctor defends payments

In e-mails sent to the Journal Sentinel on Friday, Zdeblick says the vast majority of the money he received from Medtronic was from royalties on more than 20 patents on devices he helped develop. The patents involved a variety of spinal implants.

Zdeblick and the university confirmed that UW did not share in the royalty payments, though Zdeblick has worked at the university since 1989. In recent years, his UW salary has been about $900,000 a year.

One unanswered question is how Zdeblick could work as a full-time employee of the university and develop inventions with royalties in which the university did not share. Often, such payments go through the Wisconsin Alumni Research Foundation.

A spokesman for Reilly said Reilly did not want to comment and referred a reporter to officials with the Madison campus.

Robert Golden, dean of the medical school, was not available for comment. Jeffrey Grossman, president and chief executive officer of the UW Medical Foundation, also was not available for comment.

In e-mail to the Journal Sentinel, Zdeblick says: "My patent work was not performed within a UW laboratory, or with UW or federal funding, so royalty sharing with the university is not required. Managing conflict when you are an innovator is not easy, and I have done the best I can."

Zdeblick also notes that he follows all the university's conflict-of-interest policies and always informs his patients of his financial relationship with Medtronic.

In addition, to avoid a conflict in patient care, he says he does not receive royalties on any devices that he implants in his patients.

"I have been a leader in spine innovation for 20 years, and have developed numerous procedures and implants that benefit patients tremendously," he said. "There is absolutely no shame in being paid well for having good ideas. I have followed every rule and practice to the highest ethical standard."

Grassley obtained the information about the royalty payments to Zdeblick from Medtronic as part of his investigation.

In the next few days, Grassley and Sen. Herb Kohl (D-Wis.) plan to reintroduce their Physicians Payments Sunshine Act, which would require makers of drugs and medical devices to disclose payments they make to physicians. The payments would be available for review online through the U.S. Department of Health and Human Services.

A spokeswoman for Medtronic said Zdeblick has been working with the Minneapolis company more than 15 years. He is listed on 25 U.S. patents and 41 patents outside the United States.

"As with any successful commercial product, royalty streams for patent holders can be large," said the spokeswoman, Marybeth Thorsgaard. "This does not in any way imply that these royalty streams are inappropriate."

Find this article at:
http://www.jsonline.com/news/wisconsin/37748554.html

Side Effects | Money, Medicine, and Patients

Faculty disclose outside payments

Some UW doctors get 6-figure sums from drug, medical firms

By John Fauber of the Milwaukee Journal Sentinel

Posted: June 20, 2009

At least 11 doctors with the University of Wisconsin School of Medicine and Public Health received more than $50,000 from drug or medical device companies last year, including seven who pulled in six-figure amounts, according to records obtained by the Journal Sentinel.

As part of an effort to enforce more stringent conflict-of-interest rules, UW doctors for the first time have had to specify how much outside income they receive.

The disclosure forms show that orthopedic surgeons, who command some of the highest salaries among university and state employees, also got some of the biggest outside income checks, mostly from companies that make medical devices.

With the outside payments, several of them had total annual income of near or more than $1 million.

Some of the orthopedic surgeons also were among the most vocal opponents to the university's new disclosure requirements, referring to the more stringent disclosure requirements as voyeuristic.

In the past, they and other doctors who earned large sums working as consultants, speakers or from royalties could merely state that they received more than $20,000 without having to tell their patients or the university the actual amount.

The issue of doctors, especially those with university positions, working for drug and device companies has come under scrutiny in recent years, including in congressional investigations, medical journal articles and the media. The Journal Sentinel has published an ongoing series of stories on connections between UW doctors and medical firms.

Topping the list of those receiving large sums from medical companies was a group of UW orthopedic surgeons. They include:

•Paul Anderson, a professor of orthopedic surgery, who got $150,000 for eight days of work as a consultant from medical device-maker Medtronic. Anderson, who could not be reached for comment, also earned a UW salary of $755,000 in 2007.

•Ben Graf, an associate professor of orthopedic surgery, who got $770,000 in royalties from device company Smith & Nephew. Graf, who could not be reached for comment, also earned a UW salary of $591,000 in 2007.

•Clifford Tribus, an associate professor orthopedic surgery, who got $310,000 for 15 days of work as a speaker and consultant and from royalties from device company Stryker Spine. Tribus also earned a UW salary of $618,000 in 2007.

In an e-mail, Tribus said about $250,000 of the $310,000 he got from Stryker was from royalties on an implant invention. The rest was from consulting work.

He said he does not receive royalties from devices he implants in his patients and the patients are informed of his financial relationship.

He said his consulting work involves giving talks about the devices to other doctors, for which he is paid $450 an hour. He said that was a lot different than a doctor being paid to give a talk about a drug.

"These are technology- and technique-driven ideas," he said. "It's not taking a pill with some milk or water."

• The largest sum - $2 million - paid in 2008, went to orthopedic surgeon Thomas Zdeblick from Medtronic.

The money came from royalties on inventions and from working eight days as a consultant.

In an e-mail response last week, Zdeblick said his 2008 income from Medtronic also came from royalties on his patented inventions.

"I do not receive any royalties for cases performed at UW," he added. "Patients are informed that I work on product development with industry."

Zdeblick also received $890,000 in compensation from UW in 2007. He is a professor and chairman of the department of orthopedics and rehabilitation.

In January, the Journal Sentinel reported that Zdeblick received more than $19&enspmillion in payments from Medtronic from 2003 through 2007.

The payments, mostly from royalties, were revealed in a letter from U.S. Sen. Charles Grassley (R-Iowa) as part of an investigation of payments to doctors from medical companies that Grassley is conducting.
Doctor heads company

Diane Heatley, an associate professor in the division of otolaryngology-head and neck surgery, received the second highest payment from a medical firm.

Heatley, president and founder of Med-Systems Inc., a Madison-based company that manufactures and markets the SinuCleanse over-the-counter saline nasal wash system, reported receiving $1.3 million from the company and working 40 days.

The company, in which she holds a 37.5% interest, has sold millions of the devices over the years, she said.

Heatley, who works with pediatric patients, said that when nasal washing is deemed appropriate, the family is shown several different washing devices, including SinuCleanse, which is available through UW Hospital.

She said some patients already are using nasal washing when they see her.

"Those who use other manufacturers' systems are never encouraged to switch systems," she said in an e-mail.

When asked about whether she tells families about her financial interest in the device, she said, "Yes. My name and picture are on the box as developer of SinuCleanse products."

Jeffrey Grossman, head of the UW Medical Foundation, said all of the financial relationships will be formally reviewed by the university.

"The entire purpose of our exercise is to address the concerns of the public and the profession about the potential influence of drug and device companies on health care practice," he said in an e-mail.

Because of the influence they hold, university physicians often are sought out by drug and device firms. Often patients are unaware of the financial relationships.

Critics of these arrangements say they increase the cost of medicine, potentially compromise patient care and damage the integrity of medical research.

University doctors often are hired by the companies to work as consultants or to give talks.

That could lead to more prescribing of expensive, brand name drugs when cheaper generics might work just as well, or more costly procedures when less invasive therapy might be appropriate.

It also could lead to more off-label use of drugs and devices. Off-label refers to using a drug or device for a condition for which it was not originally approved, which is legal and often advisable, but which also can lead to expensive prescribing that is not based on sound science.

Trend since 1980s

Arnold Relman, a former editor-in-chief of the New England Journal of Medicine and a doctor since the 1950s, said the financial relationships, which took off in the 1980s, have turned the practice of medicine into a huge business. He said it also is destroying the American health care system.

"We can't afford it," he said.

And simply requiring doctors to disclose how much money they are paid doesn't eliminate their conflicts of interest.

"The time has come for medical schools and universities to recognize that disclosure is not enough," Relman said. "It is time to simply make conflicts of interest off limits.

"People have to choose. Do they want to be salaried members of a medical school or freelance entrepreneurs of a medical company?"

Relman said it was outrageous that seven UW doctors received more than $100,000 from medical firms last year. But, he said, just as troubling are the many others who made less than $50,000.

"It's all bad," said Relman, a professor emeritus of medicine and social medicine at Harvard Medical School. "You can't draw a line."
Practice defended

However, Kenneth Noonan, an associate professor of orthopedic surgery at UW, has an entirely different view.

Noonan said interactions between the medical industry and university doctors are important, and physician scientists can help improve patient care.

"In that capacity, the physician becomes a contractor who has a right to compensation generally achieved through contractual relationships," he said in an e-mail. "These contractual relationships must always bow to the primary interest of the physician and the patient - optimal patient care - but they are not inherently inappropriate."

Noonan, who is a member of the committee that has recommended changes to the UW conflict-of-interest policy, received $181,000 from EBI-Biomet, a medical device company, in royalties from a variety of implant products in 2008.

He said he did not get any royalty money from products implanted at any UW facility.
Find this article at:
http://www.jsonline.com/features/health/48692952.html

Side Effects | Money, Medicine, and Patients

Physicians' disclosures to UW, journals inconsistent

At least 9 doctors' links to industry did not match

By John Fauber of the Milwaukee Journal Sentinel

Posted: Nov. 7, 2009

Earlier this year, Minesh Mehta, a cancer specialist at the University of Wisconsin School of Medicine and Public Health, co-authored a medical article on TomoTherapy, a radiation therapy system developed by researchers at the university.

Any doctor reading the article would have thought Mehta was an unbiased researcher with no conflict of interest or financial stake in TomoTherapy Inc.

After all, the journal article said Mehta reported no potential conflicts of interest.

But documents obtained from the university tell a different story.

Those records show Mehta had told the university he would make more than $20,000 in 2008 working as a TomoTherapy consultant. He also owned stock options in the company.

Mehta was one of at least nineUW physicians whose conflicts listed on financial disclosures to the university did not match what was revealed to the medical world in their published articles. The inconsistencies were found in a spot check conducted by the Journal Sentinel of about 40 UW physicians whose work has been published since 2005.

Disclosing conflicts of interest is a bedrock principle of modern medicine. It alerts doctors and others who read medical journals to potential bias and allows them to weigh the credibility and value of the articles.

In the last two years, a lack of disclosure in several high profile national cases has undermined the integrity of the medical field.

"There has been a consistent pattern of people not disclosing," said Merrill Goozner, editor of a health care newsletter and former director of the Integrity in Science Project of the Center for Science in the Public Interest.

The reason for the lack of disclosure can lie with either the researcher or the journal.

Just last month, a study in the New England Journal of Medicine showed orthopedic surgeons routinely failed to disclose financial ties to medical device makers in presentations at the 2008 annual meeting at the American Academy of Orthopedic Surgeons.

The issue is so important that editors of some of the world's leading medical journals last month banded together to demand stricter and more consistent disclosure of conflicts of interest.

However, even with more stringent disclosure demands, the system largely is voluntary and self-policing.

"The investigators are pretty much on the honor system," said Nora Disis, deputy editor of the Journal of Clinical Oncology.

She said disclosure is crucial to the integrity of the system.

"When you work in trying to improve human health, it's very important that you share knowledge," she said. "People need to know . . . that you are receiving compensation. That allows the reader to take a much more critical look at the conclusions that are being drawn from the data."
Disclosure is relevant

Mehta's piece on TomoTherapy, published in the International Journal of Radiation Oncology Biology Physics, involved an assessment of 3,800 treatments using TomoTherapy.

On July 3, 2008, the article was received by the journal. A revised form of the article was received Nov. 6 of that year, and it was accepted for publication a week later.

While two other co-authors from UW revealed their financial ties to the company, no such disclosure was made for Mehta, although his financial relationship with the company should have been fresh on his mind.

Less than two months earlier, on May 21, he told the university that he had begun working as a consultant to TomoTherapy in April and that he was reducing his university time by 10% to accommodate the lucrative new job.

At the time, he said his 2008 compensation from TomoTherapy Inc. would exceed $20,000. He also got stock options valued at the time at less than $10,000.

Ultimately, his consulting income with the company in 2008 would total $75,000, for 20 days' worth of work, according to records he filed with the university in April of this year. By then, the stock options were valued at $10,000 to $20,000.

The article was published in March of this year.

James Cox, editor of the journal, said Mehta's financial ties to TomoTherapy were Mehta's responsibility to disclose.

"Clearly it was very relevant," said Cox, head of radiation oncology at the University of Texas MD Anderson Cancer Center. "I have to ask myself how many authors out there have done the same thing. I can't go chase them down. There are too many authors."

In Mehta's case, he would not have to look too far. Mehta is a member of the journal's editorial board.

Cox said he likely will bring the matter up with the board of directors of the American Society for Radiation Oncology, which publishes the journal.

A variety of actions are possible, he said, ranging from publishing a notice about the failed disclosure to a censure. Mehta also could be dropped from the editorial board, Cox said.

"We take it very seriously," he said.

Mehta declined to discuss the issue with the Journal Sentinel.

Paid for talks

In 2008, UW doctor Barry Fox co-authored a medical journal article on treating antibiotic-resistant staph infections.

In the section of the article where doctors are supposed to list any potential conflicts of interest, it said "the authors have no financial disclosures to report."

However, documents Fox filed with the university show that he earned tens of thousands of dollars working for several drug companies giving talks to other doctors about antibiotics.

The article appeared in Plastic and Reconstructive Surgery, a journal published by the American Society of Plastic Surgeons. It could be used by doctors to earn required continuing medical education credit.

Such presentations and articles generally require the instructors to disclose their conflicts of interest.

Rod Rohrich, editor-in-chief of the journal, said Fox signed a form saying he had no disclosures to make.

If Fox had revealed his consulting work, the journal would have disclosed it in the article, Rohrich said.

"We are pretty rigid on that," Rohrich said. "The lack of disclosure was not the fault of the journal."

He said Fox may have made an honest mistake in signing the form. Rohrich said he re-read the article, and it did not appear to have commercial bias.

However, Goozner, the former head of the Integrity in Science Project, said every doctor who read that article for credit needs to be notified there was a failure to disclose conflicts of interest.

"It is just misleading the readers," he said.

Fox did not respond to attempts by the Journal Sentinel to reach him.

Narrow definitions

Sometimes the lack of disclosure is the fault of the medical journal.

In October 2008, Perry Pickhardt was among a group of UW researchers who co-authored a study in the journal Radiology on CT colonography, a non-invasive way to look for colon cancer.

Pickhardt has done extensive research in the field. He also has pulled in tens of thousands of dollars from several companies that make products used in CT colonography and owns stock options in one such firm.

However, the article said Pickhardt and the authors had no financial relationships to disclose.

In fact, Pickhardt had revealed many potential conflicts to the journal, which decided not to list them, said Herbert Kressel, editor of the journal and an emeritus professor of radiology at Harvard Medical School.

Kressel said the journal had a narrow definition of what constituted a conflict. He said that definition entailed writing about a specific product rather than a topic that might involve companies that make products in that field.

The journal now is considering a stricter policy, in part because readers are entitled to know about such conflicts, he said.

"Our journal would be better off being more transparent in publishing all of the stated conflicts," he said.

Pickhardt could not be reached for comment. He has disclosed conflicts in articles he co-authored in other journals.

Vague disclosures

The disclosures made in orthopedic surgery journals tend to be vague and incomplete. Often they don't say what the financial relationship is or spell out how much money has been paid. Sometimes the disclosures don't even say which company is paying the author.

There is a reason for that, says Charles Rosen, an orthopedic surgeon and president of the Association for Medical Ethics, an organization concerned with the pervasive influence of drug and device companies.

"People are worried no one will listen to them anymore if they know how much they are being paid by a company," he said. "They are going to discount it."

In 2007, UW orthopedic surgeon Paul Anderson co-authored an article in the journal Spine on the Bryan cervical disc prosthesis made by Medtronic, one of several device-makers for which he has moonlighted.

For years, UW doctors did not have to tell the university how much money they actually made working for drug and device companies. Rather, they merely had to state whether it was in excess of $20,000, the top range, or some other lower range.

From 2003 through 2007, Anderson pulled in undisclosed sums of more than $20,000 a year from Medtronic. In 2008, the first year that UW doctors had to specify their outside income, his Medtronic income was $150,000.

However, based on his article in Spine, it is hard to tell if he received anything from Medtronic.

In part, the disclosure reads:

"One or more of the author(s) has/have received or will receive, benefits for personal or professional use from a commercial party related directly or indirectly to the subject of this manuscript: e.g. honoraria, gifts, consultancies, royalties, stocks, stock options, decision making position."

Rosen said the statement doesn't say anything about Anderson's financial relationship with Medtronic.

"It's gibberish," he said. "It's covering your legal butt."

Anderson, who also serves as an associate on the journal's editorial board, did not respond to the Journal Sentinel's attempts to reach him for comment.

Loretta Pickett, managing editor of Spine, said authors are not asked to disclose details of financial conflicts such as whether it is from speaking or royalties, or how much money they receive. Instead, they are allowed to pick a statement such as the one used in the article.

"We've always gone on the honor system," she said.

The journal now is considering requiring authors to disclose more detailed conflict information, she said.

In 2009, UW orthopedic surgeon Thomas Zdeblick co-authored an article in the Journal of Bone & Joint Surgery that involved two other Medtronic products, the LT-Cage, a device used in spinal fusion surgery; and BMP-2 a bioengineered protein that promotes bone growth.

The study concluded that the two products had long-term effectiveness, reduced pain and improved other clinical outcomes.

Zdeblick has a long and lucrative relationship with Medtronic, both as a consultant and as someone who has received at least $19 million in royalties for a variety of devices that he invented and patented with the company.

One of the devices is the Novus LT Cage, for which he received $1.4 million in royalties in 2007, according to a January 2009 letter to UW from U.S. Sen. Charles Grassely (R-Iowa), who has been investigating payments to doctors by medical firms.

However, the journal article does not mention that Zdeblick receives royalty payments from Medtronic, which funded the study.

Instead it states that he and the other authors are consultants to Medtronic and that one or more of them or a family member got payments or other benefits of more than $10,000 from Medtronic in any one year.

Zdeblick, chairman of the department of orthopedics and rehabilitation, had no comment other than to say he followed all appropriate procedures that were in place at the time.

Rosen, a clinical professor of orthopedic surgery at the University of California-Irvine School of Medicine, said there is a huge difference between $10,000 and $19 million.

"I have no objection to people making as much money as they can or inventing something and making a fortune off it," he said.

But the amount of money they make and how they make it should be fully disclosed when they present research, he said.

That is especially true with royalties, he said, because they are closely tied to financial success of the doctor and the company that makes the device that is the subject of the article.
Differing policies

In contrast to the cryptic, legalistic disclosures of Anderson and Zdeblick are the uncommonly detailed disclosures of Robert Lemanske, a UW pediatrician.

In a 2009 article on asthma therapies, he not only spelled out the type of compensation, but how much.

For instance, the disclosure section of the article said he had been paid $29,000 in 2005; $31,000 in 2006 and $15,000 in 2007 for speaking by Merck.

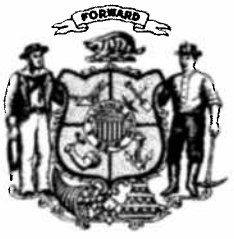
Robert Golden, dean of the UW School of Medicine, said journals have differing policies about what is disclosed.

"We do not control what the journals require, nor how they present disclosures or lack thereof," he said in an e-mail.

Golden said he could not comment on any investigations into a lack of disclosure.

More coverage online To read past stories in the "Side Effects" series, which looks at the conflicts of medical doctors, go to www.jsonline.com/sideeffects


WISCONSIN STATE LEGISLATURE


FORWARD

H1N1 Influenza Prescription Information

Some observations from Wisconsin and the nation

The IMS Health – CDC National Influenza Surveillance Project

During the autumn of 2009, IMS Health launched a program of information provision to the U.S. Centers for Disease Control and Prevention. This ongoing research project's aims are to complement and enhance CDC's existing means of disease surveillance, to create an additional early warning system, and to provide the agency's doctors and epidemiologists with the best tools possible for pandemic tracking and planning.

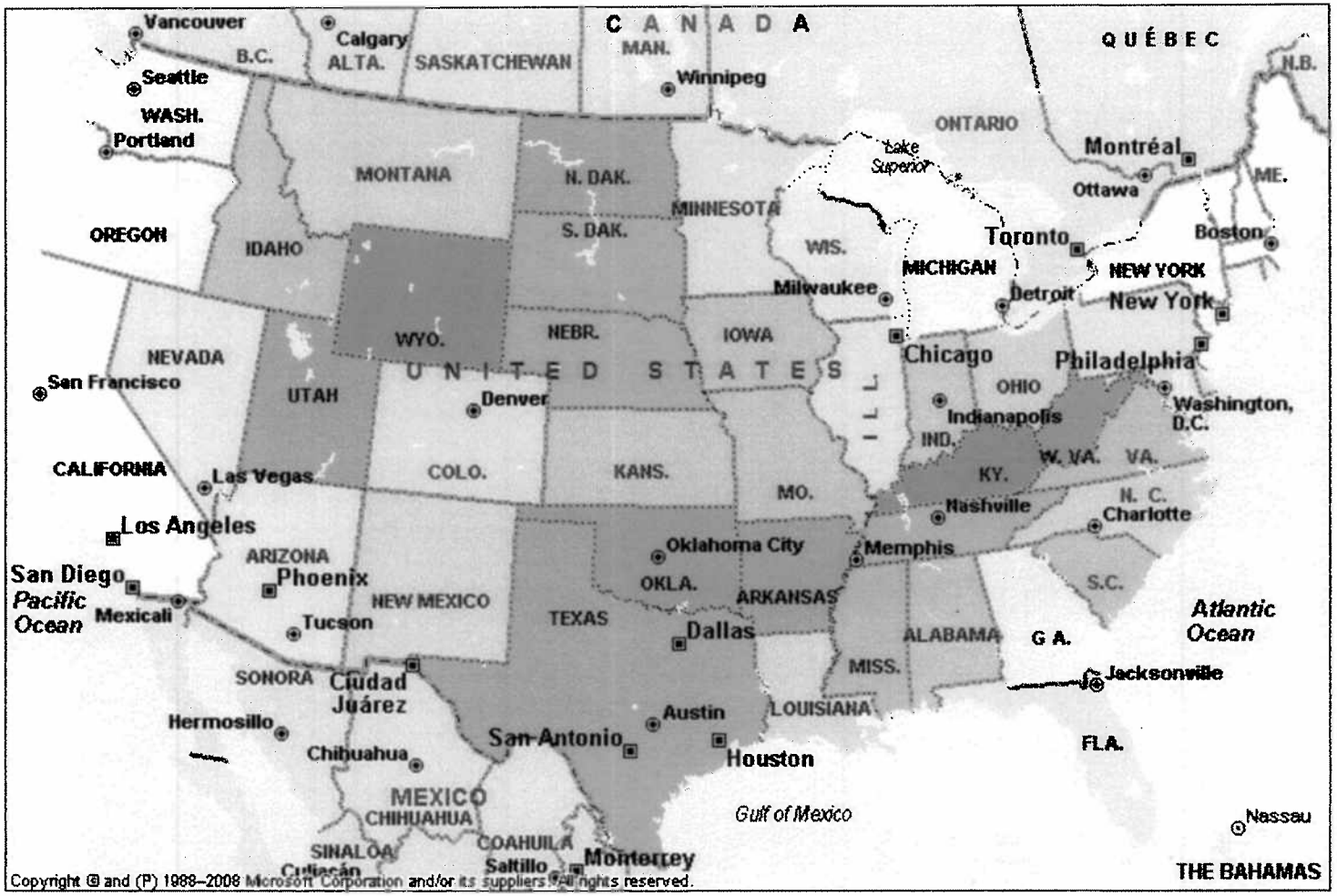
Weekly reports based on IMS Health's data allow CDC doctors to track the dispensing of prescriptions for antiviral drugs with unparalleled speed and geographic precision, and to make comparisons with historic trends. Analysis of this information allows scientists and public health authorities to respond more quickly in specific areas of the country where new outbreaks of influenza might be emerging.

ims

Influenza Antiviral Prescriptions Per Capita

USA by State

October 2009



Prescriptions Per Capita

0.025

0.013

0.000

ims

*Flumadine (rimantadine HCL), Relenza (zanamivir), Tamiflu (oseltamivir phosphate) and generic rimantadine HCL make up the influenza antiviral market

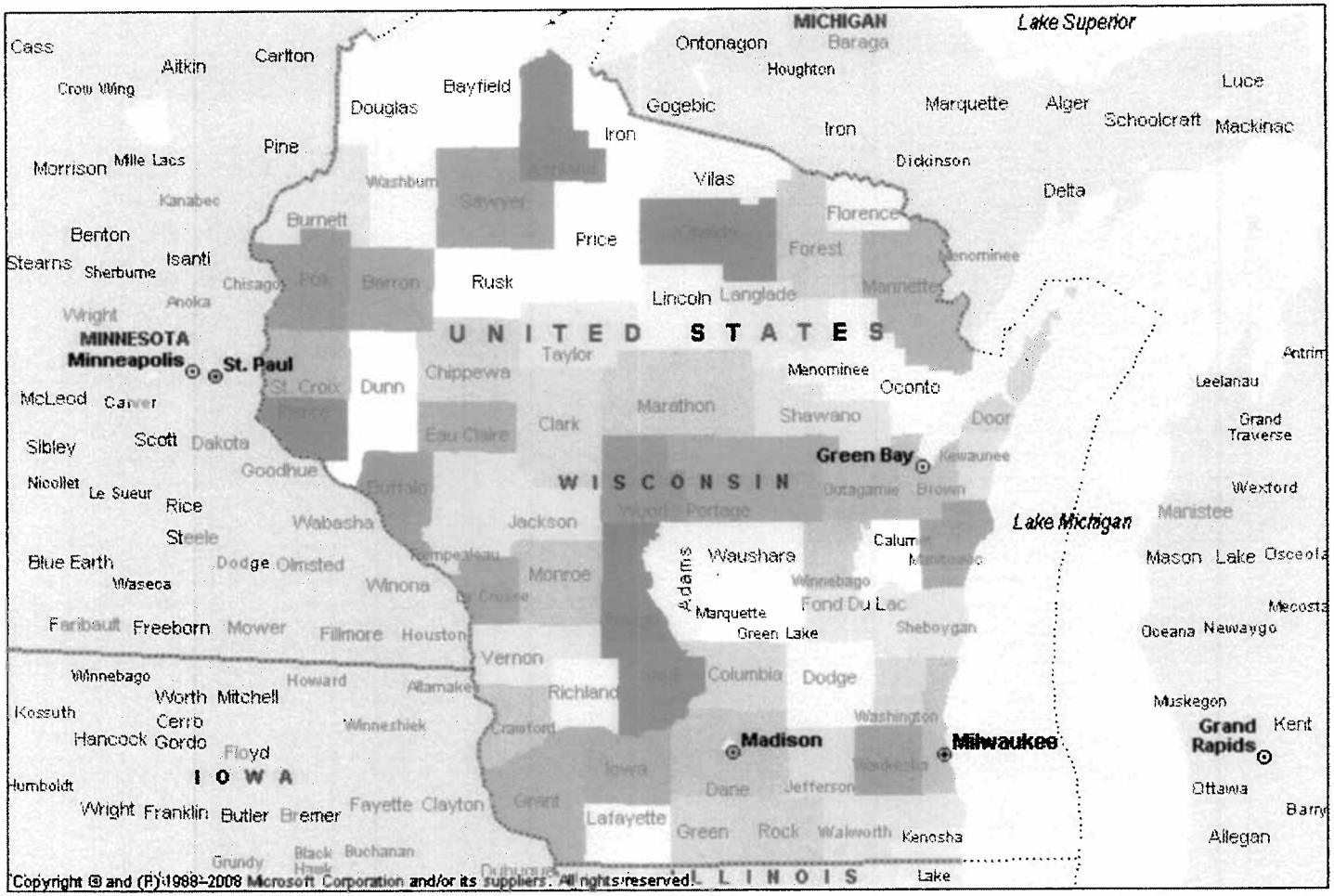
**Based on the US Census' estimated 2008 population

IMS Data Source: Xponent

Influenza Antiviral Prescriptions Per Capita

Wisconsin by County

Oct 2009



WI Prescriptions Per Capita

0.014

0.007

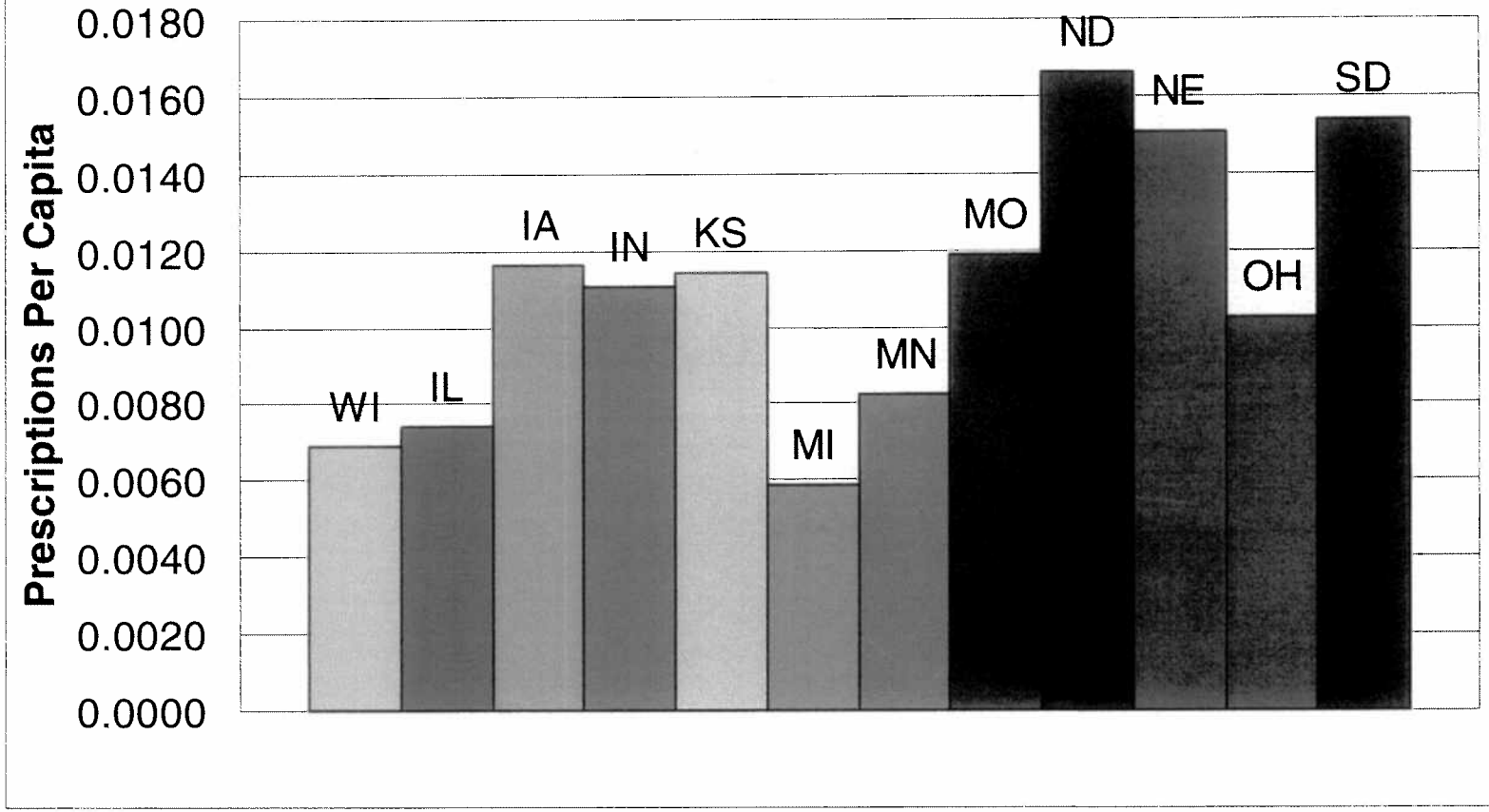
0.000

*Flumadine (rimantadine HCL), Relenza (zanamivir), Tamiflu (oseltamivir phosphate) and generic rimantadine HCL make up the influenza antiviral market

**Based on the US Census' estimated 2008 population

IMS Data Source: Xponent

Influenza Antiviral Prescriptions, State Per Capita
Region: Midwest
Oct 2009



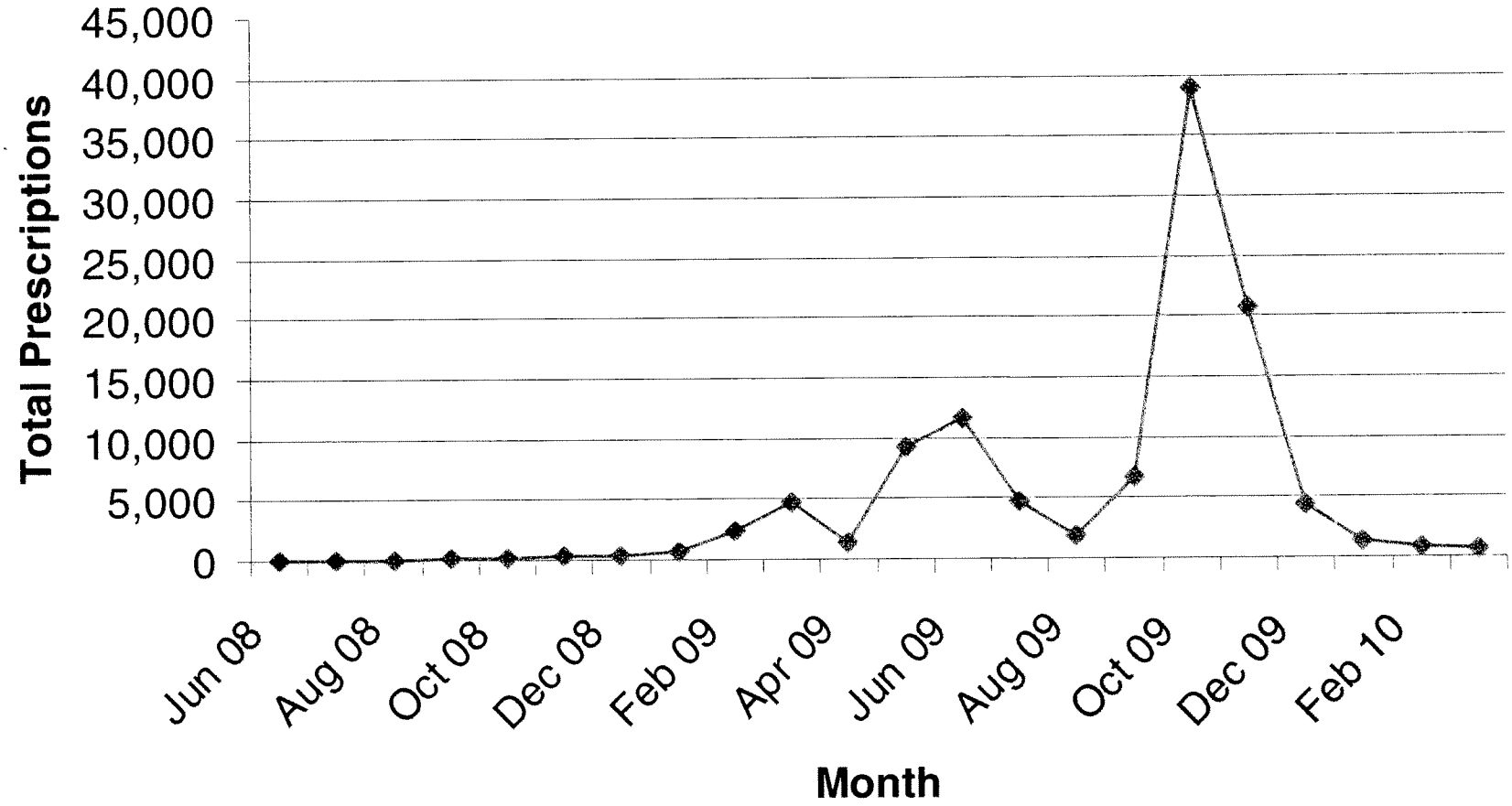
*Flumadine (rimantadine HCL), Relenza (zanamivir), Tamiflu (oseltamivir phosphate) and generic rimantadine HCL make up the influenza antiviral market

**Based on the US Census' estimated 2008 population

**Based on the US Census' defined regions

IMS Data Source: Xponent

Wisconsin Influenza Antiviral PrescriptionTrend
Jun 2008 - Mar 2010



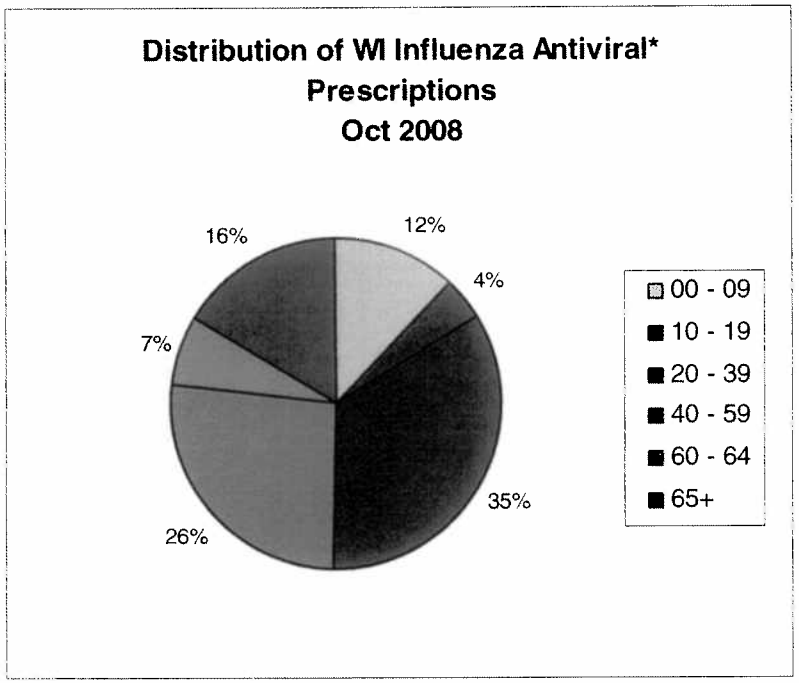
*Flumadine (rimantadine HCL), Relenza (zanamivir), Tamiflu (oseltamivir phosphate) and generic rimantadine HCL make up the influenza antiviral market

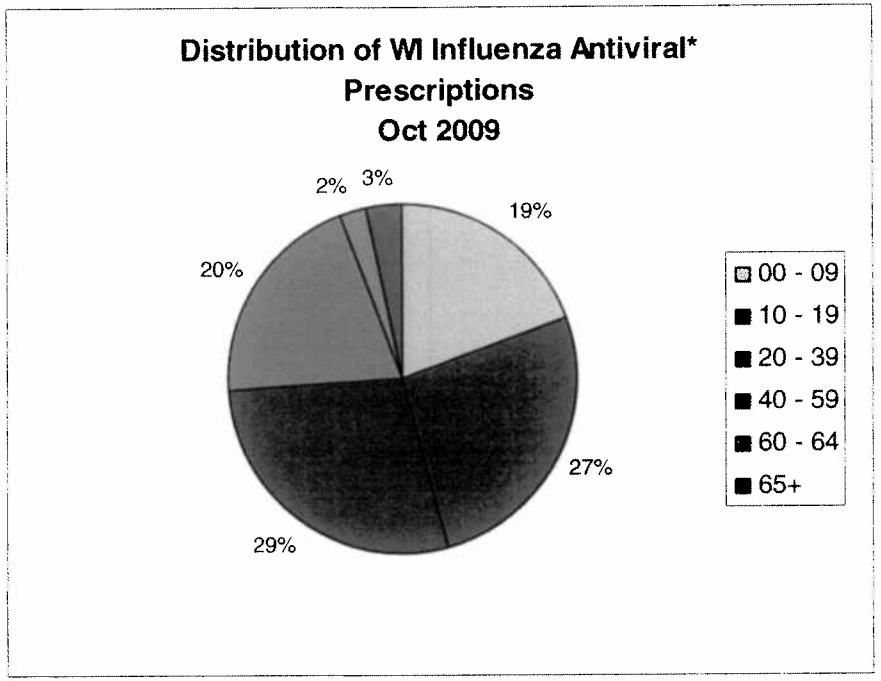
IMS Data Source: Xponent

Influenza Antiviral Prescription Report

Age Distribution Variation, 2008 vs. 2009

State: Wisconsin

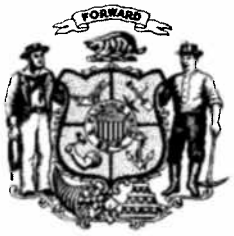




*Flumadine (rimantadine HCL), Relenza (zanamivir), Tamiflu (oseltamivir phosphate) and generic rimantadine HCL make up the influenza antiviral market

IMS Data Source: Xponent

WISCONSIN STATE LEGISLATURE



Wisconsin's Relative Utilization of Pharmaceuticals

ims

Comparison by State: Average Annual Prescriptions per Capita 2009

Rank	State	Avg Rx	Rank	State	Avg Rx
1	West Virginia	18.0	27	Florida	11.7
2	Tennessee	16.7	28	Puerto Rico	11.6
3	Kentucky	16.6	**29**	**Wisconsin**	**11.4**
4	Alabama	16.0	30	Oklahoma	11.2
5	Rhode Island	15.9	31	Vermont	11.1
6	Louisiana	15.4	32	New Jersey	11.1
7	District of Columbia	15.1	33	Virginia	11.0
8	North Dakota	14.7	34	Illinois	11.0
9	Mississippi	14.0	35	Minnesota	10.6
10	Arkansas	13.7	36	South Dakota	10.6
11	Massachusetts	13.2	37	New Hampshire	10.4
12	Pennsylvania	13.2	38	Maryland	10.3
13	South Carolina	13.1	39	Texas	10.2
14	Ohio	13.0	40	Montana	9.9
15	North Carolina	12.9	41	Oregon	9.8
16	Missouri	12.9	42	Hawaii	9.7
17	Nebraska	12.8	43	Washington	9.7
18	Conecticut	12.7	44	Nevada	9.6
19	Indiana	12.4	45	Utah	9.5
20	New York	12.4	46	Wyoming	9.5
21	Maine	12.3	47	Arizona	9.5
22	Kansas	12.2	48	Idaho	9.3
23	Delaware	12.1	49	New Mexico	8.9
24	Iowa	11.9	50	California	8.3
25	Michigan	11.9	51	Colorado	7.9
26	Georgia	11.8	52	Alaska	7.1

National average - 11.5 annual prescriptions per capita

Sources: IMS Health *Rx Insight*, US Census Bureau 2008 population estimates

Comparative Oxycodone Utilization by State

ims

A State Comparison: Total Annual Oxycodone Prescriptions 2008

Rank	State	Total Disp Rx	Rank	State	Total Disp Rx
1	Florida	4,010,840	27	Texas	625,224
2	Pennsylvania	3,178,829	28	Oklahoma	553,298
3	Ohio	2,857,867	29	Utah	547,639
4	New York	2,671,116	30	Illinois	535,701
5	New Jersey	2,228,522	31	Nevada	491,513
6	North Carolina	2,090,531	32	West Virginia	443,407
7	California	2,018,448	33	Kansas	408,471
8	Massachusetts	1,893,710	34	Arkansas	403,296
9	Tennessee	1,610,922	35	New Mexico	387,609
10	Maryland	1,478,757	36	Delaware	378,048
11	Arizona	1,460,864	37	New Hampshire	366,341
12	Georgia	1,450,311	38	Mississippi	317,754
13	Washington	1,419,827	39	Maine	298,358
14	Virginia	1,285,899	40	Iowa	240,890
15	Missouri	981,651	41	Rhode Island	237,573
16	Colorado	939,338	42	Nebraska	207,876
17	**Wisconsin**	**920,136**	43	Montana	159,297
18	Connecticut	913,050	44	District Of Columbia	152,661
19	Oregon	843,279	45	Idaho	134,856
20	Kentucky	821,507	46	Hawaii	130,297
21	South Carolina	797,794	47	Vermont	129,599
22	Michigan	762,504	48	Alaska	118,334
23	Indiana	750,670	49	Wyoming	81,786
24	Minnesota	697,183	50	North Dakota	80,766
25	Louisiana	695,050	51	South Dakota	73,612
26	Alabama	640,966			

Average of all states = 920,074 annual oxycodone prescriptions

A State Comparison: Average Annual Oxycodone Prescriptions per Capita

Rank	State	Avg Rx	Rank	State	Avg Rx
1	Delaware	0.43	27	Missouri	0.17
2	Massachusetts	0.29	28	Virginia	0.17
3	New Hampshire	0.28	29	Montana	0.16
4	Maryland	0.26	**30**	**Wisconsin**	**0.16**
5	Connecticut	0.26	31	Louisiana	0.16
6	Tennessee	0.26	32	Wyoming	0.15
7	District Of Columbia	0.26	33	Oklahoma	0.15
8	New Jersey	0.26	34	Georgia	0.15
9	Pennsylvania	0.26	35	Kansas	0.15
10	Ohio	0.25	36	Arkansas	0.14
11	West Virginia	0.24	37	Alabama	0.14
12	North Carolina	0.23	38	New York	0.14
13	Maine	0.23	39	Minnesota	0.13
14	Rhode Island	0.23	40	North Dakota	0.13
15	Arizona	0.22	41	Indiana	0.12
16	Oregon	0.22	42	Nebraska	0.12
17	Florida	0.22	43	Mississippi	0.11
18	Washington	0.22	44	Hawaii	0.10
19	Vermont	0.21	45	South Dakota	0.09
20	Utah	0.20	46	Idaho	0.09
21	New Mexico	0.20	47	Iowa	0.08
22	Kentucky	0.19	48	Michigan	0.08
23	Colorado	0.19	49	California	0.05
24	Nevada	0.19	50	Illinois	0.04
25	South Carolina	0.18	51	Texas	0.03
26	Alaska	0.17			

Average of all states = 0.18 annual oxycodone prescriptions per capita

Sources: IMS Health *Rx Insight*; US Census Bureau 2008 population estimates

C-II Controlled Substance Utilization by State

ims

A State Comparison: Total Annual C-II Narcotic Prescriptions 2008

Rank	State	Total Disp Rx	Rank	State	Total Disp Rx
1	Florida	7,228,970	27	Connecticut	1,644,544
2	Pennsylvania	5,627,431	28	Oregon	1,631,245
3	California	5,448,216	29	Oklahoma	1,339,146
4	Ohio	5,325,981	30	Utah	1,125,332
5	New York	5,316,257	31	Arkansas	1,123,494
6	Texas	4,480,090	32	Kansas	1,048,169
7	North Carolina	4,237,693	33	Mississippi	923,882
8	Georgia	3,582,154	34	West Virginia	918,755
9	New Jersey	3,489,443	35	Iowa	910,782
10	Massachusetts	3,466,998	36	Nevada	872,374
11	Tennessee	3,310,859	37	New Hampshire	737,279
12	Michigan	3,058,865	38	Maine	678,858
13	Virginia	2,855,545	39	Delaware	673,458
14	Washington	2,689,681	40	New Mexico	672,676
15	Maryland	2,678,063	41	Nebraska	510,551
16	Illinois	2,560,761	42	Rhode Island	498,209
17	Arizona	2,507,239	43	Idaho	385,897
18	Indiana	2,321,196	44	Montana	355,394
19	Missouri	2,290,179	45	Vermont	302,392
20	**Wisconsin**	**2,195,206**	46	District Of Columbia	283,604
21	Louisiana	2,057,417	47	Hawaii	252,267
22	Alabama	1,988,562	48	North Dakota	235,994
23	South Carolina	1,979,614	49	Alaska	228,155
24	Kentucky	1,798,335	50	South Dakota	214,442
25	Minnesota	1,680,890	51	Wyoming	167,849
26	Colorado	1,651,225			

Average of all states = 2,030,620 annual C-II prescriptions

A State Comparison: Average Annual C-II Narcotic Prescriptions per Capita

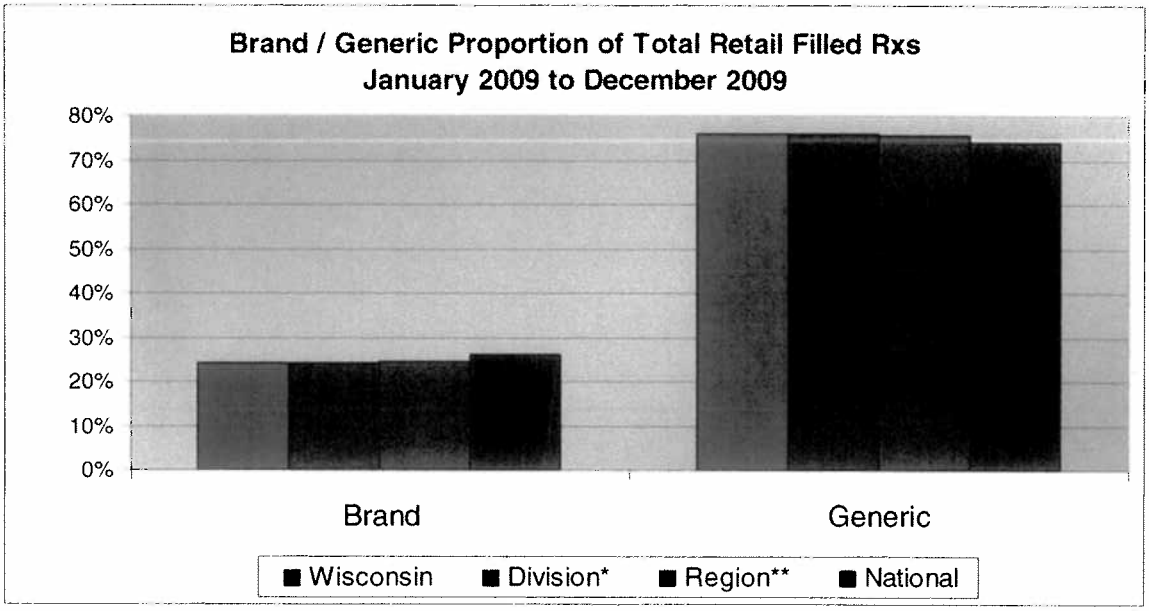
Rank	State	Avg Rx	Rank	State	Avg Rx
1	Delaware	0.77	27	Arizona	0.39
2	New Hampshire	0.56	28	Kansas	0.37
3	Massachusetts	0.53	29	Georgia	0.37
4	Tennessee	0.53	30	North Dakota	0.37
5	Maine	0.52	31	Oklahoma	0.37
6	West Virginia	0.51	32	Virginia	0.37
7	Vermont	0.49	33	Montana	0.37
8	District Of Columbia	0.48	34	Indiana	0.36
9	Maryland	0.48	35	New Mexico	0.34
10	Rhode Island	0.47	36	Nevada	0.34
11	Connecticut	0.47	37	Colorado	0.33
12	Louisiana	0.47	38	Alaska	0.33
13	Ohio	0.46	39	Minnesota	0.32
14	North Carolina	0.46	40	Wyoming	0.32
15	Pennsylvania	0.45	41	Mississippi	0.31
16	South Carolina	0.44	42	Michigan	0.31
17	Oregon	0.43	43	Iowa	0.30
18	Alabama	0.43	44	Nebraska	0.29
19	Kentucky	0.42	45	New York	0.27
20	Utah	0.41	46	South Dakota	0.27
21	Washington	0.41	47	Idaho	0.25
22	New Jersey	0.40	48	Illinois	0.20
23	Florida	0.39	49	Hawaii	0.20
24	Arkansas	0.39	50	Texas	0.18
25	**Wisconsin**	**0.39**	51	California	0.15
26	Missouri	0.39			

Average of all states = 0.39 annual C-II prescriptions per capita

Sources: IMS Health *Rx Insight*; US Census Bureau 2008 population estimates

Utilization of Generics in Wisconsin

ims



* Division - Illinois, Indiana, Michigan, Ohio
** Region - Illinois, Indiana, Iowa, Kansas, Michigan, Minnesota, Missouri, Nebraska, North Dakota, Ohio, South Dakota, Wisconsin

Brand / Generic Proportion of Total Retail Filled Rxs
January 2009 to December 2009

Rx Type	Wisconsin	Division*	Region**	National
Brand	14,776,687	114,049,158	186,756,340	879,161,653
Generic	46,828,355	357,521,501	579,414,073	2,496,197,098
Total	61,605,042	471,570,659	766,170,413	3,375,358,751

Rx Type Ratio	Wisconsin	Division*	Region**	National
Brand	24.0%	24.2%	24.4%	26.0%
Generic	76.0%	75.8%	75.6%	74.0%

* Division - Illinois, Indiana, Michigan, Ohio
** Region - Illinois, Indiana, Iowa, Kansas, Michigan, Minnesota, Missouri, Nebraska, North Dakota, Ohio, South Dakota, Wisconsin

Utilization of Generics in Wisconsin

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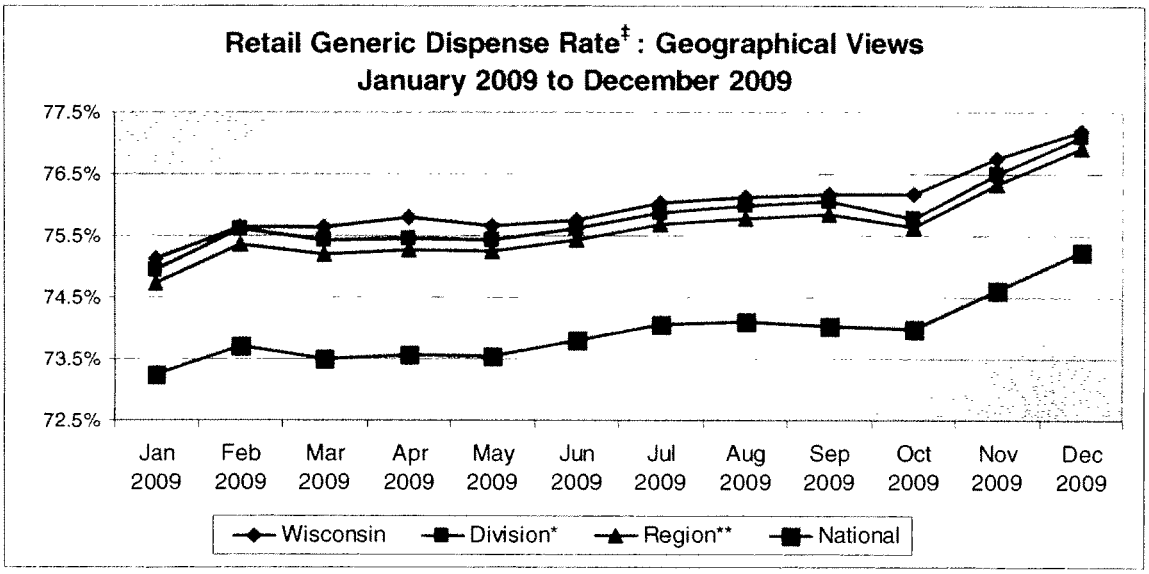
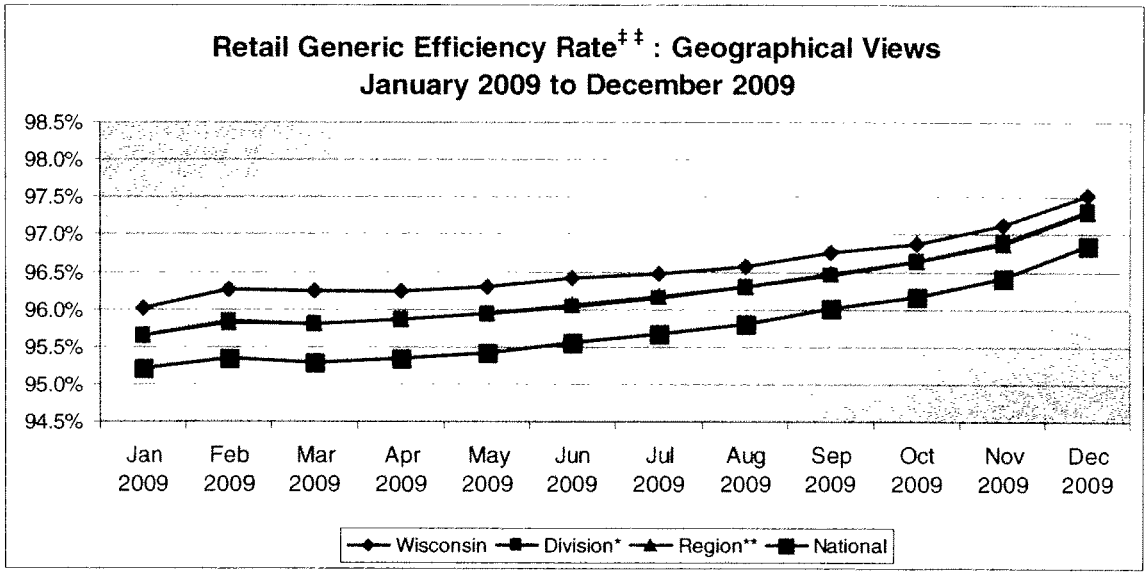
Retail Generic Dispense Rate Over Time
(Percent of Total Retail Prescriptions Filled with Generics)



* Division - Illinois, Indiana, Michigan, Ohio
** Region - Illinois, Indiana, Iowa, Kansas, Michigan, Minnesota, Missouri, Nebraska, North Dakota, Ohio, South Dakota, Wisconsin

Retail Generic Efficiency Rate Over Time
(Frequency with which a Generic is Used When a Generic is Available)



* Division - Illinois, Indiana, Michigan, Ohio
** Region - Illinois, Indiana, Iowa, Kansas, Michigan, Minnesota, Missouri, Nebraska, North Dakota, Ohio, South Dakota, Wisconsin

Pharmaceutical Utilization Patterns in Wisconsin

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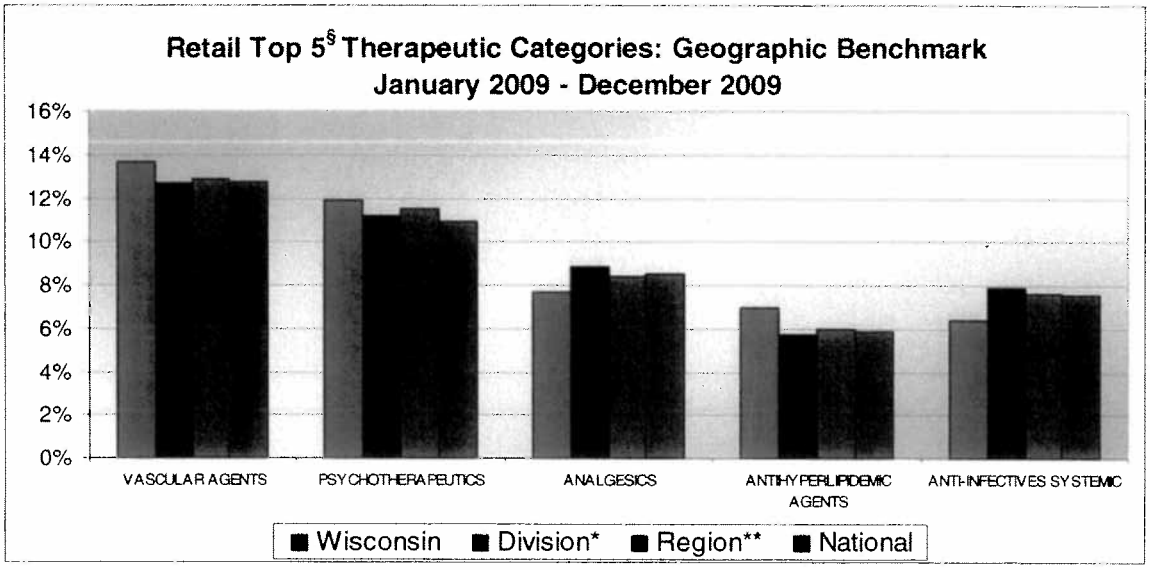
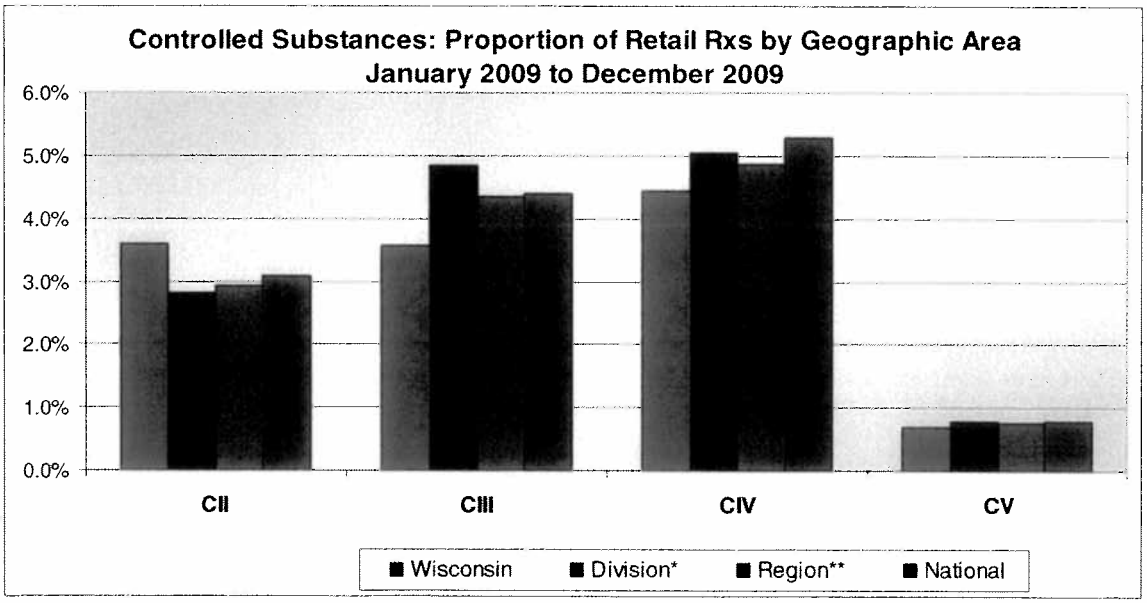


*Division - Illinois, Indiana, Michigan, Ohio
** Region - Illinois, Indiana, Iowa, Kansas, Michigan, Minnesota, Missouri, Nebraska, North Dakota, Ohio, South Dakota, Wisconsin
§Top 5 Therapeutic Categories based on Total Retail Filled Prescriptions Jan 2009 to Dec 2009

Controlled Substance Utilization Patterns in Wisconsin



*Division - Illinois, Indiana, Michigan, Ohio
**Region - Illinois, Indiana, Iowa, Kansas, Michigan, Minnesota, Missouri, Nebraska, North Dakota, Ohio, South Dakota, Wisconsin
§Controlled Substance Utilization based on Total Retail Filled Prescriptions Jan 2009 to Dec 2009

C-II Controlled Substance Utilization in Wisconsin Medicaid

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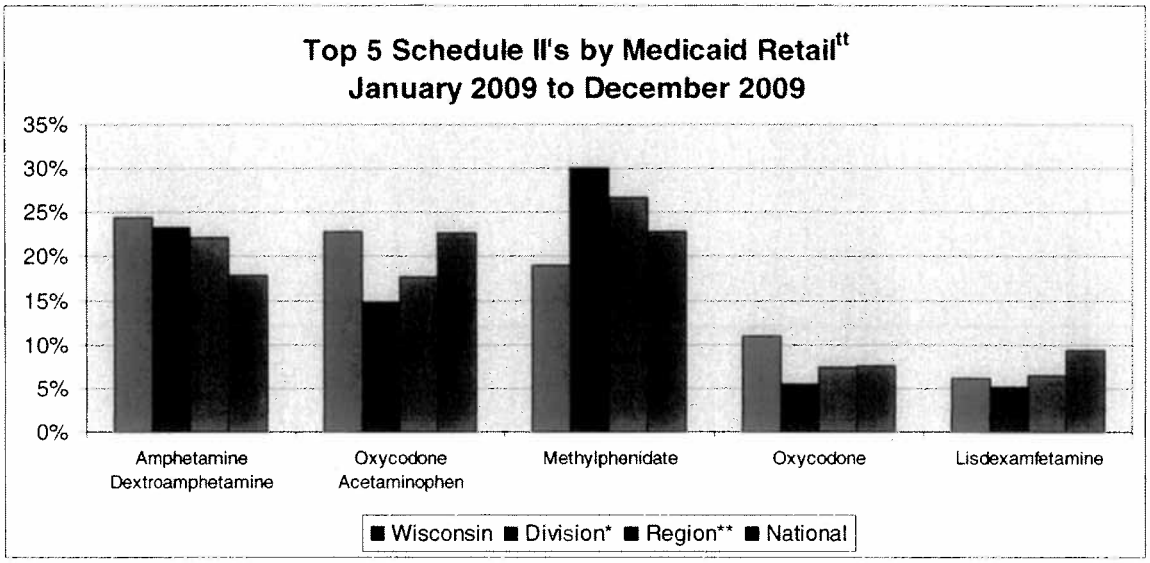
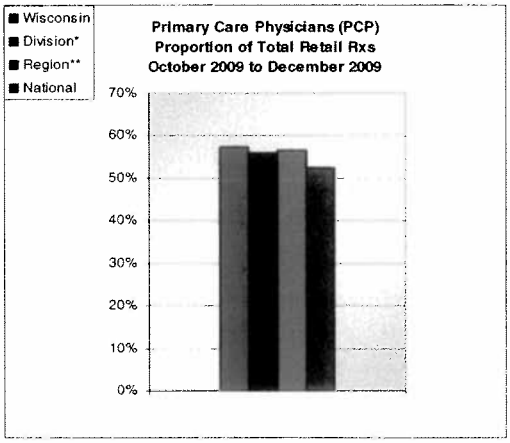
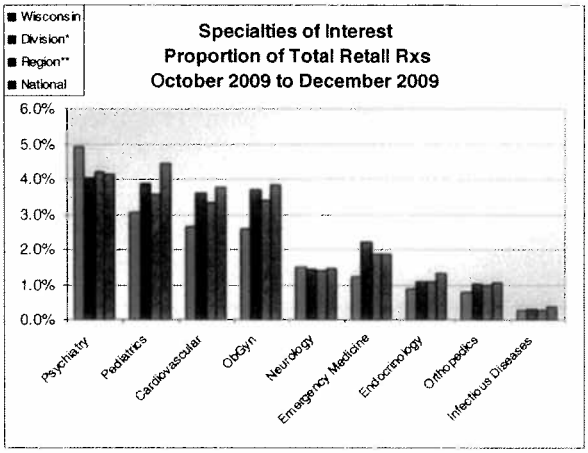


* Division - Illinois, Indiana, Michigan, Ohio
** Region - Illinois, Indiana, Iowa, Kansas, Michigan, Minnesota, Missouri, Nebraska, North Dakota, Ohio, South Dakota, Wisconsin

Aggregate Prescribing by Specialty in Wisconsin





* Division - Illinois, Indiana, Michigan, Ohio
** Region - Illinois, Indiana, Iowa, Kansas, Michigan, Minnesota, Missouri, Nebraska, North Dakota, Ohio, South Dakota, Wisconsin

Specialty Analysis, HIV/AIDS Prescribing in Wisconsin

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Total Retail Prescriptions, Year Ended March 2010

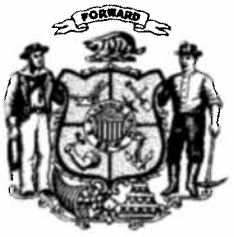
	23,921	428
HIV Therapy Prescriber Specialties:	**Prescriber Count**	**Rxs**
Infectious Diseases - IM	15	18,961
Internal Medicine	7	13,355
Nurse Practitioner	3	4,004
Family Medicine	3	2,597
Rheumatology	1	2,109
Physician Assistant	1	852
Immunology	1	568
Prescribers Responsible for 80% of HIV Rxs	**31**	42,446

Specialty Analysis, Alzheimer's Disease Prescribing in Wisconsin

Total Retail Prescriptions, Year Ended March 2010

	23,921	4,249
Alzheimer's Prescriber Specialties:	**Prescriber Count**	**Rxs**
Internal Medicine	489	75,271
Family Medicine	453	62,518
Neurology	116	30,539
Psychiatry	63	10,080
Nurse Practitioner	45	7,687
Family Practice	55	7,162
Internal Medicine - Geriatric Medicine	19	6,986
Geriatric Psychiatry	6	2,546
Physician Assistant	11	1,872
Family Practice - Geriatric Medicine	3	1,599
General Practice	10	1,161
Internal Medicine - Pediatrics	7	1,117
Cardiovascular Diseases	7	654
Infectious Diseases - IM	3	470
Child and Adolescent Psychiatry	5	391
Clinical Neurophysiology	3	297
Dentist	1	174
Pediatrics	1	144
Emergency Medicine	1	142
Critical Care Medicine - IM	1	113
Physical Medicine and Rehab	1	109
Obstetrics/Gynecology	1	102
Anesthesiology	1	91
Pulmonary Disease	1	90
Gastroenterology	1	88
Otolaryngology	1	86
General Surgery	1	81
Family Practice - Sports Medicine	1	73
Addiction Medicine	1	69
Child Neurology	1	65
Endocrinology	1	57
Prescribers Responsible for 80% of Alzheimer's Rxs	**1,310**	211,834

WISCONSIN STATE LEGISLATURE



Treatment Delayed is Treatment Denied— The Unintended Consequences of State Laws to Ban the Use of Physician Level Data

Executive Summary

Since 2006, more than twenty states have considered legislation to ban the commercial use of physician level data. Although three states (New Hampshire, Maine and Vermont) passed such laws with the intent to reduce costs of branded medications, none have done so since 2007. In contrast, opponents of these laws (as well as two federal judges) have proposed that restrictions on commercial use of data would not achieve the stated goals, would compromise patient care and health research, and that alternatives that do not have the potential to harm patients already exist.

The Massachusetts Biotechnology Council (MassBio), a not-for-profit organization founded in 1985, is committed to providing information to aid local, state and federal officials and the general public in making informed decisions about issues concerning biotechnology. Foremost among our objectives is to create an environment that recognizes and supports the development of science, technologies, and medicines that benefit people worldwide.

In line with these goals, we present a case study of unintended consequences of data restriction laws—"the canary in the coal mine." Further, this report illuminates the process of care and dissemination of FDA-approved information supported by such data, and the dangerous ripple effects of selectively reducing access to information as a means to alter drug utilization.

MassBio member, Eisai Inc., which has a research facility in Andover, MA, is a U.S. pharmaceutical subsidiary of Tokyo-based Eisai Co., Ltd, a research based human healthcare company dedicated to developing and marketing specialty drugs that address unmet needs. In January 2009, after approval by the FDA, Eisai launched BANZEL® (rufinamide)—a prescription drug, approved for the adjunctive treatment of seizures associated with Lennox-Gastaut Syndrome (LGS) in children 4 years and older and adults. LGS is a rare and catastrophic form of epilepsy.

Using physician level data, Eisai—after approval by the FDA—quickly delivered information regarding the clinical use of BANZEL to a specific, targeted physician population, and developed a rigorous, ongoing process for ensuring appropriate use of BANZEL by:

- Identifying the small population of physicians who treat patients with LGS
- Limiting promotion of the drug to child neurologists and epileptologists—neurologists who have completed specialized training in epilepsy and treat only epilepsy—with patients known to have LGS
- Working with physicians to manage risks related to specific concerns
- Providing professional services to enhance patient care
- Monitoring physician experience with BANZEL to quickly and effectively communicate new information to a broader physician community

The data restriction law in New Hampshire resulted in a lack of transparency about which neurologists in the state treat patients with LGS and created uncertainty for Eisai about which neurologists they should contact about BANZEL. Eisai's experience in New Hampshire points to how these laws reduce effectiveness and efficiency in the dissemination of information that impacts patient care and may increase the time it takes to get new drugs to patients—most importantly in this case, potentially delaying access to an effective product for a catastrophic illness.

As states and the federal government move toward healthcare reform, it will be critical for legislators to understand the system of care in order to assess how changes in policy will broadly impact health research and the public welfare.

Introduction

MassBio represents 630 biotechnology companies, universities and academic institutions. Three hundred and seventy (370) member companies are directly engaged in research, development and manufacture of innovative products that bring great benefit to people around the world. MassBio members are at the forefront of a trend in biomedical research that increasingly focuses on treatments for diseases that serve smaller populations.

Many states have leveraged private investment and public support for biotechnology research and development, e.g., Massachusetts' $1 billion life sciences initiative.[1] Reasons for these investments include the advancement of clinical research and the development of new industry and employment in the respective state(s). Given the magnitude of these investments, it is important to consider any public policy initiative that effectively undermines the nurturing environment intended by political leadership.

Under the rubric of patient privacy and reducing healthcare costs, many states have considered restricting commercial use of HIPAA-compliant, physician level data. While the potential of such legislation to reduce costs is hypothetical at best, unintended consequences associated with loss of these data are quite clear.

These data have many uses impacting patient safety, physician education and commercial realization of innovative new therapies. In effect, these (patient-anonymous) data are essential to achieving clinical and commercial success.

Uses bridge private, public and government sectors and include:

- Identifying clinicians who specialize in specific illnesses (physician specialty alone is not adequate in today's environment of sub-specialization)
- Accelerating recruitment of clinical investigators and research processes
- Enhancing communication among clinicians, researchers and the FDA/CDC in their efforts to track communicable disease
- Disseminating appropriate guidelines for safety and effectiveness once the FDA approves a drug
- Collaborating with the FDA and clinicians in risk management and risk minimization programs*

In the vast majority of states, data restrictions laws have not advanced. While the reasons differ by state, concern for patient care has been the prevailing consideration.

Within this context, the following case is a fact-based review of how Eisai judiciously and responsibly used physician level data to quickly deliver their new drug to patients and examines the potential impact of data restriction legislation on patient care.

Treatment Delayed Is Treatment Denied: A Case Study

Background

In November 2008, the FDA approved BANZEL®, a drug developed by Eisai Inc., for adjunctive use in the treatment of seizures associated with Lennox-Gastaut Syndrome (LGS) in children 4 years and older and adults. LGS is a rare and catastrophic form of epilepsy. In a pivotal clinical trial, BANZEL was shown to significantly reduce total seizures in patients with LGS and received approval under the Orphan Drug Act (which defines an orphan disease as one that affects less than 200,000 people).[2-4]

Lennox-Gastaut Syndrome

Lennox-Gastaut Syndrome is a devastating form of childhood-onset epilepsy characterized by multiple types of seizures occurring many times a day (100 or more in some cases) and delayed intellectual development (Table 1).[5] Seizures are often resistant to therapy, which results in high

*Of note, the 110th Congress passed the FDA Reauthorization Act. In the legislation there are increased demands for pharmaceutical and biotechnology companies to expand the scope of drug safety monitoring and post-market surveillance, in addition to rigorous standards already in place that require companies to contact providers about everything from product recall to labeling changes. New and existing safety provisions will be difficult to pursue and perhaps might even be unworkable without access to HIPAA-compliant provider level data.

rates of injuries due to tonic and/or atonic seizures, also known as "drop attacks" or "drop seizures." Patients with LGS often wear protective helmets with face guards (Figure 1).[4]

Table 1. Most Common Seizure Types in Patients with LGS

Seizure Type	Description
Tonic	Stiffening of the muscles lasting a few seconds to minutes
Atypical Absences	Interruption of consciousness where person appears vacant and unresponsive
Sudden Tonic or Atonic Falls ("Drop Attacks")	Brief loss of muscle tone and consciousness causing falls
Non-convulsive Status Epilepticus	Atypical absences with varying degrees of altered consciousness and periodic recurring brief tonic seizures
Myoclonic	Rapid contraction of the muscles causing jerking movements. Can also cause falls.
Other	Focal seizures, tonic-clonic generalized seizures, and unilateral clonic seizures are also common

Source: Excerpted from Arzimanoglou A, French J, Blume T, et al. Lennox-Gastaut syndrome: a consensus approach on diagnosis, assessment, management, and trial methodology. Vol 8, January 2009. www.thelancet.com/neurology Accessed on 9/25/09.

Incidence and Mortality: A Child Dies Every Day

Of approximately 300,000 children under the age of 14 who have epilepsy in the U.S., up to 4% have LGS. Long-term prognosis is poor. Eighty percent of patients will continue to have seizures into adulthood. Although types of seizures may change or lessen with age, behavioral issues and impaired functioning remain a challenge. Deaths of patients are often due to accidents and occur at the rate of 3% (360 children per year).[2,4] That means that a child dies every day from the disease.

Figure 1. Patient with LGS wearing a protective helmet with face guard to protect against injury from "drop attacks."

Source: Glauser, TA, Morita, DA. Lennox-Gastaut Syndrome. Emedicine from WebMD. http://emedicine.medscape.com/article/1176735-overview Updated: 1/05/10. Accessed on 1/18/10.

Treatment Options

Because of the complexity of the disorder and the high rate of complications, management of LGS requires a multidisciplinary team of medical specialists and psychosocial support.

Goals of treatment are to achieve the fewest seizures and the fewest adverse events with the least number and severity of medical interventions, so that patients can have the best quality of care possible. Antiepileptic drugs that have a broad spectrum of activity against multiple seizures types are first-line treatment. However, since no one drug alone has been shown to be effective in managing LGS, multiple drug therapy and other approaches are often necessary—including catastrophic and costly surgery in which half the brain is removed or disabled (Table 2).[3-7]

Burden of Illness

Patients often endure years of treatment trials and complications with varying effects on seizure reduction. Kim SanInocencio, the mother of an adult son with LGS and co-founder with her daughter Christina of the LGS Foundation, says, "Every family experiences LGS differently, but we all share one thing in common, and that is living with the unexpected. Because day to day, the seizures—and the consequences—are different, we all live in great anticipation of new treatment options that could make a difference."[6]

Table 2. Treatment Options for LGS

Type	Description
Combination therapy with multiple antiepileptic drugs (AEDs) and other classes of drugs	Few clinical studies exist on comparative efficacy of medications; response rates vary Side effects may include irritability, mood disorders, depression, sedation, cognitive issues and behavioral problems; class labeling for AEDs includes increased risk for suicide
Ketogenic diet	High fat diet with low carbohydrates and protein (4:1 ratio); requires strict supervision and even the slightest departure may cause the diet to lose its effect. Results vary; may decrease seizures by 50% in some patients; 10%-15% become seizure free Side effects: dehydration, constipation, kidney stones, bone fractures, vomiting, high cholesterol levels, slower growth rates in children
Vagus nerve stimulation	A device that is implanted surgically under the patient's arm or near the chest and emits electrical impulses to help control seizures. Side effects include infection, pain, chest spasm, voice alteration, increased coughing Estimated cost: $15,000 to $20,000
Brain surgery including resection, corpus callosotomy, functional hemispherectomy, and multiple sub-pial transection	May be recommended to patients who do not respond to antiseizure medications; degree of improvement and side effects are variable Estimated cost: $50,000 to $200,000 based on type of procedure

Sources:

LGS Foundation Website. www.lgsfoundation.org Accessed on 9/25/09.

Arzimanoglou A, French J, Blume T, et al. Lennox-Gastaut syndrome: a consensus approach on diagnosis, assessment, management, and trial methodology. Vol 8, January 2009. www.thelancet.com/neurology Accessed on 9/25/09.

Epilepsy Foundation of American website. www.efa.org Accessed on 9/25/09.

For patients with LGS, many of whom are wheelchair bound, common everyday activities are severely limited by uncontrolled seizures and behavior problems. According to a recent study conducted by the LGS Foundation, almost 50% of children no longer attend school while 21% miss school 50% or more of the time.

Lennox-Gastaut Syndrome affects the entire family, testing emotional, physical, social and financial resources. Because children with LGS need constant care and vigilance, parents often give up employment to become full time caregivers and advocates and/or struggle with decisions about placing their child in an institution or group home. Siblings, too, are often involved as caregivers and their lives are affected as the family's attention and resources are focused on the needs of the child with LGS.

The stress of having a child with uncontrolled seizures is compounded by the stress of reduced income, social isolation, and the demands of interacting with a complex support system consisting, in part, of healthcare providers, insurance companies, and school officials. And

yet, these families are remarkable in their ability to advocate for their children and sustain hope that effective treatments will be found.

For Kim SanInocencio's son, Michael, that hope was realized when BANZEL was added to his antiepileptic drug treatment. After living with LGS for 18 years, enduring many injuries and complications, treatment failures with almost all antiepileptic drugs as well as implantation and removal of a vagus nerve stimulation device, Michael has had a good response to BANZEL. Michael and his family report a reduction in the number of seizures he experiences and less worry about his having seizures on a daily basis.[6,8]

The Challenge: Finding the Right Physicians with the Right Patients

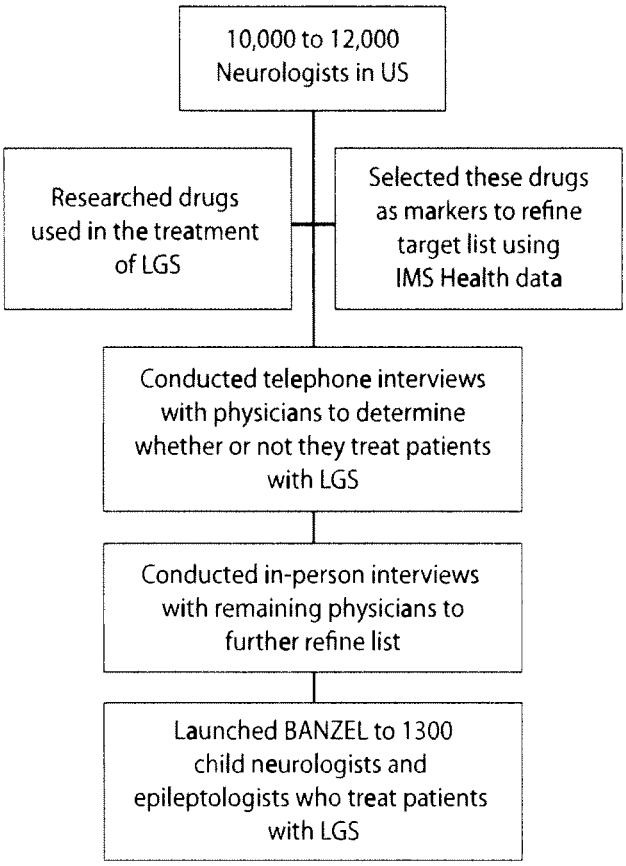
The potential for inappropriate use of BANZEL and its impact on patient safety, created an imperative for Eisai to refine the target audience for launch. Essential to this process was the use of physician level data, which Eisai licensed from IMS Health, the nation's largest health information organization.

The steps used for identifying the appropriate target audience for BANZEL are outlined in Figure 2. By this process, Eisai identified a list of 1300 child neurologists and epileptologists—from a universe of 10,000 to 12,000 general neurologists—and was able to target messaging to those physicians most knowledgeable about how to use and evaluate BANZEL in clinical practice.

Clearly, the value of physician level data lies in the ability to identify clinicians among all neurologists who are actually treating patients with LGS. The objective was to ensure that the product was made available as quickly and responsibly as possible to appropriate physicians. The ability to use physician level data was essential in achieving that goal, not only in terms of communicating appropriate use and patient safety information but it also allowed the most effective and efficient use of resources. Without this ability, the cost of identifying and communicating with the right physicians would have been exorbitant.

The experience in New Hampshire did not serve

Figure 2. How Eisai Identified the Right Physicians with the Right Patients to Ensure Appropriate Use of BANZEL



patient care well as there were delays at the physician-interaction level—an example of how data restriction laws there made identifying the right physicians very difficult and prevented immediate and direct communication with physicians about the benefits and risks of BANZEL.

Managing Risk

In all other states, physician level data facilitated early communication with targeted physicians by sales representatives about possible adverse events, e.g., in patients with familial short QT syndrome and drug-drug interactions, especially the synergistic interaction with valproate which increases BANZEL blood levels by 16% to 70%.[9]

Eisai believed it was critical for initial use of BANZEL to be carefully assessed by experts in LGS since inappropriate utilization may result in negative patient outcomes and, as a consequence,

lead to other patients being denied effective treatment.

Communicating Safety and Efficacy Information

Clinical study results and insights from researchers experienced with the adjunctive use of BANZEL were rapidly disseminated through interaction with healthcare providers, supported by the use of physician level data. Representatives also provided physicians with information about visiting faculty, on-line programs, and materials for caregivers including printed brochures.

Prior to development of these programs, the Eisai marketing, medical services, and sales team underwent comprehensive training that addressed disease state, the full range of treatment modalities as well as the patient/family experience of living with LGS.

Creating Ongoing Dialogue

Using physician level data, Eisai was also able to monitor experience with BANZEL and to create ongoing dialogue with physicians about benefits and risks. These data are fundamental to the role of representatives as clinical liaisons providing additional service and support to ensure that patients are receiving the highest quality of care. For example, they provide:

- Efficient distribution of valuable samples (which are limited due to BANZEL's orphan status) to targeted physicians who can assess treatment effects in individual patients without having to prescribe a full course of therapy thereby delaying patient co-pay until efficacy and safety have been established
- Timely access to drugs at the pharmacy level to ensure that patients will not have to delay treatment. Representatives coordinate with physicians to make sure that the pharmacies used by their patients are informed about and stock BANZEL
- Quick and effective diffusion of clinical experience with BANZEL, including serving as intermediaries to link physicians who share information and consult on patient cases

Unintended Consequences of Data Restriction Laws

Delaying the dissemination of new products and information to patients is an unintended consequence of data restriction legislation. At the patient level, treatment delayed is treatment denied. And for patients with critical conditions like LGS, denial of care could result in tragic consequences.

During the 2009-2010 legislative session, physician level data restriction bills have been filed in over twenty states around the country with most states deciding against banning use. In the three states that have enacted laws to prohibit commercial use of data—New Hampshire, Maine and Vermont—proponents argue that the legislation will improve patient privacy, reduce inappropriate marketing practices, protect physician privacy, and reduce healthcare costs. Opponents argue that privacy is not an issue and that other ways to manage cost are working in the system, for instance, tiered formularies.

Those who support the ban further argue that physicians learn about treatment innovations from medical journals and their peers, and that there is no need for sales representatives to provide education. Yet, these methods may be insufficient for rapid dissemination of information, especially to the specific subgroup of physicians whose patient populations can benefit from it the most. This may cause a delay in treatment for those patients with the greatest need for help—such as those with LGS.

New Hampshire is the "canary in the coal mine," proving the real world consequences of passing this legislation. As predicted by opponents, and confirmed by Eisai's experience of trying to market BANZEL in New Hampshire, the benefits of this legislation are unknown, while the harm is clear: these laws create inefficiencies in the dissemination of information and may result in delayed access for patients to new products like BANZEL.

At a time when Americans are worried about healthcare rationing, this legislation amounts to arbitrary rationing rather than a system of care based on clinical facts, benefits, and risks.

Summary

In conclusion, this case presents one example of how MassBio member companies are engaged in and dedicated to improving patient care through the discovery, development and responsible marketing of innovative treatments. State support of the life sciences, as demonstrated by Massachusetts' $1 billion life sciences initiative, creates a nurturing and open environment that is vital to the development of new science, technology, and safe and effective medicines that benefit people worldwide. It is important to consider carefully any public policy initiative that jeopardizes that environment.

Moreover, as advocates of physician level data predicted, and experience in New Hampshire bears out, restricting the use of physician data has the potential to hinder quality of care. In effect, at the patient level, treatment delayed is treatment denied. In addition, the inability for company representatives to target communications to the appropriate physicians could make the cost to educate them about drugs so prohibitive as to limit research and development of orphan drugs for rare and devastating diseases like LGS.

With Eisai's experience in New Hampshire as an early warning, legislators need to give careful consideration to the consequences of legislation restricting the use of physician level data. Of paramount concern: how widespread delays in the dissemination of information about new medications will delay patient care and impair the overall quality of healthcare in their respective states.

Eisai's judicious and responsible use of data to launch BANZEL supports the role of physician level data as essential to the safe and appropriate use of pharmaceuticals and to bringing new, life-saving and life-enhancing drugs to patients in the most effective and efficient way possible.

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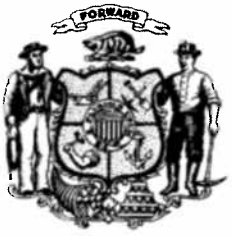
FORWARD

WISCONSIN POLICIES AND PROGRAMS

HIGHLIGHTS

- *Wisconsin's biopharmaceutical industry supported 42,000 jobs and contributed $7.2 billion to the state economy in 2006, including direct, indirect and induced impacts*
- *The State of Wisconsin made a 10-year, $375 million commitment to create the Wisconsin Institutes of Discovery, a public-private partnership that will create a large, new, multidisciplinary campus-within-a-campus at the University of Wisconsin*
- *Wisconsin offers a 25 percent tax credit to angel and venture capital investors who invest in Wisconsin-based start-up and emerging technology companies, including in the biopharmaceutical sector*

Wisconsin's Biopharmaceutical Industry

Wisconsin's biopharmaceutical sector has emerged in recent years into an industry modest in size but characterized by growth.[1] In 2006, state biopharmaceutical firms provided 4,900 direct jobs and supported a total of 42,000 jobs, including its direct, indirect and induced employment impacts.[2] The industry is a significant driver of the state economy, supporting a total of $7.2 billion in total economic output, including direct, indirect and induced effects. Wisconsin has a sizable biomedical research infrastructure, with 1,608 active clinical trials underway in 2008.

Biopharmaceutical Sector Performance Measures	WI	US
Direct Employment, 2006	4,914	686,442
Direct Employment Growth (CAGR), 1996-2006	3.7%	3.1%
Average Annual Wages (Direct Employment), 2006	$71,721	$88,929
Total Supported Employment (incl. Direct), 2006	41,979	3,233,920
Total Economic Output, 2006 ($ billions)	$7.2	$294.6
Direct Output per Direct Employee, 2006	$394,688	$128,925
Active Clinical Trials, 2008	1,608	21,795

Source: Archstone Consulting, *The Biopharmaceutical Sector's Impact on the U.S. Economy*, prepared for PhRMA, 2009.

CAGR = Compound Annual Growth Rate

Since 2000, employment in the Madison region's primary sector biotech workforce (which includes R&D, drug development, and medical devices) has increased by 95 percent—from 2,900 to 5,700.

Thrive (economic development organization for eight-county Madison region) http://www.thrivehere.org/biotechnology, accessed 2009

Wisconsin's Approach to Growing the Biopharmaceutical Industry

The biopharmaceutical sector in Wisconsin is characterized by small- to mid-sized innovative companies emerging from or clustering around the University of Wisconsin-Madison. Faculty at the university have made some of the more important and profitable discoveries in human health over the last century, including most famously Vitamin D enrichment and the invention of a blood thinner. In recent decades, the university's patent and licensing arm has intensified its efforts to license biomedical technologies to locally based start-ups and spinoffs.

The university licensing enterprise has been so successful over many decades that state government policy has focused mainly on capital construction that allows the university to continue to expand its R&D capacity. Public investment has been particularly strong in the area of regenerative medicine. Major projects, such as the Wisconsin Institute for Medical Research proposed in the previous decade, are now open. The institute is described below.

UW-Madison researchers have applied for a patent on a novel compound that could be used in the treatment of cancer patients and HIV. The compound, betulinic acid, is a naturally occurring compound derived from the bark of white birch trees, and has shown some efficacy as a skin cancer therapeutic, HIV inhibitor, neurodegenerative disease treatment, and antibacterial agent.

Wisconsin Alumni Research Foundation, "Drug Discoveries" http://warf.org/technologies.jsp?techfield=Drug+Discovery &casecode=P07498US

Under Governor Doyle's "Grow Wisconsin Plan" of 2003,[3] which emphasizes the attraction of high-wage jobs, the Wisconsin Institutes for Discovery have emerged as this decade's signature investment in biomedicine. The WID is a public-private partnership that will create a large, new, multidisciplinary campus-within-a-campus at UW. UW-Madison also continues to build out its highly successful University Research Park, which includes ample business incubation capacity for biopharmaceutical firms.

Grow Wisconsin has also led to adoption of a major package of venture investment tax credits under Act 255, under which qualifying angel and venture capital investors in Qualified Small Business Ventures (as certified by the Department of Commerce) may receive tax credits of 25 percent.[4] Following a recommendation of the 2008 Grow Wisconsin update, the 2009/2010 budget raised the program cap to $4 million in credit-eligible investment per qualifying venture, of which no more than $1 million can come from angel investors. As of 2011, the cap will rise further to $8 million. The annual statewide pool of credits was tripled to $18.25 million for the angel credit and $18.75 million for the venture credit. Another way in which Wisconsin has tried to increase the availability of early-stage capital is through the State of Wisconsin Investment Board, the state's pension fund. The Board has invested $200 million in venture funds that are managed by four Wisconsin firms, two of which invest in healthcare and life sciences firms.

Wisconsin will also begin offering an exemption to the sales and use tax for machinery and other tangible personal property used for qualified manufacturing or biotechnology research in the state, effective Jan. 1, 2012.

> A start-up biopharmaceutical firm chose to relocate to Wisconsin in order to take advantage of Wisconsin's tax credits. "Wisconsin's investment tax credit had everything to do with the pending move," said the company's lead investor.
>
> BioRegion News
> July 17, 2009
> http://www.genomeweb.com

Major State Initiatives to Attract and Grow the Biopharmaceutical Industry

Wisconsin Institutes for Discovery (WID)

WID is a partnership of the Morgridge Institute, a newly endowed private-nonprofit dedicated to human-health research, and the public Wisconsin Institute for Discovery, a multidisciplinary program of the University of Wisconsin. The three-building physical campus-within-a-campus was financed by $50 million donated by the Morgridge family, $50 million from the state, and $50 million from the Wisconsin Alumni Research Foundation, the exclusive patent, licensing and commercialization/tech-transfer agent for the University of Wisconsin System that regularly recycles its earnings into programs of the UW Graduate School. While the WID also embraces IT and nanotechnology, a strong third thrust is on clinical and translational medical research, including collaboration with the nearby Wisconsin Institute of Medical Research. The research program specifically includes regenerative biology, virology, and pharmaceutical informatics. The first tower of WID opened in 2008. A second building is under construction and a third is in the planning and development phase. Physical construction will be accompanied by 100 "cluster faculty hires."

> Technology-based economic development is a key element of Wisconsin Governor Jim Doyle's Grow Wisconsin Initiative. The state has tax credits and grants and loan programs to assist high-potential technology businesses. Wisconsin has also made a $375 million commitment during the next 10 years to biotechnology in the form of the Wisconsin Institute for Discovery. "This project will bring together interdisciplinary forces to encourage ideas that support emerging technology companies," (a senior official at Forward Wisconsin, the state economic development agency) says. "Technology incubators and financing are in place to help capitalize on the resources in the sciences here."
>
> "Industrial Muscle Propels Biosciences"
> Global Corporate Expansion Magazine
> Spring 2008
> http://www.gcx-online.com/gcx/article.asp?magarticle_id=649

Research Park

University Research Park, the 255-acre park at UW-Madison that is known for its laboratory-equipped MGE Innovation Center incubator complex, is adding an 80,000 square-foot accelerator for later-stage life science companies. URP is also moving toward groundbreaking on a 270-acre Phase 3 development project.

Technology Development Fund

Wisconsin's Technology Development Fund supports activities, including R&D, that

- Will lead to a new or significant improvement in products or processes
- Have a high probability of commercial success
- Will provide significant economic benefit to Wisconsin.

Biopharmaceutical companies, among others, qualify for 5- to 7-year low-interest loans for development of technological innovations, either independently or in partnership with an in-state university.

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[1] The biopharmaceutical sector is defined as including pharmaceutical and medicine manufacturing and scientific research and development services. The bioscience sector is broader and includes medical devices and agricultural feedstocks and chemicals in addition to biopharmaceuticals. Some states use the term life sciences or biomedical sciences, which often include hospitals and health care institutions as well.

[2] Archstone Consulting, The Biopharmaceutical Sector's Impact on the U.S. Economy, prepared for PhRMA, 2009.

[3] Grow Wisconsin (2003):

http://www.wisgov.state.wi.us/docs/Doyle_Economic_Package.pdf.

[4] Wisconsin Department of Commerce, "Technology Commercialization Programs," http://www.commerce.wi.gov/act255/.

PhRMA 2010

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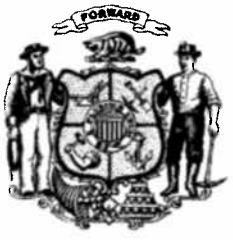

Provision	Patient Protection Affordable Care Act – Passed House and Senate
Start Date for Recording	January 1, 2012
Start Date for Reporting	March 31, 2013
Publication of Reports	September 30, 2013 and June 30th in future years
Definition of Entity (Who Reports)	Applicable group purchasing organization' means a group purchasing organization (as defined by the Secretary) that purchases, arranges for, or negotiates the purchase of a covered drug, device, biological, or medical supply which is operating in the United States, or in a territory, possession, or commonwealth of the United States. The term 'applicable manufacturer' means a manufacturer of a covered drug, device, biological, or medical supply which is operating in the United States, or in a territory, possession, or commonwealth of the United States. The term 'manufacturer of a covered drug, device, biological, or medical supply' means any entity which is engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply (or any entity under common ownership with such entity which provides assistance or support to such entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological, or medical supply).
Report on self-referral	a requirement that the referring physician inform the individual in writing at the time of the referral that the individual may obtain the services for which the individual is being referred from a person other than a person described in subparagraph (A)(i) and provide such individual with a written list of suppliers (as defined in section 1861(d)) who furnish such services in the area in which such individual resides.".
Form of Reporting	• Electronic • Searchable • Easily Downloaded
Included in Disclosure	• Name; • Business address; • Physician specialty; • National provider identifier; • The value of the payment or transfer of value; • The name of the related drug, device, or supply, if

	available; to the level of specificity available;
	• A description of the form of payment;
	  ○ Cash or cash equivalent
	  ○ In-kind items of services
	• Drug samples, the name, number, date, and dosage units of the sample.

Definition of Payment	• Gift; • Food; • Entertainment; • Travel or trip; • Honoraria; • Research funding or grant; • Education; • Research; • Charitable Contribution; • Direct Compensation for Serving as Faculty or Speaker for Medical Education Program; • Consulting fees; • Ownership or investment interest; • Royalties; • license fee; • speaking fees; • dividends; • profit distribution; • stock or stock option grant; • Any categories of information the secretary determines appropriate;
Covered Recipient	• Physician; • Teaching hospital;
Excluded from Reporting	A transfer of anything the value of which is less than $10, unless the aggregate amount transferred to, requested by, or designated on behalf of the covered recipient by the applicable manufacturer during the calendar year exceeds $100. • Product Samples (separate provision) • Educational Materials • Loan of a device for short term trial period (90 Days) • Warranties • Received as a Patient • Discounts • In-Kind used for provisions of charity care • Dividends from stock ownership in publically traded companies • Self Insurance Payments from Manufacturer for Employees

	• Non Medical Professional Services • Legal Services
Product Development	Payments under a product development agreement must be reported for services furnished in connection with the development of a new drug, device, biological, or medical supply, and must also be reported with the following information: The date of the approval or clearance of the covered drug, device, biological, or medical supply by the Food and Drug Administration; and Payments made four calendar years after this date
Clinical Investigations	Confidential until either: • Date of FDA approval or clearance; • Payments made four calendar years after this date;
Penalties	A civil money penalty of not less than $1,000, but not more than $10,000, for each payment or other transfer of value or ownership or investment interest not reported. The total amount of civil money penalties will not exceed $150,000. Knowingly failing to submit payment information will result in a civil money penalty of not less than $10,000, but not more than $100,000, for each payment. The penalty will not exceed $1,000,000.
Third Party Payments	Reported if they are requested by or designated on behalf of a physician
Reports	• Annual Reports to Congress • Annual Reports to States
Pre-emption	Pre-Empts State Laws that are similar or weaker than this provision Does not pre-empt more restrictive laws (lower limits of payments, gift bans....)

Other Transparency Sections

In addition to payments from manufactures, there are several other transparency measures addressed law include:

Insurance Companies

- To ensure transparency and accountability, health plans would be required to report the proportion of premium dollars that are spent on items other than medical care.

Hospitals

- Hospitals will be required to list standard charges for all services and Medicare DRGs.

Drug Samples

- Submit to the Secretary of HHS rather than make available (as the current law requires) data on drug samples including recipient, amount, theft and losses.

Nursing Homes

- Discloser of Ownership
- Staffing Data
- Results of State Facility Surveys
- Enforcement Actions
- Expenditures on Staffing Expenditures for Direct Patient Care

Imaging Services

For Imaging Services the referring physician must inform the individual at the time of the referral that:

- The individual may obtain the services from a person other than the referring physician; a physician who is a member of the same group practice as the referring physician; or an individual who is directly supervised by the physician or by another physician in the group practice.
- The individual must be provided with a written list of suppliers who furnish services in the area in which the individual resides.

Summary

Passage of this law will bring about a systemic shift in the health care industry, with government taking a larger roll in care of patients. For CME, grants will be reported if they are requested on behalf of a specific physician and/or are given to a teaching hospital.


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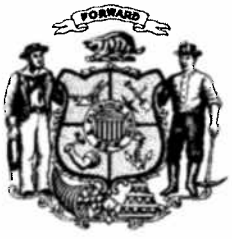
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NEW FEDERAL GOVERNMENT DATA SHOW THAT PRESCRIPTION DRUG SPENDING GROWTH IS AT ITS LOWEST LEVEL SINCE 1961

On January 5, 2010, the Centers for Medicare & Medicaid Services (CMS) Office of the Actuary (OACT) released the Federal government's figures on national health care spending for 2008.[i] OACT's data shows the ongoing sharp decline in retail prescription drug spending growth, leaving medicines as one of the slower growing areas of health care expenditures.

The 3.2 percent growth in prescription drug spending is the lowest growth rate in 47 years and below the growth rate for health care overall. Prescription drug spending growth, as measured by data from OACT's National Health Expenditures, has declined in 8 of the last 9 years.

According to data from OACT, prescription drug spending growth reached a historic low of 3.2 percent in 2008, the lowest rate since 1961, and below the rate of growth for health care overall.

- Retail prescription drug spending (which includes changes to price, mix, and utilization), grew 3.2 percent in 2008, down from 4.9 percent in 2007.
- The 2008 growth rate for medicines was below the growth rate for health care spending overall (4.4 percent) and for other major services (e.g., hospital services grew by 4.5 percent and physician and clinical services by 5 percent).[ii]
- Furthermore, the growth rate for medicines is 4 percentage points below the average growth rate for the previous five years and 8 percentage points below average for the prior decade.
- According to OACT, prescription drug price growth of 2.5 percent in 2008 was "below recent historic rates, as the average annual growth in prescription drug prices was 4.1 percent between 1997 and 2007."[iii]
- Prescription medicines accounted for 7.4 percent of health spending growth between 2007 and 2008; 92.6 percent of spending growth was attributable to other services.[iv]

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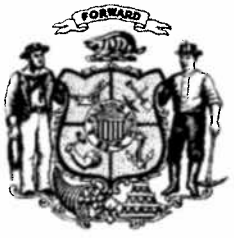
[i] M. Hartman et al., "Health Spending Growth at a Historic Low in 2008," *Health Affairs* January/February 2010.

[ii] M. Hartman et al., op cit.

[iii] M. Hartman et al., op cit, p. 152.

[iv] Centers for Medicare & Medicaid Services, "National Health Expenditures," 5 January 2010, http://www.cms.hhs.gov/NationalHealthExpendData.


WISCONSIN STATE LEGISLATURE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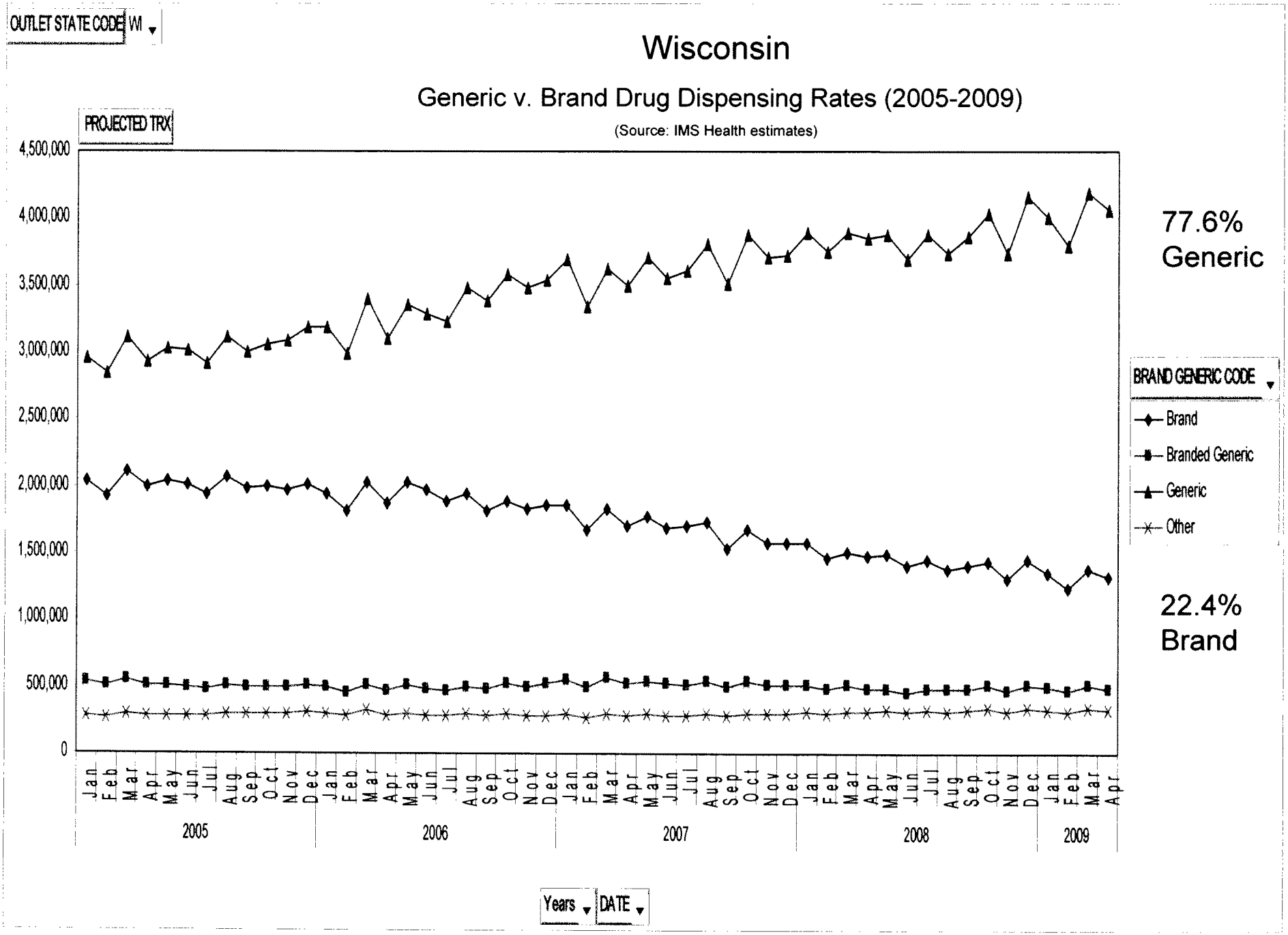
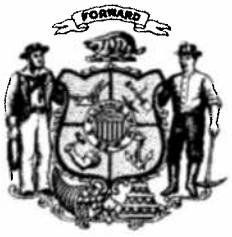

OUTLET STATE CODE WI
Wisconsin
Generic v. Brand Drug Dispensing Rates (2005-2009)
(Source: IMS Health estimates)
PROJECTED TRX
4,500,000
4,000,000
3,500,000
3,000,000
2,500,000
2,000,000
1,500,000
1,000,000
500,000
0
77.6% Generic
22.4% Brand
BRAND GENERIC CODE
Brand
Branded Generic
Generic
Other
Jan Feb Mar Apr May Jun Jul Aug Sep Oct Nov Dec
2005
2006
2007
2008
2009
Years
DATE

WISCONSIN STATE LEGISLATURE



AARP REPORT ON DRUG COSTS PRODUCES SKEWED RESULTS; FAILS TO RECOGNIZE HISTORIC SLOWDOWN IN PRESCRIPTION DRUG GROWTH

AARP recently released an Rx Watchdog report[i] claiming that drug prices are increasing rapidly. But a closer look shows that the AARP report's methods produce exaggerated measures of consumer costs[ii] -- and miss the historic slowdown in drug cost growth reported by the U.S. government's actuaries and the Congressional Budget Office.

Prescription drug spending growth is at a historic low and is projected to remain low in the future.

- The Centers for Medicare and Medicaid Services (CMS) Office of the Actuary (OACT) reports that drug spending grew 3.2% between 2007 and 2008, slower than the 4.4% growth for health care overall.[iii]
- IMS Health reports that drug spending in 2008 grew by 1.3% and forecasts that market growth will remain at "historically low levels" through 2013, at an average annual rate of 3.5%.[iv]
- In 2008, OACT reduced its 2008-2017 cumulative projection for prescription drug spending by 14%, or $515 billion. This compares to a decline of 3% for all health care except prescription medicines.[v]
- The share of overall health cost growth attributable to medicines fell from 18% in 2002 to 7% in 2008, according to data reported by OACT.[vi]

Prescription drug prices have risen in line with overall medical inflation for a decade.

- The government's publicly available data for overall medical inflation is the best, most current measure of price trends for medical costs. The prescription medicines component (CPI-P) includes a market basket of brand and generic drugs that reflects what consumers actually buy. These government CPI data show that prices for prescription drugs increased by an annual average of 2.9% per year, similar to the 3.8% rate for all health care, from December 2005 through December 2009 (since the Rx Watchdog report began using its current prescription drug market basket).[vii]
- One analyst writes of the AARP report: "Comparing list prices for a single product category to a computed, non-list price index for a broad basket of goods (CPI-U) is mathematically illogical. After all, the CPI-U for prescription drugs increased at a rate less than half the rate of list prices."[viii]

AARP's methods produce exaggerated measures of consumer costs.

- Currently, ten of the drugs on AARP's top 25 brand drug list are sold as generics.[ix] These drugs are counted in AARP's brand price calculation as though consumers continue to use the same volume of these drugs today as they did in 2006,[x] even though brand drugs typically lose about 90% of their sales after going generic.[xi] This means that AARP greatly overstates consumers' actual costs for these therapies.
- For example, the AARP report lists Zocor (simvastatin) as one of the top brand medicines. But CMS data show that by 2008, Zocor was ranked 546th in cost.[xii] In fact,

simvastatin has been available as a generic since 2006, and data from IMS Health show that by 2009 less than 1% of sales were for the brand form of the medicine.

- Between 2006 and 2009 the average price per prescription of simvastatin (including purchases of brand and generic forms) *declined* by 58%.[xiii] AARP's methods bias their results by calculating price growth as if (1) the volume of the brand drug used today is the same as it was in 2006 even though 99% of use is now generic and (2) consumers are paying brand price for this drug, even though they are paying the generic price.
- Our health system is designed to (1) fund the next generation of medical advances through innovator drugs that have a limited time on the market before going generic while (2) achieving cost savings through high use of generics that do no research contributing to medical advances. In fact, powerful payers use numerous tools to drive the generic percentage as high as possible, while negotiating aggressively for rebates on brand drugs. Under this system, drug costs as a whole are growing slowly, not fast--and consumers use drugs that were once innovator molecules as generics in large volume for many years. AARP's report doesn't recognize this, even though AARP itself markets health insurance products that engage in the very practices that result in slow growth of drug costs. Therefore, the AARP report produces skewed, inaccurate findings.
    - In fact, IMS Health data show that roughly 75% of prescriptions are filled with generics.[xiv] At the same time, the number of brand prescriptions declined by 9% in 2007, 16% in 2008, and 12% in the 1st quarter of 2009.[xv]

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[i] AARP "Rx Watchdog Report: Brand Name Drug Prices Continue to Climb Despite Low General Inflation Rate," May 2010.

[ii] Also note that AARP's data lacks information about rebates paid by brand manufacturers that lower drug costs. The Medicare Trustees have reported that in the Medicare prescription drug program many brand drugs carry rebates of 20-30% and that rebate amounts in the program are higher than expected and have grown since the program began in 2006—a savings not reflected in the AARP reports.

[iii] M. Hartman et al., "Health Spending Growth At A Historic Low in 2008," *Health Affairs* January 2010.

[iv] IMS Market Prognosis 2009 - 2013: North America, United States Update, September 29, 2009.

[v] A. Sisko et al., "Health Spending Projections Through 2018: Recession Effects Add Uncertainty To The Outlook." *Health Affairs*, February 2009.

[vi] M. Hartman et al, *op cit.*

[vii] PhRMA analysis based on Bureau of Labor Statistics, Consumer Price Index, All Urban Consumers (Current Series), accessed February 1, 2010.

[viii] Quote from Adam Fein, President of Pembroke Consulting, in "Drug Pricing and Pharmacy Profits," posted on Drug Channels November 18, 2009, available at http://www.drugchannels.net

[ix] The eight drugs are: Norvasc (2 forms), Zocor (2 forms), Ambien, Fosamax, Flomax, and Protonix.

[x] AARP Rx Watchdog Report: Trends in Manufacturer Prices of Prescription Drugs Used by Medicare Beneficiaries 2008 Year-End Update, April 2009. p. 37

[xi] Medco, Drug Trend Report, 2009.

[xii] 2010 Part D Symposium, Part D Drug Utilization and Cost Trends, slide 19.

[xiii] PhRMA analysis, based on SDI/Verispan Vector One National data for January 2006 through October 2009.

[xiv] IMS Health, 2010. Analysis for PhRMA.

[xv] M. Aitken, "The Impact of Healthcare System Changes on the Pharmaceutical and Diagnostic Industries: Implications for Genomic Technologies." Secretary of HHS Advisory Committee on Genetics, Health, and Society. June 11, 2009.