BIOSIMILARS: The Patient Perspective

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Introduction

Andrew Spiegel, Esq.

- Patient Advocate since 1998
- Co-Founded the Colon Cancer Alliance
- Executive Director of the Global Colon Cancer Association (GCCA)
- Chair, Digestive Disease National Coalition
- Board Member, International Association of Patient Organizations (IAPO)
- Co-Founder and Steering Committee Member of the **Alliance for Safe Biologic Medicines**

Sharing Patient Perspectives Worldwide

Europe:

- 2015: World Biosimilars Congress- Basel, Switzerland

North America:

- 2016: Three FDA Arthritis Advisory Committee Hearings
- Numerous U.S. State Legislatures 2010-2016

Latin America:

- April 2016: PANLAR (Pan American League of Associations for Rheumatology, Panama City)
- September 2016: Latin American Biosimilars Forum (All Together Against Cancer)- Sao Paulo, Brazil

icdra

International Alliance of Patients' Organizations

XIX PANLAR PANAMA
City of Panama
April 10-14 2016
Pre-Congress: April 10th

TODOS JUNTOS CONTRA O CÂNCER

Patient Advocacy

- Over 1.2 Million diagnosed with CRC EACH YEAR worldwide, over 600K deaths.
- Global Colon Cancer Association, advocates for a global community of over 6 million colorectal cancer patients.
- Global experience has raised awareness of the importance of physician/ patient-led, not government or payer-led decision-making in treatment.
- In late 2010, Co-founded ASBM to bring the PATIENT PERSPECTIVE to discussion about biologics/biosimilar policy.

Patients and Biologics

- About 350 million people around the world are benefiting from a biologic medicine.
- Biologics are unique medicines used to treat serious, long lasting conditions.
- Many patients take years to find a medicine that works for them to help control disease:
  - biologic medicines may be the most or even the only effective treatment.
  - For patients that are on a biologic that is working for them, decisions related to switching therapy should be carefully considered.
  - Changes in therapy could lead to an immune response and/or a loss of response to the new and old therapy, exposing patients to a scenario with no or fewer, or more serious treatment options.

Example: Improved Treatments For Colorectal Cancer Patients

- Access to new medicines have given our patients TIME and HOPE.
- We've gone from one drug to nearly ten in a decade, half biologics.
- The life expectancy of late stage patients has almost TRIPLED, from 11 months to almost THREE YEARS. From "months" to "years".
- This means more time with their families- meeting their grandchildren, attending weddings of their children.

The Promise of Biosimilars

- Biosimilars offer many benefits to patients:
  - Increased access to biologic therapies
  - New therapeutic choices
  - Lower-cost alternatives
- Available in E.U. and Canada for several years, now in U.S.
- U.S. currently developing biosimilar policy at the Federal and State level.
- We want to make sure these policies work for patients.

What Are Our Overall Objectives?

To be unbiased representatives of the patient community, advocating on critical issues important to patients.

- **Increased access** to biosimilars.
- **Patient-centered standards** for naming, safety and tracking of biosimilars.
- **Informed patient/physician** in the case of substitution of a biosimilar in place of prescribed biologic.

Patient/Physician Confidence Is Key

Naming, Labeling and Substitution are all fundamentally issues of <u>TRANSPARENCY and DATA.</u>

ASBM's approach has been to EDUCATE stakeholders, and to work with regulators to promote policies which BUILD PHYSICIAN/PATIENT CONFIDENCE IN BIOSIMILARS by requiring TRANSPARENCY and DATA.

Biosimilar Substitution: Patient Perspective

Non-Medical Switching

Switching a patient's medicine, often by a third party for reasons other than that patient's health and safety.

Issues Surrounding Non-Medical Switching

- Changing your treatment may change the control a patient has over their condition.
- Patient and doctor should have the final say about treatment choices- which biologic to use, and if and when switching is appropriate.
- If your medicine is working for you, most doctors don't think it is a good idea to switch from one biologic to another for cost reasons only.

Forcing Patients to Switch Medicines

- Health insurers may encourage a change from a biologic to a non-interchangeable biosimilar, for the sole reason of reducing costs.

- No patient protections exist to prevent insurers from forcing a patient to switch therapies:
  - Higher out of pocket costs (coinsurance, copay, etc.) for your current therapy
  - Formulary design changes mid-plan year and plan-year to plan-year
  - Disadvantage products by changing tiers
  - Blocking the use of co-pay cards

Some data suggests that Non-Medical Switching actually increases costs for the individual and the health care system because of an increase in hospitalizations, doctor visits and other health care services.

Arthritis Advisory Committee Hearings

- On February 9th, July 12th, and July 13th 2016 the FDA's Arthritis Advisory Committee (AAC) held day-long meetings to discuss three new biosimilars.
- All three are TNF inhibitors, which are used to treat Rheumatoid Arthritis, Ankylosing Spondylitis, Psoriasis, Crohn's Disease and Ulcerative Colitis.
- On Feb. 9th: AAC voted 21-3 to recommend FDA approve an **infliximab** biosimilar, Inflectra for all indications of the reference product for which it applied. It provided data in RA and AS.
  - The 3 Advisory Committee Members who voted NOT to approve expressed concern about EXTRAPOLATION to the IBD Indications (Crohn's Disease, Ulcerative Colitis).

July 12th-13th FDA Arthritis Advisory Committee Hearings

- On July 12th, AAC voted 26-0 to recommend FDA approve an **adalimumab** biosimilar for all indications of the reference product for which it applied.

- On July 13th, AAC voted 20-0 to recommend FDA approve an **etanercept** biosimilar for all indications of the reference product for which it applied. Approved August 30 as Erelzi (etanercept-szzs).

- Each provided clinical biosimilarity data for RA and Psoriasis

- BUT several members expressed concerns with lack of clinical data and extrapolation to IBD conditions and emphasized the need for robust POST-MARKET SURVEILLANCE.

Differing Clinical Data Requirements Globally (Example: Inflectra)

- In 2013, the EMA approved Inflectra for ALL indications of its reference product.

- In 2014, Canada approved for RA and AS indications based on data, allowed extrapolation for Psoriasis due to a similar mechanism of action, but required additional clinical data before approving for UC and CD two years later.

- But, FDA AAC Members were only given the choice to recommend approval for ALL INDICATIONS or NONE AT ALL. Vote was 21 for, 3 against.
  - This Omnibus "All or Nothing" approach does not support patient safety.

- What would AAC votes look like if members were allowed to vote on each indication separately, as in Canada?

How Does This Pertain to Pharmacists?

The Patient-Pharmacist Relationship

- Pharmacists are the **last link in the chain that brings us our live-saving treatments** - this includes the researcher, the regulator, the manufacturer, the physician, and finally, the pharmacist.
- As the people who prepare and dispense these medicines – you are our **last line of defense** on patient safety.
- We turn to you for questions on our medication, and expect that you will have **informed answers**.
- We expect that you will **work cooperatively with our physicians** in our treatment.

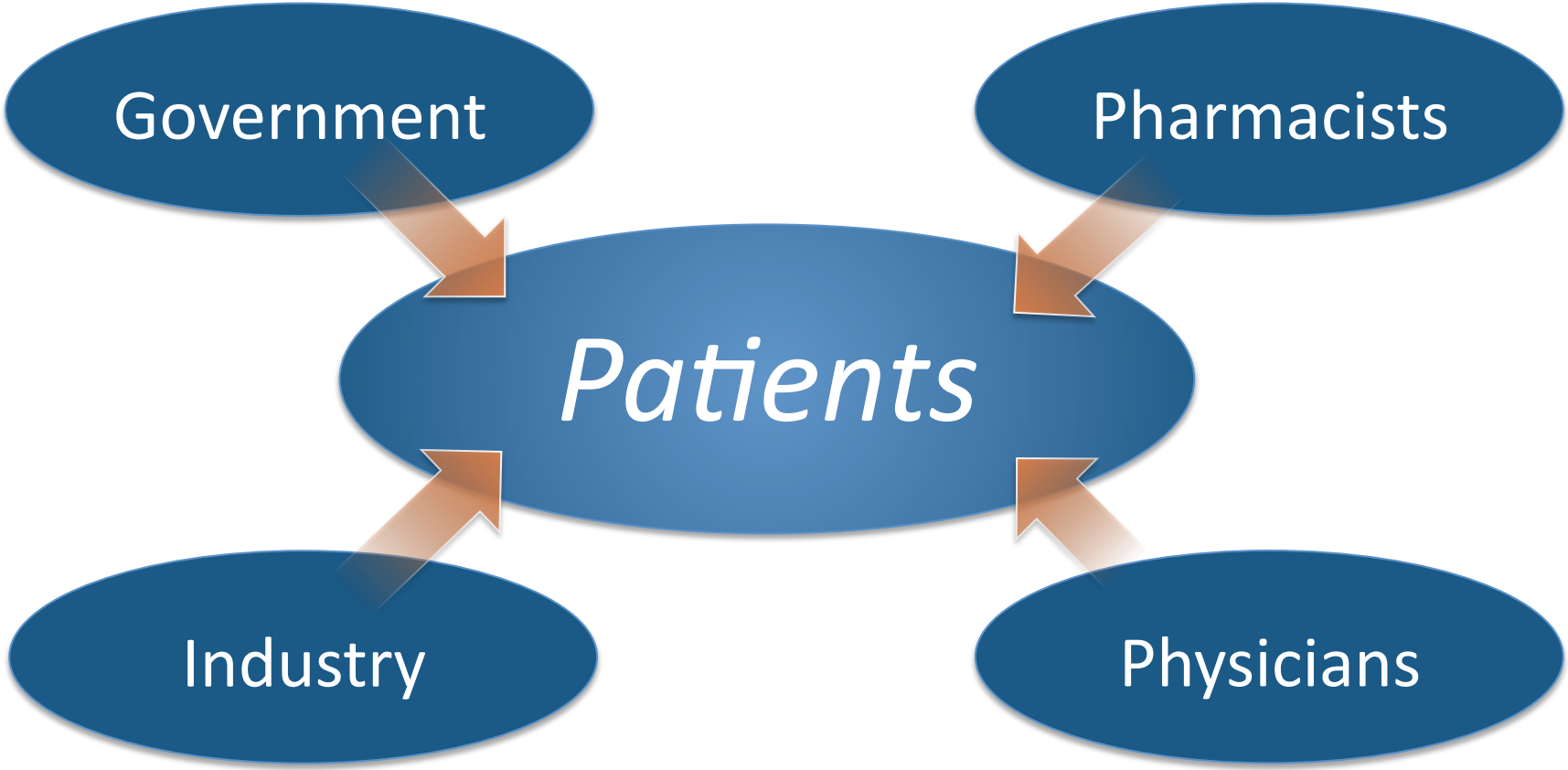
Working at the State Level

GCCA has testified in support of legislation under consideration in many U.S. states that would allow a pharmacist to **substitute an interchangeable biosimilar** in place of a prescribed reference biologic medicine, provided the physician is notified after the substitution has occurred.

This legislation:

- Lowers treatment costs
- Improves access
- Promotes patient safety
- Preserves doctor-patient relationship
- Improves pharmacist-patient relationship

We want **PATIENTS** at the CENTER of all Health Care and Policy



What We, As Patients, Expect:

- We have the right to expect that **the life of the patient** remains the primary guiding principle of biosimilar policy discussions- not potential cost savings.
- We have the right to expect access to biosimilars and assurance that they are held to a similar standard of **safety, purity, and efficacy as their reference medicine.**
- We have the right, with our physicians, to determine the course of our treatment. This includes choosing which biologic medicine to use initially, and choosing if and when to switch.

Thank You For Your Attention