SafeBiologics
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GENERICS AND BIOSIMILARS INITIATIVE
Building trust in cost-effective treatments

BIOSIMILAR RED TAPE ELIMINATION ACT (S2305):

Weakening FDA Regulatory Standards for Biosimilars, Undermining Physician Confidence and Jeopardizing Patient Health

Thursday, 31 October 2024 | 10:30 am – 11:30 am (EDT)

Online Event

This webinar aims to educate policymakers, healthcare providers, and patients on the current regulatory framework for biosimilars in the US, emphasizing the importance of maintaining the US FDA's robust approval standards for interchangeable biosimilars, and highlighting the potential risks to patient safety and treatment efficacy that could arise from lowering those standards.

10:30 – 10:35 **Welcome and Webinar Objectives**

Michael S Reilly, Esq, Executive Director, Alliance for Safe Biologic Medicines, USA

10:35 – 10:45 **Physician Perspectives**

Ralph McKibbin, MD, FACP, FACG, AGAF, Chair, Alliance for Safe Biologic Medicines, USA

- Contrast with European definition and substitution practices
- Success of current framework – approvals, market share, savings

10:45 – 10:50 **Development of US State Biosimilar Substitution Policy**

Professor Philip J Schneider, MS, FASHP, FASPEN, FFIP, College of Pharmacy, Ohio State University, USA

- Generics model does not apply. Only interchangeables (those having furnished more data) may substituted by pharmacy w/o physician approval

10:50 – 11:10 **Regulatory Perspective on Biosimilar Red Tape Elimination Act**

Michael S Reilly, Esq, Executive Director, Alliance for Safe Biologic Medicines, USA

- Inappropriately treats biosimilars as generics, conflates two classes of biosimilars, transfers scientific decisions to legislative committee leaders
- Removes US FDA's ability to request additional clinical studies that may be needed
- Incorrectly characterizes interchangeable status as barrier to uptake; market share primarily determined by PBM/insurer formulary design is dominant factor

11:10 – 11:15 **Patient Perspective**

Andrew Spiegel, Esq, Executive Director, Global Colon Cancer Association, USA

- Concerns with third party substitution, interchangable standards, new physician survey data

11:15 – 11:30 **Panel discussion and Q&A**
Panelists

Michael S Reilly, Esq
Ralph McKibbin, MD, FACP, FACG, AGAF
Professor Philip J Schneider, MS, FASHP, FASPEN, FFIP
Andrew Spiegel, Esq

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JOIN the discussion with policy expert, physician, pharmacist, patient advocate, at the 'BIOSIMILAR RED TAPE ELIMINATION ACT (S2305)' webinar. REGISTER NOW!