



AMERICANS FOR TAX REFORM

# LEGISLATIVE ALERT

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**TO:** Congress  
**FROM:** Grover Norquist, President  
Americans for Tax Reform  
**DATE:** July 18, 2002  
**RE:** **The assault on medical innovation**

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*I am enclosing an article from National Review Online entitled "Hazardous to Your Health: The Assault on Pharmaceuticals" by Peter Ferrara.*

*The debate over prescription drug plans is reaching a climax this week. I am worried that some in Congress are playing a dangerous game with the future of medicine—some only want a political issue at the expense of medical innovation.*

*Please read the attached article which outlines a careful review of the facts before coming to any conclusion on casting votes.*

*Most importantly, bear in mind that **ATR will be monitoring all votes taken on this issue, especially those that create new regulations and price controls—they are hidden taxes.***

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July 18, 2002, 9:15 a.m.

## **Hazardous to Your Health**

The assault on pharmaceuticals.

By Peter Ferrara

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The Senate opens debate on rival Medicare prescription-drug plans this week. That debate could be a killer — literally.

At issue is an even bigger problem than the high costs of a new prescription-drug entitlement. The problem is that the regulations and potential price controls liberals are insisting must be added to the plan may well end up shutting off the wellspring of new miracle drugs now being generated by America's pharmaceutical companies. And this is just one aspect of a more general assault on the pharmaceuticals — all of which adds up to a serious threat to the public health.

The pharmaceutical companies are providing growing numbers of miracle drugs that save or dramatically improve the lives of those suffering from debilitating diseases. One experimental vaccine, for example, may be able to boost levels of HDL, the good cholesterol, by blocking its transition to LDL, the bad cholesterol that ultimately causes heart attacks and strokes. A newly developing gene therapy would prompt the body to grow new blood vessels to bypass blocked arteries without surgery. And another experimental drug has been shown to cut fatal blood clots in half among those undergoing angioplasty to clear clogged arteries.

Also in the pipeline, moreover, are 402 new anti-cancer drugs, many of which will obviate the need for frequently destructive radiation and chemotherapy treatment. These include 60 new drugs for lung cancer, 59 for breast cancer, 52 for prostate cancer, and 56 for colon cancer.

A new oral drug is now being tested to stop the growth of solid tumors in children, which could potentially counter the deadliest disease afflicting the young. Another drug would sharply reduce asthma attacks among the 7.7 million children who suffer from them. Still another would cut off the infections among children that cause rheumatic fever and toxic shock syndrome.

Thirty medicines in development will control the epidemic of diabetes, which affects 20 percent of all seniors. Another 14 will address chronic obstructive pulmonary disorder, the fourth leading killer in America. Still another 17 drug innovations will address the tragedy of Alzheimer's disease. Other new drugs would stop the blindness caused by macular degeneration and diabetes retinopathy.

Given the advances of modern biomedical research, these developments will only accelerate, producing a revolution in the capacity of modern medicine to save and improve lives. At some point in the near future, your own life — or the life of a parent or child — may well be saved by one of these cutting-edge miracle drugs.

Last year alone, America's pharmaceutical industry invested an astounding \$30.3 billion to research and develop these new miracle drugs. No one else is going to be able to do this nearly as well — certainly not the U.S. government, or the socialized-medicine systems of other Western countries.

But this private American industry of miracle-makers is now under assault from all directions. Many people apparently want the miracle medicines without paying for them, or without paying nearly enough to keep them coming.

All sorts of charlatans are rushing forward to posture as champions of the poor, the sick, and the needy by attacking the pharmaceuticals. But all these self-appointed saviors put together have never produced a single drug or medicine that has ever benefited anyone.

Take the developing congressional debate over a Medicare prescription-drug plan. The leading Democratic plan in the Senate would subject the covered drugs to rigid price controls and inadequate reimbursement schemes. Moreover, a planned Democrat-sponsored amendment would allow the unrestricted importation of American-made drugs from Canada, which imposes sharp price controls on drug sales.

Such proposals would drastically reduce the revenue flow to the pharmaceuticals. That in turn would, in effect, sharply slash the nation's true budget for research and development for the miracle drugs that save lives and greatly reduce the pain and suffering of the sick.

Solid profits on the drugs that work are necessary for a time to make the whole process of modern biomedical development viable. Research and development is costly, averaging \$800 million for each new drug, and the investment is a very long-term one — as it takes well over 10 years for a successful research effort to start making any money. Then there are all the R&D dead ends that were necessary along the way, which themselves entail high costs with no return. About 80 percent of newly developing drugs actually fail to pan out. The profits for the successful drugs must ultimately cover these costs as well as their own in order for the system to be economically viable.

If the charlatans manage to stop investors from getting these reasonable returns, then the investment money for modern, cutting-edge biomedical cures will dry up. That means you and I and our families will not have available the drugs that could have saved our lives, or rescued us from some highly disabling disease.

Unfortunately, even some in industry are now piling on against the pharmaceuticals in a different, threatening attack. A coalition of 13 major companies — including such household names as General Motors, Kodak, and Motorola — has joined with eleven governors and some local unions to form Business for Affordable Medicines (BAM). The purpose of BAM is to assault the patent and intellectual-property rights of pharmaceuticals, in a misguided attempt to reduce costs for employer health plans. BAM has now recruited two trendy political demagogues, Sens. John McCain (R., Ariz.) and Charles Schumer (D., N.Y.), to introduce appropriate legislation.

Patents for new prescription drugs now last 20 years, which is an international standard. However, the first eight to 12 years of a patent's life are generally consumed by the clinical trials and approval process required by the Food and Drug Administration (FDA). That generally leaves around 10 years (or fewer) for the developer of the drug to market it exclusively and earn the profits necessary to recover the high costs of development of biomedical miracles.

The proposed legislation would allow generic manufacturers who have been sued for patent violations to go ahead and market their product until the court reaches a final decision. Current law requires the generic manufacturer to wait up to 30 months for a final decision. Where a patent is infringed, the original manufacturer would be losing a large chunk of the precious time during which the costs of developing the drug must be recovered. The only recourse would be to obtain damages — which may not be sufficient coming from a patent infringer, who may be unable to pay them.

The legislation would also assault the intellectual property of pharmaceuticals on the back end of a patent's life, by allowing the marketing of falsely labeled generic drugs. Generic drugs are knockoffs of the original patented drug. They are produced by manufacturers who did not bear the research and development costs of the original drug and so do not have to recover those costs.

The generic manufacturers typically do not have the exact formula for the original patented drug. But they can learn enough by examining it and its effects in the market to produce a drug that is identical in scientific effect to the original drug. The generics may then (and rightly) say they are a complete substitute for the original drug, and can be marketed once the patent on the original drug has expired.

The McCain-Schumer legislation promoted by BAM, however, allows generics to be marketed even if they do not have the same scientific effect as the original. Under the proposed legislation, the generic can claim to be the same drug as long as "no significant differences in therapeutic effect are expected."

This misleads consumers. It will also undermine their health. The market pressure for cheaper and cheaper generic alternatives will lead to generics that are less and less effective than the original. Indeed, the BAM employers pushing the legislation are doing so precisely in order to palm off cheaper drugs to their workers. The vaguer, looser standard for what can be called a generic in the new legislation will not be sufficiently strong to counter this process.

The legislation further adds to this problem by limiting the ability of third parties to file petitions with the FDA questioning the safety and effectiveness of a new drug. This will undermine an important avenue for examining whether the generic really does have the same therapeutic effect as the original.

The politicians, ideological saboteurs, and corporate interests assaulting the pharmaceuticals today are a threat to the public health, and to the personal health of you and your family.