



**Testimony of Kevin Lembo, State Healthcare Advocate
Before the Public Health Committee, Connecticut General Assembly
In Support of Senate Bill 1189
March 14, 2007**

Good morning Senator Handley, Representative Sayers, Senator Roraback, Representative Carson, and members of the Public Health Committee. For the record, I am Kevin Lembo and I am the State Healthcare Advocate. I offer this testimony in support of Raised Bill 1189, An Act Requiring Pharmaceutical Manufacturing Companies to Disclose Incentives Provided to Health Care Providers.

This legislation requires drug companies to disclose to the Commissioner of the Department of Public Health (DPH) gifts and other financial incentives that the companies give to healthcare providers in marketing the drugs. This is common sense, accountability legislation that will give DPH the ability to gather and report information. I urge your unanimous support.

The amount of money spent on provider and consumer advertising of prescription drugs is directly tied to prescribing patterns and volume. If it were not so, there would be less of this marketing. When thirty percent of the cost of a prescription drug goes to prescription drug marketing, it is clear that savings for consumers can be achieved by cutting back on the practice.

I view this bill as part of a larger effort in healthcare reform and cost containment. Medical providers and their staffs often find themselves relying on the pharmaceutical representative for information on the latest in clinical practice. The information itself is probably helpful. But it is the gifts and incentives that come along with the heavy sales pitch for the latest and "greatest" generation of medication, which are expensive and suspect. As we discussed when I appeared before you in January, the research shows that the latest and "greatest" drug is often not the best, but always the most expensive – adding unnecessary cost the system.

At the end of the day this is a case of a powerful commercial influence being wielded over prescribers and consumers. That influence needs to be reigned in. S.B. 1189 will not eliminate aggressive marketing, but it will shine a light on the subtle, and not so subtle, incentives offered by pharmaceutical companies. S.B. 1189 can create a sentinel effect where pharmaceutical companies and providers, driven by a desire to "stay off the list," will end the gift practice themselves.

This legislation is not an attempt to blame healthcare providers for writing prescriptions that are related to the marketing of prescription drugs. The bill acknowledges that our

medical providers are already under tremendous pressure, and does not subject them to additional reporting requirements. This bill does put the reporting burden where it should be, on the drug companies.

The provision of free samples and payments for participating in clinical trials would still be permitted under S.B. 1189. This is especially important for those patients who do not have insurance and for ongoing medical research.

In S.B. 1189, the legislature has before it a simple but effective tool to contain costs and improve clinical practice. Through its passage, you can help ensure that medications are prescribed based on effectiveness and cost-efficiency – the hallmarks of system reform.

In support of this testimony and passage of the bill, I have attached:

- 1 “No Free Lunch,” by Paul Jung (Health Affairs, Narrative Matters, Volume 21, Number 2, 2002), a brief essay by a doctor who chronicles his experiences with the marketing practices of the pharmaceutical industry.
- 2 A list of Frequently Asked Questions on this subject (printed on 2/6/2007 from www.nofreelunch.org/faqs.htm).
- 3 “Pa. launches academic drug detailing,” by Christopher Guadagnino, PhD (Physician’s News Digest, December 2005), a news article on Pennsylvania’s attempt to develop a system, driven by science, for deciding which drugs will be included in the state’s drug formularies as well as their efforts to provide an Independent Drug Information Service to prescribers.

I urge your support for and ultimate adoption of Raised Bill 1189. Thank you.

No Free Lunch

A young doctor's take on why residents' souls should matter more than their stomachs.

BY PAUL JUNG

PREFACE: It is no secret that drug companies operate in a world of high risks and potentially high gains. Recouping large investments made in new drug research and development and maximizing corporate profits depend on persuading the medical community to prescribe as much of specific medications as possible. That persuasion takes many forms, including funding research, sponsoring educational events, and providing a variety of promotional gifts to physicians. The ubiquity and expense of these efforts raise difficult ethical questions for physicians and the public. Paul Jung, an internist recently out of residency, and Howard Brody, a veteran medical educator, explore the vulnerabilities of physicians to the blandishments of drug promotion. Jung is concerned about physicians' hunger, real and metaphorical, and Brody about a sense of entitlement that tends to drop physicians' guard to potential intellectual compromises. Frank Davidoff, editor emeritus of the *Annals of Internal Medicine*, recounts his experience struggling with the conflicts of interest inherent in manuscripts submitted by authors whose research was sponsored by drug firms. Commenting on the articles from the perspective of the industry, Bert Spilker, a senior vice-president of the Pharmaceutical Research and Manufacturers of America, explains the valuable role that drug representatives can play in educating physicians about new drugs and, in turn, improving treatment for patients.

A FEW MONTHS after settling into my internship four years ago, I found a pack of M&M candies in my mailbox. Assuming that the chief residents were rewarding their charges with a little treat, I took the packet, then noticed the sticker: "Compliments of Boehringer Ingelheim Pharmaceuticals, maker of Atrovent and Combivent." The same packets sat in most of the other residents' boxes, and empty wrappers littered the corner trash can. I immediately wrote a note to our program director, attached the M&Ms, and placed both in his in-box. His secretary could tell that I wasn't pleased.

Every year U.S. pharmaceutical companies spend an estimated \$10,000 per physician on advertising. About half of the more than \$11 billion that the industry annually invests in advertising goes toward equipping sales representatives with trinkets and toys that they dispense to physicians and residents at hospitals, clinics, and private practices. Debate rages over whether such practices affect physicians' prescribing behavior. And some consumer groups blame high drug

Paul Jung, <pjung@jhspsh.edu>, finished his residency in internal medicine and is now a Robert Wood Johnson Clinical Scholar at the Johns Hopkins University in Baltimore.

prices on these marketing costs. Regardless of any such link, the ethical question remains: Should physicians accept gifts—large or small—from a company that may influence, or at least appear to influence, our medical decisions?

Gifts And Good Food

PHARMACEUTICAL COMPANIES SPONSORED two or three free lunches a week throughout my residency. These occurred during our noon educational conferences. Each buffet was arranged so that while standing in line for food, residents had to pass by one or two drug reps, trained to talk up their drug and reinforce their message with freebies such as pens, notepads, rubber “stress” balls, stuffed animals, refrigerator magnets, and laminated index cards with helpful dosage formulas. Americans bash HMOs on the grounds that their decisions are based on money rather than medical need. How would they feel if they knew that doctors’ prescription decisions may hinge on who pays for lunch? One study shows that 85 percent of medical students feel it is improper for a politician to receive corporate gifts, yet only 46 percent believe that physicians should refrain from accepting handouts. We physicians apparently hold politicians to higher standards than those for ourselves.

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After reading my note, the residency program director issued a policy prohibiting any further gifts or ads in our mailboxes. He invited me to review the policy on resident interactions with drug reps so that I could propose changes to the program director’s committee. My recommendation: No more advertisements or gifts at our lunch conferences and no one-on-one interactions between drug reps and hospital physicians. Instead, the reps could contribute to a fund to pay for lunches and receive recognition for doing so at the year-end graduation banquet.

“How would Americans feel if they knew that doctors’ prescription decisions may hinge on who pays for lunch?”

I felt so strongly about this because the issue of undue influence is most critical during residency training, when young physicians’ knowledge and decision-making skills are being nurtured. New medical developments are constantly emerging, to be sure, but residents should be hearing about them from faculty at educational conferences—not from drug reps at drug company-sponsored lunches.

Trying To Change Minds

AT THE NEXT PROGRAM DIRECTOR'S MEETING we discussed my proposal. Comparing noon conference sign-in sheets between days with free lunches and days without revealed no large differences in attendance. Hoping to sway opinion, I distributed copies of my annotated literature search, "There's No Such Thing as a Free Lunch." The research it cited provided scientific evidence of the effects of pharmaceutical gifts on physicians' prescribing behavior. For instance, literature shows that physicians who interact with drug reps favor the advertised drugs. This finding holds true for direct financial gifts and for less direct interactions such as free meals and brief conversations with drug reps. Studies also indicate that residents who attend educational programs given by drug reps tend to overprescribe and misprescribe the advertised drug. Surveyed residents and physicians agree that such interactions compromise medical judgment yet insist that they personally are not affected. Despite this evidence, fellow residents on the committee were ambivalent about my proposal. So much for evidence-based practice.

At that meeting our program director gave us three options: the status quo, the "Jung plan," or the "high road," as he called it—a ban on all pharmaceutical interactions. As the discussion ended, he reached over and pulled a penlight out of my coat breast pocket. Expecting to see a pharmaceutical name on it, instead he found our

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"A fellow resident asked why I was trying to take away our free lunches. 'You want us to buy our own pens?!' he exclaimed."

hospital's logo. Relieved, he raised one eyebrow. "I didn't even know we made these penlights," he said. We ended the meeting with no final decision. He cautioned the resident representatives that no matter what our personal opinions, our first responsibility as committee members was to gauge the opinions and concerns of the house staff.

Discussions with other residents revealed a common attitude: Residents were overworked and underpaid, so why not allow us a free lunch now and then? At one noon conference a fellow resident pulled me aside to ask why I was trying to take away our free lunches. After a fairly heated exchange, he exclaimed, "You want us to buy our own pens?!"

Later I learned that the hospital's pharmaceutical and therapeutics committee had taken up the matter and decided to propose the high road—barring all pharmaceutical reps and their money from the hospital. We were told that this proposal obviated the need for

a departmental policy. I let the committee's decision rain from above; it was guaranteed to be unpopular. As a chief resident put it, "There are good arguments on both sides, but no one wants to be known as the Grinch who took lunches away from the residents."

Back To Square One

EVENTUALLY THE PROPOSAL WENT BEFORE the hospital's full graduate medical education (GME) committee. Almost everyone in that group opposed the ban. As the debate unfolded, one gastroenterologist remarked that a hospitalwide prohibition against house staff's interacting with drug reps would not adequately prepare us for the real world, where we would be bombarded with larger, potentially more corrupting gifts such as drug company-sponsored research funds or plane tickets to sponsored conferences. The cheap toys we were given in residency were only the tip of the iceberg. In addition, if all lunch interactions were banned, residents would be flooded with offers for off-campus, extracurricular dinners. These would not only be unsupervised but would provide free alcohol. Better instead to keep the interactions in house, with faculty supervision.

His solution was to require a faculty member to attend all conferences where drug reps were present. This would be easy to do; as a rule, many faculty attended educational conferences. The GME committee agreed that this was a good idea—akin to holding our hands as we crossed a busy street instead of prohibiting us from crossing at all. The definition of and conditions for supervision, however, were not made explicit. No one mentioned that pharmaceutical lunches with faculty "supervision" might convey tacit approval, even encouragement, to accept favors.

After this new default policy went into effect, faculty were indeed present at resident conferences. But their specialties did not coincide with the products being pushed, leaving them in a poor position to evaluate the information the drug reps were dispensing, let alone to screen it for residents. Rheumatologists appeared at lunches sponsored by Viagra, cardiologists at conferences sponsored by Cipro. And faculty never "supervised" the reps; maybe they didn't know it was their newly assigned duty to do so. They usually sat on the other side of the room, enjoying their subsidized lunch.

"One would think that becoming a practicing physician with quadruple the income of a resident would curb the need for cheap baubles."

Practicing physicians are not immune to drug company goodies. In the home of an older, well-to-do cardiologist, I once sighted an Evista clock on the living room wall and a box of Vioxx tissues in the bathroom. At a meeting I saw an endocrinologist wearing a watch displaying a Humulin logo with a small fork and knife as hour and minute hands. One would think that becoming a practicing physician with quadruple the income of a resident would curb the need for cheap baubles, but that's not what I have observed.

One infectious-disease faculty member pulled me aside and joked that instead of moonlighting, residents could simply rent the space on the back of their white coats for pharmaceutical ads. If athletes can have corporate logos on their jerseys and race cars, he said, laughing, why couldn't we do the same?

A Stopped Buck

I DIDN'T THINK THAT THE AGREEMENT to have faculty supervise drug-sponsored lunches went far enough, so I continued to try to set up a more effective policy. Without much support from my peers, I relied on our program director, a genial man who brought his own lunch to work every day. He was responsible for all final decisions about the residency program and often pointed to a placard on his desk that said, "The Buck Stops Here." I considered this a good sign, because he felt the same way I did about pharmaceutical marketing. However, a contentious issue required discussion in his committee and among the residents. Prohibiting drug lunches proved to be impossible when all but one resident opposed the idea.

Two years later, as a senior resident, I observed no change in the drug lunch situation. I was about to request a reconsideration of my original proposal, but more immediate concerns took over. The closing of several smaller hospitals in the city combined with a flu epidemic to swell our admission rates. Things got so bad that we were forced to board medicine patients on psychiatry and rehabilitation floors. House staff were swamped with work. My quest for an ethically clean residency training program, at first so clear, became muddied. In times like these, it was difficult to think that a free lunch here and there wasn't a small reward for our hard work. One final meeting with my program director near the end of my residency revealed an administration thrown headfirst into the health care crisis. I decided to let my point ride until things settled down, which they never did. I finished my residency with no significant change in the hospital's drug rep policy.

Feeding The Soul

ONE WAY TO HELP PHYSICIANS-IN-TRAINING avoid the temptation of drug-sponsored lunches might be to have the hospital supply them instead. At \$4 per meal for a class of thirty residents, an internal medicine residency program would spend less than \$100,000 a year on providing free lunches every weekday. This is pocket change compared to a teaching hospital's total budget. Perhaps instead of trying to restore diminishing GME funding in Medicare, Congress could simply instruct the Centers for Medicare and Medicaid Services to provide free lunches to house staff nationwide.

Residency programs are charged with training and guiding this country's future physicians. These programs should provide an educational environment that sets us on a straight path toward appropriate medical care. Allowing pharmaceutical companies to pander to our hunger under the guise of exposing us to "real-world" situations is an excuse for convenient lunches. "An army runs on its stomach," my program director had said to me during my futile struggle to end drug company-sponsored lunches. In difficult times for public hospitals like the one in which I was trained, I can't deny this. But we must spend less time worrying about residents' stomachs and more time worrying about their souls.

**"One way to help
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FAQ'S



HOME
MEDICAL STUDENTS
REQUIRED READING
THINGS YOU CAN DO
OTHER RESOURCES
PARAPHERNALIA
CHARGING BEHAVIOR
SAMPLES
TIAS

read

- I'm not influenced by all these gifts anyway, so what's the problem?
- Surely you're not suggesting that something as inconsequential as a pen could possibly influence what I prescribe?
- What about gifts that benefit patients? A textbook will help me to be a better doctor.
- My friends in the business world are wined and dined all the time. Why should doctors be held to a different (higher) standard than business people?
- But conflict of interests exist everywhere—what's so different about this one?
- Doesn't disclosure eliminate the "conflict of interest problem?"
- Advertising is just part of our society, like it or not, and aren't gifts just a form of advertising?
- What if I'm already prescribing the rep's medication on the best evidence, what's wrong with accepting a few freebies?
- How are doctors supposed to keep updated about new medicines without reps?
- I meet with reps in order to get samples for my patients – what am I supposed to do without my samples?
- I have lunch provided by different companies each day. Doesn't the bias cancel out?"
- I work long hours, studied for many years, and have paid my dues. Aren't I entitled to all this stuff?
- I'm a medical student and can't prescribe anyway; so where's the conflict?
- Aren't you just communists?

Q. I'm not influenced by all these gifts anyway, so what's the problem?

A. Doctors, like everyone else, are influenced by promotion. Though there have been no randomized trials, there have been plenty of observational studies, and all of them have reached a similar conclusion (see [Wazana](#)): Doctors' prescribing behavior as well as other behaviors (for example, requests to the hospital formulary) are influenced by promotions and interactions with reps. Doctors who practice on the basis of promotion, meet with reps, and use information provided by them are more likely to prescribe more expensive, inappropriate medication. Though the possibility of publication bias exists, no study has shown that practicing on the basis of promotion leads to more cost-effective prescribing. And while no study has looked at the influence of gifts, or small gifts, *per se*, it is reasonable to extrapolate the vast social science literature on gifts (see below) to physicians. Though many physicians may believe otherwise, there is no reason to think that they are immune.

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Q. Surely you're not suggesting that something as inconsequential as a pen could possibly influence what I prescribe?

A. That's exactly what we're suggesting. And the social science literature suggests the same. Gifts create relationships; they create obligation, the need to reciprocate (See [Katz, et al](#)). For this reason even small gifts can be disproportionately influential. Though many individuals, as well as most professional society guidelines make distinctions among gifts of small and large value (permitting the former while proscribing the latter), presuming that larger gifts influence more than smaller gifts, this distinction is probably baseless (see [Dana & Lowenstein](#)).

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Q. What about gifts that benefit patients? A textbook will help me to be a better doctor.

A. A week of R&R in the Caribbean would probably make you a better doctor, but that doesn't mean the pharmaceutical industry should pay for it. A gift is a gift, and gifts entail obligation. There is no ethical distinction between different types of gifts. If a drug company buys you a textbook, it merely frees your money up to buy something else, like a trip to The Caribbean, for example.

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Q. My friends in the business world are wined and dined all the time. Why should doctors be held to a different (higher) standard than business people?

A. Because the doctor-patient relationship, unlike many (but not all) business relationships—but like that between a lawyer-client or congressperson-citizen, is a *fiduciary relationship*. A fiduciary is someone with specialized skills or knowledge; holds the trust and confidence of others; is accountable and obligated both ethically and legally; who is held to a higher standard of conduct, and who therefore avoids conflicts of interest. All of these characteristics pertain to physicians. Though some may see medicine as "just a business," clearly—at the present time at least—patients, and society do not see it this way: Patients rightly expect their physician to act in their (the patient's) best interest. Patients do not enter the examining room *caveat emptor*. Patients should be confident that the drug being prescribed is the best, the most cost-effective, not the best promoted.

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Q. But conflict of interests exist everywhere—what's so different about this one?

A. It's true, conflicts of interest are ubiquitous, but that doesn't mean they are all the same and are all acceptable. There are conflicts resulting from academic, political, as well as family interests (I may, for example, not heed all my patient's complaints if I am in a rush to get to my son's soccer game at 6PM). Some conflicts are unavoidable; but that doesn't make all conflicts permissible. Conflicts of interest should be avoided when possible, and the conflict resulting from the acceptance of gifts from industry is both voluntary and unnecessary.

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Q. Doesn't disclosure eliminate the "conflict of interest problem?"

A. Disclosed information is only useful if the discloser knows what to do with the information that is disclosed (see Dana and Lowenstein). What do we do with the disclosure that a speaker or author is a paid consultant for the manufacturer of the drug she is speaking or writing about? Disregard the results? Listen or read more critically? This is by no means clear. Or consider the patient perspective: Even if a physician were to disclose to a patient (not likely) that she had been taken to dinner by the company who makes the PPI she is about to prescribe, what would the patient do with this information? If you think about it, disclosure only points to a potential problem; it doesn't do anything to resolve the problem.

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Q. Advertising is just part of our society, like it or not, and aren't gifts just a form of advertising?

A. Gifts do share some characteristics with other types of advertising and promotion: Like other types of advertising, they cost money (patients' money?) and also like other forms of promotion, they influence behavior. But there is an important distinguishing characteristic: Gifts, unlike other forms of advertising, create obligation, a sense of indebtedness, and a need to reciprocate (see above). This has been called the "reciprocity rule" (see Katz, et al): When someone does us a favor (e.g., gives us a gift), we are expected to return the favor at some future time. Notably (and most relevantly in regards to pens and notepads), the sense of indebtedness is not related to the size of the gift (in other words, small gifts may produce an obligation to perform a large favor). Those who fail to reciprocate are viewed negatively ("ingrates," "moochers," "freeloaders.") Further, there is not just an obligation to repay, but an obligation to receive (that is to say, turning down gifts is viewed somewhat negatively); this results in less choice in regards to whom we are indebted. This gift giving-receiving behavior is well studied by social scientists, and appears to be present in all societies. (see Cialdini)

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Q. What if I'm already prescribing the rep's medication on the best evidence, what's wrong with accepting a few freebies?

A. Because the company has other medications. And now you have developed a relationship with the rep and his/her company, and are open to all that comes along with this (see above). And while the economic argument is admittedly complex, it is hard to justify being wined and dined by drug companies when our patients cannot afford the medications we are prescribing them (perhaps on account of these lunches!). These are not "freebies:" There is, after all, no free lunch.

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Q. How are doctors supposed to keep updated about new medicines without reps?

A. There is no longer any reason (excuse?) for providers to rely on promotional sources—which are likely to be biased—for information. While many reps may be knowledgeable about their products, they get paid for selling, not educating, and get rewarded when their products are prescribed, not when they are prescribed appropriately. There now exist (see Sources of Drug Information) many non-promotional and less biased sources of information that the proverbial busy provider can access via computer or PDA in a matter of seconds. It is true, that these sources do not come with free lunch, but physicians may just have to get used to the idea of paying for their own lunch.

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Q. I meet with reps in order to get samples for my patients – what am I supposed to do without my samples?

A. Not for nothing does the pharmaceutical industry spend over 1/2 its promotional dollar on "free" samples: Once a patient is given a sample, there is a good chance that this patient—and other patients—will be prescribed that medication at a later date, even though equally effective (or perhaps more effective, less expensive—and possibly less hazardous—) medications are available. (See Chew, et al) Vioxx (and before Vioxx, Rezulin, Trovan . . .) was heavily sampled and heavily prescribed. Patients would have been better off (and some of them still alive), if they had been prescribed older, safer drugs.

While it is often stated that "samples are better than nothing," this argument is a straw man: It is not "samples vs. nothing:" Patient Assistance Programs are available from the companies themselves, and these have become easier to use and manage via the internet. Also, with more and more drugs going off-patent, less expensive generics are often available. If physicians spent as much time advocating for universal health care as they did defending their free samples (and the food that comes with them), we might not be forced to use whatever sample is lying around the office as a solution to our patients' lack of health insurance.

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Q. I have lunch provided by different companies each day. Doesn't the bias cancel out?"

A. No.

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Q. I work long hours, studied for many years, and have paid my dues. Aren't I entitled to all this stuff?

A. Yes. And you are also entitled to a Nobel Prize; but you aren't going to get that either. You may be entitled to a high salary, and this is why the physicians' salaries, in the U.S. at least, are considerably above the National average. But you are not entitled to gifts from the pharmaceutical industry any more than a congress-person is entitled to gifts from lobbyists. And even less so if these gifts drive up drug costs and lead to inappropriate prescribing.

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Q. I'm a medical student and can't prescribe anyway; so where's the conflict?

A. As a medical student you have the longest prescribing life ahead of you than anyone else, and industry is well aware of this. If you develop a pattern of interacting with sales reps, of accepting gifts, of creating relationships with drug companies, these patterns of behavior will last a very long time and may become very hard to break.

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Q. Aren't you just communists?

A. No. We support the capitalist system and a free market (if only there were one!): May the best drug win. But not the drug whose manufacturer provides the best lunch. We are not talking about breakfast cereal here. We are talking about medications, sometimes life saving medication, the provision of which is under the control of the physician. We suspect no one cares if their grandmother drinks Pepsi because she likes the commercials. But there are few—if any—grandchildren who wouldn't care if she was taking the wrong medication because her doctor had been taken out to dinner the night before.

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Pa. launches academic drug detailing

By Christopher Guadagnino,
Ph.D.

Published December 2005

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Susan L. Anderson is chief of staff and deputy director of the Governor's Office of Health Care Reform. She is co-director of the Commonwealth Pharmacy Policy and Administration Project, along with Pennsylvania PACE Program Director Tom Snedden.

PND: Can you describe the state's new drug detailing initiative?

SLA: When we formed the pharmacy project out of the Governor's Office of Healthcare Reform, we looked at what we thought were good policies with regard to prescription drugs that ought to be implemented across all of our Commonwealth programs. One of the projects – the Independent Drug Information Service – is generically called academic detailing. Going back to 1995, we experimented with an academic detailing demonstration project by putting in the field half a dozen people to see how effective it might be. In 1996 we shut it down and we didn't restart it again because we felt that the PACE program's drug utilization review initiative, which has mandatory edits at the point of sale, accomplished more than counter-detailing without the added expense. For the PACE system to shut down the prescribing of a drug like Vioxx, for example, it doesn't

cost more than a few cents because we just change the protocols at the point of sale to reject the claim. But that doesn't result in very much education. Nothing we can do through the prospective drug utilization review process can impart the kind of information that we can by actually visiting the doc and discussing it with them. In recent years we have taken another look at academic detailing because this administration wants to expand some of the things that we've done in PACE to all the other state pharmacy programs, in which case a concept like this becomes more cost-effective.

PND: How does the drug detailing program work?

SLA: We have people out in the field who, not unlike detailers for the pharmaceutical manufacturers, are calling on physicians who have a high number of PACE enrollees and educating them with respect to prescribing in appropriately half a dozen different therapeutic classes, starting with Cox-2 inhibitors and proton pump inhibitors. Administration of the program falls under the Office of Health Care Reform, with PACE doing most of the day-to-day management of it. The clinical direction is coming out of Harvard Medical School in the person of Jerry Avorn, M.D., who is an international expert on such a program and has trained a team of people from Pennsylvania for three days at Harvard on academic detailing, the drug classes that were selected for attention and why they were selected, and the message that we wanted to get across to physicians. We have ten detailers with backgrounds largely in nursing and pharmacy – a couple of them have doctorates in pharmacology – who are going out and sitting one-on-one with the doctors. They ask for 15 minutes of a physician's time to go in and educate the physician with regard to a particular category of drugs.

PND: Which drugs will the program cover?

SLA: We've pulled out certain categories of drugs where we think there is the potential for overutilization or misutilization, where we believe that the physicians truly

need to have medical evidence, in terms of when they should be prescribing these products and when they should not, given the diagnoses and medical history of the individual. Two classes – Cox-2 inhibitors and proton pump inhibitors – are the ones that we will address exclusively between now and the end of the calendar year. There's been a lot of controversy surrounding the use of Cox-2 inhibitors and despite the fact that there's only one left in the U.S. market, we still have concerns about the possible overuse and misuse of Celebrex. Proton pump inhibitors – I think it's pretty widely known and accepted – are overused to a significant extent. Beginning in 2006, we'll also be looking at pain medication, statins, antihypertensives and antiplatelets. This is not about not prescribing a particular drug because of cost. It's really about what makes the most sense for the patient. The average person on PACE is a 78-year-old widow, and one of the first groups that went out started detailing doctors about underutilization of anti-osteoporosis medications.

PND: When did the program begin?

SLA: It launched back in the spring, while the boots on the ground happened in September.

PND: Where will the program operate?

SLA: In 29 Pennsylvania counties, primarily in the southwest around Pittsburgh, southeast around Philadelphia, northeast in Allentown and Wilkes-Barre, and in Harrisburg. The areas were picked because they have the largest PACE enrollee concentration. We're visiting physicians who have the highest percentage of PACE enrollment. In Philadelphia, for example, we have selected 300 docs who represent the highest volume PACE prescribers. This isn't picking bad docs versus good docs – this isn't profiling. We're picking the highest volume prescribers because we think from the data we have that over-prescribing in all of these classes is just endemic. By early 2006 we want to fold in physicians in Medicaid and the State Employee Retiree

Benefit Program.

PND: How many physicians are on your list currently?

SLA: We're starting with 500.

PND: How many physicians would your list ultimately include?

SLA: I would say several thousand, once we fold in all the other state programs.

PND: When will the program be statewide?

SLA: Probably say not until mid-2006. We want to see how it goes in these 29 counties for the first year and then determine whether or not we should go statewide with it.

PND: Pharmaceutical reps typically use incentives to gain physicians' time. Will you be utilizing any incentives?

SLA: Not the same kind. We use knowledge as the incentive. That's why it's called the *Independent Drug Information Service*. The way we're promoting it is that it's the Commonwealth - state government - that is providing the impetus and the underwriting for this initiative through the Harvard Medical School, which I think is a fairly prestigious name, and we are offering an educational benefit to physicians. I have not found from past or current experience that there is any lack of incentive here. What I find from physicians is, first and foremost, they're elated that somebody representing the Commonwealth in an official capacity is coming to talk with them.

PND: How often would an individual physician's practice be visited?

SLA: I can't imagine that we would do more than two or

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three visits a year. But if a physician practice wanted us to come back for some reason, I can't imagine we wouldn't do that. With respect to all of the drug classes, there will be a four- to five-page leave-behind that will condense what is available in the class, what its appropriate use is, and recommendations for following nationally endorsed and accepted protocols on treating illnesses within each of the respective classes.

PND: Has this program been used elsewhere?

SLA: This type of program is used in other countries around the world. West Virginia started a similar program for state-employed retirees within the past year. There's not another state that has taken the concept and expanded it so comprehensively. What we gleaned from the experience of the program's applications in other countries is that it's been very effective. But health care systems of other countries are a lot different from what we have here in the United States.

PND: How costly is Pennsylvania's program?

SLA: We're looking at about \$80,000 a month to run this benefit. That isn't a lot when you have an entity that's spending \$3 billion a year on prescription drugs - that's the amount that the Commonwealth either directly spends or reimburses through all of its programs that offer prescription benefits, including the state Medicaid program, the PACE program and the state employee retiree program.

PND: By rationalizing appropriate use of these classes of drugs, how much money could the state be expected to save?

SLA: I'd have to say tens of millions, but I couldn't quantify it any better than that because it's hard to ascribe causality. Just because our detailer visits a doc and their Cox-2 prescribing in PACE drops by 50 percent doesn't necessarily mean that it was directly as a result of our visit. It's a high probability, but not directly. The

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harder part comes when you try to estimate the savings by saying, "Okay this person lived another 15 years, was on this medication for all of that time, and the price during that time has gone up by this amount."

PND: Are you using this detailing program to encourage the use of particular drugs that the state has negotiated discounts on?

SLA: No. This has nothing whatsoever to do with that. These folks are not going in and talking about any specific brand. They're going in and educating the doctor as to the class of drugs and the kinds of things that you need to be looking at before you ever get to the issue of a prescribed product.

PND: To the extent that there are different brands of drugs in a given class, how does brand name distinction enter into the detailing presentation?

SLA: Not directly. We're not interested in promoting any brand over another. What we're suggesting to physicians is that some brands within a class may be more appropriate than others, given their side effect profiles. It doesn't have anything to do with who is the manufacturer or what the brand is.

PND: Do you think Pa.'s new program could lead to further escalation of detailing efforts by pharmaceutical companies?

SLA: My personal opinion is no. In fact, I'm seeing a contraction of detailing by the industry - I think that's pretty well documented. I don't think an expansion or contraction of detailing by the pharmaceutical industry will have anything to do with what we're doing. On the scale of things we're just a blip. We live in a country that represents a \$240 billion-a-year retail drug expenditure. As big as Pennsylvania is, we're only a \$10 billion market. I can't see any company stepping up their detailing force in Pennsylvania just to counteract this program.

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PND: Earlier in the interview you used the term "counter-detailing." Are you detailing because it's the most effective way to get information to physicians, or are you doing it to counteract pharmaceutical promotional information?

SLA: We think it's primarily the former. One-on-one with docs is the most effective way, particularly when you're in their office setting. As far as counteracting what the pharmaceutical manufacturers are doing, that's not necessarily the purpose of this initiative, but it certainly does work that way, to some extent. I used to call this counter-detailing until Jerry Avorn at Harvard came up with what I'll call the euphemism "academic detailing." Unfortunately, a side effect of what we're doing is to offset what the drug manufacturers are trying to do in marketing their product.

PND: Have you done any research to determine physicians' willingness to participate in the program?

SLA: The anecdotal evidence we had in the mid 1990s was that physicians embraced it because they appreciated the opportunity to speak with an official representing the Commonwealth and get information that was not market-biased. In the present program, one detailer in Pittsburgh reported that she has had very positive experiences with the physicians she's visited.

PND: Have you tried anything else to impact physician prescribing patterns?

SLA: We've tried lots of things over the last 20 years, starting with physician profiling and writing letters to physicians who we thought were out of track with their peers. Our evaluation of that was that it just took us nowhere. We tried a retrospective drug utilization review (DUR) in the late '80s where we sent letters to physicians immediately after the drug was dispensed if we had a concern, and there was never any evidence to show that that worked very effectively. That's what led us to the online, real-time point-of-sale drug utilization review in

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'92, which time and again has shown it is very effective, particularly from an administrative cost standpoint. But it doesn't do a good job in educating the physician about why we took the step that we did and trying to convince the physician that it's better to prescribe in a different manner, and having that transfer to other patients in the practice. So, we've tried lots of things. I don't know that there is anything out there that we haven't tried. Prospective DUR, which has now been around 13 years, has stood the test of time as being quite effective and we're just now trying to complement it by wrapping it around an educational component that can benefit not just PACE but all state pharmacy programs.

PND: How are you going to evaluate the effectiveness of this program?

SLA: At least for the time being, we're going to look generally at whether or not there is a change in the prescribing pattern of the physicians we visit a month or two after the visit. Whether or not we can attribute causality to that is another question - only a rigorous, independent evaluation would address that. We're not planning at this point to do any formal, independent evaluation. That may come later, but the cost associated with that could be pretty significant. We'll be able to get a good sense internally as to how well the program is working.

PND: Is there a magnitude of shifted prescribing patterns that you'll be looking for?

SLA: No, not at this point. We don't want physicians to get the sense that the state is preparing a report card on their prescribing and that there may be some adverse reaction coming down the road. I would like to dispel any notion that that's the purpose of this initiative. It's not. It's purely education.

PND: Participation by physicians is voluntary?

SLA: Absolutely. They will be called and asked if one of

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our folks can come in and meet with them for 15 minutes. If they say no, they say no. It doesn't mean we won't try again. This is really a service on our part. Physicians shouldn't feel like the state is looking to bring some sort of licensure action because they don't open their door, or because we don't get the results we think we should see. It has nothing to do with that at all. It's simply about trying to help physicians better understand what might be the best clinical practice based upon the evidence that we have today. In the PACE program, we believe in the concept of open access and an open formulary. Where we limit access is based solely on clinical considerations, not with costs. We've felt, for the better part of 20 years, that if you can get good, clinically justified prescribing - eliminate or significantly reduce over-prescribing and mis-prescribing - you don't have to have closed formularies. The evidence of overuse of prescription medications among Americans, particularly older Americans, has been profoundly demonstrated to be a major problem. We feel that, if you can squeeze that out, open access shouldn't be an issue.

PND: How long will the program run?

SLA: Until June 30, 2008. We'll have to see how well this goes - how widely it is accepted, what kind of impact it has - to determine whether it makes sense to continue it. We'll be doing that periodically over this three-year period. So far, the evidence is that this program is going to be a success because we've visited 80 physicians, all of whom seem to have felt it was a very good experience. There's only one physician that declined the visits. What remains to be seen is whether or not the information that we have imparted will make a positive difference in physician prescribing patterns.

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