

Opening Statement of Senator Herb Kohl  
Special Committee on Aging Hearing  
The Generic Drug Maze: Speeding Access to Affordable, Life Saving Drugs  
July 20, 2006

I call this hearing to order and welcome our witnesses. As always, I thank my Chairman, Senator Smith, for the opportunity to put together this hearing. If other Committees could operate in the same spirit of comity and bipartisanship as Senator Smith runs this Committee, I believe we would have far fewer problems in the Senate today.

I want to offer a special welcome to Commissioner Liebowitz. As many of you know, Jon served for years as my Chief Counsel on the Senate Judiciary Committee. Jon, it is a great pleasure to see you here – but it is even a greater pleasure to control the red light that can cut off your comments. That's more power than I ever had during our time together in the office.

Today, the Committee will examine the bureaucratic and legal barriers that stop new generic drugs from entering the market – and what we can do about them. This is of particular interest to the Aging Committee as we work to help seniors cope with the high costs of prescription drugs.

But rising drug prices don't just harm the elderly – they hurt us all as they undermine our private and public health systems. Health insurance premiums continue to skyrocket, largely due to escalating drug costs. And the federal government, with the new Medicare prescription drug benefit, feels the squeeze as well.

Yet, the pharmaceutical industry remains one of the most profitable industries in the world, returning more than 15% their investment. As a businessman myself, I respect an industry's right to maximize their profits. But they are charging Americans the highest drug prices in the world, forcing employers to drop health coverage for their employees and squeezing the budgets of state and federal governments. Just as in the case of price gouging and the oil industry, Congress must act when companies manipulate the private market in a way that does so much public damage.

According to the Congressional Budget Office, generic drugs save consumers \$8 to \$10 billion every year. Just last week, the Committee heard from Richard Wagoner, CEO of GM, who could not state strongly enough how important using generic drugs were in reducing GM's health costs. GM employees and retirees substitute generic drugs for brand name drugs in 90% of the cases in which a generic exists, and each percentage increase in generic use saves them \$4 million per year. That's nearly \$400 million dollars in savings every year as a result of generic drugs for GM and their workers.

Today we will hear testimony from analysis by PCMA that seniors and the Medicare Part D program could potentially save, at a minimum, more than \$23 billion

dollars over the next five years as at least 14 major brand-name drugs commonly used by seniors are slated to become available in generic form. Of course, these savings are in danger if we don't ensure those generic drugs get on the market and are of course utilized under the Medicare Drug benefit.

One way to allow more consumers to realize these sorts of savings is for Congress to monitor more closely and adequately fund FDA's Office of Generic Drugs. Earlier this year, the FDA had a backlog of more than 800 applications to bring new generic drugs to the market – an all time high. And this number continues to grow as more and more brand drugs lose their patent protections.

According to FDA guidelines, the agency should take no longer than six months to review a generic application, yet the wait averages nearly two years. I have been working with FDA to cut this time down. Earlier this year, I was able to add \$10 million for generic drug review at FDA in the Agriculture Appropriations bill and will fight to keep those additional dollars in conference. While, increasing funding for this program is step one, I'm pleased the Director of the Office of Generic Drugs is here today to outline steps two, three, and four, so we can get generics to pharmacy shelves as soon as possible.

Since passage of the Drug Price Competition and Patent Term Restoration Act, commonly referred to as Hatch-Waxman, we've seen wider availability of generic drugs with little affect on the profitability of drug manufacturers and their ability to do research and development. Unfortunately, brand name pharmaceutical manufacturers have learned to circumvent Hatch-Waxman, using litigation and other means to extend the life of patents and keep generics from entering the market. Courts and the FTC have determined that some brand name drug manufacturers even collude with generic drug manufacturers to delay the marketing of competing generic products.

One form the collusion takes is pay-off settlements -- a drug company that holds a patent on a blockbuster, brand name drug pays a generic drug maker off to delay the sale of a competing generic drug. While the brand name drug company and the generic manufacturer make out like bandits, patients lose big-time.

The FTC has taken a strong stand against these types of pay-offs, but they still flourish because of recent court rulings allowing the back -room deals. I've introduced bipartisan legislation, the Preserve Access to Affordable Generics Act, to prohibit these pay-offs once and for all. Today, I hope to talk about my bill, as well as ways to address other practices used by the drug industry to delay generic drug entry to the market.

We cannot profess to care about the high cost of prescription drugs while turning a blind eye to backlogs at the Office of Generic Drugs and anticompetitive backroom deals between brand and generic drug companies. Today, at this hearing, let's ally ourselves instead with the consumers – and especially the elderly – whose lives and health we can markedly improve by increasing access to affordable generic drugs. And

let's ally ourselves with employers, whose ability to provide quality, affordable health care can improve by increasing access to affordable generic drugs.

We look forward to hearing from our witnesses and now turn to Chairman Smith for his opening statement.