SafeBiologics
ALLIANCE for SAFE BIOLOGIC MEDICINES

Promoting Biosimilar Development, Access and Uptake

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Introduction

Madelaine Feldman, MD FACR

- Practicing Rheumatologist
- Founding Member and Past President of the Rheumatology Alliance of Louisiana
- Vice-president of the Coalition of State Rheumatology Organizations
- Clinical Associate Professor of Medicine at Tulane University School of Medicine
- Chair, Alliance for Safe Biologic Medicines

About ASBM

- Formed in 2010, currently more than 135 members.
- **<u>Steering Committee composed entirely of patient and physician member organizations.</u>**
- Have presented to FDA, Health Canada, TGA, Spanish and Italian Health Ministries, & European Commission
- Have participated in past 10 of the WHO's INN Consultations
- On July 12th, held the 2nd in a series of stakeholder meetings on International Harmonization of Biologic Nomenclature in Washington, DC with the FDA, Health Canada, and WHO among the participants.

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STEERING COMMITTEE

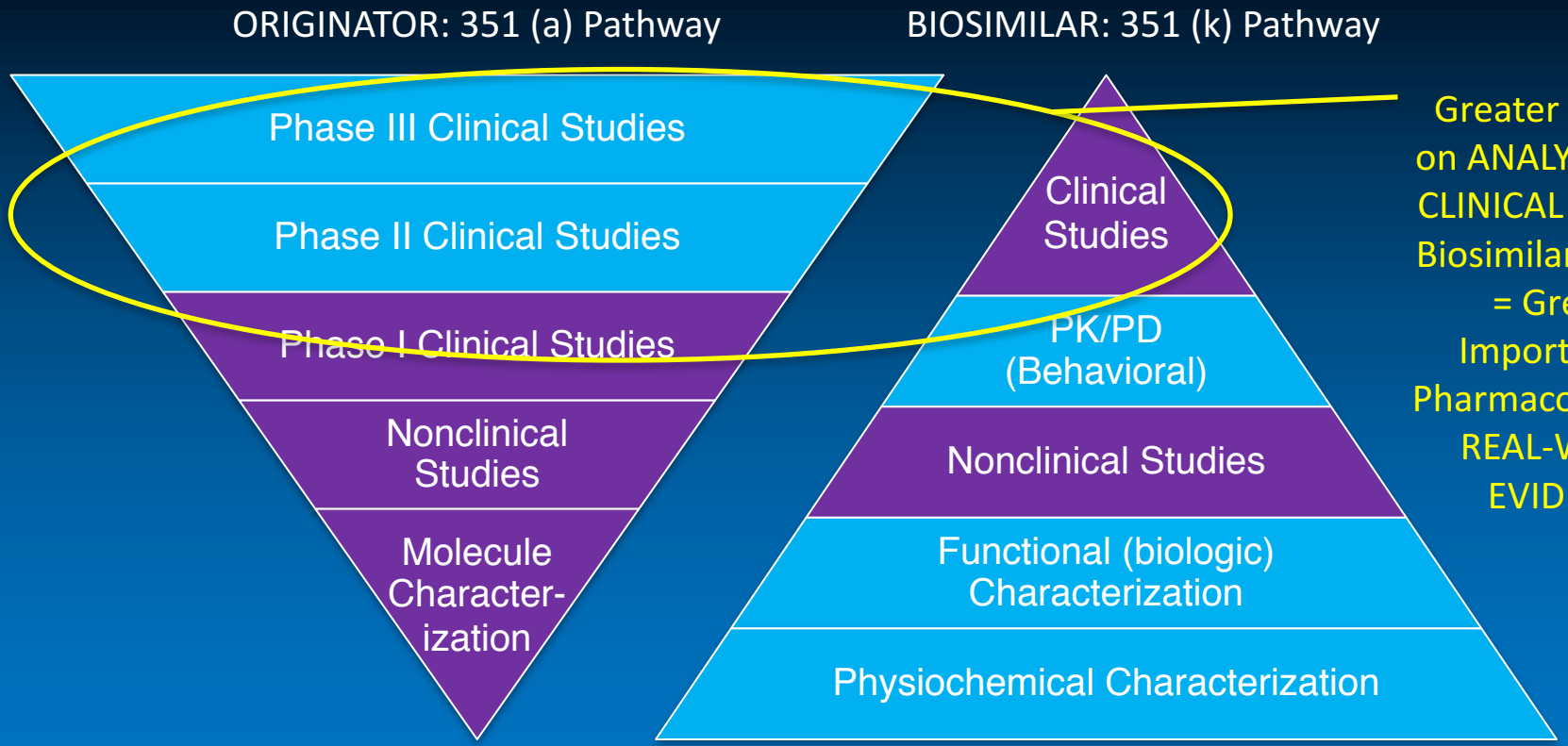
AfPA Alliance for Patient Access
AAD American Academy of Dermatology 1938
American Autoimmune Related Diseases Association, Inc.
ACRO Association of Clinical Research Organizations
colorectal cancer alliance
Global Colon Cancer Association
GLOBAL HEALTHY LIVING FOUNDATION
HealthHIV
ican international cancer advocacy network the virtual lifeline for proactive cancer patients
Kidney Cancer Association
LUPUS and ALLIED DISEASES Association, Inc.
NATIONAL PSORIASIS FOUNDATION
NHMA National Hispanic Medical Association
ZERO THE END OF PROSTATE CANCER

The FDA is On the Right Track…

- **ASBM commends FDA for its biosimilar approval process, including its rigorous scientific standards.**
- We are not far behind Europe, and catching up.
- 12 biosimilars approved – roughly keeping pace with EMA (9-year head start)
- FDA's first Biosimilar MAb approved only 2.5 years after EMA's
- At this pace, the US may overtake Europe in approvals.


Undoubtedly Many Regulatory Agencies Are Under Pressure to Speed the Number of Approvals by Lowering Standards- Don't.

Building Confidence Through Post-Market Surveillance, Real World Evidence:



Building Physician and Patient Confidence in Biosimilars

- Education
- A cautious, science based approach it NOT a barrier to access or uptake.
- To the contrary, It is MORE important to build physician confidence to promote uptake.

- Clinicians are cautious and want to see data, preferably US experience.
- Especially important when switching stable patients - Data ensuring that switching can be performed safely.

Interchangeability=Transitive?

This is an important policy point which the FDA should emphasize in Guidance.

Biologic Nomenclature: FDA is Leading on this Issue.

66% of US Physicians, 68% of US Pharmacists Support The FDA issuing DISTINCT NONPROPRIETARY NAMES.*

Ensures clear communication, promotes manufacturer accountability, accurate attribution of adverse events.

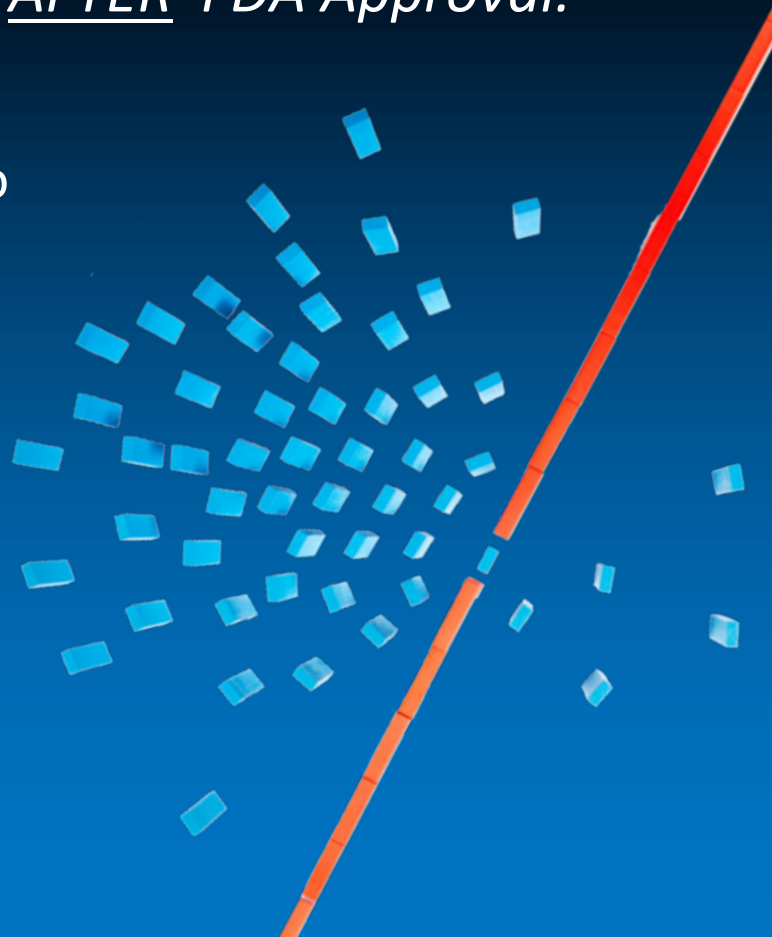
- April and July Meetings with ASBM, Health Canada, Physicians, Patients, WHO on Harmonization. DISTINCT NAMING and INTERNATIONAL HARMONIZATION are CRITICAL

- In surveys of 12 countries, roughly 1/3 of physicians used ONLY the INN when reporting Adverse Events. Including 38% of US physicians.*
- FDA should continue to work with NRAs worldwide to build a GLOBAL system of pharmacovigilance
- FDA should provide more support and encouragement to WHO to move distinct naming forward internationally.

*Source: www.safebiologics.org/surveys

The "Bottleneck" in Access is Happening AFTER FDA Approval.

- Despite 12 approvals, only 4 are available to patients.
- As Dr. Gottlieb observed at the Brookings Event announcing the Biosimilars Action Plan, the Barriers to Access Are NOT Scientific, but COMMERCIAL. We agree.
- Innovation and competition.
- Education, litigation and formulary access



But Price Competition Alone Does Not Ensure Access…

- Despite discounts of 15-33%, biosimilars remain unaffordable without insurance – not on the formulary.
- For 80% of Americans, the formulary of the top three PBMs determine what medicine is covered.
- Choosing a medicine becomes to an extent the question: *"What insurance do you have"?*
- But how does a PBM or insurer determine which medicine gets the preferred placement on the formulary?

Manufacturers Compete for the Preferred Spot…

COMPETITION DRIVES PRICES DOWN

COMPETITION DRIVES PRICES UP

BUILDING A HOUSE

WINNER= Lowest Bidder

SELLING A HOUSE

WINNER= Highest Bidder

OUR DRUG DISTRIBUTION SYSTEM

- PBMs receive rebates/fees based on a % of the list price of the medicine.
- These price concessions can be over 50% of the list price.
- **This creates a perverse incentive for HIGHER PRICED MEDICINES, not lower, because the HIGHER PRICED MEDICINE can provide the larger rebate fee package.**

Ensuring Real Access Requires Penetrating the "Formulary Wall"

- **Neither lower prices NOR faster approval seem to get a biosimilar medicine on a PBM's preferred formulary list.**
- This poses a critical barrier to access.
- To increase access to biosimilars, FDA must work with other agencies in the government on policies which address this reality.
- Options could include formularies based on efficacy, safety and lowest list price – not highest price concession based on a % of the list price.

Summary

- FDA should not compromise on its rigorous standards for safety and efficacy; either with biosimilars or interchangeable biosimilars.
- The heavy reliance on analytics vs. clinical trials in the biosimilar approval pathway does however require additional post-market surveillance and real world evidence to build physician confidence, particularly in when switching stable patients.
- FDA's sensible approach to distinct naming helps build a strong pharmacovigilance system in the US; international harmonization is critical to best realize the benefits of biosimilars.
- The FDA is doing things right; the primary barriers to access are not in the evaluation and approval stage, but post-approval. FDA should work with other government entities to encourage real price competition that benefits patients.

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Thank You For Your Attention