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Dr. Rand Paul Introduces Legislation to Cut Bureaucratic Red Tape and Lower Drug Prices



Washington, D.C. – Today, U.S. Senator Rand Paul (R-KY) introduced legislation to streamline the approval process for biosimilars by eliminating costly and redundant clinical study requirements. Dr. Paul's *Expedited Access to Biosimilars Act* will increase market competition, lower drug prices, and increase access to more life-saving treatments.

"For too long, the FDA has forced companies to jump through bureaucratic hoops and produce redundant clinical studies that offer no new

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meaningful scientific information for the approval process,” **said Senator Paul.** “My bill puts an end to wasteful and repetitive clinical requirements that create unjustified barriers, further delaying competition in the market. For years, biopharmaceutical researchers have argued that new and advanced methods of determining biosimilar clinical equivalence in early development have eliminated the need for late-stage human studies. When a biosimilar proves it is safe, effective, and similar to the brand name product in the early stages of its analytical and safety assessment, there’s no scientific justification to delay access.”

BACKGROUND

Senator Paul’s legislation will:

- Retain the FDA’s requirement for pharmacokinetic (PK) studies, but it will eliminate the FDA’s blanket requirement of immunogenicity, pharmacodynamics (PD), and Clinical Efficacy Requirements (CES) unless scientifically warranted. PK studies are essential because they are relevant tools for demonstrating clinical similarity and safety assessments.
 - Require the FDA to justify the additional study requirements, ensuring that regulatory decisions are based on scientific necessity, not outdated bureaucracy.
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- Accelerate market entrance and competition for biosimilars that are priced lower than brand-name products.



Regulatory agencies in the U.K. and European Union (EU) have dropped the blanket requirement for these redundant studies after years of research determined that early-stage PK studies were sufficient for biosimilar approval. The regulatory overreach by the FDA often dictates the practice of medicine and slows access rather than making safety and effectiveness determinations of medications. The agency's increasing demands of studies leave little room for physicians and patients to make outcome-oriented decisions for themselves.

It is time for the agency to start thinking like an innovator, not an impediment to innovation. By modernizing and streamlining the FDA biosimilar approval process, Congress can help lower patients' prescription costs without compromising safety or efficacy.

Read full the bill [HERE](#).

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