



SafeBiologics
ALLIANCE *for* SAFE BIOLOGIC MEDICINES

International Biosimilar Standards: The Patient (and Physician) Perspective

Andrew Spiegel

Executive Director, Global Colon Cancer Association

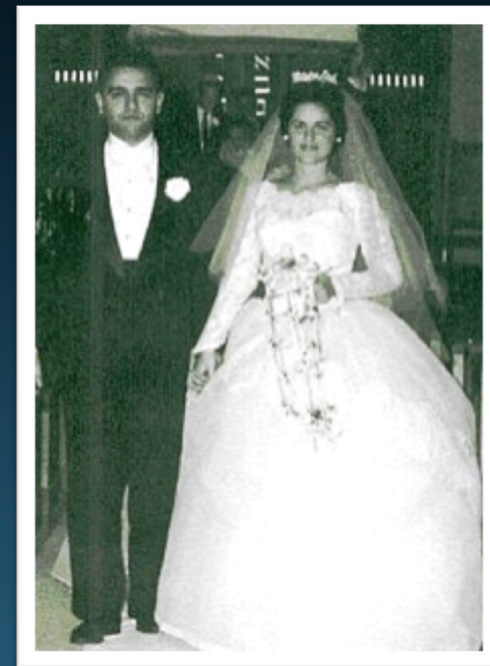
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Introduction: My History As a Patient Advocate

- In January of 1999 I lost both parents to Cancer two days apart
- That year, along with other cancer patients and survivors, I founded the Colon Cancer Alliance
- 2010: Cofounded the Alliance for Safe Biologic Medicines, and currently sit on ASBM Steering Committee
- 2011: Founded the Global Colon Cancer Association, which advocates for 6 million colorectal cancer patients worldwide
- 2013: GCCA joined The International Alliance of Patient Organizations (IAPO)
- 2014: GCCA Collaborating on Brazilian CRC campaign with Instituto Oncoguia
- August 23, 2014: Attended Alanzia Latina/IAPO Conference
- Q4 2014/ Q1 2015: GCCA launching CRC Campaign in Argentina



About ASBM

- ASBM has been active on the issue of biosimilar naming:
 - November 2012: FDLI Paper on Naming “What’s In A Name”
 - July 2014: GaBI Paper on our EU Prescriber Survey –August 2014: Letter to FDA in support of distinguishable names, signed by more than 70 patient and physician groups
 - August 14: our Chairman-elect, pediatric rheumatologist Dr. Harry Gewanter, presented at the 4th Latin America Forum on Biosimilars in Brasília on physician perspectives on biosimilars.



ASBM Chairman-Elect Presents EU Physician Survey Results in Brasília

Dr. Gewanter's presentation drew heavily from ASBM's November 2013 survey of 470 EU physicians.

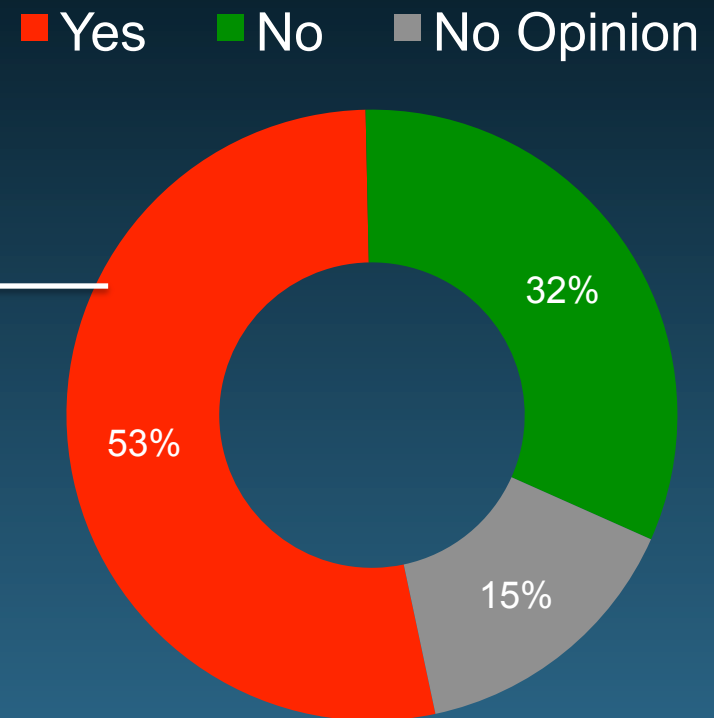
The full survey results are available on our website at www.safebiologics.org

The survey found that physician misconceptions about biosimilars, and prescribing and AE reporting practices in Europe underscore a need for a clear naming system with distinguishable nonproprietary names for all biologics, including biosimilars, to facilitate intended prescribing and traceability.

EVEN where biosimilars have been available longest, AND a system for tracking exists, providers strongly support distinguishable names for ALL biologics.

E.U. Prescriber Survey Results Show Importance of Distinguishable Names

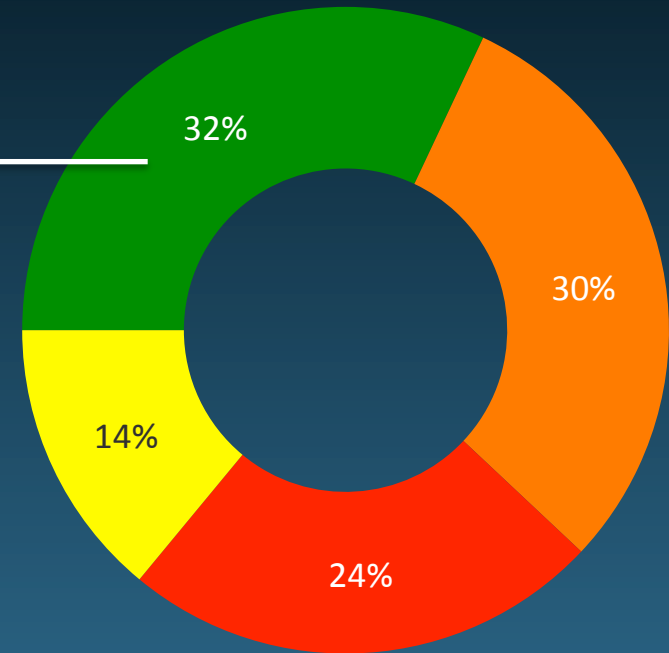
- **53%** of respondents mistakenly believe a biosimilar with identical non-proprietary name as its reference biologic is **STRUCTURALLY IDENTICAL**. *(Compare to 76% of U.S. respondents which believed this)*
- **61%** of respondents believe biosimilar with an identical non-proprietary name as its reference biologic is **APPROVED FOR THE SAME INDICATIONS**, which may not be the case.



E.U. Prescriber Survey Results Show Importance of Distinguishable Names

WHEN IDENTIFYING IN PATIENT RECORD:

- **Only 32% of respondents** use brand name and non-proprietary name (INN) to identify the exact biologic being prescribed
- **24% use INN only**, which could result in patients receiving the wrong medicine without distinguishable names for biosimilars



- Brand and Generic
- Brand Only
- Generic Only
- Varies by Medicine

Development of International Naming Standards

- ASBM's current chairman, Dr. Richard Dolinar, presented survey data at the WHO's 58th Consultations on International Nonproprietary Names (INN)
- A proposal was suggested for a BIOLOGICAL QUALIFIER (BQ) -a random string of letters added to the biosimilar product's INN
- Comments on BQ Proposal accepted until September 19
- ASBM will submit formal comments supporting BQ and will return to the 59th INN Consultation October 2014



Why Distinguishable Names For Biosimilars Are Important to Patients and Physicians

- **Patients and their caregivers are the last line of defense - unique names ensure that they can accurately identify the product.**
- Distinguishable naming provides transparency and helps differentiate **products for observing and reporting adverse events.**
- Accurate tracing of a product to the correct Marketing Authorization Holder promotes safety and accountability
- Multiple means of product identification avoid a single point of information failure



BQ Proposal: A Global Solution to a Global Problem

- Current “patchwork approach” of each NRA either using the same INN or developing its own system is not HELPFUL OR SUSTAINABLE
- The WHO’s proposal for a distinguishable INN via Biological Qualifier for biosimilars represents significant progress toward a naming system that will increase safety for patients globally
- The time is right: TODAY there are relatively few approved biosimilars, HOWEVER biologics comprise 40% of INN applications so the challenge of distinguishing among products will only grow over time
- Our data shows that distinguishable INNs are important to the practicing physicians of Europe, and it is our hope that this will be useful in crafting a global standard that will improve safety for patients worldwide
- Implementation of the BQ is workable! Australia and Japan have already allowed for it in their regulatory naming paradigm.

Summary

- QUALITY AND SAFETY OF BIOTECH MEDICINES ARE IMPORTANT TO PATIENTS
- QUALITY FLOWS FROM ACCOUNTABILITY.
 - DISTINGUISHABLE NONPROPRIETARY NAMES HELP ENSURE THAT ANY ADVERSE REACTIONS ARE ATTRIBUTED TO THE CORRECT PRODUCT – BIOSIMILAR OR REFERENCE PRODUCT
- SURVEY DATA SHOWS THAT DOCTORS MISTAKENLY THINK SAME NAME INDICATES IDENTICAL PRODUCT, INDICATIONS, ETC.
 - This misunderstanding can put patients at risk
- The WHO's BQ proposal is a POSITIVE step toward global pharmacovigilance and patient safety
- Implementation of the WHO BQ is achievable and can be simple – Australia and Japan already have policies in place to do so.
- We urge all NRAs of the world to adopt a consistent, international regulatory framework for this global issue.



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Thank You For Your Attention