

## STATEMENT OF CHAIRMAN GORDON H. SMITH

U.S. Senate Special Committee on Aging Hearing  
“The Generic Drug Maze: Speeding Access to Affordable, Life Saving Drugs.”  
July 20, 2006

Good morning.

I would like to thank Senator Kohl for holding today’s hearing. I appreciate his work in this area—as helping seniors gain access to more affordable prescription drugs is an issue we jointly support.

The most significant problem facing our nation’s health care system is rising costs of care. For many years now, the price of health care has grown faster than the overall rate of inflation. In fact, from June 2004 to June 2005, prices for health care grew at a rate almost double that of other types of consumer goods.

Driving much of this growth in costs are prescription drugs. Prices for brand name prescription drugs have grown four percent since January of this year. For some medications, like the sleeping aid Ambien, increases have been in the double digits.

If this trend holds, seniors’ access to important drug therapies will be severely undermined. The gains we have achieved with the implementation of Medicare Part D will soon be lost if we can’t control the skyrocketing prices of prescription drugs.

Generic drug alternatives hold the promise of providing consumers more affordable options. The Congressional Budget Office estimates that generic drugs save health consumers \$8 to \$10 billion every year. With a number of popular brand-named drugs going off patent in the next several years, Americans—and the federal government—could save billions more dollars by choosing to purchase generic alternatives.

Such savings will only be realized if these drugs get to market in a timely manner. There have been a number of troubling reports lately that indicate the generic drug approval process is not working as it effectively as it could be.

The Office of Generic Drugs at the Food and Drug Administration—whose Director will be testifying today—has a backlog of over 800 applications. Records also show that the approval process is also taking longer than in previous years. Yet, it claims to have the necessary resources to do its job effectively.

Given the potential cost-savings that could be gained by getting more generic drugs to market, Congress needs to carefully consider whether it is appropriately funding the FDA’s approval activities.

An even greater impediment to generic drug access is the growing number of brand name drug companies that are paying generic manufacturers to delay entry into the market. The Supreme

Court's recent refusal to hear an appeal brought by the Federal Trade Commission against a brand name drug company for making such payments suggests current law may not be clear on this issue.

As Senator Kohl noted, Congress is already taking steps to prohibit brand name drug companies from entering into agreements with generic manufacturers that could delay the market entry of a more affordable drug option.

I look forward to hearing more about this effort as well as others that seek to provide greater access to more affordable prescription drug options.

Senator Kohl has assembled a fine group of witnesses today and I know they will provide us with useful input on this issue.

Thank you.