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Association for Accessible Medicines

Biosimilars Council
A Division of the Association for Accessible Medicines

GRx+Biosims™
Generic + Biosimilar Medicines Conference

Emerging Technologies: How Can the Generic Industry Participate and Benefit?

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Background & Context

- US FDA : PAT and Pharmaceutical Quality for 21st Century
- Sandoz: Biosimilars and Complex Generics
- Advisor to several generic companies, Apotex, Dr. Reddy's,…..
- First Generic Scientific Dispute Resolution: Emerging Technology
- Advisor and shareholder Continuus Pharmaceuticals
- NIPTE's "New Prior Knowledge" Efforts

Statement of the Problem

- How can generics participate and benefit?
- Very few generics can participate and benefit as brands do
- Most will need support
  - Contract Research, Development & Manufacturing
  - Public-private partnerships
  - Certain academic consortia such as NIPTE
- What type of support
  - Technology applications for product & process development
  - Regulatory applications
  - Education, training and certification
- What FDA can do?
  - Address legacy issues and opportunities for pre ANDA meetings

Making Progress

- We cannot keep ignoring the legacy challenges
  - Initial conditions and Attractors
  - Underestimating complexity
  - Pivotal “Bio” vs Therapeutic Equivalence as a system
  - Outdated regulations and definitions
- We can establish public-private partnerships
  - NIPTE has initiated discussion with policymakers

Summary

- Few, if any, generic companies are well equipped to benefit from ET
- ET can come home only if we build target partnerships to overcome legacy hurdles and reduce complexity
- NIPTE – 17 collaborating American Universities is part of the solution

Thank You

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