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How Obama Would Stifle Drug Innovation

By Scott Gottlieb, M.D.

Most new pharmaceuticals have a one-in-ten chance of receiving approval and reaching the market. So-called specialty drugs for rare diseases have an even lower chance of approval, and the cost of development is high. Senator Barack Obama's drug price and access control proposals will distort future investment decisions and smother the financial incentives that inspire innovation.

Pfizer recently said it is exiting the development of drugs for common conditions like heart disease. This is part of a shift underway in the pharmaceutical industry to give up on routine medical problems in favor of discovering specialty drugs for rare diseases and unmet medical needs like cancer.

The shift is driven in part by the industry's critics in Washington, who have long maligned drug companies for targeting too many routine medical problems with drugs that were “merely” tweaks on existing medicines. Now these same detractors, led by House Democrats, are also proposing controls on access to and eventually pricing of the specialty drugs. This is one way an Obama administration would pay for the candidate's plan to create a Medicare-like program for the under-sixty-five cohort. These new controls—based on a view of health care as a commodity to be purchased at the lowest price, with little allowance for innovation—could push drug development over a tipping point.

Specialty drugs offer significant health benefits but for a high price, reflecting the difficulty of developing them. The regulatory process for their approval is more uncertain because the diseases are poorly understood or have not been tackled before in clinical trials. Enrolling patients with rare

conditions in trials is also expensive; they are harder to recruit and often need to undergo more extensive testing to monitor the progress. It can cost less than \$5,000 to enroll a single patient in a trial for a primary-care drug—such as a blood pressure pill—but up to \$70,000 for a big cancer study and more than \$100,000 for some very rare diseases. Specialty drugs that were once tested on hundreds of patients are often now required by the Food and Drug Administration (FDA) to be tested on thousands.

Success rates are low. On average, a drug stands an 11 percent chance of making it through clinical trials and reaching patients. Cancer drugs have only a 5 percent chance of clearing these hurdles. Specialty drugs are also harder to distribute and, by definition, have a much smaller market for sales.

The big drug makers' shift into these markets is not a measure of their strength, but a symptom of their decline, as they grope for a profitable niche amid increasing regulation. Mobilizing capital to take on these medical problems requires the promise of big returns for the few drugs that succeed. When a new drug mitigates—and sometimes cures—a previously untreatable problem, innovators can often reprice the initial treatment of a disease, charging very high prices for the administration of a drug. The initial intervention becomes more costly—but the new benefits should reduce long-term costs, extend life, or ease suffering.

Scott Gottlieb, M.D., is a resident fellow at AEI. A version of this article appeared in the *Wall Street Journal* on October 18, 2008.

This ability to reprice provides the economic incentives to pursue a lot of practical innovations. Take cancer, which now accounts for a third of all drugs in development. Cancers that once cost thousands of dollars to treat when there were not effective options now cost tens of thousands with drugs that are dramatically better. One study estimated that the lifetime cost of treating breast cancer in 1984 was, on average, about \$37,000. A more recent study of older cancer patients found that just the first twelve months of therapy for earlier-stage breast cancer can top \$18,000. But the bigger difference is that today—thanks to more effective medicines, such as Taxol and Herceptin, and better clinical research—most women live longer, and many with early cancer can expect a cure.

Similarly, a little more than a decade ago, the initial treatment for advanced colon cancer involved a drug regimen that cost hundreds of dollars. Now initial care—which incorporates three new drugs and two biologic drugs (those grown in living cells)—costs more than \$20,000. But over that time period, median survival has doubled, and more people with earlier stage tumors can use some of the same drugs to be cured.

Of course, high drug costs and repricing are deeply unfashionable in Washington, where the political focus is on cutting the cost of delivering care in order to extend government-financed coverage to more people. To pay for a Medicare-like program for younger Americans, Obama is promising to cut up to \$290 billion from the cost of health insurance, according to an analysis by my AEI colleague Joseph Antos. While some of this is supposed to come from “efficiency” and deploying information technology, the only proposals with budget teeth are Obama’s “pay or play” tax on employers, controls on access to new drugs and medical devices, and his party’s proposals to control drug pricing.

Congressional Democrats want to give Medicare the ability to negotiate specialty drug prices (referred to as “single source” drugs in some bills) or simply fix the price by forcing companies to give Medicare drug plans the same deep rebates that are mandated under Medicaid. Obama has also championed a “comparative effectiveness” agency—styled after the United Kingdom’s National Institute for Health and Clinical Excellence (NICE)—that would conduct reviews and studies on the clinical and cost effectiveness of drugs to inform central rulings on which patients should be eligible for a new treatment.

NICE’s real mission is to protect the British health care budget. Since 2000 it has denied patients the ability to use the newest cancer drugs—by my count, in 226 different indications for which American insurers and Medicare currently pay and for which the National Comprehensive Cancer Network says there is “high-level evidence” or “uniform consensus” of clinical benefit. Cancer survival rates in the United Kingdom are substantially lower than in the United States, and the gap continues to widen.

The most economically pernicious effect of price and access controls is not the impact on revenue from existing drugs—but how they distort future investment decisions. They will lower expectations that untreated diseases can continue to be repriced, even with very effective new drugs. I work with health care investors and companies firsthand. They can reallocate capital in the face of protracted political uncertainty. They can also forego traditional discovery altogether in favor of less socially useful but lucrative areas such as lifestyle medications or prescription cosmetics. The last time policymakers waged a concerted effort to control the price of and the access to the most innovative but expensive new drugs as part of broader health care reform in the mid-1990s, the percentage of venture capital going into biotech fell by almost half in a single year. A lot of that money shifted into Internet companies.

Of course, repricing diseases does not help people struggling to get basic health care or those burdened by high co-pays. But there are policy options to address these troubling issues without preying on medical innovation and its health contributions.

Specialty drugs typically appear on the “fourth tier” of health plans and have expensive co-pays. Drug companies need to explore alternative pricing mechanisms, including approaches that tie their reimbursement to evidence that an individual patient is benefiting. Health insurers need to provide new policy holders with clear, up-front disclosures on co-pays and not stick patients with unbearable bills only after sickness strikes. The FDA can also help lower overall drug spending by adopting reasonable regulatory pathways for diagnostic tests that would enable doctors to target drugs more efficiently to patients most likely to benefit.

Obama’s policies on drug access and his party’s plans to control pricing will distort the financial incentives that inspire innovations. This will shortchange the contributions innovations provide.