

President Obama Reopens Debate On Patented Biologics

Will the FDA Quickly Define an Abbreviated Pathway for Biosimilars?

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President Barack Obama's budget proposal for fiscal year 2012 reignites a controversy over biosimilar drugs that had been doused last year—at least it appeared to be—when Congress passed the Patient Protection and Affordable Care Act (PPACA). That landmark health care reform bill contained a compromise (agreed to, more or less) by both the patent-holder and generic companies, giving 12 years of market exclusivity to the first branded biopharmaceutical drug that hits the market.

These biopharmaceuticals are “big-molecule,” very expensive drugs that are manufactured in animal or plant cell tissue. Examples include etanercept (Enbrel, Amgen/Pfizer), infliximab (Remicade, Centocor), adalimumab (Humira, Abbott), bevacizumab (Avastin, Genentech), and rituximab (Rituxan, Genentech). In exchange for the 12-year period, the provision gives generic companies access to an abbreviated Biologics License Application (BLA) when they want to market either “biosimilar” or “interchangeable” generic drugs. These two newly created categories are defined later.

In his budget proposal for the year starting October 1, 2011, however, the President tossed out that compromise and asked Congress to reduce the 12 years to seven years, making it impossible for patented companies to earn an additional 12 years of patent protection when they make minor changes to the original drug.

Apparently, the Obama administration believes that subtracting five years of data exclusivity would mean that a cheaper generic would be available five years earlier, thus saving megabucks for federal health insurance programs like Medicare and Medicaid. But Stephanie Fisher, a

spokeswoman for Biotechnology Industry Organization (BIO), the brand-name company association, counters:

“Lowering the period of data exclusivity may result in some short-term savings, but it would discourage investment in the next generation of therapies and cures—which would end up costing the government money in the future.”

It is unlikely that Congress will tear up the bipartisan compromise that it agreed to last year in the PPACA; that provision was called the Biologics Price Competition and Innovation Act of 2009 (BPCI Act). It is more likely that the FDA, which is charged with writing the regulations for the BPCI Act, might try to shade its final regulations with a pro-generic (i.e., pro-federal savings) slant.

The BPCI Act calls on the FDA to set requirements for a drug to be deemed either biosimilar or interchangeable. It would be easier for a generic agent to meet the biosimilar standard; it must be *highly similar* to the reference product. An interchangeable generic drug must produce *the same clinical result* as the reference product. There are other distinctions, but these are the key differences.

The distinction between the biosimilar and interchangeable drugs is important, especially for pharmacists, who are permitted to substitute an interchangeable product for the reference product without the intervention of the prescribing health care provider.

Brian M. Meyer, MBA, Director of Government Affairs at the American Society of Health-System Pharmacists, believes that pharmacists should be able to prescribe biosimilars without a physician's approval. He notes:

Interchangeability may require additional evidence, such as that available following a period of market use that includes post-marketing studies and assessment of adverse event reports to demonstrate similar patient outcomes in broader patient populations. To support development of this evidence, health care providers should not

be restricted in efforts to substitute products that have been FDA-approved as biosimilar.

As usual, the FDA is moving slowly in defining the fine points of the BPCI Act, such as establishing the different requirements that drugs must meet in order to be considered biosimilar or interchangeable. Without the FDA's final regulations, it is not clear whether a generic company may submit an abbreviated BLA under the BPCI Act. What is clear is that generic companies are not waiting around for those final rules to be issued before trying to get their biosimilars on the market.

In early 2010, before Congress passed the BPCI Act as part of the PPACA, Teva announced that it had submitted a BLA for a generic substitute for Amgen's filgrastim (Neupogen), a granulocyte-colony-stimulating factor. Filgrastim is designed to reduce the duration of severe neutropenia and the incidence of febrile neutropenia in patients receiving established myelosuppressive chemotherapy. Teva is taking the long way through the FDA approval process as if it were a patented company. Before passage of the BPCI Act, it had no other choice.

Hospira has begun phase 1 clinical trials in the U.S. in preparation for applying to the FDA for a biosimilar version of erythropoietin (EPO) in anemic patients with renal dysfunction. Dan Rosenberg, a spokesperson for Hospira, which sells a biosimilar version of EPO called Retacrit in Europe, says that Hospira is now jumping through the designated FDA hoops as it prepares to decide whether to file either a full BLA or an abbreviated BLA if it is available. The fact that there is no abbreviated approval process for Teva or Hospira—and one is not likely to be established anytime soon—makes one wonder whether President Obama could save Medicare and Medicaid the most money by giving FDA regulation writers a kick in the pants. ■

