Monday, October 28, 2002

Volume 38, Issue 43; ISSN: 0511-4187

Remarks on prescription drugs
George W Bush

October 21, 2002

The President. Good morning. For more than a year, the Federal Trade Commission has investigated delays and abuses in the process of bringing generic drugs to the market. I have reviewed the FTC findings, and I am taking immediate action to ensure that lower cost, effective generic drugs become available to Americans without any improper delays. By this action, we will reduce the cost of prescription drugs in America by billions of dollars and ease a financial burden for many citizens, especially our seniors.

I appreciate so very much the Secretary of the Department of Health and Human Services, Tommy Thompson, for his good, steady, and hard work on this issue.

Secretary Thompson. Thank you, Mr. President.

The President. I want to thank Les Crawford, who is the Deputy Commissioner of the FDA, who so ably led this agency for the last year. I appreciate your hard work, Les. And I'm proud, also, that Mark McClellan is with us, who is the newly confirmed FDA Commissioner. Mark has been on my staff with the Council of Economic Advisers, and he will soon take over the FDA to work with Les to make sure the policy I'm announcing is fully implemented.

We live in an age of miracle drugs. Millions of Americans and citizens from many other lands, for that matter, have found healing and hope from medicines discovered and created in this country. New drugs allow children with rheumatoid arthritis to walk and to go to school. New drugs shrink cancerous tumors, and they control the advance of HIV, slow the progression of multiple sclerosis. In the treatment of many diseases, major surgery has been replaced by a single pill. And this has been a special blessing to many Americans, particularly our seniors, who are living longer and better lives.

As a nation, we are committed to encouraging the promise of new miracle drugs in two different ways. First, we recognize innovators must be able to be financially rewarded for their creativity and hard work so they will continue investing and researching, putting new resources and talents in the creation of new drugs. Every time we hope for a cure or a breakthrough, we're counting on the success of a researcher and the success of a drug company. Second, we want these breakthroughs to become affordable and widely available, Both of these goals, innovation and accessibility, are essential; both are possible.

In America, one of the ways we reward innovation is by granting a patent. If you take a risk and you make an investment and succeed,

you have the exclusive right to sell what you invent, and you have the right to profit if you can. A new drug can cost as much as $800 million to develop and bring to the market. Without patent protection, few would take such a risk, few would be willing to invest. With patent protection, America's brand-name drug companies have become the greatest in the world, and health care systems around the world depend on American innovations they could not possibly duplicate.

Patents, of course, expire after a number of years, and this is one of the ways we are able to make drugs more accessible. After the patent expires, other companies are free to offer the drug in generic form at far lower prices. Last year, the average brand-name drug cost more than $72 per prescription. The average price for generic drugs, which are just as safe and effective as the brandname drugs, was less than $17 per prescription. Generic drugs make America health care far more affordable.

Current Federal law and regulations attempt to carefully balance the goals of innovation and accessibility. New drugs, on average, are sold for 11 years under patent protection, then generic versions become available. Unfortunately, the careful balance of the law is being undermined.

The FTC investigation discovered that some brand-name drug manufacturers may have manipulated the law to delay the approval of competing generic drugs. When a drug patent is about to expire, one method some companies use is to file a brand new patent based on a minor feature, such as the color of the pill bottle or a specific combination of ingredients unrelated to the drug's effectiveness. In this way, the brand-name company buys time through repeated delays called automatic stays that freeze the status quo as the legal complexities are sorted out.

In the meantime, the lower cost generic drug is shut out of the market. These delays have gone on, in some cases, for 37 months or 53 months or 65 months. This is not how Congress intended the law to work. Today I'm taking action to close the loopholes, to promote fair competition, and to reduce the cost of prescription drugs in America.

The Food and Drug Administration is issuing a proposed rule that will permit only one automatic stay per generic drug application, a move that in many cases will reduce the public's wait for generic drugs by years. Some patents will no longer be entitled to protections like the 30-month stay, including patents on packaging and others that have little or nothing to do with valuable innovation and drug therapy.

These steps we take today will not undermine patent protection. Instead, we are enforcing the original intent of a good law. Our message to brand-name manufacturers is clear: You deserve the fair rewards of your research and development; you do not have the right to keep generic drugs off the market for frivolous reasons.

Over the next 3 years, about 200 drug patents are set to expire. By

cutting out delays and maneuvering, our reforms will yield cost savings of more than $3 billion a year. Those savings will come to employer health plans, to State Medicaid programs, and to seniors when they buy medicines on their own.

This is another important advance in the cause of bringing affordable prescription drugs to our seniors. Already, we have cleared the way for States to provide prescription drug coverage to more seniors with modest means through our Medicaid Pharmacy Plus Program. We're working to provide seniors on Medicare with drug cards that provide discounts from drug manufacturers on brand-name drugs, like the ones available in private health plans. And we will not rest until we've reformed and strengthened the Medicare program, itself, so that a prescription drug benefit is available to every senior in America.

The House of Representatives took strong action in passing legislation to improve Medicare. The Senate failed to act. The challenge of health care reform is to increase access to quality care, while we preserve the finest health care system in the world.

I thank the good people at the FTC and the FDA for helping in this effort and for working to make these critical drugs more affordable for every American.

Thank you for coming.