Clinical Perspectives on Biosimilars

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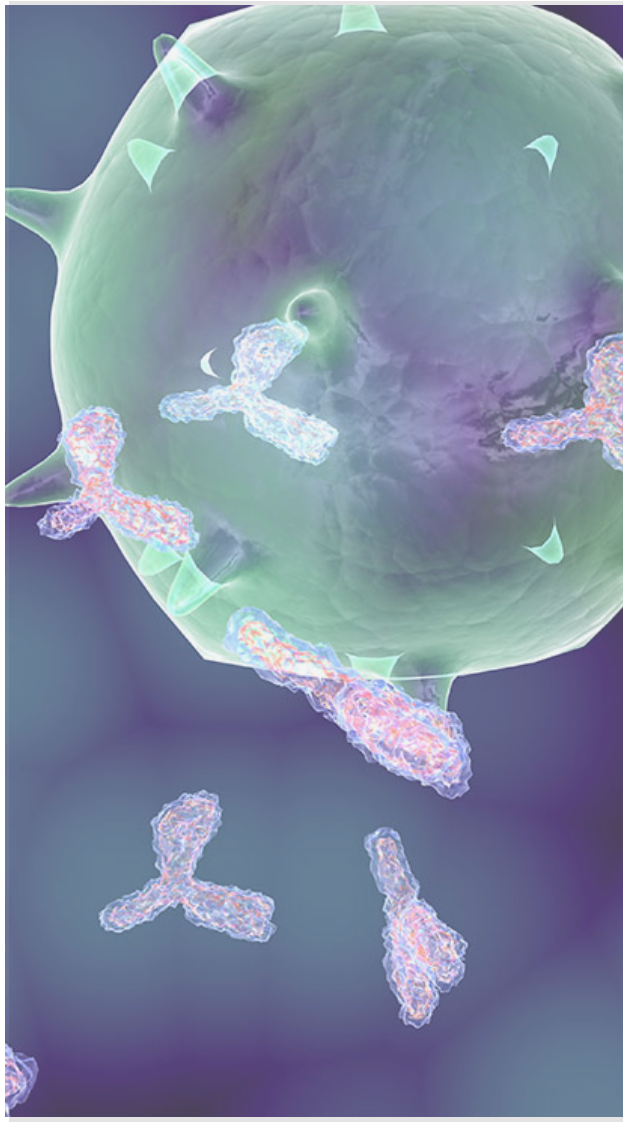

Introduction

Richard Dolinar, MD

- Clinical Endocrinologist, Phoenix, Arizona
- Senior Fellow in Healthcare Policy, Heartland Institute
- Member of The National Legislative and Regulatory Committee, American Association of Clinical Endocrinologists (AACE)
- Member of the Editorial Advisory Board, *Endocrine Today*
- Member of the Editorial Board, *Journal of American Physicians and Surgeons*
- First Chairman, Alliance for Safe Biologic Medicines (2011-2014)

Question 1: How to Help Biosimilars and Interchangeable Biosimilars Reach Patients More Quickly

Clear Naming is Critical.

- **FDA is right to require distinct nonproprietary names.** The 4-letter suffix system is an excellent way to ensure clear product identification.
- But current names use a suffix which is nonsensical and difficult to pronounce. These suffixes are untethered to anything and difficult to remember.
- Drugs that can't be easily pronounced or remembered are less likely to be prescribed, and less likely to reach the patient.

Recommendations:

- **Consider permitting more memorable and meaningful names in brand names, and especially in the design of the distinguishing suffixes.**
- **FDA should work with the WHO to advance the use of distinct naming systems worldwide.**

Question 2: Making the Purple Book More Useful to Stakeholders

More Education and Availability

- More education and promotion is necessary.
- Familiarity is low among physicians.
- It is difficult to locate a copy of the Purple Book. Amazon?
- Poor familiarity and availability put biosimilars at a disadvantage.

Recommendation:

- **FDA should increase promotion of the Purple Book directly to physicians, patients, pharmacists, and other stakeholders.**

Question 3: Facilitating the Evolution of the Biosimilar Marketplace

Educating the Public (Patients)

- The general public has very low familiarity with biosimilars.
- As with physicians, more education is needed.

Recommendation:

- **FDA should consider use of Direct-to-Consumer (DTC) advertising both from FDA itself and industry.**
- **These can highlight what biosimilars are, their benefits as new treatment options and their lower pricing.**

Question 3: How to Increase Confidence in Biosimilars?

Data Over Time Builds Confidence.

- First, FDA should maintain its high standards in evaluation and approval. Lessening these standards would be a mistake and undermine physician confidence in biosimilars.
- Extrapolation in the approval process will not be easily accepted by physicians without clinical studies to support it.
- Ground lost is ground lost. Safety is Paramount.

Recommendation:

- **Ideally, clinical studies should be done for every indication.**
- **Switching studies will help physicians feel comfortable switching patients.**
- **Regardless, robust post-market monitoring is essential.**
- **Here again, distinct naming is helpful to avoid pooling of adverse events.**

Question 4: Biosimilar Development and Analytical Characterization

Extensive Analytical Studies Are Needed.

- Short cuts could prove to be penny wise and dollar foolish if patients suffered or even lost their lives.
- Actual number of lots tested should be based on statistics.

Recommendation:

- **Short cuts should not be taken- again, this has the potential to undermines confidence in biosimilars.**

Question 9: How FDA Can Address Other Challenges that Could Disrupt Balance Between Innovation and Competition

Reduce Distortion of Treatment Decision-Making by PBM's

- **PBM's are interfering with the doctor's best medical judgment.** They often make it impossible, for all practical purposes, to choose the best drug therapy for the patient.
- Doctors instead of using their best medical judgment are forced to use their second, third or fourth best medical judgment.
- PBM's will often place hurdles in front of doctors in order to maintain "walk away rates" of 65% or higher. **Thus only 35% of the patients submitting scripts for the drug are getting the one the doctor felt it was best to get.**
- The PBM's need to be reined in. One way to do that is to remove the rebates. Rebates create a perverse incentive for higher list prices. Payola was done away with in the music industry. Why does it still exist in healthcare?

Recommendations:

- **The FDA should encourage use of the consumer protection laws which are already in place in order to stop bait and switch by the PBM's.**
- **When a Medicare patient signs on for a drug benefit plan that plan should not be able to drop drugs a few months later from its formulary. This is bait and switch. The patient signs on for a year. The formulary should have the listed set of drugs for the year.**

Conclusions

- **FDA's Science-Based Approach to Biosimilar Approval is Sound.**
- **Strong standards for safety & efficaciousness must be upheld** to ensure biosimilars are accepted by physicians.
- **Clinical trials, switching studies, and post-market surveillance** will also build confidence in biosimilars.
- **Distinct Naming** is critical to strong pharmacovigilance and thus to building physician confidence. More memorable names are preferable to increase familiarity and use.
- **More Education is Needed** on the benefits of biosimilars- to physicians, patients, and the public.
- Third parties such as PBM's use rebates and other incentives to effectively determine which product will be prescribed to the patient. **Treatment decisions should instead be made by physician and patient.**