PATIENT SAFETY BLOG

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Patient safety at risk if testing standards for biosimilars are relaxed, FDA told at hearing

Patient safety advocates and brand-name drug makers lined up against companies that make generic drugs over just how flexible the standards should be for the clinical testing of biosimilars.

These drugs, also known as biogenerics, follow-on biologics and subsequent entry biologics, are officially approved subsequent versions of biopharmaceutical products following patent and exclusivity expiration on the original product. Until now, only a handful of biosimilars have been approved in the U.S., but that is about to change.

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At the hearing, patient safety advocates argued that the only way to be sure that a drug is safe is through extensive clinical trials, while generic biosimilar manufacturers and distributors maintained that dangerous and expensive clinical tests are not required because they will be based on drugs that are already proven safe.

But are they? Biosimilars exhibit high molecular complexity and may be sensitive to manufacturing process changes. In addition, the biosimilar manufacturer doesn't have access to any of the information or substances (e.g. molecular clone or cell bank) that the originator used to create the drug. As a result, patient safety advocates worry that biosimilars might perform differently than the branded versions, and could have potentially serious health implications.

Amgen, a brand-name biopharmaceutical manufacturer, called for biosimilars to undergo rigorous testing and recommended that the FDA:

1. Use well-designed clinical trials to establish biosimilarity

2. Ensure the product manufacturer and lot number is known for all administered biologics

3. Set scientific and practical criteria for interchangeability.

Critics of a rigorous clinical testing standard say that in addition to the expense, there are ethical questions involved in repeating potentially dangerous trials in humans. To avoid repeating human trials, U.S. Senator Bernie Sanders has proposed require generics makers to pay a fee for access to clinical data used in the manufacture of the brand name biologic.

Source: Wall Street Journal blogs

You can get more information about the FDA hearing and view video of the proceedings here.

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