

Don't Change Formula for Needed Drugs

By Sally C. Pipes

A report from the nation's leading cancer organizations revealed that America's cancer death rate is dropping. And for the first time in the 10-year history of the report, the rate of cancer incidence is dropping as well.

Thanks to lifestyle improvements, prevention programs, and new treatment options, the United States is making enormous gains in its battle against cancer. But a bill under consideration in Congress threatens to roll back some of those gains by weakening the patent protections for certain complex drugs often administered to cancer patients.

These medicines, called biologics, are created by genetically engineering living material rather than employing chemical reactions, as in the production of conventional medicines.

Conventional drugs and biologics are as different as night and day. You might just swallow an antibiotic to cure an infection, for example. But if you had multiple sclerosis, you'd likely receive an injection of biologic gene therapy to treat the disease.

Avastin is one important biologic. This genetically engineered drug was developed from a mouse antibody and stops the blood vessels that tumors use to grow from forming. When added to the standard treatment for late-stage breast and lung cancer, it can extend the lives of patients by several months.

Imagine thinking you're about to die -- and then having several more months to spend with your loved ones. That new lease on life is what biologics can give patients. And the search is on to develop drugs that

will extend lives even longer.

That search could be hampered -- or even destroyed -- if Congress doesn't take the different nature of these new medicines into account.

Because of their complexity, biologics tend to cost more than the simple chemical compounds we're used to. Therefore, many companies want to manufacture what are called "follow-on" biologics. Follow-ons could lower costs as generics have for conventional medicines.

Generic drugs are exact molecular reproductions of brand-name drugs. Because biologics are created from living organisms, a tiny change in the manufacturing environment can lead to a big change in the final product.

Given the sensitivity of our immune systems, these small differences can lead to major side effects. So it's troubling that the legislation before Congress would allow manufacturers of follow-on biologics to rush their products through the FDA approval process with reduced testing requirements.

Some lawmakers are also working to give follow-on manufacturers speedy access to the production data of original biologics. Conventional drug makers get five years of "data exclusivity" before competitors can use their information. Without the ability to sell exclusively the medicines they've spent years developing, drug companies wouldn't be able to put in the time and money needed to invent them in the first place.

Let's hope Congress aids cancer patients by preserving the incentives for researchers



and biotech companies to continue searching for a cure.

Sally C. Pipes is president and CEO of the Pacific Research Institute. Her latest book is "The Top Ten Myths of American Health Care."

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