

**Testimony by
Richard F. Daines, M.D.
New York State Commissioner of Health**

**Public Hearing:
Prescription Drug Marketing
and Purchasing Reform:
The Impact on Accessibility and Affordability**

**Conducted by
Assembly Health Committee
Richard N. Gottfried, Chair**

**Assembly hearing room
250 Broadway – 19th Floor
New York, New York**

**February 1, 2008
10 a.m.**

**Assembly Prescription Drug Marketing Hearing
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I. Introduction

Thank you, Chairman Gottfried and members of the Assembly Health Committee, for inviting me to speak on this important topic today.

Over the last decade, tremendous strides have been made in the development of new drugs that treat many of the most serious diseases and conditions.

Many of us know someone who is alive today because of one of these new wonder drugs. They extend life, they help keep people out of hospitals, and they help manage and treat chronic diseases.

That's why it's so important that we make sure that New Yorkers continue to have access to the most effective medicines available.

But, increasingly, getting access to affordable, effective prescription drugs is a challenge for consumers, government, employers and other payers of health care. As you mentioned in the notice for this hearing, the cost of prescription drugs in the U.S. continues to skyrocket, dramatically outpacing inflation.

In New York, spending for prescription drugs is among the fastest growing segments of the Medicaid program, accounting for about \$3 billion in annual spending. The State spends another \$800 million on prescription drugs for seniors.

Certainly, factors are at play that we have little or no control over. An aging population, longer life spans and the accompanying high rates of chronic disease are increasing the demand for effective medicines and contribute to the high rate of spending on prescriptions drugs.

The cost of prescription drugs is also affected by appropriate investment in research and development by the pharmaceutical industry, as well as by the resulting patents to protect their investment.

But I think we're here today to discuss undesirable factors and behavior that contribute to the high cost of drugs and to consider possible measures that will ensure that prescription drugs in New York State are affordable, accessible and effective.

In my testimony today I will highlight industry behavior that contributes to the cost of prescription drugs.

I will also describe some initiatives that are included in Governor Spitzer's proposed budget aimed at ensuring that New Yorkers get the right prescription drugs at the right price.

Lastly, I will discuss some additional bills in the Legislature that are being discussed as possible ways to promote integrity, accountability and affordability in the prescription drug sector.

II. Marketing

An area that is increasingly drawing scrutiny is the effect the pharmaceutical industry's huge investment in advertising and marketing has on physician prescribing patterns and, ultimately, the cost and appropriate prescribing of prescription drugs.

Pharmaceutical companies commit vast resources to marketing prescription drugs, possibly even outpacing their investment in research and development.

According to documentation cited in the New Hampshire court case known as IMS Health versus Ayotte:

"In 2000 the pharmaceutical industry spent approximately \$15.7 billion on marketing."

"More recent estimates suggest the industry currently spends between \$25 billion and \$30 billion per year on marketing. The large pharmaceutical companies spend roughly 30 percent of their revenues on promotion, marketing, and administration, while spending only approximately 13 percent on research and developments."

The goal is to influence the consumer's preference for certain drugs when visiting their physicians.

Consumers aren't the only targets of prescription drug advertising and marketing.

According to the court case I cited earlier, of the \$15.7 billion the pharmaceutical industry spent on marketing in 2000, \$4 billion of that amount was dedicated to marketing directed at physicians.

As a physician and a former hospital CEO, I personally observed the various forms this marketing takes. They include:

- Offers of free drug samples, gifts and other perks – ranging from pens to expensive trips and hotel accommodations.
- Paying doctors to:

- Give lectures and hospital grand rounds that tout specific drugs;
 - Allow ghost written articles touting specific drugs published in non-peer reviewed journals under their name; and
 - Enroll patients in valueless “clinical trials” or to participate in other sham “research” and “consultation” services.
- Big Pharma interests even infiltrate development of clinical guidelines that then result in increased use of a particular drug. The authors of a New England Journal of Medicine article last year demonstrated that guideline development for the treatment of sepsis was orchestrated by Eli Lilly as an extension of a marketing campaign for Lilly’s drug, Xigris (*Surviving Sepsis; NEJM 10-19-06*)

In a 2001 survey of physicians by the Kaiser Family Foundation, 92 percent of physicians indicated they had accepted free drug samples.

Some 61 percent of physicians admitted to receiving meals, free travel, or tickets to entertainment events.

In a book published last year called “Hooked,” Dr. Howard Brody likens the relationship of the medical profession to the pharmaceutical industry -- and the gifts and rewards that it dispenses -- as an “addiction.”

Dr. Brody writes:

“There is some connection between drug prices and the industry-profession relationship. Some behaviors of physicians work to drive up drug prices.”

In this environment, it would be difficult for the prescribing behavior of physicians *not* to be influenced by the pharmaceutical industry.

I find this particularly troubling in cases where that influence results in physicians prescribing a more expensive drug for a patient when a less expensive but just as clinically effective drug exists on the market.

So these are a few of the concerns about marketing tactics by the pharmaceutical industry and their impact on prescribing and cost.

III. Current DOH/Governor's Initiatives to Improve Affordability & Accessibility

In New York State, Governor Spitzer recognizes that unless we can make health care more affordable, we won't be able to achieve our goal of providing all New Yorkers with access to high-quality health care.

In his proposed budget, Governor Spitzer builds on last year's steps to improve health care affordability, accountability and quality.

These include several measures to achieve savings and improved quality in the use of prescription drugs.

Helping Physicians Make Better Prescribing Decisions

Some of the proposals are designed to help physicians make better prescribing decisions.

Expanding Preferred Drug Program

For example, the Governor's budget would expand the existing Medicaid Preferred Drug Program to include new classes of drugs.

Assemblyman Gottfried, I know you spent a lot of time and effort enacting this program, which identifies a list of drugs that are rated as "preferred" by a Pharmacy and Therapeutics Committee made up of physicians and other clinicians.

The purpose of this program is to identify the most effective and less costly drugs within a certain class of drugs.

Prescribers are expected to use these drugs when prescribing unless they determine that another drug would be more effective for a particular patient, in which case the physician prevails.

Expanding Clinical Drug Review Program

The Governor's budget would also expand the existing Clinical Drug Review Program in the Medicaid program.

The Clinical Drug Review Program is aimed at ensuring that prescription drugs are utilized in a medically appropriate manner.

The expanded Clinical Drug Review Program will add new drugs to a list of drugs identified as having known safety issues, public health concerns and

potential for abuse. Examples of these drugs include human growth hormone and Lidoderm, a patch used for treating pain.

Enhancing Retrospective Drug Utilization Reviews

Another program aimed at educating providers would enhance the State Health Department's current Retrospective Drug Utilization Review Program.

Appropriate prescribing practices lead to improved health outcomes. The Drug Utilization Review Program assures that prescriptions for Medicaid patients are appropriate, medically necessary, and not likely to result in adverse medical consequences. We are equally concerned about underuse of effective drugs for certain conditions as we are about overuse of less effective and potentially dangerous drugs.

Our efforts will identify cases where well established prescribing protocols are not being followed and communicating the results with the physician.

Academic Detailing

Another new program included in the Governor's budget – called **Academic Detailing** – is designed to counter the marketing tactics of pharmaceutical companies.

Here's how the program will work: Health care professionals will visit physicians and provide evidence-based, non-commercial information about medications for the sole purpose of improving prescribing and patient care. Educators will not be affiliated with a drug manufacturer, they will not be reimbursed based on sales performance and there will be no pharmaceutical company funding.

Pilot Data Exchange

Another initiative seeks to improve patient safety and outcomes through the review of patients' medication histories.

This is a pilot program involving the State Health Department and the New York City Department of Health and Mental Hygiene. With the patient's written consent, a doctor participating in the pilot would be able to electronically retrieve the most recent 90 days of that patient's Medicaid reimbursed prescriptions.

This leading edge pilot makes prescription drug data available to physicians at the point of care in order to increase patient safety and save both doctors and pharmacists valuable time. Each year, millions of Americans seek hospital or doctor treatment as a result of an adverse drug event including drug interactions. Many of these adverse events can be prevented if the physician has

accurate and timely information about the prescription and non-prescription medications that the patient is taking.

Medication Therapy Management

The Budget also includes a Medication Therapy Management initiative to help patients become better consumers of prescription drugs by adhering to medication therapies, especially when they are using multiple medications.

Under this program, specially trained pharmacists will be paid to provide one-on-one counseling with patients to identify medication problems and improve compliance with drug therapies.

This program would first be piloted in a geographic region, such as the Bronx, where data on hospitalizations and other medical treatment indicate poor drug management of patients' medical conditions, such as asthma.

Right Prices for Right Drugs

Finally, other Budget measures will ensure that New York pays the right prices for the right drugs.

Specialty Pharmacy

One measure will involve obtaining certain specialty drugs at a reduced cost.

Specialty drugs are expensive but effective bio-engineered drugs used for treating certain conditions. For example, the drug Humira (generic adalimumab) can have a significant impact on rheumatoid arthritis.

Under this proposal, the Medicaid program will contract with speciality pharmacies to buy drugs at a reduced cost. Specialty pharmacies will be required to ensure safe and timely delivery of medications, in most instances to the location where the drug will be administered.

Manufacturer Rebates

Bulk Purchasing

The Governor's State budget includes a bulk purchasing provision. Assemblyman Gottfried you were an early proponent of bulk purchasing. As a major purchaser of prescription drugs, the State Health Department will seek to leverage the state's combined market power to purchase prescriptions at a lower price through bulk purchasing.

EPIC Discount Card

The last Budget initiative would fill a major gap in prescription drug coverage for non-elderly low-income, uninsured New Yorkers.

This program will allow uninsured individuals to obtain an EPIC discount prescription drug card regardless of age. The card will entitle the recipient to pharmacy and manufacturer discounts when purchasing prescription drugs at the pharmacy.

IV. Other Legislative Proposals

We are reviewing the legislative proposals highlighted in your hearing notice and look forward to continuing discussions about these bills.

Require Pharma Gifts Disclosure

Other proposals would ban all gifts to physicians by the pharmaceutical industry or require drug companies and physicians to publicly disclose those gifts.

For example, physicians might change their behavior of accepting gifts and payments from pharmaceutical companies if they were required to disclose the extent of those gifts on a public web site.

Consumers might also think twice about selecting a physician they learn accepted \$20,000 in the past year from pharmaceutical companies.

Sale of prescription drug information

These include proposals that would limit the sale of information listed on prescriptions that identifies specific patients and prescribers.

Specialized pharmacy-information companies buy prescription data from local pharmacies on what drugs individual doctors are prescribing and then sell the information to pharmaceutical companies.

Pharmaceutical companies then provide the information to their drug reps, who use it to target their messages and visits to physicians.

Public Disclosure of Clinical Trials & Studies

When Governor Spitzer was Attorney General, he brought a major case against GlaxoSmithKline on grounds the company had deliberately concealed the results of four studies of the antidepressant drug Paxil, which showed that it either did not work well or caused harm when used by adolescents or children.

The outcome of the lawsuit was that the company was required to post objective descriptions about the outcomes of nearly all the clinical trials on virtually all of their drugs on a publicly available web site.

In the book, "Hooked," that I referred to earlier, the author calls this case a "tipping point" in countering the abuses of the pharmaceutical industry. I'm pleased to tell you that we convinced the attorney who led this case, Rose Firestein, to join our staff.

Last year Congress created a clinical trials results database containing much of the same kinds of information that GlaxoSmithKline was required to provide as a result of this case. This federal law, however, restricts states from taking similar actions.

IV. Conclusion

Many positive steps have been implemented or proposed to protect the safety of New Yorkers as well as improve the accessibility and affordability of prescription drugs. I've discussed several here today.

Additional measures are being proposed or are under consideration by members of this committee and other members of the Legislature.

There is no higher priority than ensuring that New Yorkers have access to high-quality affordable health care. The Department of Health stands ready to work with you to achieve this goal.

Thank you.