Patient Safety is Paramount: Regulators Must Take Thoughtful Approach to Biosimilars Naming

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Patient safety must continue to be the top priority of regulators as the U.S. Federal Trade Commission (FTC) and U.S Federal Drug Administration (FDA) discuss issues surrounding biosimilars, particularly the establishment of a policy on naming. The single best way to ensure the safety of vulnerable patient populations is through policy, which requires clear, distinguishable and traceable names for biosimilars. As a long-time patient advocate and practicing pharmacist for the past 40 years, I am pleased that the FTC regulators are giving appropriate weight these issues, as seen in their recent workshop on February 4, and encourage them to continue to do so in subsequent conversations.

Regulatory bodies should prioritize patient safety

The proper management of clinical patient care requires that patients their physicians and pharmacists are able to specifically identify and quickly trace the supplier of a treatment. This is particularly critical for biosimilar products, which, unlike generic chemical compound drugs, are similar-to, not exact replicas, of the original biologic.

To ensure patient safety, the FDA, with the support of the FTC, should take the following fundamental steps:

1) Mandate distinguishable and unique product names for biosimilar products;
2) Implement a regulatory process and environment that prioritizes patient safety, and allows for the evaluation of therapeutic interchangeability, value and bioequivalence of unique molecular variants of products.
3) Require a unique nomenclature or coding of biosimilar products to ensure manufacturer and supplier accountability.

Distinguishable names are critical to patients’ safety and rights

While biosimilars have great potential to decrease the cost of biologics, they are also a very new and un-validated line of products that are similar-to, but still molecularly differentiated, from the original biologic. They have not yet been validated in their efficacy and equivalency to the originator products.

If untraceable biosimilars become the norm, and should unforeseen issues arise with a particular product, then the efficacy of all biosimilars as well as biologics would be in doubt and require additional, costly scrutiny to the detriment of patient health. It could also potentially irreparably damage this market, in the long-term through the loss of consumer and practitioner confidence.
As a practicing pharmacist, I have experienced firsthand why it’s critical for pharmacists and physicians to be able to rapidly identify the precise components of a treatment. We keep accurate records that identify products dispensed or immunizations administered because it is critical to protect the health of patients. Should an adverse event happen, it is essential that our records show the precise manufacturer and product administered to the patient in order to course correct.

Core regulatory safeguards are needed to ensure safe use of biologics and biosimilars

To adequately protect the health and safety of patients, the FDA must put regulations in place that seek to achieve a true balance between access, safety and cost. Those regulations and practices established must ultimately: 1) prevent commercial abuse of biosimilars, 2) ensure access to quality products that are of reliable, consistent therapeutic value while still allowing for traceability, and 3) confirm these products can be safely used with critically ill patients.

This is not an easy balancing act for FDA, but it is a necessary one. It is my hope that FTC’s long and valued tradition of advocating for full and transparent disclosure of product identification will help to guide FDA regulatory action to require accountability and transparency in the supply chain of all biologics, including biosimilars.

About the author:
Dr. Giorgianni was at Pfizer for 27 years. His last assignment was as the Director External Relations and Editor-In-Chief of The Pfizer Journal. During his tenure there he was engaged in several US and global product launches including for Cefobid, Aricept, Lipitor, Zoloft and Viagra. He was responsible for developing and directing relationships with professional and voluntary health associations and for various image and reputation management projects to support product and research strategies. He is the author or co-author of over 55 peer reviewed and general public articles and presentations on health. Currently, Dr. Giorgianni is Chair of the American Public Health Association's Men's Health Caucus and an Advisor to Pharmacist Partners. Dr. Giorgianni is President of Griffon Consulting Group Inc., and is a practicing pharmacist.