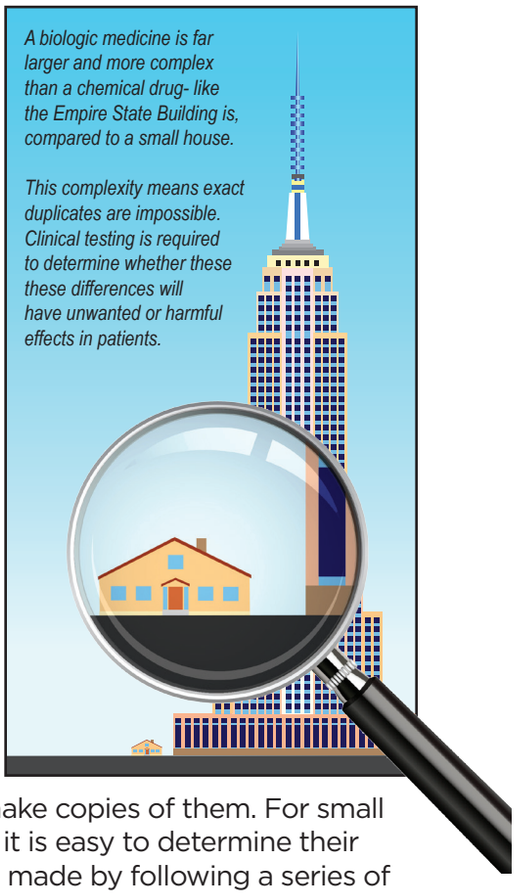
WHAT DO I NEED TO KNOW ABOUT BIOSIMILARS?

BIOSIMILAR BASICS

NEW CHOICES, NEW CHALLENGES

BIOLOGIC MEDICINES are used to treat millions of patients with serious illnesses like cancer, arthritis, and psoriasis. The patents for many biologic therapies are expiring over the coming years, and copies of these, called BIOSIMILARS will enter the marketplace, bringing patients new therapeutic options at reduced cost.

But with these new choices, biosimilars bring new challenges. Regulatory authorities around the world are putting policies in place to ensure that biosimilars have been appropriately tested, and are safe and effective for patients.



WHAT IS A BIOLOGIC MEDICINE?

Most people are familiar with small molecule medicines, like aspirin. These are produced via a series of chemical reactions, and their exact structure is simple and easily identified.

In contrast, biologic medicines are very large, and very complex. Biologic medicines are made in living cells, grown in a laboratory. By way of comparison, if you think of a small molecule drug as a small house, a biologic medicine could be compared to the Empire State Building, in relative size and complexity.

WHAT IS A BIOSIMILAR MEDICINE?

When patents for medicines expire, other companies are free to make copies of them. For small molecule medicines, these copies are known as generics. Because it is easy to determine their exact structure and how they are made, IDENTICAL copies can be made by following a series of chemical reactions.

For biologics, it's not as easy. To begin with, because of their size and complexity, it is not possible to exactly determine the structure. Second, the living cells and manufacturing processes used to make the biologic are unique and proprietary to each manufacturer, as well as being far more complex than the synthesis of chemical drugs. Thus, a different company will not make the biologic in exactly the same way. Copies of biologics are SIMILAR but not identical to the original biologic, hence the name: biosimilars. Clinical evaluation is important to identify if any of the inherent differences between the two have an effect in the body. Because all biologics are large complex molecules that have the potential to cause immune reactions in the body, there are a number of factors that are important in ensuring patient safety.

INTERCHANGEABILITY

The U.S. is the only country that can approve a biosimilar as **interchangeable.** If approved as interchangeable, it can be substituted at the pharmacy without the intervention of the prescribing physician. To be approved as interchangeable, it must demonstrate that it "can be expected to produce the same clinical result as the reference product in any given patient" when substituted, and "the risk in terms of safety or diminished efficacy of alternating or

switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch." In January of 2017, the FDA issued draft guidance detailing the agency's expectations for demonstrating biosimilar interchangeability.

SUBSTITUTION

State laws give pharmacists the authority to switch a patient from the prescribed product to another medicine under some limited circumstances, for example, when a generic drug is available. However, biosimilars are only similar, not identical, to the prescribed product. So it is only appropriate to give pharmacists the authority to switch a biosimilar product without a physician being involved if the biosimilar product has been deemed interchangeable by the FDA. If a switch occurs, it is important that the physician who prescribed the biologic is notified of the switch. This allows for the appropriate monitoring of a patient's response to treatment, as well as accurate tracking of adverse events.

NAMING

All biologics, including biosimilars, should have **distinguishable nonproprietary names** to ensure clear product identification, robust safety monitoring, and accurate adverse event reporting. The World Health Organization (WHO) and FDA have proposed the use of a unique suffix appended to a shared root name.

ASBM supports this suffix having a meaningful, memorable structure related to the company manufacturing the biologic, as is the case with the FDA's first approved biosimilar, Zarxio (filgrastim-sndz). Memorable suffixes promote clear communication between providers, reduces the likelihood of medication errors, and promotes manufacturer accountability for their products.

LABELING

The benefits of biosimilars will only be realized when patients and providers have confidence in them. Thus, the product label providers use to make treatment decisions and gauge patient response should be **informative** and **transparent.**

Since biosimilars are not identical to their reference products, their labels should communicate:

- That the product is a biosimilar.
- Analytical and clinical data used to demonstrate biosimilarity
- Which diseases the biosimilar is approved to treat, and whether it was studied in those diseases. This may differ from the reference product.
- Whether or not the biosimilar is "interchangeable" with the originator product.

BUILDING CONFIDENCE IN BIOSIMILARS

In order to enjoy the health and cost benefits of biosimilars, patients and physicians need confidence in their safety, quality, and efficacy. ASBM urges regulators to enact policies which promote transparency and build this confidence.

The Alliance for Safe Biologic Medicines is a diverse group of stakeholders including physicians, pharmacists, patients, researchers, and manufacturers of both biologics and biosimilars. ASBM is an organization focused on promoting the use of biologic medicines, while ensuring their safety and efficacy.

*Learn more at **www.safebiologics.org**.*

SafeBiologics
ALLIANCE *for* SAFE BIOLOGIC MEDICINES