

GET THE FDA OUT OF THE WAY, AND DRUG PRICES WILL DROP

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Congress has been under great pressure from the elderly and other consumer groups to control drug prices, because expenditures on medicines have risen sharply during the past two decades. But price controls would reduce the number of new drugs, since prices are high in part because research and development is so expensive. A much better approach is to eliminate Food & Drug Administration rules that drive up prices and reduce medical innovations.

The discovery of penicillin set off an avalanche of new drugs, including other antibiotics to fight infections, and drugs that lower high blood pressure and cholesterol, treat depression and anxiety, slow the advance of AIDS, and advance the war against cancer. New medicines are a major force behind the rapid advances in both life expectancy and the quality of life that have come during the past 50 years.

U.S. pharmaceutical and biotech companies spend more than \$30 billion a year on R&D to develop useful medications. Only a tiny fraction of those compounds investigated are considered sufficiently promising to enter clinical trials. The average cost of researching, developing, and testing drugs that receive FDA approval is astonishing: \$800 million per drug. To recover these outlays, drug companies must charge high prices during the limited period when they enjoy patent protection against generic competitors. Indeed, this is the reason for granting the monopoly power that comes with a patent.

The burden of paying for the development of the world's new drugs, however, falls overwhelmingly on Americans: Most other nations impose controls over drug prices or undermine patents through allowing cheaper generic copies. As a result, the U.S. is by far the most important market for recouping investments in new drugs, and the share of medical R&D conducted by U.S. labs has risen sharply over time.

Yet the prices faced by Americans can be lowered without price controls while drug development is encouraged, rather than stifled. A major step would be to eliminate FDA regulations introduced in 1962 that raise the cost of bringing drugs to market and artificially slow the process. Before, companies had to show only that new drugs appeared to be safe for the majority of patients likely to take them. The new regulations added an efficacy requirement: Evidence from clinical trials must indicate that a drug can treat a specific disease or condition. In the final stage of these trials, companies must use randomized clinical experiments where often half of enrolled patients receive a placebo--an inactive compound that looks like the real thing. These trials are often too small to be informative, because effects often differ greatly among patients. They are also expensive, mainly because considerable resources must be spent to induce very sick patients to enroll and stay in the trials.

Of course, even without such rules, the fear of lawsuits and the desire to maintain a good reputation would sometimes induce companies to conduct many trials before marketing

highly invasive medicines. And experience indicates that the FDA frequently has delayed approval to avoid embarrassing political and medical mistakes. For example, the FDA delayed until May, 2001, approval on enhancing baby formula with two valuable nutrients, although more than 50 other nations, including Britain and Japan, and the World Trade Organization had given their approval years earlier.

In recent years, the FDA has had a "fast track" for important discoveries, but it still takes 12-15 years, on average, from discovery to approval for new drugs--longer than was the case 25 years ago. At that time, the typical drug underwent about 30 clinical trials involving some 3,000 patients, while now it must go through more than 60 clinical trials with almost 6,000 patients. Studies indicate that the need to conduct these various stages of clinical trials adds almost 40% to the cost of R&D for a new drug.

Eliminating all requirements except a reasonable safety standard would vastly reduce drug prices in the U.S., as companies would be encouraged to develop additional compounds to compete for customers. Lower prices would also make private insurance companies and public medical programs more willing to pay for new drugs, even when effectiveness is still uncertain. Although patients and their doctors are now in a much better position to evaluate new drugs than they were several decades ago, partly because the Internet provides better access to medical resources, the FDA could try harder to improve the information flow to consumers. FDA critics have suggested that consumers should receive copies of product labels with their prescriptions, and that the FDA allow labels to list separately claims that have not been approved.

It is possible to bring down drug prices while encouraging innovations. The FDA should eliminate testing requirements that discourage the development of new drugs that could bring enormous benefits to seriously ill patients.