



**Presentation of Kevin Lembo, State Healthcare Advocate
Before the Public Health Committee
Informational Forum
Marketing of Prescription Drugs
April 21, 2008**

Good morning Senator Handley, Representative Sayers, Senator Roraback, Representative Carson and members of the Public Health Committee. Thank you for inviting me to speak today on the marketing of prescription drugs. You can tell from the remarks of the speakers here today that while we ultimately have different positions on the value, need and requirements for the marketing of prescription drugs, we must all keep our focus on the goal -- the most efficient and effective healthcare for consumers.

As a state, and a nation, we are faced with the difficult challenge of integrating meaningful prescription coverage into overall health insurance in a way that does not perpetuate the explosion of prescription drug costs and over-utilization. At the same time we recognize the important advancement of prescription medications in the treatment of acute and chronic illnesses. Appropriate prescription drug treatment plans may actually save money. It is defining "appropriate" in this context and measuring the influence of marketing on prescribing patterns that brings us here today.

The marketing of prescription drugs, eight-five percent of which targets medical professionals, together with major increases in direct-to-consumer (DTC) marketing, have undoubtedly added to significant increases in utilization and cost. We should not be coy about this. Companies advertise a product to increase sales. No one has a quarrel with that practice generally. However, if our efforts to reshape healthcare and build efficiencies based on best medical practice are to be successful, we must know how much is spent; how it is spent; who benefits; and, what are the downstream consequences? We can not manage this issue solely on the demand side of the equation: increasing use of restrictive formularies and tiered co-payments or coinsurance levels. We must think about the supply.

There are significant ways, several of which are in control of state legislators, in which prescription drug costs could be better measured as a function of the amount of marketing to physicians and consumers while not impeding access to medically necessary drugs. One is tailored disclosure of pharmaceutical gifts to providers, something we can do on a state level. The other state level prerogative is to begin bulk purchasing which may not do much to eliminate broad marketing: but by the sheer volume of medications purchased, it should drive down the cost of drugs. Another is the reporting of health plan prescription drug trends in claim costs compared to the trends of other medical services and as a function of advertising. We should compare these trends to the price inflation of drugs as compared to other medical services. The last concept is to push for a federal ban

on DTC advertising.

Some might say that there's no evidence to show that the marketing of prescription drugs, either directly to physicians or by DTC marketing, has an effect on prescribing patterns and resulting claim costs. That view, however, is not supported by the research. While PhRMA makes an interesting point on its website that "experts have not found any relationship between drug marketing and drug price," the literature cited by PhRMA to support its statement actually concludes that, "DTC advertising has a significant effect on prescription drug **spending**." See:

What Goes Into the Cost of Prescription Drugs, June 2005,
available at: http://www.phrma.org/files/Cost_of_Prescription_Drugs.pdf and,

Demand Effects of Recent Changes in Prescription Drug Promotion, May 29, 2003,
available at www.kff.org.

While it may be true that the unit cost of certain drugs has not increased with the consumer marketing of drugs, the study cited by PhRMA concluded that DTC advertising between 1999 and 2000, for the largest 25 therapeutic drug classes, accounted for 12% of drug sales during that same period. Recent literature also raises concern about the FDA's decreased oversight of DTC advertising, pointing out the substantial decline in the percentage of DTC advertisements reviewed (down from 64% in 1999 to 32% in 2004) and the FDA's discouraging the submission by manufacturers of DTC materials for prior review (Donohue, J., et al., *A Decade of Direct-to-Consumer Advertising of Prescription Drugs*, N ENGL J MED 357;7, August 16, 2007). These decisions at the national level add to the urgency to do more as a state to protect consumers in prescription drug marketing.

The 2008 Segal Health Plan Cost Trend Survey, which includes data from the major insurers in Connecticut, reports that prescription drug trends in terms of claim costs have declined from a high of 19.5% in 2003 to approximately the same rate as those of PPOs and HMOs, about 10.9%. However, the Segal Survey also states that, "although brand drug utilization is rapidly shifting to generic drugs due to patent expiration and PBM efforts, brand drug inflation continues to be a major trend driver due to ongoing focus on development and marketing of biotechnology or specialty drugs." These specialty drugs are the ones advertised often today by celebrity actors – drugs for arthritis, cancer, osteoporosis, multiple sclerosis, etc. Though managed care entities and PBMs have been able in some cases to drive down costs by adopting formularies that primarily require the use of generics, the marketing of specialty drugs goes beyond the confines of most formularies. As a result, advertising by both the DTC and direct-to-provider methods promote the use of inordinately expensive specialty drugs -- sometimes without a rational clinical reason.

Health plans may respond to the demand by adopting new Tier 4 and even Tier 5 levels of drugs in their formularies, as reported last week in the New York Times, resulting in huge co-insurance tabs for enrollees and increased health plan expenditures.

While no one wants to prevent the use of improved medications that treat conditions more effectively and in an overall cost-efficient manner, the DTC marketing of specialty drugs creates a demand that can only be moderated by a physician's accurate, and uninfluenced, understanding of the product.

We would like to see legislation similar to that proposed last year requiring 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 that will give DPH the ability to gather and report information. The reporting could be tailored to require gift and incentive reporting by drug manufacturer and specific drug. This reporting could then be linked to the number of prescriptions written or claims processed for the specific drugs by health plans to determine what association the gifts and incentives have to prescription writing and utilization.

Disclosure requirements for pharmaceutical companies are 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 and efficacy of specialty drugs. 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 that are expensive and make the process suspect. The latest and "greatest" drug is often not the best, but always the most expensive – adding unnecessary cost the system.

Requiring disclosure by drug companies of gifts to doctors is not an attempt to blame healthcare providers for writing prescriptions that may be related to the marketing of prescription drugs. We acknowledge that our medical providers are already under tremendous pressure, and do not want to subject them to additional reporting requirements. Nor is this an attempt to deny pharmaceutical manufacturers the right to responsibly market their products, or to educate providers, but our vision of disclosure puts the reporting burden where it should be, on the drug companies. We need to be able to measure the impact of marketing.

We should still permit free samples and payments for participating in clinical trials. This is especially important for those patients who do not have insurance and for ongoing medical research. However, the company would have to report the total number of free samples provided for a specific drug and dosage.

This gift and incentive disclosure requirement is a simple but effective tool to contain costs and improve clinical practice. It can help ensure that medications are prescribed based on effectiveness and cost-efficiency – the hallmarks of system reform.

Ultimately, we would prefer to see federal ban on DTC advertising. Presently, only the U.S. and New Zealand think this kind of advertising is a good idea. There is not enough information presented in most commercials or magazine ads for a consumer to make an informed decision. The billions of dollars spent on this advertising not only add

expenses to the system for the advertising itself, but also for the increased utilization of the medication, a portion of which may be unnecessary. The cost must be passed on, and so it is, to health plans, and to consumers. We would like to see the money that is currently spent on advertising redirected into additional research. Physicians should be educating consumers. After all, prescription medication is no ordinary product – it should not be treated as an ordinary product for advertising purposes.

If it is true, as PhRMA suggests in its April 2008 publication: *The Facts About Pharmaceutical Marketing and Promotion*, available at <http://www.phrma.org/files/MarketingandPromotion.pdf>, that pharmaceutical sales marketing (which includes gift giving) to providers only influences the prescribing decisions of 14% of physicians, or alternatively that 13% of physicians consider the pharmaceutical companies' information very important when prescribing, then why are the companies continuing to spend approximately \$12 billion per year to promote their drugs? Even PhRMA acknowledges that only between 2 - 7% of people who have seen DTC advertising for medications receive a prescription. PhRMA uses these conclusions to bolster its argument that advertising does not have a major effect on prescribing patterns. However, these data show that physicians and consumers are influenced by the \$12 billion in advertising, and that the value of influencing 13% of physicians must mean a financial return of more than the \$12 billion spent on the ads. If you're PhRMA, you say – money well spent. If you're an advocate, you say – money maybe better spent elsewhere. Since we don't have Connecticut specific data on these patterns, a disclosure requirement on DTC advertising in Connecticut could tell us whether these statistics hold true for our state or are potentially greater. We need to know the answer, and at the same time hold the gift-giving and marketing down by providing an incentive for the drug companies not to provide excessive gifts or to decrease their DTC advertising.

It is important to note that the effort to contain prescription drug costs and to ensure medically necessary drugs are available should not stop at reporting. We need to develop counter-detailing programs in Connecticut that aim to provide noncommercial education to physicians and pharmacists about drugs. As I have shared with you before, West Virginia and Pennsylvania, through its Independent Drug Information Service, provide an alternative to physicians for more objective information on particular categories of drugs and prescribing – no longer relying on the company drug representative.

We should also begin the lengthy and technical task of creating a statewide drug formulary for all state purchased pharmaceuticals based solely on an evidence-based purchasing strategy. We should also consider making the \$100,000 investment in the Drug Effectiveness Review Project, based in Oregon, where they are sorting through classifications of drug by using independent research to measure effectiveness and cost. As you might imagine, the initial information as reflected at Consumer Reports "Best Buy Drugs" program, shows that the newest and shiniest medication does not always offer the best clinical outcome, but is always the most expensive. We should expand the use of generic drugs through work on the State Generics Substitution Law, including a physician education component. Lastly, we must pass an outright ban on the sale of

provider prescribing data by pharmacies to the pharmaceutical industry. This information is used for intense, micro-marketing to providers. A law was passed in New Hampshire in 2006 to restrict the sale of individually identifiable information included in the prescribing data, and although the was initially successfully challenged by PhRMA in federal court (IMS Health Inc. v. Ayotte, 490 F.Supp.2d 163, (D. NH. April 30,2007), the case was appealed by New Hampshire to the First Circuit Court of Appeals. The case has been argued and a decision should be forthcoming soon.¹ In a similar law in Maine, the U.S. District Court stuck down portions of the Maine law.

Thank you for your attention, and for the opportunity to spend time with you today.

¹ In a similar law in Maine, the U.S. District Court stuck down portions of the Maine law. IMS Health Corp. v. Rowe, 532 F.Supp.2d 153 (D.Me. Dec 21, 2007). This case is also ongoing.