The Value of Patient Advocacy

Andrew Spiegel,
Executive Director, GCCA

Presented at the ASBM Forum, Washington DC
Feb 25, 2014
My Story

• Meet my parents
• Both diagnosed with cancer in 1998
• Jan. 16-18th 1999
• Co-Founder the Colon Cancer Alliance
Advocacy for Colon Cancer Patients

• Over 1.2 Million diagnosed with CRC EACH YEAR worldwide, over 600K deaths

• The CCA broadened advocacy efforts in 2011 by co-founding the Global Colon Cancer Association, advocating 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-led decision-making in treatment.

• Our mission: The GCCA is a community which enables colorectal cancer (CRC) patient groups worldwide to better serve their communities through information sharing and best practices. We help our member organizations collaborate, innovate and leverage the full potential of effectuating change to support their missions to prevent CRC, support patients and advocate for change.
• In 2010, the Colon Cancer Alliance was a founding member of ASBM

• Global Colon Cancer Association is currently member of ASBM’s Steering Committee

• Three Steering Committee members are here today on this panel.
Why Should Patients Care About Biologics?
• Access to new medicines have given our patients TIME and HOPE. One drug nearly ten in a decade, several biologics.

• The life expectancy of late stage patients has almost TRIPLED, from 11 months to almost 30. From “months” to “years”.

• This means more time with their families- meeting their grandchildren, attending weddings of their children.
Biologics hold promise to enhance and save lives

- Worldwide, nearly **200 biologic medicines** have transformed the lives of over **800 million patients** with serious illnesses.¹
- These patients suffer from diseases like cancer, blood conditions, auto-immune disorders such as rheumatoid arthritis (RA) and psoriasis, and neurological disorders like multiple sclerosis.
- Examples:
  - CRC patients
  - Diabetes patients: easier to use, faster working, longer-lasting insulins
  - Growth hormone deficiency treatments for abnormally short children

Currently, there are over 400 biologics in development worldwide for diseases such as HIV/AIDS, Cancer, Cardiovascular disease, Alzheimer's and Autoimmune diseases.

---

Why Do Patients Care About Biosimilars and Biosimilar Policy?
Increasing Patient Access to Biologic Medicines

Advocate for Methods of Increasing Affordability of Treatments:

• More Patient Assistance Programs from manufacturers
• More Government coverage
• Advocate for private insurance coverage

Increase access to Biosimilar Medications

• Lower-cost alternative to biologic medicines
• Available in E.U. and Canada, not yet available in U.S.
• U.S. currently developing biosimilar policy at the Federal and State level
Patient Advocacy Through ASBM

Testimony at FDA Hearing

6 of the 8 patient groups that testified that day were ASBM members.

“While we wish that preventative methods alone were sufficient to defeat colon cancer, this is currently not the case. Biologic medicines offer such promise and enable patients to live longer, healthier lives. Because these medicines have improved the survivorship rates, [we] have a vested interest in seeing biosimilar medicines introduced to the U.S. market.”

-Andrew Spiegel
FDA Hearing, May 11, 2011
Patient Advocacy Through ASBM

Letters and Op-eds

MEDCITY News

Patient Safety Depends on Prevention
Andrew Spiegel
June 28, 2011

Prevention is a key message of the Colon Cancer Alliance. Colon cancer can be prevented with recommended screening. Early detection and treatment of cancer is one of the most detectable and, if found early, most curable. With the widespread adoption of common screening tests, millions of lives could be saved each year.

SafeBiologics

August 30, 2012
Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hamburg,

We appreciate the opportunities that the Food and Drug Administration (FDA) has given stakeholders to provide input as the FDA develops guidance and policies on biosimilars. The Alliance for Safe Biologic Medicines (ASBM), has been working for nearly two years to support the FDA in its mission to safely bring biosimilars to patients in the U.S. In just the past few months, we submitted comments on the draft biosimilar guidance, testified at the May 11 Public Hearing and are working with our National Advisory Board to develop a position paper. Physicians, patients and industry share our commitment.

We appreciate the FDA’s efforts to ensure that the biosimilar guidance is inclusive of the entire spectrum of stakeholders, including patients. In this regard, ASBM has been a leader in advocating for the necessary elements to be included in the guidance.

ASBM’s position paper outlines the need for a clear, concise and scalable pathway for approval of biosimilars. It provides supporting evidence from all stakeholders, including patients, physicians and industry. ASBM is committed to developing high-quality, affordable and safe biologic drugs for patients. We look forward to working with the FDA to ensure that patients have access to affordable, safe and effective medications.
Patient Advocacy Through ASBM

Biosimilars Forums

Philadelphia, PA - August 17, 2011
Richmond, VA - September 28, 2011
Washington, DC - February 27, 2012
Phoenix, AZ - September 27, 2012
Denver, CO - December 6, 2012
Kingston, RI - December 13, 2012
Meetings with Patient Groups Around the World

In 2013 attended two International Association of Patient Organizations (IAPO) Events:

• Biosimilars Workshop, -May 2, 2013, Geneva

• Latin American Multi-Stakeholder Seminar on Patient-centered Access to Healthcare. -September 23, Mexico City
What is Our Overall Objective?

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

• Increased access to biosimilars

• Patient centered standards for safety and naming of biosimilars

• Informed patient/physician in the case of substitution of a biosimilar in place of prescribed biologic
We want PATIENTS at the CENTER of all Health Care and Policy.

Legislation

Regulation

Industry

Physicians

Patients
ASBM supports 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
What We, As Patients, Expect:

• We have the right to expect that **the life of the patient** remains the primary guiding principle of U.S. health policy discussions- not potential cost savings.

• We have the right to expect access to biosimilars and assurance that they are held to a high standard of safety and efficacy.

• We have a right to expect that these high standards are guaranteed to patients worldwide

• We (patient and physician) have the right to be informed if a government, insurer, pharmacist, or other third party wishes to substitute a biosimilar for the prescribed biologic.
What Can Patient Advocates Do To Help?
What can patients and patient groups do?

• Join ASBM
• Invite other groups to join our efforts
• Visit www.SafeBiologics.org and follow us. Watch for advocate alerts and join our efforts where possible
• If you work in an industry which can support advocate groups like ASBM, please support us
• Follow ASBM on social media @safebiologics and sign up for monthly enewsletter