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STATE SENATOR • WORCESTER & NORFOLK



**FOR IMMEDIATE RELEASE**

December 9, 2008

## **“Never Trust the Lamb to the Custody of the Wolf”**

Keynote Address by Senator Richard T. Moore  
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at

“Righting the Script: Improving Prescription Drug Policy  
in an Era of Health Reform”

Sponsored by The Prescription Project

December 9, 2008

Carnegie Conference Center, Carnegie Endowment for International Peace  
Washington, DC

When searching for an appropriate title for my remarks for this conference on “Righting the Script: Improving Prescription Drug Policy in an Era of Health Reform,” the words of our second President, John Adams of Massachusetts, seemed especially appropriate. When considering the need for checks and balances in government, he said, “My fundamental maxim of government is, never to trust the lamb to the custody of the wolf.” Certainly, this is, or ought to be, the guiding maxim of the Prescription Project, in that we should never trust the health of our citizens to the custody of the pharmaceutical industry!

The relationship between the pharmaceutical industry and health care providers is not a new concern. Physicians, policy makers, and even the pharmaceutical industry have wrestled with the ethics of permitting the industry to support medical research and physician education without unduly influencing the research or biasing physician prescribing behavior through profit-seeking marketing behavior with gifts and honoraria of significant value.

Last June, CBS – TV, in a special report headlined, “Are Perks Compromising MD Ethics,” a University of Quebec study was cited, which estimated that drug company payments to doctors go as high as \$57 billion a year, covering consulting fees, speaking fees on drugs, and medical

seminars on the benefits of drugs. That means the industry spends far more money marketing to doctors than it spends on advertising.

In a September 2008 article published in *State Legislatures Magazine* (6) published by the National Conference of State Legislatures (NCSL), Rachel Brand wrote:

“It’s no secret that pharmaceutical companies flood doctors’ offices with preppy, well-groomed drug detailers. They’re salespeople who arrive bearing bagels, cookies, clocks, and calendars. Medical product companies also pay lavish honorariums to physicians who lecture in favor of brand-name drugs, hire doctors as marketing consultants and pay physicians to attach their names to industry-written articles. Although the pharmaceutical industry does not release figures, published estimates put the cost of physician marketing and distributing free drug samples at about \$25 billion. Of that, an estimated \$7 billion is spent on one-on-one marketing to doctors.

“Nobody disputes that innovative biological products and drugs save lives,” Brand continues, adding that “Pills and injections save money too, by keeping patients out of the hospital. But a growing number of legislators and patient advocates say cozy doctor – industry ties push up health care costs and threaten patient safety.”

### **Voluntary Ethics Guidelines of Industry**

The American Medical Association issued voluntary ethical guidelines in 1991 and has updated those guidelines from time to time. However, as the utilization of pharmaceuticals has dramatically increased in the practice of medicine since that time, so has concern regarding the appropriateness of the relationships between the marketing and the clinical utilization of these, often expensive, products.

In an effort to demonstrate a proactive position, that some in the “Big Pharma” community hoped would thwart efforts by government regulators to ban or control drug marketing, the Pharmaceutical Research and Manufacturers of America (Pharma) adopted voluntary marketing guidelines for its member companies in 2002. They recently updated those guidelines for interaction with physicians, curiously launched when the Massachusetts Legislature was considering an outright ban on such activities.

As evidence-based research, litigation, and media investigations continued to reveal that, despite voluntary guidelines, serious ethical violations continued to occur; some professional organizations began to conclude that voluntary codes of ethics or marketing practices were not working. In January 2006, the *Journal of the American Medical Association (JAMA)* published an article entitled: “Health Industry Practices that Create Conflicts of Interest.”

The article highlighted, and I quote, “the failure of voluntary efforts to prevent ethical transgressions in the relationships between physicians and the drug and medical device industries, which it said continue to erode medical professionalism as well as the integrity of the industry. By offering physicians even subtle inducements – small gifts, modest meals and drug

samples – the pharmaceutical industry is still successfully getting physicians to prescribe the newest and often most expensive drugs when cheaper therapeutic equivalents are available, and to petition their inclusion on hospital formularies.” Among the co-authors of the article were representatives of the Association of American Medical Colleges (AAMC) and the American Board of Internal Medicine (ABIM).

The article further noted that new research determined, “permitting only small gifts, requiring full disclosures and making earnest efforts to avoid bias – hallmarks of the voluntary guideline approach – do not prevent non-rational prescribing behavior by physicians after exposure to promotional presentations by drug reps.” The JAMA article argued that, “the urge to reciprocate, even when given a gift of nominal value, operates at an unconscious level which physicians cannot effectively prevent, and recommended more external restrictions on physician contact with drug reps – specifically at academic medical centers because of their leadership role in the medical profession, their ability to organize and implement new policies rapidly, and the importance of habit-formation during physician training.”

Medical schools around the country are finally taking notice of this concern. A year ago, this month, physicians in the UMASS Memorial Health System, which includes the faculty of the University of Massachusetts Medical School, adopted what the Boston Globe called, “some of the strictest conflict of interest rules in the country, in effect, sharply limiting close ties between many doctors and the makers of drugs and medical devices.”

As the Globe reported, the UMASS faculty believes that the new policy should “significantly reduce conversations between physicians and salespeople, and therefore presumably reduce the appearance of influence over what drugs doctors prescribe for patients. It inhibits doctors and other clinical staff from eating meals paid for by companies; bans all gifts, from candy to medical journals; stops drug companies from giving money directly to individual physicians and departments for educational programs; and places a complete ban on doctors joining a company’s “speakers bureau” to give talks about products.”

The adoption of such policies by public and private medical school should be encouraged; however, there is no assurance that individual policies of academic medical centers will be any more lasting or effective than the voluntary professional and industry codes. They are subject to change by future faculty votes or administrative policies, and are difficult to track. Such voluntary efforts, in order to be sustained against the efforts of pharmaceutical marketers to undermine them, need to be based in law and government regulation.

As Dr. Victoria Rogers McEvoy, chief of pediatrics of Mass. General’s West Medical Group and assistant professor of Harvard Medical School wrote in an Op-Ed published in the Boston Globe [September 8, 2008], “While the evidence-based practice of medicine and the medical-industrial complex need each other, especially as funding becomes scarcer for research and development of life-saving medications, it is critical that we vigilantly guard against subtle pressures that can affect our judgment.”

## **State Legislation to Support Ethical Practices**

It was precisely these media reports, along with a growing volume of research that convinced legislative leaders seeking to contain health costs, that limiting the influence of pharmaceutical and medical device manufacturers must be a major part of bending the cost curve and improve patient safety.

Legislation has been filed in Massachusetts and other states for several years to provide for a ban on gifts to physicians from pharmaceutical companies and disclosure of gifts led by Senator Mark Montigny and other legislators, with support from the National Legislative Association on Prescription Drug Prices (NLARX). With the exception of Maine, New Hampshire and a handful of other states, the bills never made it through the entire legislative process. As many in this audience know, NLARX is a non-profit association established to assist legislators who are working together from a number of states to make prescription drugs more affordable and accessible to all Americans.

Six states and the District of Columbia currently have laws requiring the reporting of gifts by pharmaceutical marketers to physicians or their offices, however enforcement has been limited. Minnesota has had such a law for several years, but the reports are filed in paper format and are difficult to audit. Vermont has also had a similar provision.

According to a report by the National Conference of State Legislatures, “four years ago, a team headed by Dr. Joseph Ross from the Mount Sinai School of Medicine requested records from Minnesota and Vermont, the two states that make the records public.” The findings indicated that Minnesota’s records “were never audited and lacked substantial information.” The study also found that in Vermont “60% of the money changing hands was shielded from public scrutiny as a “trade secret.” Minnesota has since put the reports on line and has requested that reports be filed electronically.

The arguments offered against public reporting of gifts to physicians from pharmaceutical and medical device manufacturers include that: it will inhibit clinical trials, it will place companies at a competitive disadvantage with those in other states, it will violate laws governing protection trade secrets, companies will leave or not expand in the state, and it gives the state a reputation as being unfriendly to industry. There is no evidence that any of these dire consequences have occurred in those states that require gift reporting.

Hand-in-hand with gift bans or gift disclosure is the promising effort among some states known as academic or counter-detailing. This involves teams of physicians or nurse practitioners and pharmacists reviewing patient records with physicians who have a history of issuing high numbers of brand name prescriptions. The objective is to demonstrate that the physician could easily have chosen an older, less-expensive brand or generic drug that would be equally clinically effective and that the affordable prescription is more likely to be filled and used by the patient.

Certainly, Pennsylvania has the most extensive academic detailing program and has demonstrated success in countering the work of the corporate sector. However, given the significant discrepancy between how much drug and medical device companies spend on physician detailing vs. the state program, the effort seems a lot like the “war on illegal drugs” where billions are spent by the illegal drug cartels compared to the relatively small funding for law enforcement to fight drug trafficking. Nevertheless, the evidence seems to point to the benefits to taxpayers and patients to make a good faith effort to educate prescribers about alternatives to the higher cost brands.

### **The Massachusetts Experience**

Massachusetts, in 2006, enacted a landmark health care access law which, to date, has provided about 97% of residents with health insurance. From the beginning, legislators and state officials recognized that, for such an effort to be sustainable, upward spiraling health care costs – including prescription drug costs – needed to be contained. Consequently, earlier this year, Senate President Therese Murray proposed a comprehensive quality improvement and cost containment bill that included a ban on gifts to physicians, and established an academic detailing program, as well as a prohibition of prescription data mining.

Initially, there seemed to be very little opposition to these features of the bill. However, when the bill came up for Senate debate, some senators offered amendments that would have weakened these parts of the bill. Negotiations among senators, however, actually resulted in a stronger consumer protection bill passing which even included registration of those who sell pharmaceuticals and medical devices. The bill passed the Senate with a unanimous vote.

When the House of Representatives finally considered the bill near the end of the legislative session, the influence of the pharmaceutical lobby became apparent. The House version was significantly weaker, only requiring drug and medical device firms to certify that they were in compliance with the voluntary codes of their respective trade organizations – Pharma for the drug manufacturers and AdvaMed for the medical device industry.

The negotiations for a final bill involved the Senate President, House Speaker, Chairs of the Committee on Health Care Financing and their staffs. Finally, a conference committee was appointed and the recommendations formalized as a conference report. The total gift ban favored by the Senate gave way to public reporting of gifts over \$50 in value and outright prohibitions on certain gifts such as sports tickets and free travel. Unfortunately, the data-mining provisions were dropped, however the academic detailing with funding remained. The new law also directed the Department of Public Health to establish regulations governing relations between pharmaceutical and medical device companies and those who can prescribe medication that are “no less stringent” than the voluntary codes adopted by the two industries. The Department must also provide for penalties for violations and enforcement powers were given to the Attorney General, the district attorneys and the Department of Public Health.

With finalization of the conference report and its acceptance in both branches, the industry mounted a well-financed effort to try to defeat either the gift provisions or the entire quality

improvement/cost containment bill. A number of well-paid lobbyists descended on the State House, a full-page ad as well as Op-Ed articles appeared in the Boston Globe. Business groups such as the Greater Boston Chamber of Commerce, the Massachusetts Biotechnology Council, the Massachusetts High Technology Council, and the Associated Industries of Massachusetts all sent letters of opposition for what they termed “anti-business” provisions.

At best, the opposition said that Massachusetts state government was sending a “mixed message,” by approving a one billion dollar life science bill earlier in the session and then considering a bill that would have a “chilling” effect on economic growth by the life sciences industry. A group of House members led by the House Chairman of the Joint Committee on Consumer Protection and Professional Licensure, who also chairs the Legislature’s Biotechnology Caucus, tried to stop the bill at the enactment stage. Only the firm resolve of Senate President Therese Murray and the support of House Speaker Salvatore DiMasi prevented any further watering-down of the gift reporting language in the bill.

The pressure then shifted to the Governor’s Office, and industry CEO’s began personally lobbying him to veto the bill or return it to the Legislature with recommendations to drop the gift reporting provisions. To counter that intense pressure, consumer groups and health care advocates swamped the Governor with over 10,000 letters, phone calls and post cards urging him to sign the bill with the gift reporting requirements.

On August 8, 2008, Massachusetts Governor Deval Patrick signed into law one of the nation's strictest limits on gifts given to medical professionals by drug salespeople, by all accounts, the most contentious measure contained in a broad package intended to improve healthcare safety and curb skyrocketing costs. While some critics of the pharmaceutical industry had hoped to ban gift-giving altogether, arguing that the drug company largesse interferes with doctors' judgment in deciding which drugs to prescribe, all agreed that the new law was a major step forward.

### **The After-Glo of Victory**

Next, the debate shifted to the Department of Public Health for the promulgation of regulations to implement the new law. Medical device manufacturers have made a concerted effort to distance themselves from the marketing practices of drug manufacturers and argued for different standards for each industry. In fairness to DPH, their regulatory drafters were open to all sides in crafting the regulations as consumer advocates mounted an aggressive effort to counter industry lobbying.

Over this past weekend, the Department of Public Health released the long-awaited regulations. DPH officials wrote disclosure requirements into the draft regulations, but exempted research and some consulting activity from such disclosure. Under the draft regulations, which now go through a public hearing process before a vote of the Public Health Council as early as next February, the state provides new restrictions on meals and travel, bans gifts like pens and tickets, and imposes a reporting system for payments of at least \$50 for sales and marketing activities. Officials said their regulation package “largely tracks” the statutory provisions of the new law

Patrick signed in August. The draft regulations go before the council tomorrow, and the first of two public hearings is scheduled for Jan. 9.

As a result of the potential “loophole” permitting continued unreported drug company involvement in research, it is very likely that new, more restrictive legislation will be filed and that efforts will be made at regulatory hearings for further limits requiring greater disclosure of industry support of research activities. Of course, whatever regulations are developed by the Department of Public Health, they have to be enforced in order to send a clear message to the drug marketing personnel and their employers.

While no pharmaceutical or medical device manufacturer has announced plans to leave the state, and some have actually proceeded with plant expansion projects, the drug and medical device industries are still not happy by the developments in Massachusetts. The National Association of Pharmaceutical Sales Representatives, in an article published in the Boston Business Journal [October 13, 2008], rated Massachusetts as the “worst state” in which to pursue sales and marketing for the industry.

While I am proud of this designation, I also want to congratulate West Virginia, Vermont, Maine and New Hampshire who were also at the bottom of their list of friendly states. These states, as well as my home state of Massachusetts, are leading the way. We must strive to make every state house and state capitol building in America “drug free” from the perverse influence of the pharmaceutical and medical device industries!

### **New Hampshire Living Free of Data Mining**

While the victory over Big Pharma in Massachusetts was achieved through the Legislative and Executive route, another major victory was recently handed to the State of New Hampshire by the courts. The First Circuit of the U. S. Court of Appeals recently upheld the constitutionality of New Hampshire's first-in-the-nation law that restricts drug company access to some information about doctors' prescription writing habits.

The decision overturned a lower court decision that found that the New Hampshire law unconstitutionally infringed on free speech. Companies that collect, analyze and sell medical data claimed the law violated their free speech rights. These data-mining companies say the information they gather also is used by researchers, law enforcement and government agencies.

Among other things, drug company sales representatives use the information to target particular doctors and tailor their sales pitches. New Hampshire's law blocks those pitches by restricting access to data that identifies doctors and other prescribers.

Drug company salespeople use the data to identify doctors' drug preferences, whether they favor brand-name medicines over generics, and whether they have been willing to prescribe new drugs.

New Hampshire's law prohibits pharmacies, benefits managers, insurance companies and data-mining companies from selling or using prescription information that identifies doctors for commercial purposes, including influencing sales. Bulk data including prescribers' zip codes, location and medical specialties may be released.

The wording of the Appeals Court decision is really quite meaningful for those of us concerned about health care cost containment. The court said, "In combating this novel threat to cost-effective delivery of health care, New Hampshire has acted with as much forethought and precision as the circumstances permit and the constitution demands."

The appeals court decision will also apply to a similar law passed by Maine that was quashed when the lower court struck down the New Hampshire law. With the federal court decision in hand, we can expect a number of states to consider and enact their own versions of New Hampshire's anti-data mining law in the new sessions.

### **The Medical Wolf in Sheep's Clothing**

Generally, we see the physician as the passive target of drug marketers, simply going along with prevailing practice, enticed by a variety of often lucrative benefits for prescribing or attesting to the value of certain drugs. However, another side of the coin can be found in physicians who actively court drug company largesse.

At Harvard, for example, Dr. Joseph Biederman, whose research has led to huge increases in bipolar diagnoses in children – and the prescriptions to treat those children – is being asked why he allegedly failed to report \$1.6 million in fees from drug companies.

Only two weeks ago, the Boston Globe reported: "Newly disclosed court documents portray Dr. Joseph Biederman, a leading Harvard child psychiatrist, as courting drug company money by promising that his work at Massachusetts General Hospital would help promote the use of antipsychotic drugs for youngsters diagnosed with bipolar disorder."

The Globe described Dr. Biederman as "one of the central figures in the growing legal and political backlash against potential conflicts of interest in medicine, particularly in psychiatry."

Dr. Biederman, while not a defendant in the case, is a key witness in, what the Globe reports, is "a huge, multistate lawsuit brought on behalf of more than 2,000 patients, including children, who claim to have been injured by psychiatric drugs known as atypical antipsychotics, including the Johnson & Johnson drug Risperdal, also known as risperidone."

It is legal for doctors to prescribe drugs for off-label purposes, but not for drug companies to actively market such uses. To get around that restriction, drug marketers recruit and pay respected "opinion leaders" like Biederman to discuss their off-label prescribing experiences with colleagues at company-sponsored "educational" talks or meetings. This is clearly a loop hole crying to be closed!

## Conclusion

In recent years, and especially this year, we have witnessed some significant victories that will help to protect the doctor-patient relationship and promote ethical standards for both the marketers and the marketed. Much of the credit for these victories must be given to state legislators who have fought against, sometimes seemingly, impossible odds. However, our efforts have been supported by aggressive U. S. Attorney's in pursuit of fraudulent practices and by federal bureaucrats intent on containing health costs.

If the Obama-Biden Administration and the new Health and Human Services Secretary Tom Daschle want to tackle health reform and keep expanding access to care within the affordable range of American taxpayers, they will put the power of the federal government behind the strategic plan that has unfolded at the state level. Certainly, Tom Daschle's interest in promoting increased use of health information technology will provide an opportunity to develop a system that helps to better track those who violate ethical standards in drug marketing. However, if we are to see "change, we can believe in," applied to the spiraling cost of pharmaceuticals and medical devices, reform of the prescription drug and pharmaceutical device industries – governed by meaningful ethics codes and practices – will be critical to success. At the same time, the medical community needs to embrace change in this area as well if they want to retain the trust of the people of America.

If we were to send a letter to the President-Elect and the 116th Congress, I believe it should ask, at a minimum, that:

- The Drug Enforcement Administration (DEA) amend its draft regulations to regarding controlled substances to facilitate implementation of e-prescribing throughout the nation.
- The Food and Drug Administration (FDA) rescind the regulations permitting direct to consumer advertising of prescription drugs or, at a minimum, provide meaningful penalties and enforcement behind its "Violative and Promotional Labeling letters" to prevent false claims and inappropriate off-label use of medications
- Consideration of splitting the Food and Drug Administration into two agencies, given the growing importance of drugs in health care and the growing concern about food safety or, at least, ensuring adequate authority, staffing, and budget so that the critical mission or missions can be fulfilled. No regulatory body is more important than the FDA in protecting the health of Americans. The appointment of a strong, science-based commissioner who will ensure discipline and order to the regulatory process would send a positive message to consumers and advocates, and a clear message to the regulated industries.
- Amend Medicare Part D legislation to remove the ban and permit the federal government to seek competitive bids for medications purchased through Medicare in order to obtain the best price for taxpayers and consumers.

- Finally, that the White House and the U. S. Capitol Building become “drug-free” zones from the corrosive and corrupting influence of lobbyists for the pharmaceutical and medical device industries.

Thank you for your attention this morning. I look forward to the continued work of the Prescription Project and the National Legislative Association on Prescription Drug Pricing as we work with our states and the new Administration here in Washington to improve quality and safety, while containing costs, in health care.