

Ensure Safe and Expedited FDA Review of Biosimilars

B **Biologic drugs used to treat rheumatic diseases** can cost thousands of dollars per month and often have few, if any, generic alternatives. The introduction of safe and effective biosimilars to the U.S. healthcare system will lead to greater price competition and lower costs for patients, taxpayers, and businesses that purchase insurance.

What are Biosimilars?

Biosimilars are comparable versions of biologics—pioneering, complex therapies used to treat autoimmune diseases like rheumatoid arthritis, psoriasis, ulcerative colitis, and several forms of cancer. Unlike generic or small molecule drugs, biosimilars are highly complex and even small changes in the manufacturing process can lead to ineffective or dangerous interactions with the immune system. For this reason, the American College of Rheumatology (ACR) advocates for full transparency in biosimilar naming, labeling, and post-market surveillance practices.

Policy Recommendations

The Food and Drug Administration (FDA) has taken important steps to date to bring safe and effective biosimilars to market as quickly as possible. The following actions by Congressional leaders and the Administration will help to advance the FDA's efforts in this area:

1. Give FDA Budget Authority to Review and Approve Biosimilars

Congress should ensure adequate funding to enhance and expedite the FDA's review of biosimilar therapies and to issue industry guidances. To achieve this goal, Congress should create a dedicated program for biosimilar review with its own source of funding, similar to what exists for prescription drugs, generic drugs, and medical devices.

2. Support FDA Hiring Reforms

In order to ensure the safe and expedited approval of biosimilars, the FDA must be well staffed with individuals who have specific expertise in biosimilars. Unfortunately, the current hiring process takes far too long and the agency often loses qualified candidates to the private sector as a result. Fortunately, the incoming Administration can reform the process. Under Section 3072 of the 21st Century Cures Act, the FDA is permitted more flexibility in appointing drug reviewers. The ACR recommends that the Agency take advantage of this provision to ensure efficient onboarding of experts.

3. Reauthorize the BsUFA

Congress must reauthorize the Biosimilar User Fee Act (BsUFA) to ensure the safe introduction of biosimilars into the U.S. healthcare system. Under BsUFA, the FDA is permitted to collect user fees on biosimilar products to expedite the review process. The law expires in September 2017. If Congress is interested in making sure patients have access to these life-saving therapies, it should reauthorize the BsUFA as soon as possible.

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