Furthering Biosimilar Acceptance and Use Through Harmonization & Transparency

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- Pediatric Rheumatologist with more than 30 years experience treating children and young adults with chronic autoimmune conditions
- Chairman, Alliance for Safe Biologic Medicines, 2014-2017
- American College of Rheumatology (1981 - present)
- American Academy of Pediatrics (1980 - present)

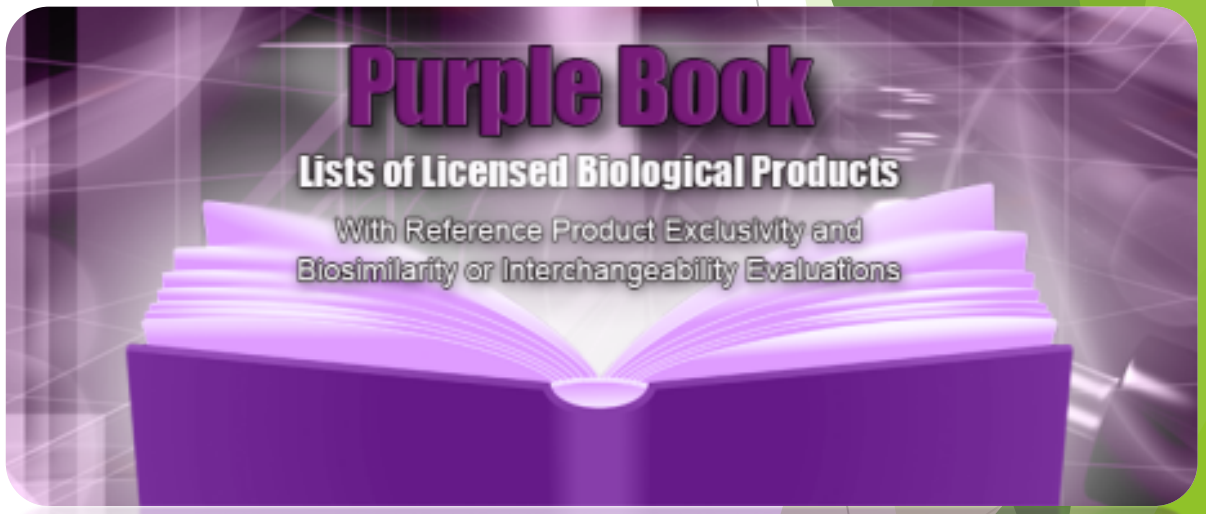
- **Can personally attest to the value of these medicines**
  - Offering new treatment choices
  - Expanding access to these life-changing therapies
  - Reducing costs to the healthcare system

Question 1:Helping Biosimilar Get to Patients More Quickly

- ADD FDA RESOURCES
  FDA should devote additional resources, including personnel, to speed biosimilar evaluation without compromising on quality and safety.
- ENSURE THERAPEUTIC CHOICES
  Ensure EHRs and formularies have ALL OPTIONS AVAILABLE with pricing.
- (PIE IN THE SKY)
  Eliminate Formularies?

Question 2: Purple Book

- Many, perhaps even most, physicians are not aware of its existence.
- RECOMMENDATIONS:
- FDA should create “CLIFFS NOTES” version
- Incorporate into EHRs, insurance and PBM literature, etc.
- Provide ongoing educational updates about the Purple Book and its use



Question 3: The Biosimilar Marketplace

APPROVAL & INTERCHANGEABILITY ≠ ACCESS

- There should be an equal playing field for all options.
- **Open formularies with transparent pricing** would create a true marketplace where prescribers & patients would determine the best personal choices based upon efficacy, safety & price.

Question 4: Biosimilar Development

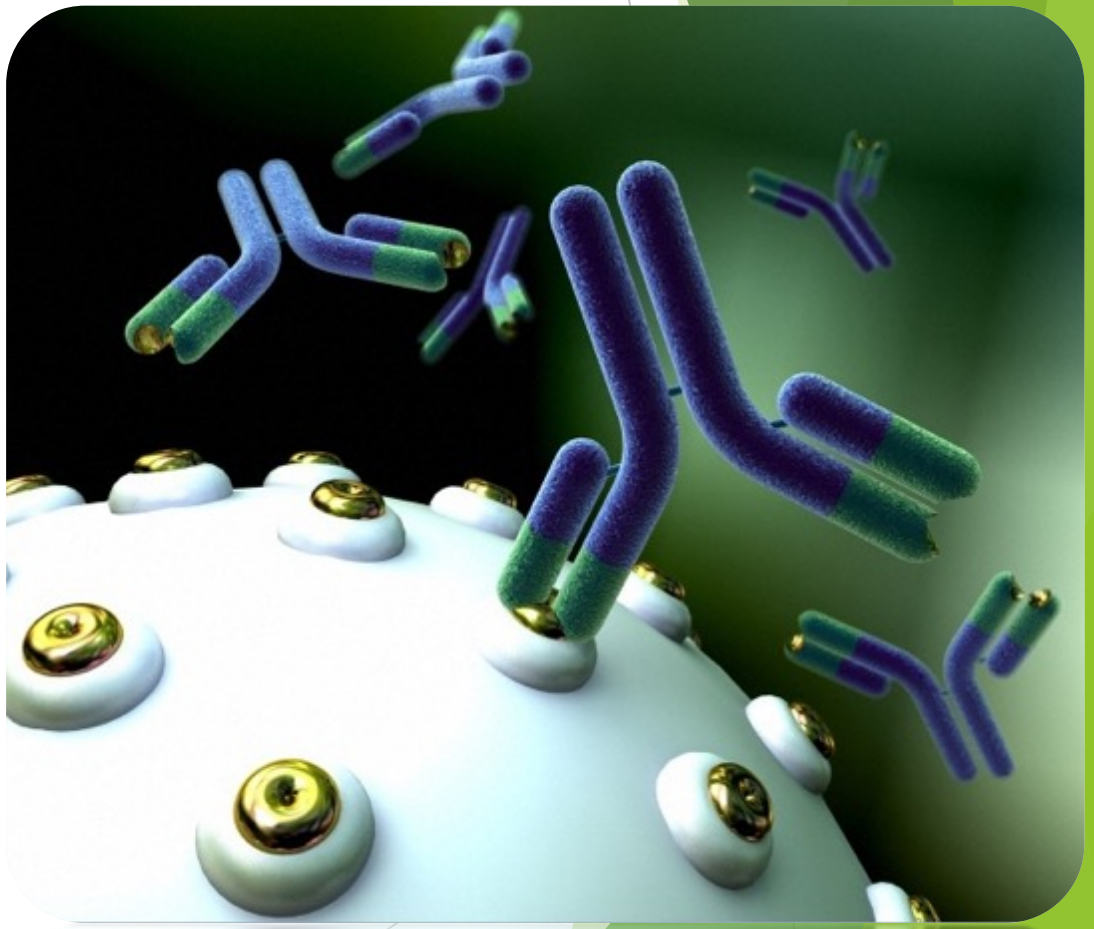
- FDA must keep its scientific rigor, even if it takes longer.
- LACK of CONFIDENCE regarding a lowering of FDA's standards will be difficult to regain if there is ever an error as a result.
- SUGGESTION: Consider having all manufacturers to provide the FDA with adequate samples that can be made available to biosimilar manufacturers.

Question 5: Multinational Development

- GLOBAL HARMONIZATION of NAMING for ALL BIOLOGICS, INCLUDING BIOSIMILARS will be a first step.
- HARMONIZE CRITERIA to encourage the same products being marketed to multiple nations, and thereby meaning more non-US comparators will be available.
- Use non-US comparators if FDA multinational data shows them to be within acceptable FDA ranges.

Question 7: Balancing Innovation & Competition

- **FOCUS ON THE MOLECULES**
- Teach prescribers and patients that it's the molecules that matter.
- Track the various uses through Patient Reported Outcomes (PROs), Real World Evidence (RWE) and registries (i.e, the American College of Rheumatology's RISE registry, etc)



Question 9: Addressing These and Other Challenges to Biosimilar Acceptance and Use

- **Eliminate costly administrative barriers** between the physician and patient treatment choices and the dispensing of that choice.
- **Transparent pricing** and actual costs.
- Have **consumers copays based upon the actual final cost** after discounts, fees, etc., similar to how copays are determined for negotiated medical pricing.
- Encourage **testing of biosimilars vs. biosimilars** to promote confidence and further our understanding of modes of action.
- **Make public a robust, active pharmacovigilance process to build confidence** that biosimilars are safe and effective, not just less costly.

Thank You for Your Attention