Blocking Drug Development

By ACSH Staff — March 13, 2009

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The U.S. pharmaceutical industry has replaced the tobacco cartel as the favorite punching bag of Congress and litigators over the last few years. The pipeline of new drugs has slowed to a crawl as the risk-averse Food and Drug Administration becomes more cautious by the day.

Nevertheless, the Obama administration wants to add another obstacle to new drug development. The health section of the new stimulus budget contains a section funding - at a $1.1 billion level - a program to evaluate drugs (and procedures) for "comparative effectiveness" (CE).

If followed to its logical conclusion, the FDA will no longer approve a drug if CE studies show that it's merely safe and effective. Henceforth, it would have to be proven better than similar drugs already on the market. If adopted, this will lead to major declines in the already-stunted drug pipeline and fewer choices for consumers.

The handwriting on the wall was exemplified recently when Pfizer, the world's largest pharmaceutical company, halted development of two new drugs during late-stage trials, after many millions of research dollars had been spent. This unusual timing - failed drugs get scrapped in their early stage trials, as a rule - occurred because, according to Pfizer, "We don't believe that they provide significant benefit over other therapies." Imagine if we held other consumer products and manufacturers to this standard: No new TVs, computers or autos would be marketed without clear evidence the newer models were "better" according to some arbitrary government standard.

The process of developing, testing and gaining FDA approval for a new drug consumes 10 to 15 years and costs more than a billion dollars. And even after passing these tests, few drugs become successful enough to recoup their development costs.

But that was before CE. Henceforth, clinical trials designed to show that a drug is superior to another active drug will have to be even larger and longer than current trials, which merely have to demonstrate superiority to an inactive (placebo) drug. Drug companies will be loath to embark on such a perilous journey. Many research pathways will be cut off before they begin. Companies will fear following the same course Pfizer did, getting deeply into clinical trials and finding that their new drug can't out-perform the leader.
Who will decide the criteria by which new drugs would be deemed superior to existing drugs? A vast new bureaucracy - the Federal Coordinating Council for Comparative Effectiveness Research - will adjudicate these complexities. Since even Dr. Sidney Wolfe of Public Citizen (who never saw a new drug he liked) has been deemed acceptable to serve on an "impartial" FDA panel, it is unlikely the Coordinating Council will be pharma-friendly.

Never mind the reassuring statements by the new health-care team asserting that judgments about less-effective drugs won't affect insurance coverage - the Coordinating Council's decisions about the quality of drugs will include cost-effectiveness among their criteria. And that means rationing, no matter their current intentions - although you won't find the word "rationing" in any part of the new health policy. The government insurance programs will not cover drugs that fail to pass the "CE" test.

The new CE policy is supposedly aimed at discouraging drug makers from wasting money and resources on "me-too" drugs that are similar to older ones that are going off-patent. But limiting choices is unfair to patients. If this policy were in place in the 1980s, we would have only one statin drug.

Some patients respond to one drug and not to others in the same class. Furthermore, having a wide range of options helps keep prices down by fostering competition. And new drugs tend to be more effective than older ones, helping save money in the long run by keeping people out of the hospital (if Congress really wanted to save health-care dollars, it would consider tort reform, reducing the costly practice of defensive medicine).

The editorial board of the New York Times recently took on the mantle of health gatekeeper, asserting that some types of colonoscopy should lose insurance coverage for not being cost-effective enough. That's the sort of guidance we'll have to look forward to under the new administration.

Pharmaceutical companies, already pinched by the economic downturn, have taken to mass layoffs and mergers. If the Obama administration continues on this anti-pharma path, expect our once-vibrant pharmaceutical industry to go the way of Europe after price controls: major contractions in drug research and the flight of companies to less-restrictive markets, perhaps in Asia.

This is not a recipe for creating a better health-care system. It's a recipe for turning health care into a state-controlled utility.