

The Senior Center for Health & Security

Enhancing the Lives of Older Americans



What You Need to Know

A special educational series

The Right Pathway to Follow-On Biologics

The regulatory pathway to “follow-on biologics” holds great promise for many patients seeking the best treatments and cures for the diseases from which they suffer, **but only if it’s done right**. Any such pathway must vigilantly protect patient safety, and fully preserve the market incentives that encourage new, innovative biotechnology products for the patients who desperately need them now, and in the future.

Biologics are complex medicines that are manufactured using live cells. They are different and far more complex than most small molecule chemical drugs or pharmaceuticals. Biologics include many of the newest breakthrough medical therapies for the most serious life-threatening illnesses such as cancer, multiple sclerosis, HIV/AIDS, and diabetes, as well as many serious rare diseases. Because of their size and complexity, biologics generally cannot be scientifically characterized to the same degree as small molecule chemical drugs. Follow-on biologics won’t be a panacea, and may not even provide the savings of today’s generic medicines.

Follow-on biologics are not generic drugs. A generic drug is one that is ostensibly the same as an innovative drug and is generally designed to be therapeutically interchangeable with the original brand-name drug. While this may work well for many, for some patients, neither the generic copy nor other drugs deemed therapeutically-equivalent work as well as the original. In other cases the supposed interchangeable replacement drug actually harms the patient, sometimes irrevocably. **Any change in medication or treatment must involve both the physician and the patient.**

Unlike generic drugs, a follow-on biologic (or “biosimilar”) is a product that is similar to, but not the same as, the innovator biologic. The follow-on biologic cannot be exactly

the same as the original innovative biologic. Even a small change in the manufacturing process can have a huge impact on the product. Thus, rigorous patient protection procedures must be a part of any follow-on biologic pathway. This **must** include:

- Extensive clinical trial evidence and data to irrefutably demonstrate the safety and effectiveness of any follow-on biologic.
- Post-marketing surveillance and post-marketing clinical studies to continuously evaluate the long-term safety and effectiveness of the follow-on product.
- Follow-on biologics must not be given unless expressly ordered by a physician.

Incentives for innovation must be preserved. Patients are waiting for new treatments and cures. To ensure innovative biologics in the future, any pathway must also:

- Include 14 years of non-patent data exclusivity, during which time follow-on manufacturers could not rely on FDA’s prior approval of an innovator biologic to support approval of their own follow-on product.
- Respect all intellectual property and other legal rights of the innovators.
- Provide adequate legal notice and process rights, and ensure that any patent challenge involving the follow-on biologic will be litigated prior to any marketing approval of the follow-on.
- Ensure transparent statutory and regulatory process and procedures.
- Continues to prioritize FDA review and approval of new therapies and cures.

Through the power of education The Senior Center for Health and Security seeks to enhance the lives of older Americans. It works to promote the promise and potential of innovative medical research and development and to highlight its critical importance in ensuring seniors live longer, healthier lives.

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