THE TENNESSEAN
TENNESSEAN.COM
http://www.tennessean.com/article/20111005/OPINION03/310050088/Drug-costs-benefits-must-align

Drug costs, benefits must align

Patient safety demands tougher biologic standards

Published 1:13 AM, Oct. 5, 2011

Written by David Charles, M.D.

In 1993, a drug just approved by the Food and Drug Administration was highlighted in a *Fortune* magazine article under the eye-catching headline “Fortune Products of the Year.”

The drug was Betaseron. And while the headline was ambitious, the new drug was a medical triumph. It provided doctors with the first successful treatment for multiple sclerosis, a progressive and disabling neurological disorder that often strikes in the prime of life.

But even more important than Betaseron’s clinical success is its origin. It belongs to an exciting new category of drugs known as “biologics.” These medical breakthroughs are manufactured from living biological processes instead of the more basic chemical processes used to produce conventional pharmaceuticals. Betaseron was one of the world’s first modern-day biologics and it changed the course of medicine forever.

The 200 or so biologics that have been developed in recent years represent the cutting edge of medical science today. Some are landmark achievements in the treatment of disabling conditions such as rheumatoid arthritis, multiple sclerosis and cancer. Because of their origin and design, biologics are creating unprecedented opportunities to develop drugs that fight highly specific diseases, and that are tailored to individual patients.

However, because of their enormous complexity, the process of developing, testing and producing biologic drugs is long and expensive. Furthermore, the complexity of that process makes it impossible to duplicate, so there is no such thing as a cheaper, carbon-copy, generic version of a biologic.

The result of these factors is that while biologics offer revolutionary therapy options, they can cost tens of thousands of dollars a year. Closing the gap between the benefits of

biologics and their high cost needs to be a national priority, but it must be done in a responsible way that balances biologic availability with patient safety and pharmaceutical innovation.

While there are no identical generics for biologics, it is possible to create so-called biosimilars. Biosimilars are as close to a generic version of a biologic as science allows and could conceivably be a less costly alternative for some patients. Congress recently instructed the Food and Drug Administration to develop procedures for approving generic biologics.

Like most physicians, I would welcome less expensive biosimilars. But patient safety demands that the biosimilar approval process be different from traditional “generic” drugs. Generics are often chemically identical to brand drugs, and their approval is thus allowed to piggyback on the precedent drug’s approval. Biosimilars, however, are far more complex, and two similar compounds could have drastically different effects. Clinical trials should be required to establish the safety and effectiveness of biosimilars.

The approval process for biologics must also protect innovation. Companies that invent biologics need some period of exclusivity on marketing the new therapies they invest hundreds of millions of dollars in developing. The reward for patients would be a growing assortment of these unique drugs, available and affordable to everyone who needs them.

On a broader level, the government should move accelerate innovation in biologics through public-private partnerships. These would bring together the best scientific talent from the National Institutes of Health and the private health-care industry. Besides sharing in the high cost of basic research, the NIH could help in encouraging public cooperation with the clinical trials using real patients that are an essential and expensive part of new drug development.

Finally, patients’ well-being requires that as the selection of biologics and biosimilars increases, the decision on which drug to use must remain with the doctor and patient. This is not a responsibility that can be subcontracted to bureaucrats.

Biologics have tremendous potential to save lives and relieve suffering, but they are not a magic bullet. They are the product of innovation and hard work, and their continued development is not assured. To realize the promise of biologic therapies all stakeholders — physicians, patients, researchers, manufacturers and government — must work together to fashion health policies that promote access, protect patient safety and contain costs.

Dr. David Charles is a neurologist practicing in Nashville and is chairman of the not-for-profit Alliance for Patient Access.