



Testimony of Senator Richard T. Moore  
Senate Chairman of the Committee on Health Care Financing  
Relative to the Regulations Concerning Gifts from Pharmaceutical  
and Medical Device Manufacturers  
January 9, 2009

I am privileged to serve as Senate Chairman of the Legislature's Committee on Health Care Financing. In that capacity, I helped to craft Chapter 58 of the Acts of 2006, the Health Care Reform law and Chapter 305 of the Acts of 2008, the Health Care Quality Improvement, Cost Containment and Transparency law. I believe, therefore, that I can offer expert clarification regarding the legislative intent of Section 14 of Chapter 305. This section amended the General Laws by creating Chapter 111N which, in Section 2 directed the Massachusetts Department of Public Health to establish a marketing code for pharmaceutical and medical device manufacturers pursuant to the provisions included in Section 2.

When this law was drafted and finally enacted by the Legislature and signed by the Governor, I envisioned regulations that would continue to carry out one of the major themes of both of Chapter 58 [2006] and Chapter 305 [2008] namely, transparency. I have some concerns with several of the provisions of the regulations; however the most pressing concern is the loophole that has been created in section 970.009(1). The language states that all pharmaceutical or device manufacturing companies must disclose to the Department any fee, subsidy or economic benefit that the company provides to any recipient in connection with the company's sales and marketing activities. This language (coupled with the definition of "sales and marketing activities") effectively exempts pharmaceutical companies and device manufacturers from having to disclose any economic benefit they bestow upon a health care practitioner for research and clinical trials. The Commonwealth has a compelling interest in making sure those pharmaceutical or medical device industry payments, gifts, or other emoluments offered to health care practitioners are transparent and that such transactions are made accessible to the public. Patients and consumers generally have no idea what kind of relationships exist between their doctors and pharmaceutical companies or medical device manufacturers, relationships that result in billions of dollars per year in payments to health care practitioner. Any reluctance by the industry to disclose those relationships makes such relationships all the more suspect. It is imperative throughout this process that the Department remember that its primary objective is to protect the interests and the health of the residents of the Commonwealth.

The draft regulations contain several provisions that are indeed laudable:

- Setting strict parameters under which meals may be offered to health care practitioners,

- Tightly regulating payments permissible for CME events and educational conferences, and
- The prohibition of other payments or promotional gifts such as event tickets

These provisions all follow the letter of the law, while also effectively balancing the industry's need to provide reasonable compensation made in conjunction with research and clinical trials. Protection of these practices through regulation makes disclosure of these payments all the more important. While the draft regulations permit support of clinical trials and research, it must be clear in the regulations that only clinical trials and research governed by institutional review board principles, which include objective peer review, should be so exempted. Where there is no adherence to IRB principles and procedures, funding for such clinical trials or research must be subject to full disclosure. The legislature carefully considered the necessary support of the industry for evidence-based research and has permitted these types of payments to continue under carefully scrutinized circumstances. It is the responsibility of the Department to carefully define objective peer reviewed research and the need for disclosure and transparency of any other payments made under the guise of clinical trials and research, but which lacks the standards present through the IRB process.

Massachusetts has a history of setting the bar for the rest of the nation on many different policy issues, but most pertinent to this conversation is, of course, health care reform. However, in regards to the Department's efforts towards regulation of pharmaceutical and device manufacturer conduct, the federal government and many companies within the pharmaceutical industry are now surpassing our efforts.

The U.S. Senate's revised version of the Physicians Payments Sunshine Act has encouraged pharmaceutical companies and trade groups alike to support the payments disclosure initiative.

This Act (which will likely be re-filed in Congress early in the new session) would require drug and medical device manufacturers to report certain gifts and payments made to physicians including funding for clinical trials. The federal legislation's intent is to let patients decide whether healthcare provider prescribing patterns are influenced by monetary incentives from the pharmaceutical and medical device industries. Among the companies and groups in support of this legislation at the federal level are Eli Lilly & Company, AstraZeneca, Merck & Company, Pfizer, Johnson & Johnson, the Pharmaceutical and Research Manufacturers of America, the American Medical Association and the Advanced Medical Technology Association.

As a response to this legislation many of these companies have taken it upon themselves to disclose information about payments and clinical trial data. The following are several examples of such initiatives:

- Lilly has announced plans to launch, in 2009, an online registry of payments made to physicians who serve the company as speakers and advisors, and plans

to, by 2011, expand the reporting capabilities of the registry to resemble the Sunshine Act Legislation.

- Merck will post grants to patient groups and professional medical societies as well as educational grants on its website. Next year payments to physicians who serve as speakers will also be posted.
- Pfizer will disclose educational and charitable grants in addition to ending support for third-party CME.
- Johnson & Johnson has committed to disclosing payments for educational grants and to patient-advocacy organizations.

In addition to self-disclosure within the industry, information about clinical trials is already publicly available at ClinicalTrials.Gov. This online registry currently has 65,825 trials registered. All information contained on this website is easily accessible by the public as well as competitors in the industry. This kind of access coupled with recent initiatives taken by manufacturers within the industry diffuses the argument that stricter regulations mandating more transparency will force disclosure of proprietary trade secret information. Clearly there is a movement towards transparency within the pharmaceutical industry driven by the increasing awareness of consumers and policy-makers about the undue influence that payments to physicians can have on their prescribing habits. Fortunately, the industry is moving towards self-regulation, but the residents and consumers of Massachusetts deserve to have their government adequately represent their interests and concerns as a whole, and provide a uniform reporting and disclosure system.

The Congressional Budget Office has also weighed in on financial disclosure in their 2009 Budget Options for Healthcare, Volume 1. The CBO recommended that pharmaceutical and device manufacturers be required to disclose to the Centers for Medicare and Medicaid Services all relationships with physicians who participated in the Medicare program. The disclosure would include support for CME and relationships in which physicians were paid to lecture about specific drugs or devices.

The CBO incorporated two studies into their recommendations which support the belief that certain relationships between physicians and manufacturers may have unintended consequences. One study found that physicians' interactions with drug companies or their representatives were associated with rapid prescribing of newer, more expensive drugs and more limited prescribing of less expensive generic medicines.

Another study found that physicians who had had contacts with a drug company were more likely than other physicians to request that the company's drug be added to a hospital's formulary, even when the drug offered no therapeutic advantage over pharmaceuticals that were already on the list.

While the CBO makes it very clear that at this time they cannot estimate what kind of impact this kind of disclosure might have on Medicare spending, they do believe that over time it does have the potential to reduce spending. The Massachusetts Legislature shares that view.

The benefits of transparency, however, reach much further than just cost savings. As stated in a Journal of American Medical Association article on disclosure laws in Vermont and Minnesota, “By making disclosures public, legislators allow patients and physicians to answer questions posed in the guidelines jointly offered by the American College of Physicians and the American Society of Internal Medicine. When gauging the appropriateness of a payment, the guidelines suggest that physicians should ask, “What would my patients think about this arrangement? What would the public think? How would I feel if the relationship was disclosed through the media?”

I would hope that our Department of Public Health utilized these guidelines to gauge the appropriateness of payments, as well as the CBO’s recommendations which consider the potential cost-savings and validates the need for transparency. They would serve the people of Massachusetts well if DPH used them as a guide in creating transparency in provider/manufacturer relationships.

I believe that the limitations on disclosure in the regulations negate the original intent of the legislature. The regulations as currently drafted create a loophole that permits the industry to continue to make payments to healthcare providers with no oversight and no accountability. As Marcia Angell, former Editor-in-Chief of the New England Journal of Medicine recently wrote, “no one knows the total amount provided by drug companies to physicians, but I (Dr. Angell) estimate...that it comes to tens of billions of dollars a year. By such means, the pharmaceutical industry has gained enormous control over how doctors evaluate and use its own products. Its extensive ties to physicians, particularly senior faculty at prestigious medical schools, affect the results of research, the way medicine is practiced, and even the definition of what constitutes a disease.”

Any publication or information regarding the final regulations published by the Department of Public Health should include the text of Chapter 111N as well as the regulations so that the entire law and regulations are available to the public, providers and industry in one source. Furthermore, I believe that the Department would do well to compile a FAQ – Frequently Asked Questions on its web site along with this information to help to clarify points that might be raised during these hearings or in other venues.

Given the stakes, it is imperative that the final regulations reflect the necessity for disclosure of all kinds of relationships between health care providers and pharmaceutical companies. We understand that these regulations require a very delicate balancing act, but there are alternatives that will represent all interests more equitably

Equally important to the provisions of the final regulations is the commitment and the ability of the Department of Public Health, the Attorney General and the several District Attorneys to vigorously enforce the provisions of Chapter 111N and the regulations. Having a law and regulations on the books, without enforcement, will be no improvement over the

voluntary codes of the industry. In fact, this would only make the public more cynical about the relations between health care providers and the pharmaceutical and medical device industries. I can assure you that the Legislature intends to monitor the implementation of the new law and regulations, and we look to the Governor's FY 2010 budget to provide adequate support for the program.

We are committed to continuing to work with you to find the appropriate balance and hope that, in the end, the interests of the people that we represent will be protected.