

United States Senate

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For Immediate Release

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Senators praise growing support for transparency in drug industry payments to physicians

WASHINGTON – The newly announced backing of a leading drug maker for a national registry of industry payments to medical doctors indicates that transparency’s time has come, according to Senators Chuck Grassley and Herb Kohl, co-authors of pending legislation to establish such a registry.

In an endorsement letter released today, Eli Lilly and Company said it supports “greater transparency in the health care system and believes this legislation represents an important step in building public trust in and understanding the relationships between the pharmaceutical and device industries and physicians.” The full letter is posted with this news release at <http://finance.senate.gov>.

Grassley said he welcomed Eli Lilly’s support for the initiative, as well as the recent endorsement of the effort by the Association of American Medical Colleges. This letter is also posted with this news release at <http://finance.senate.gov>.

“Eli Lilly deserves credit for its endorsement of the Sunshine Act and the leadership role it is taking for greater transparency in the pharmaceutical industry. Eli Lilly has been posting online its payments to medical organizations and others. The company’s forward-looking endorsement of legislation to require reporting of financial relationships between drug and device makers and physicians will be valuable in building more support for this important reform,” Grassley said. “I also appreciate the persuasive and principled support of the Association of American Medical Colleges. Transparency brings about accountability and benefits everyone, consumers most of all.”

“Eli Lilly’s endorsement goes to show that transparency of the financial ties between doctors and drug makers is not only sensible, but do-able. So many sectors of the health industry are calling for it: physicians, medical schools, the Journal of the American Medical Association, and now a pharmaceutical company. We applaud Eli Lilly for endorsing transparency and hope the rest of the pharmaceutical industry follows their lead,” Kohl said.

Last fall, Grassley and Kohl introduced the Physician Payments Sunshine Act (S.2029) in response to growing concerns about the lack of disclosure of these financial relationships. Grassley is working to include reform legislation in a Medicare bill which the Senate may consider before its August break.

Below is a summary of the working version of the sunshine proposal, along with the text of the news release issued in September by Grassley and Kohl marking introduction of their

Physician Payment Sunshine Act. Grassley is Ranking Member of the Senate Committee on Finance. Kohl is Chairman of the Senate Special Committee on Aging.

Summary of S. 2029
Physician Payments Sunshine Act of 2008
May 13, 2008

- (a) **REPORTING:** beginning 3/31/2011 requires drug and device companies to report, on an annual basis, any payment or transfer of value to any physician.
 - a. Each electronic disclosure must include:
 - i. Name of the recipient;
 - ii. Recipient's city and state;
 - iii. The value of the payment or other transfer of value;
 - iv. The date of the payment or transfer was made;
 - v. The form and reason for the payment
 - b. Also requires reporting of physician ownership of any drug or device manufacturer, group purchasing organization, or distributor.
- (b) **PENALTIES:** \$1,000 to \$5,000 per failure to report, with an annual cap of \$50,000, and \$5,000 to \$50,000 per knowing failure to report, with an annual cap of \$250,000.
- (c) **WEBSITE:** the Secretary shall establish procedures to ensure that the information is made accessible to the public through a website, with proper context given to the payments and an appeal and correction process established.
- (d) **PREEMPTION:** the act preempts state reporting requirements.
- (e) **DELAYED REPORTING:** in the case of payments made pursuant to a product development agreement, the act allows for delayed reporting for a period of two years or until FDA approval, whichever is first. In the case of payments made for the funding of a clinical trial, payments are delayed until clinical trial information is required to be posted under the Public Health Service Act.
- (f) **DEFINITIONS:**
 - a. Covered drug, device, or medical supply: any drug, biological product, device, or medical supply for which payment is available under title 18, or a state plan under titles 19 or 21 of the Social Security Act.
 - b. Covered recipient: a physician, a physician medical practice, or an entity or individual that receives payment at the request of or designated on behalf of a physician.
 - c. Payments or other transfer of value: a transfer of anything of value in the case where the aggregate amount transferred to a covered recipient during a calendar year exceeds \$500.
 - i. Such term does not include: anything below \$25, product samples intended for patients, certain educational materials, certain direct training, equipment loans, a transfer to a physician in a patient capacity, discounts and rebates, anything nominal in value, or in-kind items used for the provision of charity care.
 - d. Physician: has the meaning given that term in section 1861(r), and does not include full-time employees of manufacturers.

For Immediate Release

Thursday, September 6, 2007

Grassley, Kohl say public should know when pharmaceutical makers give money to doctors
McCaskill, Schumer, Klobuchar and Kennedy co-sponsor new Grassley-Kohl legislation

WASHINGTON — Sens. Chuck Grassley and Herb Kohl are introducing legislation to require manufacturers of pharmaceutical drugs, devices and biologics to disclose the amount of money they give to doctors through payments, gifts, honoraria, travel and other means.

“Right now the public has no way to know whether a doctor’s been given money that might affect prescribing habits,” Grassley said. “This bill is about letting the sun shine in so that the public can know. Whether it’s dinner at a restaurant or tens of thousands of dollars or more in fees and travel, patients shouldn’t be in the dark about whether their doctors are getting money from drug and device makers.”

“At our June hearing, the pharmaceutical industry told the Aging Committee that they believe their practices are above-board. If that is the case, full disclosure will only serve to prove them right. If that is not the case, full disclosure will bring their influence-peddling out from the shadows. Either way, patients win,” Kohl said.

Sens. Claire McCaskill, Chuck Schumer, Amy Klobuchar and Ted Kennedy are original co-sponsors of the Grassley-Kohl bill introduced today.

“By requiring drug companies and medical device manufacturers to report on their gifts to doctors we are empowering patients to talk with their doctors about the drugs they are prescribed and to learn more about the influence of the pharmaceutical industry on the practice of medicine. I believe that by bringing light to these relationships this legislation will go far in reducing big drug companies influence on the business of medicine,” McCaskill said.

“This bill will shine a much needed ray of sunlight on a situation that contributes to the exorbitant cost of health care. Patients have the right to know if drug and device makers are attempting to influence physician prescribing decisions with gifts, consultations and travel,” Schumer said.

“This is common sense legislation that helps ensure the integrity of our health care system,” said Klobuchar. “It’s important to shed light on the millions of dollars these companies spend on marketing – money that could be put into research or lowering the cost of prescriptions.”

The newly proposed federal legislation builds on similar initiatives in Minnesota, Vermont, Maine and West Virginia. The Physician Payments Sunshine Act (S.2029) would apply to manufacturers with \$100 million or more in annual gross revenues. Penalties for not reporting payments would range from \$10,000 to \$100,000 per violation. The legislation requires the Secretary of Health and Human Services to create a website and post payment information in a clear and understandable manner.

Grassley is Ranking Member of the Committee on Finance, where he has conducted oversight of educational grants awarded to doctors by drug companies. Kohl is Chairman of the Special Committee on Aging. He held a hearing in June to examine the financial relationship between physicians and the pharmaceutical industry.

Grassley's floor statement about today's legislation is below, along with a copy of Kohl's statement from his Aging Committee hearing. A separate Grassley floor statement on this subject, delivered in August, is posted along with this news release at <http://finance.senate.gov> in the Grassley press releases and at <http://grassley.senate.gov>. Information on the Aging Committee hearing can be found at http://aging.senate.gov/hearing_detail.cfm?id=277848&.

Floor Statement of U.S. Senator Chuck Grassley of Iowa
Ranking Member of the Committee on Finance
Introduction of the Physician Payments Sunshine Act
Thursday, September 6, 2007

Mr. Grassley. Mr. President, a month ago I outlined an important issue affecting all Americans who take prescription drugs or use medical devices – the need for greater transparency in the money that drug and device companies hand out to doctors. Today, I am pleased to introduce the Physician Payments Sunshine Act, along with Senator Kohl, chairman of the Special Committee on Aging. This legislation will bring much needed transparency to the financial relationships that exist between the drug and device industries and doctors.

There is no question that the drug and device industries have an intricate network of financial ties with practicing physicians. These financial relationships can take many forms. They can include speaking honoraria, consulting fees, free travel to exotic locations for conferences, or funding for research. Drug and device companies spend billions and billions of dollars every year marketing their products. A good amount of this money goes directly to doctors in the form of these payments.

This practice, and the lack of transparency around it, can obscure the most important question that exists between doctor and patient: what is best for the patient?

As the editorial board of the Des Moines Register wrote recently, “Your doctor’s hands may be in the till of a drug company. So how can you know whether the prescription he or she writes is in your best interest, or the best interest of a drug company?” That’s an excellent question. Currently, the public has no way of knowing whether their doctor has taken payments from the drug and device industries, and I intend to change that — not just for Iowans but for all Americans.

Payments to a doctor can be big or small. They can be a simple dinner after work or they can add up to tens of thousands and even hundreds of thousands of dollars each year. That’s right – hundreds of thousands of dollars for one doctor. It’s really pretty shocking.

Companies wouldn’t be paying this money unless it had a direct effect on the prescriptions doctors write, and the medical devices they use. Patients, of course, are in the dark

about whether their doctor is receiving this money.

The Physician Payments Sunshine Act sheds light on these hidden payments and obscured interests through the best disinfectant of all: sunshine. This is a short bill, and a simple one. This bill requires drug and device manufacturers to disclose to the Secretary of Health and Human Services, on a quarterly basis, anything of value given to doctors, such as payments, gifts, honoraria, or travel. Along with the money, these companies will have to report the name of the physician, the value and the date of the payment or gift, its purpose, and what, if anything, was received in exchange. This bill then requires the Department of Health and Human Services to make the information available to the public through a searchable website.

And this bill has some teeth, too. If a company fails to report, the Physician Payments Sunshine Act imposes a penalty ranging from \$10,000 to \$100,000 for each violation.

Many states are ahead of the curve on this and have passed, or are currently considering, similar measures. In 1993, Minnesota required the nation's first public disclosure of gifts and payments from wholesale drug distributors. Vermont passed a similar law in 2003, although much of the information is not publicly available. More recently, the District of Columbia, Maine, and West Virginia have followed suit in requiring disclosure, though not all make the information available to the public through a website. The General Assembly in my home state of Iowa may soon be requiring disclosure as well.

But this kind of information shouldn't be available only to Americans who happen to be lucky enough to live in a state already addressing this problem. On the contrary, this information should be accessible to all Americans across the country and it should be updated in a timely manner. I propose to my colleagues that now is the time to act.

I realize that some critics, including many of the drug and device companies, are going to say that creating this sort of national database is too time consuming and too expensive. I can hear the complaints already. But let me remind you again – the drug companies are already reporting their payments to doctors in Minnesota and other states. Companies already have this information available. We aren't requiring them to go out and obtain it – we're just asking them to share it with the American people.

Perhaps even more telling is that at least one industry leader has taken the goal of increased transparency into its own hands. Although it is not making its payments to doctors publicly available, Eli Lilly has taken important steps to meet the public's demand for increased sunshine. In response to my investigation of drug company payments for continuing medical education, Eli Lilly voluntarily created a website that details payments they make to organizations like patient groups and hospitals. I commend Eli Lilly for taking the lead on that issue, and I look forward to working with them on my latest effort.

This bill is careful not to burden small businesses – it applies only to companies with annual revenues over one hundred million dollars. It is the largest companies who are driving this practice, and for whom disclosure would be least burdensome.

Further, during a meeting on a separate matter with officials from Glaxo Smith Kline in early August, my staff brought up the idea of drug companies reporting payments to physicians. I am happy to say that Dr. Moncef Slaoui, the Chairman of Research and Development for GlaxoSmithKline, said that he was also interested in a little sunshine. In fact, here are his exact words: “We’re happy for transparency.” I would like to commend Dr. Slaoui for his comments and I look forward to working with him and leaders at other companies on this bill.

It’s not only industry leaders that are leading the way on the issue of increased transparency – some of America’s best medical schools are taking steps to prevent conflicts of interest among their physicians. In fact, the Yale University School of Medicine, the University of Pennsylvania, and the Stanford University Medical School have gone so far as to prohibit certain gifts and payments altogether.

So let me be clear. This bill does not regulate the business of the drug and device industries. I say, let the people in the industry do their business. After all, they have the training and the skill to get that job done. Just keep the American people apprised of the business you are doing and how you are doing it. Let a little bit of sunshine in to this world of financial relationships – it is, after all, the best disinfectant.

Opening Statement of Senator Herb Kohl
Special Committee on Aging Hearing
Paid to Prescribe: Exploring the Relationship Between Drug Companies and Doctors
Wednesday, June 27, 2007

I call this hearing to order and welcome all of our witnesses.

Today, we will examine the financial relationship between the pharmaceutical industry and physicians. Interactions between the doctors and drug manufacturer representatives often involve payments that can actually take the form of cash and gifts such as meals, travel to conferences, or textbooks. Unlike other professions, physicians are allowed to take payments from companies whose products they may choose to prescribe to their patients.

Recent studies show that the more doctors interact with drug marketers, even through receiving small gifts and modest meals, the more likely doctors are to prescribe the expensive new drug that are being marketed to them when a more affordable generic would do. Seniors lose out with unnecessarily high drug costs while doctors and drug manufacturers benefit financially.

But rising drug prices don’t only harm the elderly – they hurt us all as they undermine our private and public health systems. Health insurance premiums continue to skyrocket, and escalating drug costs have played a large role. And the federal government, now the largest payer of prescription drugs with the new Medicare drug benefit, feels the squeeze as well. Even more alarming, these gifts and payments can compromise physicians’ medical judgment by putting their financial interest ahead of the welfare of their patients.

Over the last several years there have been attempts by the federal government, medical organizations, and drug companies to curb the excessive gifts and payments to physicians. Unfortunately, as we'll hear from some of our witnesses today, financial ties between doctors and drug companies are only deepening.

In fact, a study published in the New England Journal of Medicine early this year reported that 94 percent of physicians have received food and beverages, medication samples, and other gifts and payments from drug companies.

The pharmaceutical industry remains one of the most profitable industries in the world, returning more than 15 percent on investments. As a businessman myself, I respect an industry's right to maximize profits. Nevertheless, they are charging Americans the highest drug prices in the world, forcing some employers to drop health coverage for employees, squeezing the budgets of state and federal government, and ultimately harming our seniors by putting drug costs out of their reach.

It has been estimated that the drug industry spends \$19 billion annually on marketing to physicians in the form of gifts, lunches, drug samples and sponsorship of education programs. Companies certainly have the right to spend as much as they choose to promote their products. But as the largest payer of prescription drug costs, the federal government has an obligation to examine and take action when companies unfairly or illegally attempt to manipulate the market.

Today's witnesses will discuss the current state of the physician/drug industry relationship, recent attempts at the state level to increase disclosure of payments, and attempts to reduce the influence of the drug industry on physician prescribing behaviors. We'll also hear testimony from one doctor who feels these potential conflicts of interest have reached a disturbing level in his profession and is adversely affecting medical research. Our final panel will include representatives of the pharmaceutical industry and the medical profession. They will provide us insight into their voluntary guidelines addressing physician gifts and payment.

We look forward to hearing each of our witness's perspectives on this issue and their recommendations. I take this issue very seriously and will continue oversight of the relationship between doctors and the drug industry. While there are voluntary guidelines already in place, it is clear they are not being followed. I intend to vigorously pursue stronger adherence to these guidelines, as well as propose a national registry to require disclosure of payments and gifts. We need transparency, at the minimum and at the outset. Many of these gifts are not illegal, but we need them disclosed. These interactions involving things of value between the pharmaceutical industry and doctors must be made public.

I thank everyone for their participation today.