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ASSOCIATION

# Biosimilars: The Patient Perspective

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Presented at *“The Fundamentals of Biosimilars: What Every Pharmacist Will Need to Know”*

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# My Story

- Meet my parents
- Both diagnosed with cancer in 1998
- Jan. 16-18<sup>th</sup> 1999
- Co-Founded 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.
- 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.



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# Why Do Patients Care About Biologics?



# Biologics: 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, several 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.

# 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.<sup>1</sup>
- 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.





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# 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 to FDA



## Testimony at FDA Hearing

“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, 2012

# Working with Patients Around the World

## Meetings with Patient Groups Around the World

- International Alliance of Patients' Organizations (IAPO) Biosimilars Workshop, -May 2, 2013, Geneva
- IAPO Latin American Multi-Stakeholder Seminar on Patient-centered Access to Healthcare. -September 23, 2013 Mexico City
- IAPO Meeting *"Increasing the Patient Voice in Drug Regulatory Authorities"* in Rio de Janeiro, August 22, 2014





# Sharing Patient Perspectives on Biologics Around the World

- Presented at *“Understanding Biologic Medicine: Science, Regulatory Policy and the Changing Dynamics of Biosimilars”*, an forum hosted by AbbVie on June 10th in Paris
- Presented International Conference of Drug Regulatory Authorities in Rio De Janiero on August 24, 2014
- 15th Annual Business of Biosimilars Conference in Boston- October 20-22, 2014



# 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





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# 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

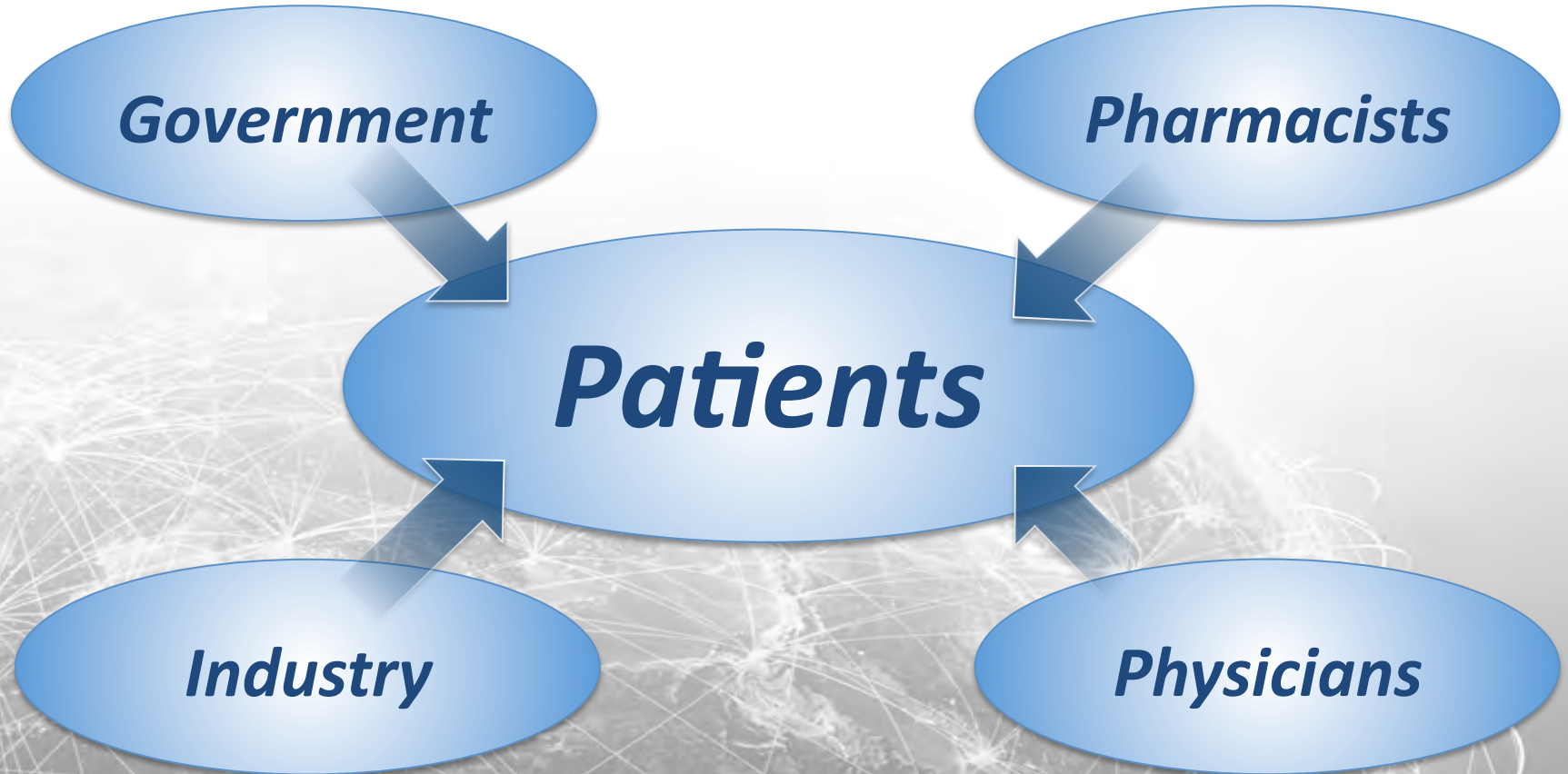
GCCA has testified in support of legislation under consideration in many U.S. states that would allow a pharmacist to **substitute an interchangeable biosimilar** in place of a prescribed reference biologic medicine, provided the physician is notified after the substitution has occurred.

## 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 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 similar standard of **safety, purity, and efficacy as their reference medicine.**
- We have a right to expect that these high standards are guaranteed to **patients worldwide**
- We (patient and our 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.



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*THANK YOU*