Are biosimilar drugs reliable replacements for their pricier counterparts?

Biologics are complex molecules, modifying our immune responses to specific chronic inflammatory conditions like rheumatoid arthritis, psoriatic arthritis, or irritable bowel disease. They are manufactured by placing genes into host cells who through transcription and translation provide the core protein. Biosimilars are biologics "generic" equivalents, except they are not.

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Biosimilars have an identical primary structure as their biologic but other factors, influencing shape may and do differ.

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[The FDA believes] if a biosimilar works for one indication and it is clinically equivalent to the biologic, then we can infer that it will work for all the indications. That logic stands on firm ground when drugs are identical, but biosimilars are not, they are similar. For example, some biosimilars have gained approval for pediatric indications, by extrapolation from studies on the biologic, they have never been clinically tested on children.

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Insurance companies and their pharmacy benefits managers earn income based upon a percentage of the drug's cost; costs we have no real way to determine. Irrespective of the actual price, income's is predicated upon a percentage of the average wholesale price, so there is no incentive to lower prices.

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Physicians have raised two concerns. First are these drugs clinically equivalent? Second, will the market forces we have seen in generics be the same as for biologics – will there be sufficient competition to significantly lower cost and improve access?

Read full, original post: Biosimilars Are Not 'Generic' Versions Of Expensive Biologic Medicines