UNDER THE INFLUENCE: CAN WE PROVIDE DOCTORS AN ALTERNATIVE TO BIASED DRUG REVIEWS?

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WEDNESDAY, MARCH 12, 2008

U.S. SENATE,
SPECIAL COMMITTEE ON AGING,
Washington, DC.

The Committee met, pursuant to notice, at 10:32 a.m., in room SD-562, Dirksen Senate Office Building, Hon. Herb Kohl (chairman of the committee) presiding.

Present: Senators Kohl, McCaskill, and Smith.

OPENING STATEMENT OF SENATOR HERB KOHL, CHAIRMAN

The CHAIRMAN. Good morning to one and all. We welcome and thank you for being at this hearing.

We would particularly like to thank and welcome all of our dis-

tinguished witnesses here this morning.

Over the past year, the Committee on Aging has been taking a close look at the relationship between the pharmaceutical industry and our nation's physicians. Not only does the interaction between these two parties seem to be fraught with conflicts of interest, but it is likely that the marketing methods employed by drug companies and the manner in which they educate doctors about their products do have an impact on the rising costs of prescription drugs in America.

To address these concerns, Senator Grassley and I introduced the Physician Payment Sunshine Act, to require that all gifts, fees and other freebies given to doctors by the drug industry, medical device manufacturers and biologic companies, be reported in a National registry. The drug industry argues that such disclosure would deter physicians from engaging in the most important aspect of their relationship, which they consider to be educating doctors about their

new drugs.

The drug industry does have a point. Pharmaceutical sales reps are currently one of the only ways doctors can learn about the latest drugs on the market. However, these sales representatives often confuse educating with selling, and the evidence shows that doctors' prescribing patterns can be heavily influenced by the biased information often put forward by these sales reps.

So today, we will address the industry's concerns by presenting an alternative known as "academic detailing," that we believe would have a positive impact on both quality and cost of health care Nationwide. Academic detailing provides physicians and other prescribers with an objective source of unbiased information on all prescription drugs, based on scientific research performed at med-

ical and pharmacy schools.

The information is presented to doctors in their own offices by trained clinicians and pharmacists. Without academic detailing, physicians are often left largely uninformed about drug safety or the full array of pharmaceutical options, including low-cost generic alternatives.

For example, the National consumer group, Public Citizen, did a study on the blood pressure drug Norvasc. While most academic guidelines recommend the use of an older generic drug over the use of Norvasc, Norvasc was the drug most often distributed by doctors and, in fact, was the fourth most prescribed drug in the United States in 2004.

The study found that this was in part due to the fact that a fleet of pharmaceutical company salespeople were dispersed to physicians' offices; pitching the drug as a new and effective alternative, and offering free samples of the drug to doctors to give to their pa-

tients.

Certainly, we can agree that in some of these instances, patients were not receiving the best drug, merely the most convenient—and they were paying more for it. The monthly cost of Norvasc is between \$60 and \$70. The generic cost is about \$12.

Since the Federal Government is the nation's largest purchaser of prescription drugs, these inflated costs should be of great con-

cern both to Congress and, most importantly, to taxpayers.

In this way, a Federal academic detailing program, like the one Senator Dick Durbin and I will propose in upcoming legislation, would save the government a considerable amount of money. We are not proposing that expense be the main factor in deciding a course of treatment for a patient. But research has shown that when doctors have full access to comprehensive and unbiased data on all the drugs available, they prescribe the best drug, and not just the newest one, and health care spending is lower.

We are pleased to have a comprehensive panel of witnesses here today to outline the practice of academic detailing, speak about State and private programs already in place, and explore how these counter-detailing initiatives can reduce costs and improve health

care in our country.

So again, we would like to thank everyone for their participation today, and we turn now to the Ranking Member, Senator Gordon Smith, for whatever comments he would like to make.

OPENING STATEMENT OF SENATOR GORDON H. SMITH, RANKING MEMBER

Senator SMITH. Thank you, Senator Kohl, for bringing this interesting and important topic to the attention of this Committee. I truly thank the witnesses for being here. I look forward to learning from you and from the testimony that you will give to us today.

Obviously, the doctor-patient relationship is the cornerstone of the American health care system. That is why I am here, and that is why I am concerned about any practice that attempts to influence this relationship in a way that may or may not be in the best interests of the patient.

An important component of any successful health care approach is the dissemination of evidence-based and well researched information to physicians. Accurate, up-to-date information is crucial in order for physicians to make informed decisions when prescribing often lifesaving medication.

I am committed to looking at all the alternatives that will help our dedicated health professionals in providing the highest quality

of care to their patients.

So, to that extent, I welcome this opportunity to learn more about academic detailing and the potential it holds to serve as another resource for doctors in obtaining information on comparative efficacy, safety and cost-effectiveness of pharmaceuticals.

Again, thank you, Mr. Chairman.

The CHAIRMAN. Thank you very much, Senator Smith.

We are now pleased to welcome our witnesses to testify today.

Our first witness will be Shahram Ahari.

A former pharmaceutical sales rep from Eli Lilly's neuroscience division, Mr. Ahari left the industry to pursue public health and social justice issues. He has been a consultant to State and Federal policymakers on the issue of drug marketing's impact on public health, and the relationships between drug detailers and physicians. Mr. Ahari has a master's in public health from UC-Berkeley.

Our next witness will be Dr. Jerry Avorn. Dr. Avorn is professor of medicine at Harvard Medical School and a division chief at Brigham and Women's Hospitals. A pioneer of academic detailing approach, he studies physician prescribing practices and programs to improve the appropriateness of prescribing. Dr. Avorn received

his M.D. from the Harvard Medical School.

We will then hear from Allan Coukell, the director of Policy and Strategic Communications at The Prescription Project. As a clinical pharmacist at the Victoria Hospital in London, Ontario, he specialized in advising physicians on choice of medications and cost-effective prescribing. Mr. Coukell studied pharmacy at the University of Manitoba.

Next we have Nora Dowd Eisenhower, secretary of the Pennsylvania Department of Aging. The secretary manages a network of services provided in part through a statewide system of 52 Area Agencies on Aging. Prior, she served as the state's deputy attorney general in the Bureau of Consumer Protection, as well as the executive director of AARP of Pennsylvania. She received her law de-

gree from Antioch University.

Finally, we will have Ambrose Carrejo. Mr. Carrejo is the assistant director of Pharmaceutical Contracting and Strategic Purchase for Kaiser Permanente, where he has responsibility for contracting the program's pharmaceutical purchases. Prior to that he was the drug use manager for Northern California Kaiser Hospitals. He received his doctor of pharmacy degree from the University of California at San Francisco's School of Pharmacy.

We welcome you all here today. We look forward to your testi-

mony.

Mr. Ahari, we will start from you.

STATEMENT OF SHAHRAM AHARI, FORMER ELI LILLY PHARMACEUTICAL SALES REPRESENTATIVE, EL CERRITO, CA

Mr. AHARI. Thank you.

Among the myriad of myths that the industry uses to justify the pharma-physician relationship, none is more dangerous than the notion that the drug rep provides valuable education to the doctor. As their formal title implies, pharmaceutical sales representatives are hired to sell. Period.

The idea that the drug rep is an effective vehicle for disseminating objective science is pure fiction. Drug reps are not scientifically trained, they are not provided with objective scientific information, and it is not in their economic self-interest to distribute

evenhanded information about therapeutic choices.

While there is nothing intrinsically wrong with sales, the great extent to which physicians believe that they are recipients of a wholesome, evenhanded view of the science endangers not only the doctor's judgment, but the public's health and the very foundations of the patient-physician relationship.

To begin with, it is no coincidence that we reps are often recruited from the ranks of former cheerleaders, ex-military men or athletes, rather than those trained in the sciences. It is also no

mistake that our sales training focuses on persuasion skills.

We are taught to present our products in the best possible light, to trivialize problems associated with them and to emphasize the shortcomings of our competitors' products. Our instructors walk us through the academic articles that our marketing department has deemed most relevant to our current sales strategy, cherry-picking the data along the way.

From these selected articles, we receive neither a balanced nor a comprehensive sense of the literature. We learn only how to limit the scope of our discussions to most effectively sell our products.

This training, combined with our persuasiveness and controversial physician prescriber data, allows us to make our targeted dis-

cussions seem unrehearsed and coincidental.

To reinforce our sales efforts, we look for credible, loyal physicians to speak on our product's behalf. We count these doctors as objective thought leaders, but we have no reservations in dismissing them when their product loyalty falls into question.

Furthermore, we supply these doctors with presentations crafted by our marketing department, that expound on the points that we reps make. This provides marketing synergy. It is like the physi-

cian's repeated sales pitch masked in scientific credibility.

Although drug reps learn a modicum of science, the fact is our science training is secondary to our ability to establish a friendship with our clients, and we maximize every opportunity to befriend them.

For example, when I was recruited for Eli Lilly's elite neuroscience and sales division, selling two products—an antidepressant and an antipsychotic—that constituted over half of the company's profits, I was in a room with 21 classmates and two trainers, and I was the only one with a science background.

In fact, on the first day of training, I taught my class—and my instructors—the very basic process by which two brain cells com-

municate.

It is very likely that the majority of my class couldn't explain the difference between a neuron and a neutron prior to sales school, which is not to say that my classmates weren't intelligent. On the contrary, we were all charming, bright and—myself the obvious exception—physically attractive. [Laughter.]

Yet, for all my abilities to discuss the pharmacological benefits of my products, I can attest to the many times when my clients would begin prescribing more of my drugs, not based on the merits of my arguments, but on the fact that we shared dinner at a fancy

Manhattan restaurant.

How did I know this? The physician prescriber data showed a

distinct rise in my market share after these meals.

But a fancy dinner doesn't influence all physicians. So to better understand our clients' motivations, we were given psychological profile training, beginning with our own psychological profile. By evaluating ourselves, we learned to assess our doctors. We learn how our personality traits overlap with our physicians' traits, and

how best to ingratiate ourselves toward our clients.

We seek out personal details from our encounters with the doctors and analyze them to determine what sales methods will be the most effective. This information gets recorded, compiled and shared company wide throughout the years, without doctors' consent, or often, even their awareness. We download these details onto our laptops daily, so we can diligently pore over them before every visit to the doctor's office to best tailor our strategy to maximize sales.

We not only enter a physician's office armed with information, but also with a vast arsenal of gifts, including pens, pads, clipboards, food and samples. We have many subtle ways to remind

doctors of our generosity.

In doing so, we cultivate in them a sense of obligation, whether the physician realizes it or not. I can assure you, most often they

don't.

We befriend nurses and pharmacists to act as our agents in our efforts to affect physician prescribing. For me, nothing was more satisfying than to hear a nurse deliver my exact sales message to an unsuspecting physician. In essence, it was selling by proxy.

We tracked down formulary Committee members and lavished them with attention in effort to promote our products on a larger

scale.

In short, we are salespeople, and we market our products as one would any other product. But for obvious reasons, pharmaceuticals

are unlike other products, because they can affect health.

When my personal physician wrote me a prescription, I couldn't help but wonder, "Did he select this drug for me because of the evidence, or because he had a fancy rep dinner the night before?" Thank you.

[The prepared statement of Mr. Ahari follows:]

Letter to Congress:

As a former drug representative for Eli Lilly, I spent 20 months increasing the market share of my company's drugs. I was recruited fresh from college with an eager desire to employ my degree in molecular biology and biochemistry. Shortly after my hiring, it became clearly apparent that a drug sale had much more to do with establishing personal relationships than it did with understanding the latest science. However, any doubts I held regarding the effectiveness of such methods were dispelled by the results of my persuasiveness and the financial rewards I received for my efforts. The latter also helped me rationalize the many ethically dubious situations I routinely encountered in my work. Upon my departure from the industry, I began working for the public's health. Seven years later, as a result of my experiences and education I am more convinced than ever that the goals of the pharmaceutical industry often stand in direct conflict with the practice of ethical and responsible medicine. Nothing in my recent research causes me to believe that my experiences were anything but typical of the training and practice of the majority of drug reps plying their trade today.

The Role of Drug Reps

"There's a big bucket of money sitting in every [doctor's] office." - Michael Zubillaga, Astra Zeneca Regional Sales Director, Oncology

Ostensibly, the drug rep provides a valuable service to the practicing clinician. Their role is explained by the industry as a means to provide valuable education to physicians and to supply all-important samples, especially to those patients who normally can't afford to pay for their own medications. I am convinced that these justifications are nothing more than a distraction from the actual purpose of pharmaceutical sales representatives: to sell. To sell pharmaceuticals means convincing doctors to prescribe your product more than your competitors despite what might be the more suitable drug for the patient. It means swaying doctors to use your product in instances where they may not think to despite what might be medically acceptable usage. It means persuading doctors to use your drug when a non-medication therapy would be a better alternative. This means rewarding physicians with gifts and attention for their allegiance to your product and company despite what might be ethically appropriate. This means to sell, as one would any other marketed product.

But, of course there are clear and obvious reasons why the laws and expectations regulating the sales of medications are fundamentally different than those relating to the sales of most other marketed products. Drugs are selected by proxy, on behalf of the patient by doctors. Doctors rely on objective scientific evidence to guide their prescribing choices. Despite this, we drug reps, untrained in medicine, market our own products as the ideal choice. Our intent as sales reps is to provide a skewed perspective; one where our product is presented in the best possible light while we shine a spotlight on the shortcoming of our competitors' products. The end effect is a skewed understanding of the pharmacology, poor prescribing practices, and compromised medical professionalism. Crucial to this process is the persuasiveness, enthusiasm and charisma necessary to overcome the natural misgivings of physicians.

Recruitment

"I would think, essentially, that cheerleaders make good sales people." – Ms. Cassie Napier, TAP pharmaceutical drug representative

The majority of drug reps entering the work force today are young and attractive. The ranks of reps are replete with sexual icons: former cheerleaders, ex-military, models, athletes. Of

course, as a sales job, the reps must be eloquent and convincing. Depending on the population, certain ethnicities are preferred either to make the rep distinct among other reps or to provide them with a cultural advantage in connecting with their clients. Noticeably lacking among most new reps is any significant scientific understanding. My personal case illustrates this point rather vividly: In my training class for Eli Lilly's elite neuroscience division, selling two products that constituted over 50% of the company's profits at the time, none of my 21 classmates nor our two trainers had any college level scientific education. In fact, that first day of training, I taught my class and my instructors the very basic but crucial process by which two nerve cells communicate with one another. It is very likely that the majority of my class couldn't explain the difference between a neuron and a neutron prior to sales school. While it's certainly a bonus to have a scientifically educated representative, it is far from a primary recruitment criterion. Youth is a much higher criterion for the sales position. Youth is equated with attractiveness and enthusiasm but also younger reps are more likely to believe unequivocally in their products superiority against competitors. This combination of charisma and zealotry makes the rep a compelling personality.

Training

"It is difficult to get a man to understand something when his job depends on not understanding it." – Upton Sinclair

Training varies significantly from company to company and product to product however, certain commonalities exist. Most reps are taught a modicum of science pertinent to their product. They learn the basics of the disease their product is intended to treat but still lack a significant scientific education to place their knowledge into context. Essential to their "scientific education" is learning how to discuss critical talking points about drugs in their product's class. Reps memorize facts and statistics to support market-tested positive perceptions of their products. Reps also memorize negative facts and statistics about their competitors. Hours a day are spent learning how to weave the perceived benefits of their product into a concise, seemingly un-rehearsed message. The ability to deliver the message is further refined by learning how to handle common objections. A typical tactic is to rebut the negative medical experience of the concerned physician with positive data from the company that addresses their concern. "Doctor, that may be you're experience but the data, drawn from a much larger population, suggests otherwise ..." An equally typical tactic is to rebut the negative data a concerned physician may have with positive anecdotes of their colleagues' experiences and how their vicarious understanding should outweigh the concerns that the data may cause. "Sure, doctor, the paper may suggest that the side-effect commonly occurs, but how often have you seen it with your patients?" The use of these tactics is not mutually exclusive. Rebuttals are seen as merely tools in the toolbox: whatever will fix the problem and get the conversation back on track towards selling.

Sales representative trainers are almost always veteran sales representatives and consequently, much of the training they offer is implicit in the anecdotes they give. This informal training parallels the standard training offered by the industry and in many ways compliments it. It is tacitly accepted by management and perceived as the "real" training by many veteran sale representatives. Among the more dubious "unofficial" lessons a new rep learns are: how to manipulate an expense report to exceed the spending limit for important clients, how to use free samples to leverage sales, how to use friendship to foster an implied "quid pro quo" relationship, the importance of sexual tension, and how to maneuver yourself to becoming a necessity to an office or clinic. This handing down of tried and true techniques is common whenever a senior sales person is in close working company with a fresh recruit.

Some medical learning certainly occurs after training during the routine course of the job - doctors love to teach and it is our role as reps to ingratiate ourselves to our clients - however, given that most reps switch jobs or careers after only 2 years, it's difficult to believe they have mastered enough medicine to consistently provide a source of reliable scientific information for their physicians. Incidentally, the short tenure of drug reps seems linked to the duration of zealotry a rep holds for their product. Once the rep begins to question the notion that the product is no longer the overwhelmingly clear choice, enthusiasm diminishes and the process of sales becomes more complex. These reps are easily replaced by other, younger, less questioning recruits

A standard test given towards the end of a sales rep's training is a mock sales call on an actual paid doctor, hired to play the role of the objecting client. While the scenario is often contrived and the dialogue scripted, a camera records the encounter to provide an observer's perspective of the reps efforts. These videos are evaluated by the entire training class and scrutiny comes in a variety of forms: uncomfortable body language, a missed opportunity to personally connect with the client, a deviation from the market-tested sales pitch, a failure to criticize a competitor's product, or most egregiously, failure to be assertive in "asking for the business" - a concept so crucial to sales, even pharmaceutical sales, that it warrants its own acronym AFTB. Every sales training about which I have heard or read puts AFTB as the most important part of any sales encounter. Sales reps are taught to convert social or medical capital into an increase in market share by "asking for the business." However, the way that you curry that capital is as varied as the diversity of your clients' personalities. A very common if informal part of training is learning to classify your clients' personalities into categories defined by psychological test such as Myers-Briggs. Once recognized, reps are expected to tailor their approach to best achieve a response from the clients. Doctors who are intellectuals (these typically constitute the minority of a rep's clientele for a variety of reasons) are offered the latest scientific articles or receive polite requests to "teach" the drug rep about the science of his or her product. Doctors who are extroverted are lavished with personal attention. Small friendly dinners are common for these doctors and most likely many personal details are exchanged between the rep and the physician to build an intimacy that can later be leveraged to increase market share. Doctors who are more intuitive can be approached indirectly. By establishing a friendly relationship with a core group of physicians trusted by the intuitive doctor, one can rely on anecdotes from or personal intervention by the core to establish a relationship with the target.

Pairing

"If you do it right, it can be the most rewarding selling situation because of the synergy that multiple reps can bring to a situation. One rep might get along better with a certain person in the office, another rep may say something to the customer a little differently, and that might be just enough to turn the doctor around. It gives us more chances to be successful." – Anonymous Sales Manager – Pharmacuetical Representative Online Magazine, September 1st 2006, Two Sides of the Team

Drug reps themselves are given long and complex psychological exams to assess their personalities. One reason is to provide better management and career direction for the rep but another reason is to provide rough guidelines on the personalities the with which drug rep is compatible. However, the amount of thought invested in determining what personalities mesh best goes deeper than an expensive, exhaustive mental evaluation. Drug reps are often paired. These pairs are responsible for the same group of clients, however the pairing often occurs with the intent to increase the likelihood that a client will have something in common with one of the

reps. While female reps are more common than male reps (to cater to the disproportionate number of male heterosexual physicians), males and females are mixed whenever possible to provide a gender appeal to all clients in a territory. Quite simply put: some doctors prefer the company of men and some the company of women. The pairing often also takes into account the interests of the reps. Once a fertile common ground is found between the client and one of the reps (referred to as the "lead" rep), the pair dedicate their resources to enhancing that relationship. The reps don't both need to be "good friends" with the client. It is in fact, preferable that one of them becomes the doctor's "best friend." To achieve this, reps have occasionally played "Good Cop, Bad Cop," intentionally sacrificing the relationship of the lesser rep to enhance the relationship of the lead rep.

Tools of the Trade

"There is something called the momentum effect, which means that if a rep leaves a sample with a doctor today, that will influence that physician to prescribe the drug in the future. There will be a lingering effect: The doctor will be thinking about prescribing that rep's drug next week, and the week after, and so forth, based on what was delivered to him today." – Patrick Burns, Pharma Executive Online, June 2005, A sample plan: one of the industry's most important promotional tools is also one of its least understood.

Drug reps have a variety of weapons at their disposal in the campaign to increase market share. Regardless of the rep's choice, every decision is, on some level, weighed in a cost benefit analysis and calculated to boost sales in the long run. Tactical and strategic decisions are weighed in the minds of drug reps as they consider what assets to dedicate to their targets and what return is expected on the investment.

Some doctors are susceptible to congenial meals with friends. Others expect an abundance of free samples. Some prefer to be elevated to the ranks of official paid speakers. Some enjoy a box of doughnuts and coffee for their staff. And some will be satisfied with pleasant small talk. The expected yields are just as varied. A meal may involve colleagues beleaguering their friend to use more of the host rep's product. Extra samples may be left behind contingent on being given to new patients as opposed to sustaining therapy (and thus "cannibalizing" sales). Invitations to join the speaker circuit are rescinded when doctors fail to show their loyalty by prescribing more of the sponsor's product ... or if speakers fail to convince their audiences to use more of the sponsor's product. Routinely providing meals and cultivating friendships are among the most effective ways of influencing a physician's prescribing habits without addressing the science. The quid pro quo in all of these scenarios is tacit and never directly stated. However, clients learn fast that these gifts come with strings attached.

Samples

"Although samples are the single largest marketing expense for the drug industry, they pay handsome dividends: doctors who accept samples of a drug are far more likely to prescribe that drug later on." – Carl Elliot, The Atlantic, The Drug Pushers, April 2006

Among the gifts with which drug reps ply their clients, samples are the most routinely used to defend the need for pharmaceutical sales representatives. Doctors claim to use the samples to help indigent patients. While this may be the case, it is difficult to believe that the legions of reps with exorbitant salaries and expense budgets are the most effective means of disseminating bottles containing only 14 pills each. Pharmaceutical companies are not charities, and the delivery of samples is merely another means to promote business ... again at the expense

of the public and potentially at the expense of the patient. Drug reps are taught to use samples in myriad ways. As a gift, samples win the gratitude of doctors, who in turn win the gratitude of their patients when they offer a week's supply of free medications. Unfortunately, few patients with chronic diseases immediately realize that this "free gift" is for a drug that they will be taking for a long, long time. Compounding this tragedy is that for many drugs a generic alternative is available that is cheaper and usually just as effective, but once a medication has been started, doctors are reluctant to change their prescription. Reps cleverly limit the number of samples they allocates to each clinic or office to make their return in 2 weeks a necessity. Reps are also instructed to parley "extra" samples left on the physicians desk as a gift to be used exclusively for new patients. In essence, the rep is using tactics similar to those employed by illegal narcotics dealers: the first drug is free and then you're hooked and you have to pay. Doctors who continue to insist that samples help sustain the therapies of poor patients need only be informed that drug reps do not visit every doctor in their territory - they only visit the ones that are most likely to give them a good return on their investments of time, money, food, gifts, samples and friendship.

Prescriber Data

"Physician behavior drives today's pharmaceutical marketing tactics, and sales representatives are often tasked with 'changing physician behavior.'" – Jane Y. Chin Pharmaceutical Representative Online Magazine, October 1st 2006, <u>Get Educated</u>

Helping drug reps triage which clients to see, prescriber data identifies which doctors in a given region write the most scripts (i.e., prescriptions). The data scores physicians on a scale of 1 to 10, with 10 being the greatest writers and 1 indicating a writer of very few prescriptions. 10-ranked physicians are known by all the drug reps in a territory. They are given the most attention and the most lavish gifts. Doctors who are 5-ranked, on the other hand, rarely see the drug reps. They may be invited periodically to a dinner but rarely receive the perks of their higher-prescribing colleagues. The argument for the use of these data is to allow drug reps to determine which physicians most crucially need their "scientific expertise." Sadly, this approach focuses on a strict minority - leaving the smaller but much more common practices, which treat the majority of patients in a given territory, with little opportunity to draw from the reps "expertise." It defies logic to believe that a well-paid, gift-bearing, charismatic, twenty-four year old, liberal arts college graduate is the most efficient vehicle to disseminate up-to-the minute scientific information to doctors.

In addition to the information that gauges a physician's market value, the data also catalog what products a physician is prescribing. This information helps determine how reps will tailor their sales pitch to appropriately juxtapose the rep's product against the physicians preferred choice. Most physicians prefer not to share their prescribing practices with drug reps. When the data are available the physician's attempt at privacy becomes moot. In fact drug reps are trained to study their target's prescribing patterns to best consider what sales pitches will work. Oftentimes, the juxtaposition is subtly made without mentioning the physician's preferred drug and arousing his or her suspicion.

Personal Client Information

"When you're out to dinner with a doctor, the physician is eating with a friend. You are eating with a client." – Anonymous Sales Rep Trainer

The most troubling aspect of pharmaceutical sales is systematic befriending of our

clients. In addition to the psychological profiling mentioned above, drug reps are taught to constantly be on the lookout for personal effects that will help us connect to our doctors. When entering an office for the first time, we nonchalantly survey it for clues to ingratiate ourselves with our client. Similarly, conversations are intentionally steered into the realm of personal details such as religion, family, or hobbies to acquire similar information. As a matter of training, we collect this data subtly. In the course of a conversation with clients, we may glean facts about their prescribing preferences, the dates of their children's birthdays, where they were born, or what music they enjoy. Training encourages us to commit these details to memory just long enough to return to our cars and instantly type up a "call report" listing the details of our conversation. On a daily basis, we connect our computers to a central database that uploads the information we've acquired, allowing us to share it with our partner drug reps and company marketers. Subsequently, drug reps interweave pieces of conversation specifically tailored to appeal to their client drawn from personal information that wasn't necessarily shared with them. For example, Dr. Jones will be nothing but grateful when I supply him with a cake celebrating his children's birthday when, in fact, he told my partner (and not me) the birthdates several months prior in a personal conversation.

The prescriber data and personal client information make our laptops the single most important tool in our arsenal after our personalities. Reps take their laptops to the field and examine them prior to every client visit to help them develop an appropriate plan of attack. While reps see only an average of 8-10 physicians in a normal 8 hour work day (a seemingly small number considering that a single office may hold 4 important clients or that an effective sales exchange can occur in less than 2 minutes), they spend a considerable amount of time studying their computers for strategy purposes. This laptop-stored information is arguably the best kept secret of drug-repping - most doctors are completely unaware of the existence of these files on them. For our part, we drug reps are instructed never to enter an office with our laptops, to avoid showing physicians their profiles, and if ever confronted about the existence of such information, to downplay its importance to our work. From my lectures and in conversations with physicians, I have yet to find an audience where a significant portion of the physician audience hasn't been surprised by the existence of such information. From my research and conversations with drug reps, I have yet to find a company that openly discloses its client information to their clients.

Thought Leaders

A rarely used but powerful tool to create changes in prescribing habits is the lure of coveted company-sponsored speaking engagements. Drug reps scour their territory to find potential speakers who can persuade their peers to increase their usage of a particular product. Characteristics that we look for in our speakers include the following:

 Charisma – the speaker must have the ability to capture his/her audience's attention

2. Credibility - the doctor must be respected by his/her peers

 Convincing – the doctor must adequately address concerns about the product so as to ultimately increase sales.

4. Constancy – with respect to his/her prescribing of the company's product. When the client is first recruited, he or she is given local speaking engagements. Evidence of effectiveness is monitored and, depending of the degree of their success, the doctor may be informally promoted to speaking engagements in a wider area and given larger honoraria. In

effect the physician speaker becomes a second arm of a marketing strategy that relies on "synergy." Adding to this complementation in sales, doctors are often supplied with presentations crafted by the marketing department to emphasize the specific advantages of our products that will yield the greatest sales benefits – not surprisingly, they are often very similar to what the reps are scripted to speak of. While physicians are generally reluctant to become mouthpieces of industry marketing in such an overt fashion, most accede to these conditions. Such rationalizations can be attributed to a variety of reasons: no one will know that it presentation was company made, the doctor still believes that they remain wholly objective, and failure to meet company expectations can result in a cancellation of the talk (even the day of the expected event.)

While most doctors are genuine in their belief in the products about which they speak, the relationship exists for the profit of the sponsoring company. For example, should a doctor have a change in mindset about the product, fail to convincingly address an audience's objections about the product, refuse to use the slides created by the company or simply fail to write enough prescriptions for the sponsor's product, then the sponsor is free to cancel the relationship. While a common and acceptable business practice, this behavior risks creating a coercive relationship with speakers who wish to speak (and get paid) more than they wish to teach. Again, we must ask ourselves, how much marketing at the expense of distorting the balance of objective information is permissible?

Gifts

"Not accepting a gift is one thing, but restricting sales reps' ability to give healthcare professionals valuable information about their drugs would be a big mistake."- Scott Lassman, PhRMA's senior assistant general counsel Pharmaceutical Representative Online Magazine, November 1st 2006, Gifts That Keep on Giving

Aside from the above tactics and tools, drug reps are armed with a wide assortment of gifts and deep pockets to further influence physician prescribing. Whether pens, pads, clip boards, or anatomical models, companies take great pains to make their gifts vibrantly colored and clearly logo'ed. The strategy behind these gifts is to draw attention to the pharmaceutical products and to serve as reminders of the company's generosity. These reminders generate a conscious or subconscious desire to return the "favor." Referred to as "reciprocity" (a well known term in psychology and marketing), this desire is cultivated by drug reps with whom doctors have a social bond.

While PhRMA, the leading pharmaceutical industry association, has set out guidelines to remedy conflicts of interest, the effort is largely cosmetic. Of course, it is necessary to point out that not all drug companies are represented by PhRMA. Without enforcement measures, these guidelines are merely wishful thinking that the fox will change its nature and actually guard the henhouse. Furthermore, the notion that permissible gifts are those that "benefit the practice of medicine" does nothing to change the nature of how these gifts still sway physicians. The gifts still come from reps who work for companies that have obligations to shareholders – with a goal that is not based on scientific evidence, the patient's well-being, or public health but on company profit. Also, the total amount of spending on these gifts hasn't been reduced by the PhRMA guidelines. For example, in the past, as a rep, I would spend a \$100 on a golf club for a physician allowing him/her to spend \$100 on a medical textbook. Today, I buy the book and he/she buys the golf club. It is still a gift, still a perk, and still \$100.

Sales Representative Culture

"I want you out there every day selling Neurontin. Neurontin is more profitable than Accupril so we need to focus on Neurontin. Pain management, now that's money. We don't want to share these patients with everybody, we want them on Neurontin only. We want their whole drug budget—not a quarter, not half-the whole thing. We can't wait for them to ask, we need to get out there and tell them up front. Holding their hand and whispering in their ear: 'Neurontin for pain, Neurontin for everything.' I don't want to see a single patient coming off Neurontin before they've been up to at least 4,800 milligrams a day. I don't want to hear that safety crap, either. Have you tried Neurontin? Every one of you should take one just to see there's nothing. It's a great drug!" - John Ford, senior marketing executive for Parke-Davis

More often than not, what is deemed acceptable or necessary behavior for the job is also passed down between representatives. Sadly, while many companies have strict guidelines on what is acceptable and unacceptable behavior, the incentives and pressures to perform encourage many reps not only to work harder but to bend the rules when necessary to achieve their goals. Most managers are willing to look the other way in the case of a well performing salesperson. When ethical infringements become public knowledge and a punishment is handed down, most reps acknowledge the bizarre working environment that superficially demands a strict adherence to ethical standards while rewarding unethical behavior. The recent news is replete with examples of questionable behavior but a particularly telling quote from an Astra Zeneca regional sales director best conveys the spirit of pharmaceutical sales: "There's a big bucket of money sitting in every [doctor's] office." Drug reps are not given promotions on how many doctors they educate, nor how many patients are cured, nor are they given bonuses for the number of indigent patients that receive necessary medications. They are rewarded for increasing their market share and they are encouraged to be creative in achieving that goal. No industry is made up of saints; however, when the problem extends beyond a few errant reps such as the off-label marketing of Neurontin, or the suppression of negative data on Vioxx, or the denial of Oxycontin's addictive properties, it becomes an issue of incompatible goals and responsibilities. The industry cannot be expected to temper its obligation to shareholders to better serve the public's health and the medical establishment without some form of effective external regulation.

Why I Left

"I will remember that I remain a member of society, with special obligations to all my fellow human beings, those sound of mind and body as well as the infirm." – Modern Day Medical Oath

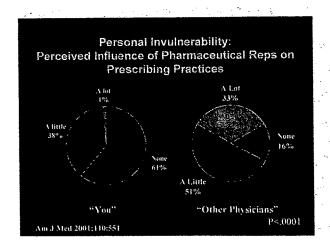
As a drug representative, I found myself in constant conflict with the values imprinted upon me by my family of medical practitioners — the doctor is in service to the patient above all other concerns. I was troubled that I could walk into an office filled with waiting patients but know that I would be seen first by the doctor by virtue of our friendship. I was bothered to know that doctors who denied my products' medical effectiveness would prescribe copious amounts of it after a friendly (but expensive) dinner in Manhattan. I was angered that the exorbitant expense budgets used for meals and gifts could instead be used to help the many patients who couldn't afford our products. It made me wonder, what I would think of my doctor if he prescribed me a medication that was made by the company that bought him dinner the night before. There is nothing wrong with profit but there is something wrong when that profit comes at the expense of medical professionalism, broken trust between physicians and patients and the public's health.

Addendum: The Data

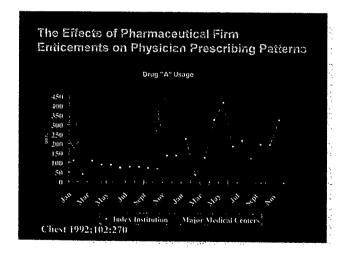
cognitive dissonance, noun: psychological conflict resulting from simultaneously held incongruous beliefs and attitudes (as a fondness for smoking and a belief that it is harmful)

Much in the same vein as I have been taught at Eli Lilly, I have presented my case in this memo with an appeal to the emotions as the primary basis for my argument. This would cause the casual thinker that there is very little data to actually support such a perspective. Nothing can be further from the truth. The overwhelming body of peer-reviewed, academic articles makes a clear case for how marketing has negative effects for the medical community, physician behavior and the public. And while I am confident in my academic credentials, there are more qualified researchers who have quantifiably evaluated the industry's impact beyond the marketplace. Here are two compelling pieces of evidence that measurably relate the story of marketing.

This graph is from an article written by Dr. Michael Steinmann from the University of California, San Francisco. A common refrain from physicians when asked how vulnerable they are to marketing is "I am too smart to be influenced." When the question asks them to judge their peers, the result is strikingly reversed - "I can't believe how much of that pharma propaganda my colleagues swallow?!" A simple point that is worthy of repetition is that reps have multiple sophisticated mechanisms to evaluate the effectiveness of their sales efforts. They are shrewd in their cost-benefit assessments and will unlikely retain a professional relationship with a client that fails to benefit their business to some extent. If a rep is in common contact with a physician, they are invariably an asset to the rep's business and the doctor is likely unaware of the influence marketing holds on their prescribing practices. It exposes a critical illusion that drug reps do their utmost to cultivate: "Marketing can't possibly sway you doctor. You have several years of training and education far in advance of my own. How can I possibly influence you?" The result is a level of cognitive dissonance so pervasive and profound as to cause a physician to rationalize unethical behavior. Sadly, it is a reminder of the anecdote statistic that 90% of physicians believe they graduated in the top half of their medical school class.



This second graph provides an interesting insight on how "medical education" has impact on a large scale. The red line represents the average use of a particular medication at several similar hospitals. The yellow line represents the prescription of 20 physicians at the hospital of interest. The green arrow shows the when the product was introduced to the hospitals formulary. You'll notice that prescriptions at this institution were similar to the control group. However, at the blue arrow point, all 20 physicians received an all-expense paid invitation to a medical conference pertaining to the medication in question. Incidentally, this conference was held in a location renown for its contributions to higher learning - the Caribbean. Immediately following the acceptance to the invitation, one detects a marked rise in written prescriptions. Generally speaking, most physicians innocently want to accrue greater experience with the product they will soon be lectured on. From a marketing perspective, this is an expected phenomenon. The precipitous drop in prescriptions denoted by the red arrow does not represent any dissatisfaction with the product or a limit in supply. Instead, it is reflective of the physician's inability to continue prescribing while ostensibly learning in the Caribbean. However, any losses in prescription are made up for with great enthusiasm upon returning from their medical conference and far exceed the average at similar medical centers. When one considers the duration of medication associated with each prescription (years to a lifetime) one can surmise that any expenditures accumulated from the trip are paid for by the subsequent month's prescriptions. And while there in nothing inherently wrong with providing "medical education" or profit, the fact that 19 of the 20 physicians in this particular study felt that they were not influenced by such an experience and found their prescribing to be normative belies marketing's ability to transform the prescribing culture of an entire community with scarcely little awareness of its members. Given the objectives of the sales force to both expand the market and expand market share, it is small wonder that these practices have raised alarms for bio-ethicists, physicians, health policy experts and public health researchers alike.



The CHAIRMAN. Thank you, Mr. Ahari. Dr. Avorn.

STATEMENT OF JERRY AVORN, PROFESSOR OF MEDICINE, HARVARD MEDICAL SCHOOL, BRIGHAM AND WOMEN'S HOS-PITAL, BOSTON, MA

Dr. AVORN. Thank you, Senator Kohl, Senator Smith.

If they are used well, especially in older patients, prescription drugs can reduce disability late in life and be very cost effective. But they can also cause needless drug-induced illness, especially in older patients, and it can impose a heavy burden on patients and on public budgets. Some preventive drugs are actually under-used in the elderly.

I am here today to discuss with you an approach that can improve the quality and accuracy of medication use, as well as con-

tain its spiraling costs.

There is a huge gap between the best available drug knowledge out there and the prescriptions that many patients actually receive from their doctors. Each week, medical journals publish so much new information that it is nearly impossible for doctors to keep up with it. Important findings might be reported in any of 100 journals, and it is no one's job to make sure that we see them or monitor how well our prescribing is being done.

But into that void rushed tens of thousands of attractive, articulate people like Mr. Ahari, who come and visit us in our offices each week, nicely dressed and often bearing gifts, to teach us how to prescribe for our patients, even though, as was noted, most of

them don't have any formal scientific training.

They are drug company salespeople, or detailers, who are paid based on how much they can increase sales of their company's products. Unfortunately, for many primary care doctors, this information about drugs—especially new ones—is the most important

source of information about prescribing.

The sales reps are smooth, cordial and concise. The material they give us is slick, engaging and easy to understand. There is always a clear, final, take-home point at the end of their presentation, pushing use of their company's usually costly product, even if it has less of a safety track record and is no better than what we have been prescribing for years, or perhaps even less effective.

This informational playing field is not level. Manufacturers of generic drugs don't have the funds or the incentive to come to our offices and present their side of the story, even when the evidence is on their side. Those of us who are on medical school faculties, I must admit, are often not very good communicators, although we

do tend to have a more balanced viewpoint.

We give our continuing education courses in big lecture halls. We drone on for hours in darkened rooms, showing slides that are as

visually interesting as the Congressional Record.

The articles that we write in medical journals may contain vital data, but they are often boring to read and cover only a sliver of the clinical topic. As a result, doctors prescribe the drugs that are the most heavily promoted, not necessarily the ones that would be the safest, the most effective or the most economical for our patients.

We have seen that happen recently with Avandia, Vytorin, Vioxx several years ago, and other widely used drugs, with bad, negative consequences, both clinically and economically.

Ironically, much of this misuse is paid for with taxpayer money—enough to fund more balanced drug education programs dozens of

times over.

For nearly 30 years, my colleagues and I at Harvard have been working on this idea. What if we could take the very effective communications and behavior change tools that the drug companies use so well, but instead deploy them simply to give doctors the latest and best balanced facts about the drugs that we prescribe?

To do this, we trained pharmacists and nurses to go visit physicians as un-sales reps, to provide educational outreach about common prescribing topics. I named the approach "academic detailing," because it used the detailer approach of sending someone to meet with a doctor in his own office, but we did it from a non-commercial and academic perspective.

We have shown that the concept works in several large, randomized trials published in the "New England Journal of Medicine" and

other journals.

The vast majority of physicians who are offered this service accept it, and we have shown that it significantly improves their prescribing. In a formal benefit-cost analysis, we found that such a program could save \$2 for every \$1 that it costs to run. This was not a surprise. It is how the drug companies move prescribing in the directions that they want. They know exactly what they are doing.

Many additional studies have shown that academic detailing programs can improve the use of a wide variety of drugs, from antibiotics to sedatives, in settings from primary care offices to teach-

ing hospitals to nursing homes.

Some of these programs have also tracked clinical data, and have shown that patients' outcomes also improve, as expected, with more evidence-based prescribing. Today, academic detailing services have been set up in England, the Netherlands, Canada, Australia and several U.S. states.

The Pennsylvania program, which we will hear about from Nora Dowd Eisenhower, is the largest publicly funded service at present

in the country. You will hear about that shortly.

It is conducted on a completely nonprofit basis in collaboration with my colleagues and me at Harvard Medical School. We develop the materials based solely on the best evidence in the medical literature, with no interference from the State. Sometimes we encourage greater use of expensive drugs, if that is the best thing to do for the patient.

Doctors can get continuing medical education credit from Harvard through participating, and they find this to be a user-friendly and efficient way to keep up with the medical literature. We put everything we produce on the Internet for free, non-commercial use by anyone at our rxfacts.org. I have a packet of our materials to

share with the Committee.

Economically, we have found that just one of our modules has saved over half a million dollars a year through the PACE program alone—not counting the savings to Medicaid, Medicare and private

insurers. Other programs around the world have also shown that their costs are largely offset by savings from reducing excessively costly prescribing, not even counting the benefits that result from

improved clinical care.

In sum, academic detailing is not a "just say no to drugs" program. Prescribing is one of the most useful and challenging things that we doctors do. We crave accessible, unbiased data about the medicines that we use every day. Getting current, noncommercial, balanced drug information out to doctors is an important public good.

I commend the Committee for proposing such programs on a larger scale. Now that Medicare has become the nation's single biggest payer of drug bills, it would be fiscally irresponsible not to equip doctors with the balanced information we need to make the

best choices for our patients.

Well-run academic detailing services would enhance both the medical effectiveness and the affordability of the drugs we prescribe, especially for our older patients.

Thank you.

[The prepared statement of Dr. Avorn follows:]

HARVARD MEDICAL SCHOOL

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BRIGHAM AND WOMEN'S HOSPITAL

Chirf, Division of Pharmacoepidemiology and Pharmacoeconomics

Statement of Jerry Avorn, M.D.

Professor of Medicine, Harvard Medical School
Chief, Division of Pharmacoepidemiology and Pharmacoeconomics,
Brigham and Women's Hospital, Boston
Director, Harvard Interfaculty Initiative on Medications and Society
Author of "Powerful Medicines: the Benefits, Risks, and Costs of Prescription Drugs" (Knopf)

Used well, prescription drugs can reduce the burden of disability for older Americans and lengthen their lives, and can be very cost-effective. Unfortunately, they can also cause preventable drug-induced illness, especially in the elderly. Affordability is another growing problem; many patients are prescribed medications that are far more expensive than others that would work just as well – a cost that is rising faster than necessary, damaging both public and private budgets. And some drugs, like those to manage cholesterol or blood pressure or osteoporosis, are actually under-used in the elderly. I am here today to discuss with you an approach that can improve the quality and accuracy of medication use, as well as containing its spiraling costs.

An important gap exists between the best knowledge available about medications and the prescriptions that many patients get from their doctors. There are several reasons for this. Each week, medical journals publish so much new information about drugs that it is nearly impossible for even the most diligent doctor to keep up with it. Important findings may be reported in any of a hundred journals, and it is no-one's job to make sure we see them or to monitor how appropriate or up-to-date our prescribing is. But into that void rush tens of thousands of attractive, articulate people who come and visit us in our offices each week, nicely dressed and often bearing gifts, to "teach" us how to prescribe for our patients. These are not researchers or medical school faculty; most of them don't even have any formal scientific training at all. They are drug company salespeople, or "detailers," who are paid based on how much they can increase sales of their company's products. For most primary care doctors, information about prescription drugs - especially new ones - comes mostly from these and other commercial sources.

These sales reps are smooth, cordial, and concise; they come to where the doctor is, and chat interactively with us about their products and those of their competitors; the materials they give us and the ads backing them up that fill the medical journals are slick, engaging, and easy to understand. And there is always a clear final "take-home point" at the end of their presentation, encouraging use of their company's (usually costly) product.

This informational playing field is not level. Manufacturers of generic drugs, who make just fractions of a penny on each pill, don't have the funds or incentive to come to the doctor's office and present their side of the story, even when the evidence is on their side. And those of us on medical school faculties, I must admit, are often not very good communicators. We give our continuing education courses in big lecture halls, drone on for hours in a darkened room, showing slides that are as visually interesting as the Congressional Record. The articles we write in redical journals may be erudite and contain vital data, but they're often boring to read, and cover only a sliver of a unitical topic.

1620 Tremont Street, Suite 3030, Boston, MA 02120 e-mail: javorn@partners.org

Tel: +1 (617) 278-0930 Fax: +1 (617) 232-8602 www.DrugEpi.org As a result, doctors more and more prescribe the drugs that are the most heavily promoted, not necessarily the ones that would be the safest, or best, or most cost-effective for their patients. The pharmaceutical industry spends at least \$30 billion per year on such promotion, a higher proportion of revenues than it spends on meaningful research and development. There's a huge financial incentive for them to do so. Every time a doctor prescribes an expensive new blood pressure or diabetes pill that costs the patient over \$1,000 a year, every year, instead of a generic drug that costs under \$50 a year, that's like an annuity for the company – even if the generic drug has a better track record of safety or effectiveness than the new, more expensive drug. We've seen that happen with Vioxx, Avandia, Vytorin, and many other widely used drugs, with substantial negative economic and clinical consequences. Americans spent billions of dollars a year on those drugs, even though less overpriced alternatives would have worked as well or better. Ironically, much of that was taxpayer money – enough to pay for more balanced drug education programs dozens of times over.

Back in 1979, I wrote a grant to the federal government proposing the following idea: What if we could take the very sophisticated communications and behavior-change tools that the drug companies deploy so effectively, but instead use them to give doctors the latest and best facts about drugs' comparative efficacy, safety, and cost-effectiveness? My colleagues and I trained pharmacists in four states to go visit physicians as "un-sales reps," so they could provide doctors with educational outreach about several common prescribing topics. I named the approach academic detailing because it used the "detailer" approach of sending someone to meet with a doctor in his or her own office to discuss a given drug topic, but we did it from a non-commercial, "academic" perspective.

We showed that the concept worked in a large four-state randomized trial involving over 400 doctors. As we reported in *The New England Journal of Medicine*, 92% of the doctors who were offered this service accepted it, and those who were randomized to the academic detailing group significantly improved their prescribing. In a formal benefit-cost analysis, we found that such a program could save \$2 for every \$1 it cost to run. This was not a surprise; it's how the drug companies move prescribing in the directions they want. They know exactly what they're doing.

Since then, many additional studies have shown that academic detailing programs can improve the use of a wide variety of drugs, from antibiotics to sedatives, in settings from primary care offices to teaching hospitals to nursing homes. Some of these programs have also tracked clinical outcomes, and have found that patient outcomes also improve – as expected – with more evidence-based prescribing. Today, academic detailing services have been set up in England, the Netherlands, several Canadian provinces, and the entire nation of Australia. In the U.S., some integrated health care systems, particularly Kaiser, have mounted their own academic detailing services, and programs of varying size have been established or legislated in Pennsylvania, South Carolina, the District of Columbia, Vermont, New Hampshire, Maine, and other states.

The Pennsylvania program, which that state's Department of Aging asked us to establish in 2005, is the largest publicly funded service. Supported by that state's PACE program, we train pharmacists and nurses to meet with doctors in their offices to provide commercial-free educational outreach about the best treatments for several common conditions in the elderly. The program is conducted on a completely non-profit basis. My colleagues and I at Harvard Medical School develop the materials based solely on the best evidence in the medical literature, with no interference from the state – as is the case in nearly all such programs. Sometimes we encourage greater use of expensive drugs, if that's what the clinical trials show is the best thing to do. Physicians can get continuing medical education credit from Harvard, and have received the program with enthusiasm. They find it to be a user-friendly and time-efficient way to keep up with the medical literature, without having to sit through any slanted sales pitches. We put everything we produce on the Internet for free, non-commercial use by anyone, at www.RxFacts.org.

1620 Tremont Street, Suite 3030, Boston, MA 02120 e-mail: javorn@partners.org Tel: +1 (617) 278-0930 Fax: +1 (617) 232-8602 www.DrugEpi.org In an ongoing evaluation, we examined the prescribing of doctors who were offered the program compared to similar physicians in counties where it is not in effect. That analysis found that the module on gastrointestinal drugs alone – which addressed overuse of "purple pills" such as Nexium – is estimated to have saved over \$500,000 per year through the PACE program alone, not counting the savings to other payors such as Medicaid and private insurers. Economic analyses of other programs, such as Australia's continent-wide service, have likewise shown that their costs are largely offset by savings from reducing excessively costly prescribing, not even counting the benefits resulting from improved clinical care.

In sum, academic detailing is not a "Just Say No To Drugs" program. It begins with the assumptions that prescribing is one of the most useful and challenging things we doctors do, and that we doctors crave accessible, unbiased data about the drugs we prescribe. If war is too important to be left to the generals, then drug information is too important to be left primarily to the pharmaceutical industry. Proactively getting current, non-commercial, evidence-based drug information to doctors is an important public good, like good roads, primary-school education, and clean air. I commend the Committee for considering making such services to doctors a reality on a larger scale. Now that Medicare has become the nation's single biggest payor of drug bills, it would be fiscally irresponsible not to equip doctors with the information we need to make the best choices for our patients. The marketplace has not done this adequately, and will not. Over 25 years' worth of experience and data show that a well run academic detailing service would be welcomed by physicians, and can enhance both the clinical quality and affordability of the drugs we prescribe, particularly for our older patients.

The CHAIRMAN. Thank you very much, Dr. Avorn. Mr. Coukell.

STATEMENT OF ALLAN COUKELL, DIRECTOR OF POLICY AND STRATEGIC COMMUNICATIONS, THE PRESCRIPTION PROJECT GROUP, BOSTON, MA

Mr. COUKELL. Good morning, Mr. Chairman, Senator Smith.

I am the director of policy for The Prescription Project, which is funded by the Pew Trusts to promote appropriate prescribing and to encourage a stronger ethical framework between medicine and

industry.

I appreciate the opportunity to appear today, and to focus on the savings from the prescriber education programs known as academic detailing. These are programs that provide doctors with unbiased information on the safest, most effective and, other things being equal, the least costly drugs. Choosing the best drug means cost savings for patients, for public and private programs and for taxpayers, whether or not they take medication.

I would like to begin with a number that Dr. Avorn mentioned, that for every dollar spent on an academic detailing program, two dollars can be saved in drug costs. The number comes from his economic model, and it is based on real world effectiveness data.

The original study in the "New England Journal of Medicine," involved 141 doctors in the Medicaid programs of Arkansas, New Hampshire, Vermont and the District of Columbia. It focused on three particular drugs that tended to be overprescribed, and found that educational visits substantially reduced use, at cost savings of about \$20,000 a year.

That is more than enough to offset the cost of running the program. Those savings were only to Medicaid, even though these doctors also saw patients with other types of coverage. The total net

real savings were almost certainly higher.

The model then looked at expanding this pilot program to a full-scale program that would visit 10,000 doctors a year, and concluded, as I have said, a most likely benefit-to-cost ratio of almost two to one.

I should say, this study was in the early 1980's, when the cost of prescription drugs was much, much lower. Labor has increased since then, but not as much as drugs. Drugs that seemed expensive then would be a bargain today. That suggests even greater potential for savings.

Next, let me turn to the PACE program in Pennsylvania, about which you will hear more shortly, and an analysis that focused on just one group of drugs, the so-called "little purple pill" for acid

reflux, and its cheaper, equally effective cousins.

This program demonstrated reduced drug costs of about \$120 per doctor per month. For the heaviest prescribers, the reduction was \$378 per doctor per month. If the pattern persists for a year, it would reduce spending by half a million dollars against total costs for running the program of about \$1 million.

It is important to point out again, these are savings only for one class of drugs, and the program focuses on multiple classes, and only for patients in the PACE program, who are just a fraction of the total caseload for any physician. Savings in other drug classes

and to other programs, including Medicaid, Medicare Part D, State employees and private plans, are likely to more than offset the cost

of running the program.

Other countries, notably Canada and Australia, make extensive use of academic detailing. With nearly 12,000 doctors, the Australian program is the largest and most established in the world, and over the past decade has produced savings—net savings—of a \$300 million.

While there are differences between health systems, again, in general, prescription drugs are much more expensive in the United States than in these other countries. That suggests even greater

potential savings.

I can't review every available economic analysis today, but a table in my written testimony summarizes them. Let me emphasize that these programs consistently improve prescribing and do it better than other approaches.

Senator Smith. Could I ask you a question?

Mr. COUKELL. Yes, sir.

Senator SMITH. I do this with the chairman's permission. In Australia, I believe they have some limitation on how drugs are marketed. Do they prohibit the kind of slicked up approach that Mr. Ahari spoke of?

Mr. COUKELL. That also exists in Australia. Senator SMITH. They allow it there as well?

Mr. COUKELL. They do.

Senator SMITH. Is there any requirement that the doctors also

get academic detailing.

Mr. COUKELL. Academic detailing. It is a voluntary program, although, on the order of 80 to 90 percent of doctors offered this service participate.

Senator SMITH. Do they use it? Mr. COUKELL. They do, clearly.

Senator SMITH. I am not sure if physicians in Australia have the same liability concerns that physicians in America have. But I would assume in America physicians have every incentive to provide the best choice in care, in part due to liability concerns.

Mr. COUKELL. Absolutely. Senator SMITH. Thank you.

Mr. COUKELL. In terms of the broader potential for savings, let me say that it is estimated that we as a nation could save \$8.8 billion each year from the optimal use of generic drugs. Even if we look at just one condition, the treatment of hypertension (or high blood pressure) estimates say that we could save \$433 million a year, just by prescribing the drug that experts agree should be the first choice for most patients.

Instead, we see the extensive use of heavily marketed and expensive newer drugs that don't have clear advantages. There are studies to demonstrate that academic detailing can improve matters in

a cost-effective way.

Finally, so far I have been talking only about drug savings, only about the drug budget. But even more important may be the potential to change prescribing in a way that improves health and prevents disease. Imagine the health care savings when a change in

prescribing avoids just one heart attack, or gets an elderly person off an inappropriate sedative, and thereby prevents a broken hip.

Such studies exist. One showed enormous savings from an academic detailing program that changed prescribing, and thereby prevented gastrointestinal bleeds. Another looked at changing prescribing for people with heart failure. In that case, the program was estimated to cost about \$2,500 per year of life gained. That is a low price to pay to give someone an extra year of life.

I would like to thank you for examining this important issue. The Federal Government has long been the major funder of graduate medical education for doctors. Medicare Part D, means the government now also pays a very large share of drug costs. We are pleased that you see the potential to extend the Federal role in

physician education to save lives and save taxpayer dollars.
[The prepared statement of Mr. Coukell follows:]

Testimony of Allan Coukell, BSc (Pharmacy) Director of Policy The Prescription Project Community Catalyst

Before the Senate Special Committee on Aging March 12, 2008

Good morning, Mr. Chairman, Senator Smith and members of the Committee. My name is Allan Coukell. I am the Director of Policy for the Prescription Project, which is funded by The Pew Charitable Trusts to promote appropriate prescribing and address the conflicts of interest in medicine caused by pharmaceutical industry marketing.

I appreciate the opportunity to appear before you today to discuss the prescriber education programs known as academic detailing, and particularly the cost impact of such programs.

Academic detailing provides prescribers with unbiased information, encouraging the use of the safest, most effective and – other things being equal – least costly drugs. Cost savings in this context means savings for patients, for public and private insurers and for taxpayers, whether or not they take medication.

Arkansas, New Hampshire, Vermont, D.C. Medicaid Study

I'd like to begin with an important estimate: that for every dollar spent on an academic detailing program, two dollars can be saved in drug costs. This number is from an economic model developed by Dr Avorn's group, and based on real-world effectiveness data.

The original well-designed study in the New England Journal of Medicine² compared the prescribing of doctors who were offered education visits with those who were not. These were doctors in the Medicaid programs of Arkansas, New Hampshire, Vermont or the District of Columbia, and the study showed that educational visits substantially and significantly reduced the number of prescriptions for three often over-used drugs.^a

That change in prescribing equated with a decrease in costs of about 20 thousand dollars for 141 doctors, more than enough to offset the cost of running the program. And those are savings were only for the first year of the program, and only to Medicaid, even though doctors also saw patients with other types of coverage. The real savings were almost certainly higher.

^a n = 435; intention-to-treat analysis; reduction in units prescribed after education visit: cephalexin (p = 0.0006), propoxyphene (p = 0.04), papaverine (p = 0.02), all three drugs (p = 0.0001).

^b Savings of \$105 per prescriber over the 9-mo study. Estimated year one savings = \$19,740. Cost per physician visit about \$100.

The researchers then modeled an expansion to a full-scale program involving ten thousand doctors a year, making projections for staffing and duration of effects. They concluded, as I've said, a most-likely benefit-to-cost ratio of nearly 2 to 1.°

It is important to note that the cost of prescription drugs has increased much more rapidly than the costs of labor since this early 1980s study. Medications that seemed expensive then would today be considered a bargain. That suggests even greater potential savings.

Pennsylvania PACE Analysis

Next, I'd like to turn to recent data from the PACE program in Pennsylvania.³ Although the program focuses on several classes of drugs, this is an analysis of just one class – the so-called "little purple pill" for acid-reflux and its cheaper, equally effective cousins.

The analysis shows reduced drug costs of about \$120.per doctor per month. Among the heaviest prescribers, the reduction was \$378 per doctor per month. If these changes in prescribing persist for a year, they would equate to cost savings of \$572 thousand, against total program costs of about \$1 million.

It is important to point out that these are savings only for a single class of drugs, and only for patients in the PACE program, who make up just a fraction of the caseload for any physician. In all likelihood, savings in other drug classes and savings to other programs, including Medicaid, Medicare Part D, state employees and private plans, would more than offset the cost of running the program.

Australian Experience

Academic detailing programs are extensively used in other countries, particularly in Australia and Canada. While both of those countries have healthcare systems that differ from ours, it is important to point out that prescription drugs in those countries are, in general, considerably less expensive than here in the United States. That may suggest the potential for even greater savings here.

In Australia, the National Prescribing Service program generated net savings of 300 million Australian dollars over ten years on visits with 11,500 prescribers contracts. 5, f

^c Cost-benefit 1.8:1, assuming detailers see average 5.4 physicians per day in the field and behavior change effects decay to zero in year 2.

^d Comparing the seven months before and after the educational intervention, reductions were \$122 per doctor per month compared with "control" doctors in the same country who did not receive educational visits (p = 0.05). Compared controls in other counties, the reduction was \$124 (p = 0.09).

^{*} As of mid-2007, drug information consultants in this program had met with 716 physicians on a range of topics and several classes of drugs.

Over a nearly ten-year period (1997-2005), estimated savings have consistently been greater than budgeted. In 2006-2007, 11,500 individual GPs voluntarily participated in NPS core activities, which reflects a steady increase from 2,500 participants in 1998-99.

Other published studies

Time won't permit a thorough review of every published economic analysis, but a table attached to my written testimony summarizes the literature. In general, I would emphasize that academic detailing programs consistently change prescribing behavior, and do it better than other approaches. ^{6,8} Published studies of generally small programs tackling only one or a small number of drugs generally reflect the potential for savings.

Potential savings

In terms of broader potential savings, we'd point out that optimal use of generics^h would alone produce national savings of about \$8.8 billion dollars per year.⁷

Looking only at high blood pressure, the evidence shows that for most patients the first choice drug should be an inexpensive thiazide diuretic instead of one of several new, expensive and heavily marketed drugs. The potential US saving from appropriate use of thiazides is estimated at \$433 million a year. And there published evidence shows that academic detailing drive this shift in a cost-effective way.

This illustrates the potential savings from appropriately applying information on the comparative effectiveness of drugs. But as the Congressional Budget Office recently noted, ¹⁰ any potential savings are realized only when the information is translated into changes in clinical practice. That is what academic detailing helps to achieve.

Finally, it must be pointed out that all of the analyses I have discussed today focus on potential savings within the drug budget. Yet this misses an area of even greater potential cost savings – the potential to prevent disease. Such analyses are harder to conduct, but imagine the healthcare savings when a change in prescribing avoids just one heart attack or prevents a broken hip by getting an elderly person off an inappropriate sedative.

One study of academic detailing showed enormous savings by preventing gastrointestinal bleeds. 11,1 Another, in heart failure, 12 estimated a net cost of about twenty-five hundred dollars per year of life gained. That is a low price to pay to give someone an extra year of life.

Conclusion

In conclusion, I would like to thank the Aging Committee for examining this important issue. The federal government has long been the major funder of graduate medical education for doctors. Medicare Part D means the government now also pays an

⁸ See also Bloom for a discussion of individual education visits compared with practice guidelines and didactic presentations.

h Based on data from a nationwide representative survey of the US population, generics account for 56% of all prescriptions – far lower than the 75-80% rate achieved in many of the best programs. The \$8.8b is in year 2000 dollars.

¹ For more detail, see appended table.

^{\$2602/}life-year gained

enormous share of drug costs. We are pleased that this committee sees the potential to extend the federal role in physician education, to save lives and save taxpayer dollars.

Appendix

Assessing the cost impact of educational outreach programs is challenging. ^{13,14} The term "academic detailing" is used inconsistently across studies and programs. Therefore, comparison across studies is difficult. Experienced practitioners attest that the success of a program depends on the program focus and the training and skill level of the clinical educators. Longer running programs, where physicians and educators develop trusting relationships may be expected to increase the effectiveness of the intervention. However, most academic studies are short-term initiatives. Limited conclusions may be drawn from studies where failure to demonstrate a cost impact was secondary to failure to change behavior.

For a discussion of individual education visits compared with practice guidelines or didactic presentations, see Bloom. 15

Table: Published studies evaluating the economic impact of academic detailing.

Study	Setting	Design/ Intervention	Change in prescribing/ clinical care	Cost impact	Comments
	controlled tria	ils			
Freemantle et al. 16 Mason J et al. 17	UK General practice	Educational visits by community pharmacists on 4 disease/drug topics vs. no visit	Educational outreach produced 5.2% increase in patients treated within recommendations	Cost-effectiveness: ACE inhibitor for CHF \$2602 / YLG Tricyclic antidepressant instead of SSRI: cost of outreach exceeds savings (\$82 v \$75)	As anticipated, encouraging the use of an ACE inhibitor increased drug costs. However, such therapy is life-prolonging and the authors conclude that the educational intervention is cost-effective.
Franzini et al. ¹⁸	Houston, TX Pediatrics, family medicine private practices	Education on immunization or control (n = 186)	3-5% increase in immunization rates vs. control (NS)	Intervention cost \$424-550 per 1% increase in immunization	Authors conclude this cost is higher than potential societal savings.
Freitheim et al. ¹⁹	Norway, General practice	Practices received educational outreach visit on hypertension treatment (n = 70) or control (n = 69)	Thiazides prescribed to 17% vs. 11% in Intervention, control group, respectively	Cost per additional patient started on thiazides = \$454	Authors conclude intervention is cost effective. Net annual savings of a national program estimated at \$761,998.
Ofman et al. ²⁰	Orlando, FL Managed care org.	Disease management program for acid-related diseases, including academic detailing (n =	Use of recommended regimen 96% vs. 10% (p = 0.001); discontinuation of PPI therapy: 70% vs. 26% (p = 0.04)	No difference in total costs over 6 mos	Cost savings on pharmaceuticals offset by increased testing for H. pylori bacteria, a clinically appropriate outcome.

		83)			Authors report improved process measures and some outcomes through a cost-neutral intervention.
Simon et al. ²¹	Harvard Community Health Plan (New England) HMO	Retrospective cost analysis of education about blood pressure treatment: mailed information (control) vs. individual vs. group academic (nessential practices)	Both individual and group detailing improved prescribing of desired drugs (individual more than group)	Estimated net yearly cost reduction per vs. mailed info: Individual outreach \$20.37 Group outreach = no change	Individual detailing more cost effective than mail or group visits, despite higher intervention costs. Extrapolated to plan level, estimated potential net savings of \$155,000 for antihypertensive therapy.
Quasi-exper	imental studies				I I and beauty
Coopers & Lybrand ²²	Australia General practitioners/ specialist	Educational visits with focus on NSAID use (n=210)	28% reduction in dispensing compared with control group (see ²³)	Net direct benefit, including hospitalizations avoided = \$745,000 to \$1,028,000	Improved health outcomes (gi bleeds avoided) had a greater economic impact than reduced drug costs, but drug
			hospital admissions for GI disorders compared with controls	(Discounted value \$675,000 to \$932,000)	savings alone approx equal to project costs.
Hill et al. ²⁴	Major Midwestern HMO	Peer-to-peer education visits focus on antihistamines, lipid lowering and antibiotic use (n = 254 physicians vs. 409 in control group)	Assessed total cost of prescribing	Total pharmaceutical costs increased 0.9% vs. 2.9% in controls, corresponding to \$232,218 savings over 6 mos	Authors estimate a return on investment of 14.4% to 281% for a large-scale program.
Keys et al. ²⁵	Pennsylvani a PACE program	Pharmacist education of physicians identified through review of prescriber profiles (n = 254)	Assessed total cost of prescribing	Academic detailing by 6 part-time pharmacists saved more than \$12,000/mo in the 3 mo after implementation	Program run by commercial contractor focusing on high-cost prescribing patterns. Savings to cost ratio estimated at 4:1
Regier ²⁶	Saskatchew an, Canada. Primary care	Educational visits on NSAID prescribing (n = 56)	Total number of prescriptions increased slightly in intervention group.	7.4% decrease in cost per NSAID prescription among doctors who received visits.	City-wide decrease in cost of Can\$42,725 for this class of drugs vs. an increase of \$179,933 in a comparator city.

Abbreviations:
ACE inhibitor = a class of drugs used to treat hypertension and heart failure;

CHF = congestive heart failure;

mo = month: = months: mos

= the number of physicians (or physician practices) in the study, or the number assigned to receive educational visits;

NS = not significant;

NSAID = non-steroidal anti-inflammatory (the class of pain relievers that includes ibuprofen)

PPI = proton pump inhibitor (the class of acid-reducing drugs that includes Nexium and

Prilosec);

= selective serotonin reuptake inhibitor (the class of antidepressants that includes SSRI

Prozac);

YLG = year of life gained.

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⁴ Maclure M et al. Show me the evidence: best practices for education visits to promote evidence-based prescribing. Canadian Academic Detailing Collaboration / Drug Policy Futures (report) 2006.

National Prescribing Service. Evaluation Report No. 10. Dec 2007

⁶ O'Brien MA et al. Educational outreach visits: effects on professional practice and health care outcomes. Cochrane Database of Systematic Reviews 2007, Issue 4. Art. No.: CD000409. DOI: 10.1002/14651858.CD000409.pub2

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¹³ Maclure M. et al. Measuring prescribing improvements in pragmatic trials of educational tools for general practitioners. Basic and Clinical Pharmacol and Tox 2006; 98: 243-252

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15 Bloom BS. Effects of continuing medical education on improving physician clinical care and patient

health: a review of systematic reviews. Int J Tech Assessment 2005; 21(3): 380-385

¹⁶ Freemantle N. et al. A randomized controlled trial of the effect of education outreach by community pharmacists on prescribing in UK general practice. Br J Gen Practice 2002 (Apr): 290-295 ⁷ Mason (2001) ibid.

¹⁸ Franzini, L et al. Cost-effectiveness analysis of a practice-based immunization education intervention. Ambulatory Pediatrics: The Official Journal of the Ambulatory Pediatric Associatio (2007); 7(2): 167-175

Simon SR ibid

22 Coopers & Lybrand Consultants. ibid

²⁴ Hill, C. D., Bunn, D. N., & Hawkins, J. R. Stretching the managed care dollar in the new millennium: The practice of detailing primary care physicians. *Managed Care Quarterly*, 10(2), 18-23.

25 Keys PW, Goetz CM, Keys PA, et al. Computer-guided academic detailing as part of a drug benefit

program. American Journal of Health-System Pharmacy: AJHP 1995; 52(20): 2199-203

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¹⁹ Fretheim A, Aaserud M, Oxman AD. Rational Prescribing in Primary Care (RaPP): Economic Evaluation of an Intervention to Improve Professional Practice *PLoS Medicine* Vol. 3, No. 6, e216 doi:10.1371/journal.pmed.0030216

²⁰ Ofman, J. J., Segal, R., Russell, W. L., Cook, D. J., Sandhu, M., Maue, S. K., et al. (2003). A randomized trial of an acid-peptic disease management program in a managed care environment. *The American Journal of Managed Care*, 9(6), 425-433

²³ May FW et al. Outcomes of an educational outreach service for community medical practitioners. *MJA* 1999; 170: 471-474

The CHAIRMAN. Thank you, Mr. Coukell. Ms. Eisenhower.

STATEMENT OF NORA DOWD EISENHOWER, SECRETARY, PENNSYLVANIA DEPARTMENT OF AGING, HARRISBURG, PA

Ms. EISENHOWER. Good morning, senators. I am really pleased to be here today to talk to you about a program that we have been working on in Pennsylvania for several years.

But before I do that, I would like to talk to you a little bit about

the history of our program.

PACE is the senior pharmacy program in Pennsylvania. It has been around since 1984. During this past fiscal year that ended on June 30, 2007, Pennsylvania spent 10 percent of its annual budget—that is \$2.5 billion—reimbursing for prescription medications for over two million of its residents. That is older Pennsylvanians who qualify for the PACE and PACENET program Medicaid recipients, State employees and retirees.

Many of the individuals who are covered under these programs are in frail health with multiple chronic conditions requiring daily maintenance medication. They are enrolled in a dozen different and disparate programs, most of which provide comprehensive prescription drug coverage with nominal cost sharing to the beneficiary.

Over 80 percent of our annual prescription drug spending is for three programs, Medicaid, our State employees and retiree program, and PACE our senior pharmacy assistance program—one of the best in the country. It has led the way in many areas, because doctors like Jerry Avorn and Tom Snedden, the director of the program, have been managing the program.

Tom has been director of the program for over two decades. PACE has led the way in many areas, and academic detailing is an area we think should be adopted more broadly, because of the

effectiveness we see in PACE.

When Governor Rendell took office in 2003, enrollment in our program was low, and the effects of direct-to-consumer advertising was driving utilization of many medicines. Most importantly, we saw explosive growth over several years preceding in the direct-to-physician promotion—very effective promotion that you have heard described here. We really noticed that the physicians we spoke to, and the consumers in our program were very frustrated by this and looking for independent information, and it was very, very hard to obtain.

So, we saw that utilization review—or edits at the point of sale at the pharmacy—were effective, but rather heavy-handed. What we wanted to do in using academic detailing is to go directly to the physicians and return them to their place of prominence in the prescribing decision. That is exactly what I think this program does.

You have heard statistics. You have heard about sales pitches, very smooth sales pitches—that are very effective. We have tried to take the best in that and use the social marketing approach that Dr. Avorn has developed. You will see that demonstrated in the

materials available here.

They are very—they are not slick, but they are very professional. They inspire the doctors to have confidence that what they are prescribing is really the most effective, and not just the most cost-ef-

fective. Although I can tell you that identifying the most cost-effective is a big part of our goal in making this information available

and working with doctors the way we have.

In addition to that, there are materials that the doctors can give to their patients. I think every one of us has experienced watching an ad on television. We are not quite certain what the advertisement is for. We figure it out. We go into the doctor and we want that. We want the little purple pill. You have heard about the effectiveness of this program in helping people understand that the little purple pill may not be the best thing for them.

That is really where this program is different from other programs that I have seen in government, some occur at the point of sale to cut off a prescription without an explanation. Academic detailing steps back and gives the doctor the information they need at the point in time when she or he is discussing medication with

a patient and this make this prescribing much more effective.

We know doctors want this evidence. They have told us so. They want the data, which helps them make their decisions better decisions. We know that the expert in prescribing decisions need to be the doctor. The information that we are providing makes sure that happens

That is the end of my presentation. I would be happy to answer

any questions for you today.

[The prepared statement of Ms. Eisenhower follows:]

PENNSYLVANIA'S ACADEMIC DETAILING PROGRAM

During the fiscal year ending June 30, 2007, the Commonwealth of Pennsylvania spent ten percent of its annual budget, \$2.5 billion, reimbursing prescription medications for over two million of its state residents. These individuals, many of whom are in frail health, with multiple chronic conditions, requiring daily maintenance medication, are enrolled in a dozen different and disparate programs, most of which provide comprehensive prescription drug coverage with nominal cost sharing on the part of the beneficiary.

Over eighty percent of our annual prescription drug spending is for three programs: Medicaid, our state employees and retirees, and our senior pharmacy assistance program PACE. In the past, with all of these programs, we have noticed a persistent and disturbing problem involving inappropriate prescribing and the misutilization of prescription medications among a significant number of the enrollment, particularly in our PACE program. To address this problem, we have adopted some effective interventions: physician profiling, drug utilization evaluations and mandatory point-of-sale edits. These interventions have achieved measurable and significant degrees of success.

However, as a complement to these interventions, we determined a few years ago to test a program of proactive educational outreach targeted at improving the clinical appropriateness of physicians' prescribing in our PACE program.

Since its inception in 1984, the Pennsylvania Pharmaceutical Assistance Contract for the Elderly, the PACE/PACENET Program, better known as PACE, has provided lifesustaining medications to over one million older Pennsylvanians. It assists qualified state residents who are 65 years of age or older in paying for their prescriptions. The upper income levels for the highest tier, PACENET, are \$23,500 for single persons and \$31,500 for married couples. There is no asset test in determining eligibility. Both PACE and PACENET provide prescription coverage alone or in conjunction with Medicare Part D. The beauty of PACE is the comprehensive prescription drug access it affords to nearly 400,000 older Pennsylvanians of low to moderate income to improve their quality of life; the risk is the enormous potential for harm from the misuse of powerful drugs in an aging, increasingly frail population.

Since 1987 when direct to consumer advertising was authorized, prescribing physicians have received an enormous amount of their prescription drug knowledge from a cadre of well-prepared drug representatives with the primary goal of increasing the sales of their company's product. Would physicians appreciate a different resource? Would they value a resource with the goal of providing unbiased, evidence-based drug information that gives them a thorough review of the literature and applies the information to subgroups of the populations they see as patients? Preliminary data indicate that they do want, appreciate, and value a new service offered by PACE.

Academic Detailing brings to Pennsylvania physicians' offices a reliable, unbiased and non-commercial source of information about the drugs they frequently prescribe. Drug

information consultants offer the intervention to community physicians who see above average numbers of program enrollees. The goal is to improve the appropriateness of medication use by beneficiaries covered by a Pennsylvania's premier senior pharmacy program.

Academic detailing is a cost-effective way of improving physicians' drug choices as well as enhancing patient care. This program has been developed in conjunction with the Division of Pharmocoepidemiology and Pharmacoeconomics, of the Harvard Medical School, under the leadership of its Chief, Jerry Avorn. The group identifies therapeutic topics by analyzing both current utilization and the best available literature on medications used commonly in primary care. After the paring down of massive amounts of information into concise, clinically relevant summaries, media experts develop patient and professional tools for presentation to practitioners by the independent drug consultants who are specially trained pharmacists, nurses and allied health professionals from Pennsylvania.

Academic Detailing is an expansion of a previous project, conducted with Dr. Avorn. A 2002 PACE/Harvard research collaboration, the *Healthy Bones Project*, focused on improving the management of osteoporosis among Pennsylvania's elderly. The study sought to improve osteoporosis management by examining the impact of visiting primary care, community physicians. Over a six-month period, educators trained in social marketing, similar to the marketing techniques of pharmaceutical companies, conducted one-on-one visits with physicians. Using evidence-based data, educators discussed treatment algorithms, fall prevention, patient vignettes, and Harvard Medical School Continuing Medical Education (CME) materials. This pilot confirmed the feasibility of completing a moderate number of interventions in practice settings.

Since the September 2005 launch of Academic Detailing, there have been nearly 3,000 educational encounters with an average length of 20 minutes which occurred with nearly 1,000 practitioners. Nearly 500 CME post-tests have been completed. Together, the PACE Program and the Harvard team have responded to over 200 special requests for information from the physicians visited. Over 200 physicians have answered a 5-point scale, physician satisfaction survey yielding an average survey score of 35.5 out of maximum score of 40. The highest scoring items:

- The program provides me with useful information about commonly used medications. 4.6±.5
- The content represents unbiased and balanced information about drugs, 4.6+.5
- My consultant is a well-informed source of evidence-based information about drugs 1 prescribe, 4.6+.5
- I would like to see this program continue. 4.6+.6

The lowest scoring items:

- Being able to get CME credits from Harvard is a valuable component of the program. 4.0+1.2
- I find the patient materials useful in my practice. 4.3±.8

Rather than just discussing the cost of the products, the first Academic Detailing intervention delivered a drug safety message on the rational use of coxibs and non-steroidal anti-inflammatory drugs, as well as other analgesics, such as, acetaminophen and opioids.

Preliminary data show that the intervention was effective in changing prescribing behavior. Prior to the beginning of Academic Detailing, the use of coxibs declined due to safety concerns. However, project data indicate that there was another decline among doctors in the academic detailing group when compared to physicians in the control cohort. Measurable reductions in spending equaled \$60 per physician per month at 6 months post-intervention. A post-visit period that extends beyond the usual number of refills will likely deepen the project's effect.

The Department of Aging funds Academic Detailing for about \$1 million per year, compared to PACE costs of \$700 million in 2007. This level of funding allows ten independent drug consultants to work in the 28 most populous counties. Eventually, the program will be statewide, covering 67 counties. Four drug classes that present special contemporary concerns in relation to quality of care or cost are chosen per year as topics. Classes to date include non-steroidal antiinflammatory drugs, cox-2 inhibitors, gastrointestinal medications, anticoagulants, lipid lowering Under development is the antihypertensive class. drugs, and anti-hypertensives. dissemination will address other state sponsored drug programs, beginning with the retired state employee population. This population overlaps the PACE population by age and geography. With additional signs of success, the number of covered programs will increase and funding is likely to be shared by the agencies whose constituents receive the benefit of improved prescribing practices. Inquiries about Academic Detailing have been numerous given the media coverage received within Pennsylvania and in national news outlets. Some organizations are looking to collaborate with the state government to add value to the project or to cover additional populations. Other states have inquired about how the program could work for them.

Pennsylvania's Academic Detailing initiative has helped physicians decide which medications to prescribe by arming them with information to select the most effective drug, not necessarily the one with the biggest advertising budget. In Pennsylvania we believe this has been a good investment that we plan to continue in our PACE program and expand to our other state pharmacy benefit programs in the future.

The CHAIRMAN. Thank you.

In your presentation, did I miss it, or did you describe how exten-

sive this program is in Pennsylvania right now?

Ms. EISENHOWER. Well, we are beginning it in Pennsylvania. We have it in several counties now and are targeted doctors who we know are prescribing higher levels than we think they should in particular medications. One example is the proton pump inhibitors. But there are several other areas that we cover. We are expanding it to other medications. We started the academic detailing in 2005, and we are growing it.

There are 12 detailers in the field—nothing compared to the detailers that are in the field for the pharmacy industries, but it is

a strong start.

The CHAIRMAN, OK.

Ms. EISENHOWER. We think that that is a good start and plan to expand it.

The CHAIRMAN. OK. It is a pilot program?

Ms. EISENHOWER. Yes.

The CHAIRMAN. Thank you.

Mr. Carreio.

STATEMENT OF AMBROSE CARREJO, ASSISTANT DIRECTOR, PHARMACEUTICAL CONTACTING AND STRATEGIC PLAN-NING, KAISER PERMANENTE, LIVERMORE, CA

Mr. CARREJO. Good morning, Chairman Kohl, distinguished Committee members.

am Ambrose Carrejo, a pharmacist leader for Kaiser Permanente. We are the nation's largest integrated health care delivery system, providing services to more than 8.7 million members in nine states and the District of Columbia.

Permanente physicians prescribed, and Kaiser pharmacists dispensed, more than 60 million prescriptions last year at a cost of

over \$3 billion.

For most of my 18-year career with Kaiser Permanente, my work was focused on organizing and conducting academic detailing, programs to ensure that our physicians have the information they need to make the best possible prescribing decisions.

At Kaiser Permanente, we call academic or counter detailers "drug education coordinators," or simply DECs.

Our DECs are all doctors of pharmacy. They begin by evaluating clinical evidence and reviewing prescription drug utilization data, and then work with physician leaders to communicate one-on-one and in groups with all Permanente physicians.

Today, I would like to discuss one example of how our program provided both great economic value and great quality and safety improvement in drug use. It is the COX-2 inhibitors, such as

Celebrex, Vioxx and Bextra.

They represent a type of non-steroidal anti-inflammatory drug-or NSAID, if you will—that has been used to treat pain and inflammation due to arthritis. It was believed that COX-2 inhibitors would provide an advantage over the older NSAIDs, like ibuprofen, or Motrin, and naproxen, or Naprosyn.

These are presumed to cause significant gastrointestinal side ef-

fects, including bleeding from gastrointestinal ulcers.

We now know that high doses of these drugs represent a significant cardiovascular risk for patients. As of today, two of the three COX-2 inhibitors—Vioxx and Bextra—have been removed from the market.

Even before the early hints of the serious cardiovascular risk were confirmed and widely accepted by the medical community, work done by scientists at Stanford University showed that the potential gastrointestinal safety benefit of COX-2 inhibitors was largely limited to patients who were at high risk of serious gastrointestinal bleeding from the traditional NSAIDs. This was important, because they found that fewer than 5 percent of patients are actually at high risk for those side effects.

In the very practical response to these data, the same scientists developed a scoring tool to apply to patients who were candidates for NSAIDs, to determine their risk limits. Kaiser Permanente adopted this scoring tool to provide physicians with simple, automated methods to know the risk levels of the patients they were

seeing.

We used academic detailing to educate physicians about the tools and the science behind it, and to help them decide which patients

stood best to benefit from what drugs.

The concerted work of physicians and pharmacists resulted in limiting Kaiser Permanente's use of COX-2s to below 5 percent of all NSAIDs. During the same period of time, COX-2s represented close to 50 percent of the National NSAID market. Our work targeted these agents to appropriate patients, and ultimately decreased the number of individuals exposed to the increased risk of cardiovascular events.

Without the experience we gained over the years from academic detailing techniques, we would have had a far more difficult time implementing this program, and physicians would not have been as well prepared to respond to patient requests for the drugs generated by the breathtaking levels of consumer advertising of

COX-2s.

In 2004 alone, if community use of the COX-2s compared to traditional NSAIDs had matched that of Permanente physicians, U.S. consumers and businesses would have saved over \$4 billion, or al-

most 2 percent of all drug spending.

Expanded use of academic detailing has a potential to provide the same great value to all Americans that it does for Kaiser Permanente members. I applaud the Committee for its leadership in highlighting and encouraging this important work.

Mr. Chairman, thank you for the invitation to testify here today,

and I would be happy to answer any questions you may have.

[The prepared statement of Mr. Carrejo follows:]



Testimony of

Ambrose Carrejo, Pharm.D.

Assistant Director, Pharmaceutical Purchasing and Strategic Contracting

Kaiser Foundation Health Plan, Inc.

on behalf of the

Kaiser Permanente Medical Care Program

Before the

Special Committee on Aging United States Senate

March 12, 2008

Chairman Kohl, Senator Smith, and distinguished Committee members, I am Ambrose Carrejo, a pharmacist with responsibility for national contracting for prescription drugs to be dispensed to Kaiser Permanente members. For most of my 18-year career with Kaiser Permanente, my work has focused on organizing and conducting academic detailing programs to assure that physicians in the Permanente Medical Groups have the information they need to make the best possible prescribing decisions, and that Kaiser Permanente members receive high quality prescription drug benefits and services. I appreciate the opportunity to testify here today on academic detailing, a subject that has been at the center of my career. I feel strongly that expanded use of academic detailing has the potential to provide the same great value to all Americans that it does for Kaiser Permanente members. I applaud the Committee for its leadership in highlighting and encouraging this important work.

I am testifying today on behalf of the national Kaiser Permanente Medical Care Program. Kaiser Permanente is the nation's largest integrated health care delivery system. We provide comprehensive health care services to more than 8.7 million members in our 8 regions, located in 9 states and the District of Columbia. In each Region, the nonprofit Kaiser Foundation Health Plan enters into a mutually exclusive arrangement with an independent Permanente Medical Group to provide all medical services required by Health Plan members.

In our organization, virtually all pharmacy services are provided directly in Kaiser Permanente facilities by our own pharmacists. This year, Permanente physicians will prescribe and Kaiser pharmacists will dispense more than \$3 billion worth of prescription drugs. Our physicians and pharmacists make their best efforts to ensure that our members receive the highest possible quality and most cost-effective pharmaceutical care based on the best, most current available and objectively proven clinical evidence. This is supported by a strong culture of cooperation and collaboration between our medical groups and our pharmacy program.

It is this very close partnership between the pharmacy operations team of our Health Plan and the physicians of the Permanente Medical Groups that allows Kaiser Permanente to maintain very high levels of use of generic drugs. While the Generic Pharmaceutical Association reports that 63 percent of prescriptions in the United States are written for generic drugs, approximately 80 percent of all prescriptions written by Permanente physicians nationally are for generic drugs. This has saved our members and organization many millions of dollars, and it would not be possible to achieve this level of quality and efficiency without academic detailing.

Determining the Preferred Drugs for Kaiser Permanente Members

At Kaiser Permanente, we take very seriously our obligation to deliver the highest quality care to our members. In the pharmaceutical arena, the use of the best clinical and scientific evidence in supporting drug selection is of paramount importance. To work effectively, academic detailing must be grounded in solid evidence. The physicians whom

¹ California, Colorado, Georgia, Hawaii, Maryland, Ohio, Oregon, Virginia and Washington

academic detailing is intended to support must have complete confidence in the underlying evidence being presented by academic detailers for it to be effective. As with virtually all other health plans, each Kaiser Permanente region establishes a formulary that includes a list of drugs that are preferred as first-line therapies. The formulary is established by a regional pharmaceutics and therapeutics (P&T) committee.

Our P&T committees are comprised of Permanente physicians from a broad range of medical disciplines and the regional pharmacy services director. When a new drug becomes available to treat a particular condition, or when a review of existing drug therapies is undertaken, the P&T committee is commonly aided by physicians with expertise in the appropriate specialty.

When a new blood pressure medicine becomes available, for example, a panel of cardiologists and internists will make recommendations to the P&T committee. Their recommendations will reflect the latest information on all drugs in the therapeutic class as presented in a monograph prepared for the P&T committee by our pharmacist-staffed internal drug information service. The drugs included on the preferred drugs lists are those that, first and foremost, evidence indicates are clinically superior to the other drugs in the therapeutic class. If the preferred drug is available as a generic, the generic version will virtually always be the preferred drug on the formulary.

This same process generates the information that supports our academic detailing efforts.

Academic Detailing Activities within Kaiser Permanente

At Kaiser Permanente, we call academic or counter-detailers Drug Education Coordinators, or "DECs". DECs are all Doctors of Pharmacy. They incorporate Dr. Avorn's model of academic detailing when providing information and education to Kaiser Permanente physicians.

Methodologies used by DECs to educate physicians include:

- · Acquire, evaluate and summarize clinical evidence for use with physician meetings;
- Review prescription utilization data for patterns of use:
- Evaluate drug usage and conduct chart reviews;
- Organize physician opinion leaders to speak at department meetings;
- · Attend specialty physician department meetings;
- Meet face to face with individual prescribing physicians;
- Communicate key concepts via email, newsletters, flyers, posters and Frequently Asked Ouestions:
- Present lectures;
- · Conduct physician drug luncheons;

- Provide answers to drug information questions;
- · Conduct new physician orientation;
- Provide clinical information to nurses and pharmacists; and
- Organize pharmaceutical sales representative activities.

While we have many examples of the impact that DECs have had in our organization, I will discuss in detail one that provided both great economic value and great quality and safety improvement in drug use.

Cox-2 Inhibitors and other Nonsteroidal Anti-inflammatory Drugs

Cox-2 inhibitors (such as Celebrex, Vioxx and Bextra) represent a type of non-steroidal anti-inflammatory drug (NSAID) that has been used to treat the pain and inflammation that comes with various forms of arthritis. It was believed that Cox-2 inhibitors would provide an advantage over older NSAIDs (like ibuprofen and naproxen) because they were presumed to cause significant gastrointestinal side effects, which can include bleeding from gastrointestinal ulcers. They have never been considered superior pain relievers, although heavy promotion of these drugs may have led many patients to believe they are. We now know that high doses of these drugs represent a significant cardiovascular risk for patients and as of today, two of the three Cox-2s, Vioxx and Bextra, have been removed from the market. Caution dictates that physicians should reserve the remaining Cox-2 inhibitor, Celebrex, for those patients who fail on traditional NSAID therapy and do not have significant cardiovascular risk factors.

Even before the early hints of serious cardiovascular risk were confirmed and widely accepted by the medical community, work done by scientists at Stanford University showed that the potential gastrointestinal safety benefit of Cox-2 inhibitors was largely limited to patients who were at high risk of serious gastrointestinal bleeding from traditional NSAIDs. This was important because they found that fewer than five percent of patients are actually at high risk of serious gastrointestinal side effects.

In a very practical response to these data, the same scientists developed a scoring tool to apply to patients who were candidates for NSAIDs to determine their risk levels. Kaiser Permanente, with the enthusiastic support of our Regional chiefs of rheumatology and internal medicine, adopted this scoring tool to provide physicians with simple, automated methods to know the risk levels of the patients they were seeing.

The Drug Education Coordinators, with the evidence in hand, were charged with getting the message out to the Medical Groups. A variety of approaches were used by the DECs including but not limited to: partnering with key opinion leaders within the medical group; presentations; email; print materials; attendance at physician specialty department meetings; and one-on-one office visits. These approaches and other tools aided the DECs in achieving the ultimate goal of appropriate use of these new medications.

The concerted work of physicians and pharmacists resulted in limiting Kaiser Permanente's use of COX-2s to below five percent of all NSAIDs. During the same period of time, COX-2s represented close to 50% of the national NSAID market. This work targeted these agents to appropriate patients and ultimately decreased the number of individuals exposed to increased risk of cardiovascular events.

We estimate that in 2004 alone, if U.S. use of the three Cox-2s compared to traditional NSAIDs had matched that of Permanente physicians, U.S. consumers and businesses paying for prescription drugs would have saved over \$4 billion dollars, or almost 2 percent of all U.S. drug spending. Here is a great example where promoting the use of high-quality generic drugs can be not only significantly less costly, but safer.

This same approach has been used to decrease inappropriate use of antibiotics in predominantly viral diagnoses and to decrease the use of high-risk medications by the elderly.

A Greater Role for Academic Detailing in the Health Care System

Academic detailing can be particularly helpful in encouraging greater use of generics when drug manufacturers pursue a "product lifecycle management" strategy to extend their product monopolies past the expiration of their initial patent. Manufacturer strategies include the development of extended release products and reverse isomer products as well as other efforts to maintain their franchise without meaningfully improving the quality of pharmaceutical therapy. There are many examples of this approach such as promoting Nexium after Prilosec lost its patent and promoting Clarinex after Claritin lost its patient. Slight modifications to a molecule that convey no added therapeutic value but do yield a new patent are excellent targets for education. In many of these examples, the new patented medication can cost \$3 to \$4 per dose while a therapeutically equivalent generic can provide the opportunity for 80% to 90% cost savings.

Lastly, academic detailing would benefit greatly from efforts to support and expand comparative effectiveness research that compares the benefits, risks, and costs of alternative strategies to manage specific health conditions. The Agency for Healthcare Research and Quality, supported by other research entities, has led this effort to date but greater funding and a more long-term commitment by the federal government is needed.

Relying on solid evidence and structured in an appropriate manner, academic detailing can greatly expand access to affordable, high quality drug therapy. Given that public programs such as Medicaid, Medicare Part D and other drug coverage programs represent almost half of the U.S. pharmaceutical market, taxpayers and the government have an enormous stake in the benefits that academic detailing can provide. This committee should be commended for bringing attention to the opportunity.

Mr. Chairman, thank you for the invitation to testify here today. I would be happy to answer any questions you may have.

The CHAIRMAN. Thank you, Mr. Carrejo.

Mr. Ahari, in your experience, did the doctors that you talked to question your facts as you presented them in comparison with pharmaceutical company-produced information about the drugs that you were trying to sell?

Mr. Ahari. Rarely, Senator. Doctors were more, I guess, welcome to see me as a reprieve to their day than they were to question the

actual merit of my academic arguments.

We were possibly the only person to step into their office not complaining of any illness, not having a handful of paperwork for them to fill out. We had an armload of gifts, generally speaking, made us very welcome in most offices.

The CHAIRMAN. You had an armload of what?

Mr. Ahari. Gifts.

The CHAIRMAN. Gifts?

Mr. AHARI. Gifts. Pardon me. The CHAIRMAN. Like what?

Mr. Ahari. Pens, pads, clipboards, umbrellas on occasion, clocks, ballpoint pens, highlighters.

The CHAIRMAN. Well, that was my second question. These phar-

maceutical reps often come with considerable gifts.

Mr. Ahari. Yes.

The CHAIRMAN. Do you feel that the physicians look forward to this and some of the emollients that they get, and the gifts and the opportunities they get from the pharmaceutical reps, which I assume not be nearly what you are prepared to offer, because part of what they are doing is enticing? That is not what you do.

So, why would they be so pleased to see you and deal with you, when the pharmaceutical reps they deal with oftentimes come with the kinds of considerations that are of great value to physicians?

Mr. AHARI. I am sorry, Senator, can you reframe that question?

The CHAIRMAN. Well, speaking engagements.

Mr. Ahari. Oh.

The CHAIRMAN. You are not offering speaking engagements. You are not offering meals. You are not offering trips. Right?

Mr. Ahari. My.

The CHAIRMAN. That is what they are offering—along with whatever information they are bringing, they are bringing things of value to physicians. Right?

Mr. AHARI. Yes, Senator. Actually, I should clarify. I am not an academic detailer. I was formerly one of those slick salesmen. Now

I am actually a researcher, detached.

The CHAIRMAN. How you imagined this would work.

Mr. Ahari. I see.

Well, I have to confess. I think that there is a great deal of leverage that those gifts offer the sales reps. It gives them a great deal of capacity to actually get access to the physician. Again, there is the subconscious effect of actually persuading a physician to use a medication contrary to his training.

The CHAIRMAN. So, do you see this impediment as being a significant one that has to be dealt with, if we are going to get academic

detailing off the ground in a meaningful way?

Mr. Ahari. Yes, sir, I do.

The CHAIRMAN. Do you have any—yes, sir.

Dr. Avorn.

Dr. Avorn. Senator Kohl, if I can try to respond to that question. What we found over 25 years of doing this is that, while the academic detailers that we send out from Harvard don't come in with the armfuls of gifts that Mr. Ahari mentioned, what they do provide is something that is in a lot of ways much more precious to the doctor, once he or she figures it out. That is the ability to have the entire field summarized in a document and presented to them in their office in just 15 or 20 minutes.

Over time, doctors learn that that is really a very valuable kind of emollient, to use your term, that is much more important than an expensive meal in a restaurant or a clock or a ballpoint pen. Once they get it, they realize that, you know, they can buy their own pens, but this is a kind of service that really makes them

eager.

We have had the experience of sales reps like the former Mr. Ahari, sitting in a doctor's waiting room from Lilly and Glaxo and Merck and Pfizer, and the doctor asking for our people to come in first, because they know that what they are going to get is pretty valuable in a clinical and in an intellectual sense, even if we don't bring a lot of goodies.

Mr. Ahari. Senator, if I may coattail on that, actually, my experiences having lectured to 40 medical schools around the country

actually echo Dr. Avorn's comments.

I feel that once physicians are aware of the circumstances and the underlying nature of the relationship, they begin to appreciate the benefits of academic detailing, and recognize the potential conflicts of interest inherent in the physician-pharma relationship. As it stands now, most physicians tend to either rationalize it or dismiss it.

The CHAIRMAN. So, the two of you feel that the academic detailer can, in fact, surmount what is being brought to the table by the sales reps.

Ms. Eisenhower, you have had this experience. What is your

sense?

Ms. EISENHOWER. I think that doctors are hungry for this kind of information. When they get it, they are very pleased with it, and

it changes the way they practice.

We have a sense that, because the pharmacy promotion is really driven by bottom line profits, that it is not accurate. The doctors agree with that. They understand that. When you give them accurate information there is really a change in the way they prescribe for their patients.

In addition to that, I told you that we were demonstrating this project. We are going to continue to operate this project in Pennsyl-

vania and grow it.

We are very pleased with the results. We thought there might be some pushback from doctors who resented the intrusion into their prescribing. We have had the opposite response. Doctors, as I said, are hungry for this. They are looking for the information.

Dr. Avorn mentioned our detailers going to doctors' offices. They are welcome to those offices the second, the third and additional

times.

The doctors that we deal with, who are very active in the PACE program, treating seniors, are usually family physicians. So, what we see is the change in prescribing affects all of Pennsylvania programs, and all of their patients.

So, we just think it is a wonderful program that we are going to

continue to grow in Pennsylvania.

The CHAIRMAN. You all apparently are saying that doctors are so busy that they can't really absorb all the products on the market, understand which is best, which is cheapest, which provides.

Ms. EISENHOWER. Senator, I don't think anybody can.

The CHAIRMAN. No.

Ms. EISENHOWER. There is so much advertising out there for so many things in this country.

The CHAIRMAN. They need to get information from somebody.

Ms. Eisenhower. It is our responsibility. We are paying for the

medications.

We really jumped into the breach, because we felt that we were leaving the doctors out there without the data they needed to deal with our constituents, whether it is enrollers in PACE or a Medicaid recipient. We really needed to step up to the plate and do our job. That is where working with Harvard has been so effective.

In addition to meeting with the doctor, the doctor gets continuing medical education credits. So, that is a real plus for them, because they have a mandatory requirement to meet through the year. The intervention that we do, unlike the sales representative, really does have some other benefit, other than educating the doctor.

I think that has been a very positive aspect to it also.

The CHAIRMAN. I have heard the panel. I don't know which of you said, for every \$1 spent, there is \$2 saved.

Ms. EISENHOWER. That is the minimum we have saved.

The CHAIRMAN. What is that? In a year? Or over 5, or over 10?

Do you-how do you come to that estimate, Dr. Avorn.

Dr. Avorn. Yes, that was based on our initial study that Mr. Coukell referred to. It was a randomized trial in four states in which we actually were able to look at what Medicaid spent on the prescribing by the doctors who were randomly offered this program, and doctors who were randomly assigned to be controls.

Because we knew what it cost to run the program, since we were doing it, and we knew what Medicaid was spending, because we had all the paid claims tapes from these four states from their Medicaid programs, we simply totaled up the difference in expenditures by the doctors offered the program and the controls, and then divided that by what it cost to do the program.

So, that is not an imaginary number. That was a real, observed

number of \$2 saved for every \$1 spent.

The CHAIRMAN. Yes, but isn't it. Dr. Avorn. On an annual basis.

The CHAIRMAN. Oh, for on an annual basis.

Dr. Avorn. Right. The Chairman. I see.

Ms. EISENHOWER. In addition, Senator, we didn't look at other programs that the same doctor was participating in. So, I think that savings would be magnified. I think over time, it will grow. I think we are going to show that in our programs.

The CHAIRMAN. What kind of pushback do you imagine there is from the pharmaceutical industry? Do they love you all? Do they

love your ideas?

Dr. AVORN. Well, I think, compared to some of the scarier propositions that they face in policy terms, we are often seen as the lesser evil, in that it is voluntary for doctors, it preserves the doctor's freedom to prescribe whatever he or she wants. We don't get engaged in what people ought to pay for a given drug.

It is really the provision of evidence from the medical literature

to doctors on a voluntary basis.

Given that the pharmaceutical industry at present is somewhere around the tobacco industry in terms of public mistrust, I think coming out against providing voluntary, evidence-based medicine to doctors is not a position that they are comfortable taking-at least in public.

T̂he Снаікман. Mr. Carrejo.

Mr. CARREJO. Senator Kohl, I might say they would embrace the effort, to the extent that they have a medication that would provide benefit. Medications like those, Fosinex, decrease the risk of hip fracture. To the extent that the medication provides no benefit, a molecule that is designed to extend patent, they might not so much embrace that effort.

Those medications, I believe, are the low fruit for these types of efforts. So, you go out, and in 30 seconds to a minute, educate a prescriber about what that molecule delivers or does not deliver, and the same benefits could be procured from the use of a very in-

expensive generic alternative.

The CHAIRMAN. Senator McCaskill.

Senator McCaskill. Thank you, Mr. Chairman.

OPENING STATEMENT OF SENATOR CLAIRE MCCASKILL

I appreciate you holding this hearing. I know that your work in trying to make public what drug companies and drug company reps are giving to doctors, and in terms of our registration bill, I think it is very important. I think this hearing further demonstrates the need to go further in terms of protecting the public-and frankly, after hearing the testimony and reading the testimony today, protecting the doctors.

The doctors are not the bad guys here. The doctors didn't go into this line of work because they wanted to get pens and pencils-or trips, or free lunches. Doctors became doctors because they want to

help people. They want to heal people.

I think that what has happened here is, big, big money has in-

vaded the marketplace and overwhelmed the doctors.

I think one of the things I would like to talk about in my questioning is a rule, a draft guidance that was put out by the FDA in October. It is a startling change, potential change, in policy, considering the environment that we are operating in and all the testimony we have heard in this Committee over the months since I have been here.

This draft guidance would overturn a half a century of FDA policy that prohibited the use of peer review journals in marketing offlabel, non-FDA approved uses for drugs.

Now, let me see if I get this straight. We have documented evidence that these peer reviews, some of these medical journal articles—first of all, we know that some of them have been paid for by the pharmaceutical companies. We know some of them have omitted important information that has, in fact, hurt people.

What we are going to do now is say, you can take these studies, like the Vioxx study—I think, didn't Merck order more copies of the "New England Journal" article than there were doctors in the coun-

try?

Dr. Avorn. Right.

Senator McCaskill. I mean, I think they ordered up a million copies of it, didn't they?

Dr. AVORN. Nine hundred thousand.

Senator McCaskill. I am surprised they didn't mail it to every American, and say, you know, this is the gospel, this is the holy grail when it comes to Vioxx. Clearly, the "New England Journal" had to backtrack and apologize, and call the authors of that article out about their failure to present an unbiased view of Vioxx, because of the trials that had occurred.

So, let me see if I understand this. We know that these journals have been problematic, some of these articles. The FDA is supposed to be approving use of these drugs. They are going to say, by the way, we haven't approved this, and you can use these articles to

market the drugs.

Now, I mean, we are talking about the wild, wild west already. Now what they have done is say, we are taking the sheriff out of town. I mean, if we have no sheriff, and it is the wild, wild west, what shot does the American consumer have, and doctors have, at finding the truth in terms of a factual, scientific basis on which to prescribe a drug?

I would certainly, Dr. Avorn, like your reaction to this proposed—and what in the world would be motivating this rule change right now, unless it is pure profit-making by the pharmaceutical in-

dustry?

Dr. Avorn. Senator McCaskill, you are absolutely right. As it turns out, my colleague, Aaron Kesselheim in my division and I have a paper on that very topic that will be in the "New England Journal" in the next couple of weeks, that essentially takes your

view, but perhaps less eloquently.

The worry that we have is that it really will become open season on doctors in terms of marketing, because there are a wide variety of papers, as your question implies, that are out there that may technically be in a medical journal, that are very biased or distorted views of the advantages or the safety of a given drug.

FDA has, as you say, thus far held the line and said, if the drug has not been approved by the FDA for a given use, you can't promote it. That is about to change if this proposed rule goes through.

There is an even greater concern around that very same topic, which is First Amendment challenges to the FDA's authority, which we are also seeing on kind of a parallel track. The First Amendment, of all things, is being used an argument that a company should have commercial free speech, to be able to say essentially whatever they want, as long as it is not fraudulent—outright fraudulent—about their products.

At the same time that the industry has been working to have the rule that you described changed, they are also trying to demand that FDA should have no jurisdiction over what they can say, be-

cause of their free speech rights.

With those two attacks going on concurrently, many of us are very worried that the doctor will really—and again, a doctor who may be working 12-hour days seeing patients, and going to the hospital and trying to fill out all the paperwork—the doctor is going to be easy prey for a slick person like Mr. Ahari's successors, to come in there and wave articles at them and say, well, this is not approved by the FDA, but get a look at this, this is a really use.

It is very worrisome. You are absolutely right to be concerned. Senator McCaskill. Let me ask Dr. Avorn, do residency programs or medical schools now adequately prepare physicians for this very big problem that they are going to face when they enter the practice of medicine? Are they getting—in school—are they getting cautioned about marketing versus science, and the differences between the two?

Dr. AVORN. We are not doing a good enough job, either in med-

ical schools or in residency programs.

Ironically, just yesterday I was talking to the combined residencies of the Mass General Hospital and the Brigham Women's Hospital, all of their interns, to talk with them about this very issue. What was striking about that was what a rare event that was. This is normally not discussed, and many of us are trying to get this into medical school curricula.

Interestingly, the Neurontin settlement of \$430 million for offlabel marketing of Neurontin, the attorneys general of all 50 states took a small portion of that \$430 million and set it aside as a program to support people in medical schools and in residencies to teach trainees about these very issues. I suspect that before the year is out, we may see an even larger Zyprexa settlement perhaps

going in the same direction.

So, there are some counter efforts, but it is not enough, and we

don't do a good job as medical educators.

Senator McCaskill. Is anyone policing, Mr. Ahari, the sales reps in terms of what they are saying and how they are saying it? Is there any fear that you ever had as a sales rep that something could happen to you if you pushed too hard or gave out information that was misleading or fraudulent to doctors' offices about the efficacy of the drugs that you were pushing?

Mr. AHARI. No, Senator McCaskill. It is generally a self-regulated

policy within each industry.

Quite frankly, the bottom line is the profit motive. You get a disconnect in terms of messaging as to what policies you are responsible for maintaining. But that is eclipsed by the general motivation for you to make bonus.

Essentially, my only fears would arise if I had said something to a physician that I wasn't connected with, that I didn't have a friendship with, or if my sales techniques were failing on a general level and I wasn't going to make bonus. There would be enough plausible deniability for my manager to say that essentially, I had acted alone, independently, and it was my fault.

But generally speaking, not only from my own experience, but speaking with other reps, there is great opportunity for managers to turn the other cheek when some gray area of business is occurring, if it helps the territory, if it helps the bottom line.

Senator McCaskill. Well, I mentioned in this Committee before

Senator McCaskill. Well, I mentioned in this Committee before that, unbeknownst to the people around me—I was on an airplane from St. Louis to Chicago, and I was surrounded by about 30 or

40 drug reps going to a meeting in Chicago of their company.

First of all, I felt very old, because they were all very young. I also felt very fat, because they were all very physically attractive.

[Laughter.]

The chatter and the banter between them as they talked about their work, I think would be frightening to any consumer who understood what it was they were talking about.

I mean, one was actually giving great trouble to the other one saying, well, you know, easy for you to say. You have got shrinks.

[Laughter.]

Referencing, obviously, that psychiatrists prescribe drugs to literally every patient they see—almost. I mean, maybe there might be an exception. I don't know. Dr. Avorn, you might speak to that better than I certainly could, because I have no medical training.

But it was—you know, it was really unsettling to listen to them talk about this, as if they were selling widgets as opposed to medi-

cine.

I think that we have got to take every step we can within the constitutional limitations we have to help doctors get this good information. I think the program that is in Pennsylvania, I am going to talk to the people in Missouri. Having done a lot of audits as the State auditor on Medicaid, you know, we were at a point in Missouri where we weren't even using a formulary in Medicaid.

We had a huge OxyContin problem within the Medicaid population, because of doctor-shopping. They hadn't even done the basics in terms of controlling an obviously wildly addictive drug like OxyContin. So I know we have so much work to do in terms of pub-

lic dollars being spent.

I think piloting these programs with public dollars makes such good sense, because then the doctors begin to realize, there is a better way to get the information they need to do what is right for their patients.

Ms. EISENHOWER. I think you are right. I think it comes from a

trusted source, for the most part.

Senator McCaskill. Right.

Ms. EISENHOWER. We do get some complaints about government when we first get out to speak to doctors.

Senator McCaskill. That happens to all of us in government.

Ms. EISENHOWER. It is a good thing. Eventually, the relationship that is built on trust really recognizes that the bottom line motivation is not profit-driven, and that is not appropriate in the setting. I think that is what makes the relationship positive and flourish and grow, and makes the doctor able to take that information and use it for all of his or her patients.

Senator McCaskill. I would ask finally, Mr. Chairman, if there are any suggestions that any of you have about what government

could do appropriately. I know there is a lot of talk about what

would be inappropriate for government to do in this area.

What, if you have ideas about what government could be doing, other than the pilot program that is being done through the State expenditures of funds for medicine and the academic detailing, is there anything we could do to go—and the registry that we have proposed in terms of exposing the kind of freebies that are given to the prescribing doctors—is there anything else that we could be doing that you can see, that would be helpful?

Mr. CARREJO. I think the two components—don't forget about the evidence, because no matter how good our academic detailers are, when they get in that office, if it is not evidence-based, it is not going to fly. So, the efforts that this Committee is already financing

and ensuring that there is good comparative trials.

I think the primary problem with those drugs that are on the market today—and you speak of going off-label, but just those labeled drugs—they are compared only to placebo. So, really, fortunately, I am not the marketer for the drug companies, because what I would come up with is something like, "We are better than nothing," in my ad, you know. [Laughter.]

So, the evidence needs to.

Senator McCASKILL. Somehow, I don't think they are going to use that one.

Mr. CARREJO. I had better keep my day job? [Laughter.]

Senator McCaskill. I think you had better keep your day job. Mr. Carrejo. So, the evidence definitely needs to be there, and we are doing some great work there, some early great work. But we need to continue financing that, and getting good academic detailers out there to get that message, including physicians, not just pharmacists, but within Kaiser, having key opinion leaders from that specialty—for the COX-2s it is rheumatologists, for the statins it is cardiologists—to carry that message out, much like the drug companies do.

Mr. COUKELL. Senator, I would echo that comparative effectiveness is important. The Physician Payments Sunshine Act that you and Senator Kohl have introduced is important. There are probably next steps, once we know the flow of marketing dollars to physicians. There are questions about what other organizations are those marketing dollars going to that might help advance this?

As we look to the medical profession, the professional medical associations and the medical centers, there are certainly leaders in many organizations who are trying to take responsibility for the profession, and clean it up and put these relationships on a sound-

er ethical footing.

I think attention from committees like this helps those leaders

drive that agenda within their profession.

Dr. AVORN. In thinking about how government might facilitate this, at least on the academic detailing side, there are three distinct components. One is the very important issue that Mr. Carrejo mentioned about we need the data.

We need to not rely on the drug companies to conduct and pay for and evaluate all the studies, pre-approval or post-approval. We need to have publicly funded clinical trials that compare one drug against another.

While those may cost something to do, when you consider how many billions we are spending per year of government money on drugs that are no better than alternatives, those are dollars that would pay themselves back within the space of a year, at most.

The second piece, having generated the data, is to put it in a format that is user-friendly. That is a difficult task. It is one that we spend a lot of time worrying about, because one of the real strengths of the companies is that they can condense information very selectively, but they condense it—into something that is actually readable and engaging. That is a piece of work that builds on

Senator McCaskill. It is hard for you academics, isn't it.

Dr. Avorn. It is, exactly. It goes against all of our instincts. But we also know that, you know, when in doubt I say, what do the drug companies do. We try to replicate at least half of what they do-not the other half.

Boiling information down into an actionable and user-friendly

mode is an important second piece.

Then the third piece is just paying the staffs that will be going out there, which could be done, probably not on a Federal level, but perhaps having regional competitions to see whether it is a medical school or a school of pharmacy or a medical society in a given State or region that might want to do this program.

Then, my last thought, unrelated to academic detailing is government needs to fix the FDA. The Institute of Medicine report, the GAO report, the FDA's own Science Board report, make it clear that the FDA is broken and it badly needs to be repaired. That is

another important function of government.

Senator McCaskill. Thank you, Mr. Chairman. The Chairman. Thank you. Thank you, Senator McCaskill.

These academic detailers—who are they? Where do they come from? What kind of training do they get? How much do they get paid? How can what they get paid compete with the amount of money that the sales reps probably make, which is a multiple of what these academic detailers make?

Wouldn't the best ones be enticed at some point to go off and

make twice or three times as much as sales reps?

Ms. EISENHOWER. Well, Senator, I would like to start describing that, and then I would like to turn it over to Jerry Avorn, who works daily with our detailers in Pennsylvania.

I think that the assumption is that everyone in the country is profit driven. But we can see from our earlier testimony that many of the detailers who work with us-well, at least some of them-

have come over from the dark side.

I think, in addition to that, what we see is that there is such a rewarding sense of the work that they are doing and on how effective it is, that they are really pretty satisfied. I don't think we will lose many of them.

But the details—the other thing I do want to say is we don't have a cheerleader in the bunch. At least not yet. But I think Jerry

is working on that.

Dr. AVORN. No, only if they are a pharmacist or a nurse who happens to be a cheerleader.

As Secretary Eisenhower mentioned, we seek to hire people who start out as nurses or pharmacists already, and have got really solid clinical training, which, as Mr. Ahari mentioned, is not a requirement on the industry side.

We pay them less than people in the industry pay. We pay them 50 bucks an hour. That is—they can make much more than that

working for the drug companies.

But as Nora said, I guess working in the university my whole life, I am surrounded by people who are willing to not get paid the big bucks, because they are doing something that they love and that they think is important.

Also as Nora said, we do have some of our most valuable people in the Pennsylvania program used to be pharmaceutical company sales reps, although they also happen to be pharmacists or nurses.

What they tell me is that they really welcome the opportunity to use all their knowledge in an evidence-based, neutral way, without having a particular party line or sales pitch that they have got to offer, and to acknowledge there is ambiguity here—this is not so clear, this seems to be the case for these drugs—and to be able to really use their skills. That seems to make up for them the fact that they don't get paid what pharmaceutical sales reps or what they were paid back when they were working for industry, because there is more to a job than what you get paid.

Mr. Ahari. If I may add, there is a high attrition rate with pharmaceutical sales reps. They tend to last about an average of 2 years. I think a fair amount of that is due to the ethical dilemmas they encounter, and the golden handcuffs are no longer strong

enough to bind them to the job.

The CHAIRMAN. So I take it you are rather unanimous in your opinion that, if we as a country somehow—whether it be at State-funded or Federal-funded level—spent the amount of money that would be necessary to get these people lined up, trained and out in the field talking to physicians all across the country, that in your opinion, without any question, there would be a huge multiple of savings in the pharmaceutical cost industry to the taxpayer.

Is that right?

Ms. EISENHOWER. Absolutely, Senator. I mean, usually when we come forward here we might have a few pros and cons. But I just don't see any cons in this. It has been an enormously positive thing and long overdue.

The historic enactment of Medicare Part D, I think it is a real

opportunity to step up and Federalize this kind of work.

The CHAIRMAN. Senator McCaskill, do you have any closing com-

Senator McCaskill. I don't. Thank you all for being here.

Mr. AHARI. May I add one more comment? The CHAIRMAN. Go right ahead. I am sorry.

Mr. AHARI. Again, to coattail on Secretary Eisenhower's comments, the average sales rep working for industry returns about \$10 for every \$1 invested. If academic detailing is only a fraction as effective, it will yield dividends for public health. I am fairly certain that it is more than just a fraction as effective.

Thank you.

Dr. Avorn. I guess the last point I want to make is that, what we also really care about is the quality of care that our patients get. Ironically, one can deliver care that is as good or even, often, much better at a fraction of the cost. That is true of the whole health care system, but it is certainly true of pharmaceuticals.

As Mr. Carrejo mentioned, a program that said don't use so much Vioxx, we now know, not only saved tons of money for Kaiser, but also prevented a lot of people from having Vioxx-induced

heart attacks and strokes.

By going with the evidence and our experience, you both save money and you improve the quality of care.

The CHAIRMAN. Great. Any other comments, information,

thoughts, ideas?

Dr. Avorn. We just applaud you for moving this agenda forward. The Chairman. Yes. We thank you all for coming. It has been a great hearing. With that, the Committee is adjourned. [Whereupon, at 11:39 a.m., the Committee was adjourned.]

APPENDIX



Fact Sheet

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

It is promoting policy change by working with

- State and Federal
- Policymakers · Academic Medical
- Centers Professional Medical
- Societies • Private Pavers

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

Academic Detailing: Evidence-Based Prescribing Information

Academic detailing programs provide prescribers with objective information on prescription drugs, based on the best available evidence-based science, conveniently and efficiently in the physician's office. By providing outreach visits to practitioners, the approach resembles the marketing approach of drug companies, but instead uses clinicians, pharmacists or nurses to present balanced, evidencebased information about common prescribing choices without a sales agenda. Busy physicians value academic detailing programs because unblased, objective information about prescription drugs is not easily accessible in day-to-day practice. Industry salespeople, also referred to as pharmaceutical representatives or "detail industry satespeeper, and reteried to do promotecution replacementaries or under men [and women]", use promotional information rather than balanced science to promote their company's drugs. Their job is to promote their own company's products even if they are less effective and/or more expensive than other drugs

The pharmaceutical industry spent nearly \$30 billion on promotion and marketing of prescription drugs in 2005, with \$7.2 billion directed toward physicians. The prescription drugs in 2005, with 37.2 planto the Leve Waver purposes. The industry employs over 90,000 drug representatives (reps) and spends an average of about \$8,800 directly marketing its products to each of the \$17,000 physicians practicing in the U.S. Although research shows that physicians understand the conflict of interest that exists between marketing and patient care, "contact with

¹ Donohue JM, Cevasco M, Rosenthel MB. A decade of direct-to-consumer advertising of prescription drugs. N Engl J Med. 2007;357:673-681.

² Sales Makeover, *Medical Marketing & Media*. Nov., 2003.

³ U.S. Department of Health and Human Resources. Physician Supply and Demand: Projections to 2020. Available at: http://bbpr.ivrsa.gov/healthworkforce/reports/physiciansupplydemand/currentphysicianworkforce. htm. Accessed August 22, 2007.

Chimonas, Brennan and Rothman. Physicians and Drug Representatives: Exploring

sales representatives remains one of the most important ways that practicing doctors learn about the medications they prescribe. The drug industry's influence on the medical profession and prescribing is becoming more widely recognized because:

- prescription drug costs continue to escalate, and are one of the fastest growing components of the nation's health care spending⁵; and
- after new drugs have been introduced and heavily marketed by the pharmaceutical industry, serious drug safety issues/controversies have become more common.

For example, it has been estimated that in the year before withdrawal of Vioxx, \$208 million was spent on physician detailing and \$256 million on direct to consumer advertising for this class of drugs, driving utilization for this drug class far beyond what was necessary based on patient need.⁶ An FDA official has estimated that Vioxx caused 88,000-139,000 heart attacks, 40 percent of which were fatal.⁷

An Important Part of the Solution: Academic Detailing Programs

Evidence-based academic detailing programs rely on scientific perspectives rather than marketing hype. They are an important tool to balance sales-focused information provided by the industry through its sales reps.

Specifically, academic detailing programs:

- operate independent of drug companies and are located in a medical school or school of pharmacy
- provide unbiased, balanced, evidenced-based information to physicians regarding the safety and efficacy of drugs
- employ physicians, pharmacists, nurses and other clinical professionals to give prescribers reliable guidance on potential benefits and possible harms of specific drugs
- use one-to-one interactions tailored to meet the needs of individual physicians in their own practice settings
- help promote appropriate prescribing habits and cost-effectiveness so that access to quality care and health of patients will be enhanced

theDynamics of the Relationship. Journal of General Internal Medicine. February: 22(2): 184-

nttp://www.senate.gov/~inhance/hearings/testimony/2004test/111804dgtest.pdl Accessed August 22, 2007.



⁵ Kaiser Family Foundation, Prescription Drug Trends, May 2007. Available at: http://www.kff.org/rxdrugs/3057.cfm. Accessed August 22, 2007.

⁶ Alexander, Majumdar and Stafford. Promotion and prescribing of coxibs during accumulating evidence of harms. In: Midwest Society for General Internal Medicine Regional Meeting: General Internal Medicine - Preparing the next generation. Chicago, Illinois: Blackwell; 2005. Available at: http://www.blackwellpublishing.com/sgim/abstract.asp?meeting=SGIM20058id=52272 Access August 22, 2007.

⁷ Testimony of David J. Graham, MD, MPH, November 18, 2004 to the U.S. Senate Finance Committee Available at: http://www.senate.gov/~finance/hearings/testimony/2004test/111804datest.odf

- rely on voluntary participation, typically achieving good uptake and retention rates
- often provide physicians with continuing medical educational credits for meeting with academic detailers.

Effectiveness of Academic Detailing

Accessed August 22, 2007.

Over a twenty-five year period, academic detailing has been shown repeatedly to be effective in promoting safe and appropriate drug use. A recent summary of the evidence about improving physician clinical care and patient health through educational programs concluded that interactive techniques like academic detailing are the most effective means to improve physician practices and patient outcomes.⁸ National reviews from Australia⁹ and Canada¹⁰ have concluded that academic detailing positively influences physician practices and promotes safe and appropriate drug use. Academic detailing programs have also been found to be cost-effective when subjected to economic analysis.^{11,12}

An increasing number of states are using and exploring academic detailing as a mechanism for reducing prescription drug cost, improving the quality of care, and increasing the value derived from drug coverage programs. Health insurance programs in Pennsylvania, Vermont, West Virginia and South Carolina are now using this strategy. Maine and Vermont have recently proposed and passed legislation to provide additional resources to promote and expand academic detailing in those states. Medical Societies in New Hampshire, Vermont and Maine are currently exploring options for initiating a tri-state academic detailing program in Northern New England.

¹² Mason, Freemantle, Nazareth, et al. When is it cost-effective to change the behavior of health professionals? JAMA 2001;286(23):2988-92



Bloom. Effects of continuing medical education on improving physician clinical care and patient health: a review of systematic reviews. Int J Technol Assess Health Care 2005;21(3):380-5.

⁹ May, Avorn, Silagy et al.. An overview of current practices of academic detailing in Australia and internationally - Part II. Canberra: Australian Commonwealth Department of Health.; December 1997. Report: Part III. pps.193. Available at: http://pdfserve.pharmacy.uq.edu.au/qumdatabase/PDFs/ID565_Report_1.4MB.pdf

¹⁹ Macture, Allen, Bacovsky, et al. Show me the evidence: Best practices for using educational visits to promote evidence-based prescribing. Victoria: Canadian Academic Detailing Collaboration and Drug Policy Futures; June 2006. pp.102. http://www.rxfiles.ca/CADC.htm

¹¹ Soumerai, Avorn. Economic and policy analysis of university-based drug "detailing". Med Care 1986;24(4):313-31

The Need for Academic Detailing

Although some medical schools and affiliated hospitals are attempting to ban pharmaceutical sales reps from their property, the relentless marketing campaigns of drug companies persist despite these scattered efforts. Reps often conduct business off-site, at professional society meetings, during after-hours dinner "seminars" at fine restaurants, through the ads that fill medical journals, and via direct-to-consumer advertising, which enlists patients into the role of drug sales representatives. Yet physicians recognize their need for unblased, non-product-driven information about the drugs they prescribe. When academic detailing programs are offered, clinicians readily accept such convenient educational outreach, since they know that the data provided is designed to be an accurate summary of all existing information, rather than the skewed sales-oriented pitches that pharmaceutical companies provide. If well developed, such presentations and the materials they provide can be a very time-efficient way for a physician to keep abreast of the latest information on medication effects, risks, and costs.

Americans spend more per capita on prescription drugs than any other country; reviews of prescribing patterns make it clear that much of that cost results from overuse of costly brand-name products when reliable off-patent generic drugs would work as well – or better. As a result, when academic detailing programs reduce such over-prescribing even slightly they can cover their own costs, making this approach increasingly appealing to budget-strapped state health programs. As the number of such programs increases, it is becoming possible to achieve economies of scale and ongoing quality improvement through shared use of common educational materials, training programs, and data management systems.

Samples of Existing Academic Detailing Programs

Pennsylvania: Independent Drug Information Service (IDIS) http://www.rxfacts.org/ 1-877-410-5750

- An independent, innovative program providing Pennsylvania physicians with noncommercial sources of evidence-based findings about prescribed drugs
- Sponsored by the Pennsylvania Department of Aging Pharmaceutical Assistance Contract for the Elderly (PACE) program; discussions with state officials around expanding to other state-funded entitlement programs are ongoing
- Clinical content is created by an independent group of doctors at Harvard Medical School who review current clinical information on drugs and develop printed summaries and information materials for prescribers and patients
- Trained academic detailers with a pharmacy or nursing background use these materials to provide physicians with personalized visits in their own practice setting
- Clinical topics include: pain management, upper GI symptom



- treatment, anti-coagulants, lipid-lowering therapies and blood pressure medications
- Since its launch in October 2005, the IDIS program has completed more than 2400 visits to physicians, nurse practitioners, nurses, and physicians' assistants in 23 months of operation
- · Annual cost of program: \$1 million
- Preliminary evaluation of actual prescribing data by physicians visited by the academic detailers, compared to similar 'control' physicians, has found a significant decrease in inappropriate prescribing, leading to dollar savings that offset the cost of the program

University of Vermont Medical School's (UVM) Academic Detailing Program http://www.med.uvm.edu/ahec 802-656-2179

- Offered in coordination with the Vermont Area Health Education Center (AHEC). Described as a "free educational opportunity available to Vermont health care professionals to promote high-quality, evidenced-based, patient centered, cost-effective pharmaceutical treatment decisions"¹³
- Provides educational sessions in physician offices/practices by a clinical pharmacist and physician who present an objective, unbiased overview of evidenced-based, patient centered, cost-effective evidence from studies about various drugs used to treat certain medical conditions
- Service is available to all physicians, but targets primary care
- Program offers condition specific information one condition addressed each year: 2007 Depression, 2006 Hypertension, 2005 Cholesterol, 2004 Heartburn
- Current budget of \$50,000 supports 25 visits per year, but additional funding of \$150,000 this year will allow for more detailers and visits

South Carolina Offering Prescribing Excellence (SCORE), University of South Carolina College of Pharmacy

803-767-6299

- A collaboration between South Carolina Department of Health and Human Services and the South Carolina College of Pharmacy will launch in October 2007
- Face-to-face interactions between clinical educators (clinical pharmacists) and prescribers to be used to provide unbiased information for Medicaid providers, initially focusing on mental health, with plans to expand to additional state health programs and conditions
- Drug experts are available to assist providers on drug therapy in all patients regardless of medication coverage plans

¹³ Primarily Vermont, Vermont Academic Detailing Program for 2006: Management of Hypertension, University of Vermont College of Medicine's Office of Primary Care, Spring 2006.



- The program mission is promoting quality, evidence-based, costeffective drug therapy decisions, with the patient as the focus
- Estimated program cost of \$1.9 million over two years

FOR FURTHER INFORMATION, CONTACT:

The Prescription Project: www.prescriptionproject.org; (617)-275-2853

The Independent Drug Information Service: www.RxFacts.org; (877) 410-5750



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