The Promise of Biosimilars: a Patient Advocate's Perspective

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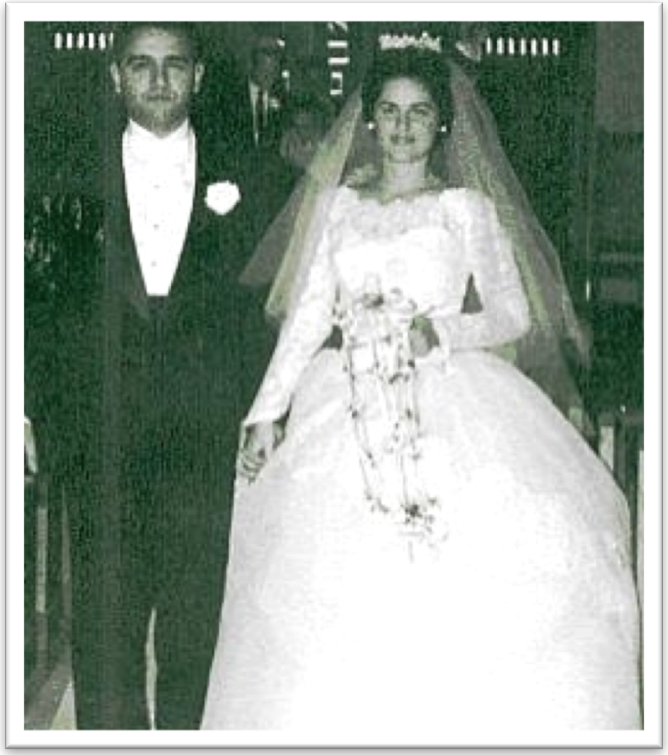
About Me

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
- Chair-Elect, International Association of Patient Organizations (IAPO)
- Co-Founder, Steering Committee Member of the Alliance for Safe Biologic Medicines



Patient Advocacy

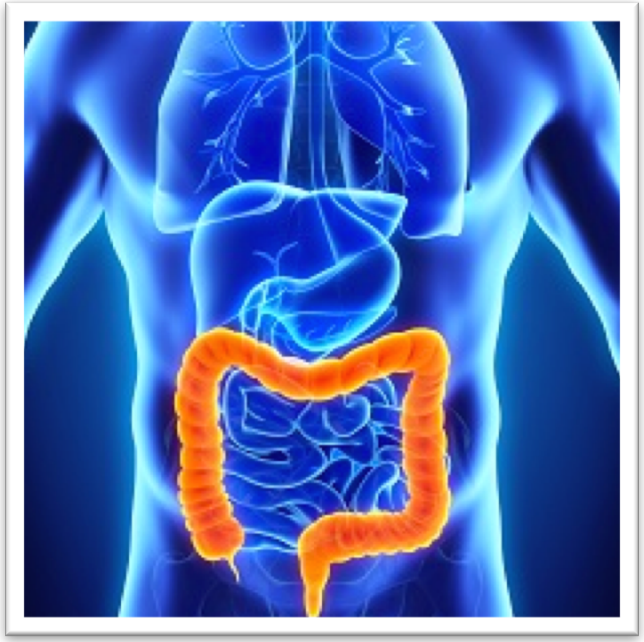
- Over 1.2 Million diagnosed with CRC EACH YEAR worldwide, over 600K deaths.
- Global Colon Cancer Association, advocates for a global community of over 6 million colorectal cancer patients.
- Global experience has raised awareness of the importance of physician/patient-led, not government or payer-led 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 800 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.

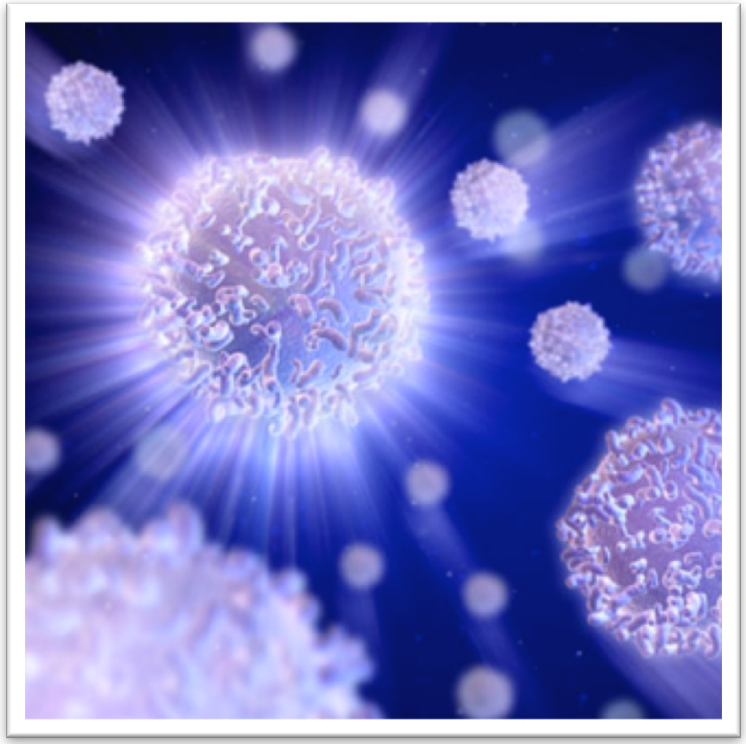
Improved Treatments For Colorectal Cancer Patients

- 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

- **<u>Patients are Excited about Biosimilars; they offer many benefits:</u>**
  - Greater access to biologic therapies
  - New therapeutic choices
  - Lower-cost alternatives
  - **But we want to make sure the Policies the FDA develops work for patients and have the following recommendations…**



1) Patients Should Come First.

Patients expect that the life of the patient should remain the primary guiding principle of biosimilar policy discussions- not potential cost savings.

2) There should be no sacrifice on quality, safety, or efficacy

Patients expect access to biosimilars and assurance that they are held to a similar standard of **safety, purity, and efficacy as their reference medicine.**

3) Collect data showing safe switching between different products.

When patients and physicians have a choice, they usually choose the originator to play it safe.

Data showing safe switching will help doctors and patients feel confident in using a biosimilar.

Europe has had biosimilars for 10 years, but failed to collect this data- a missed opportunity.

Interchangeability must be demonstrated between two products before third party substitution
(biosimilar for reference, not biosimilar for biosimilar)

4) Treatment Choice

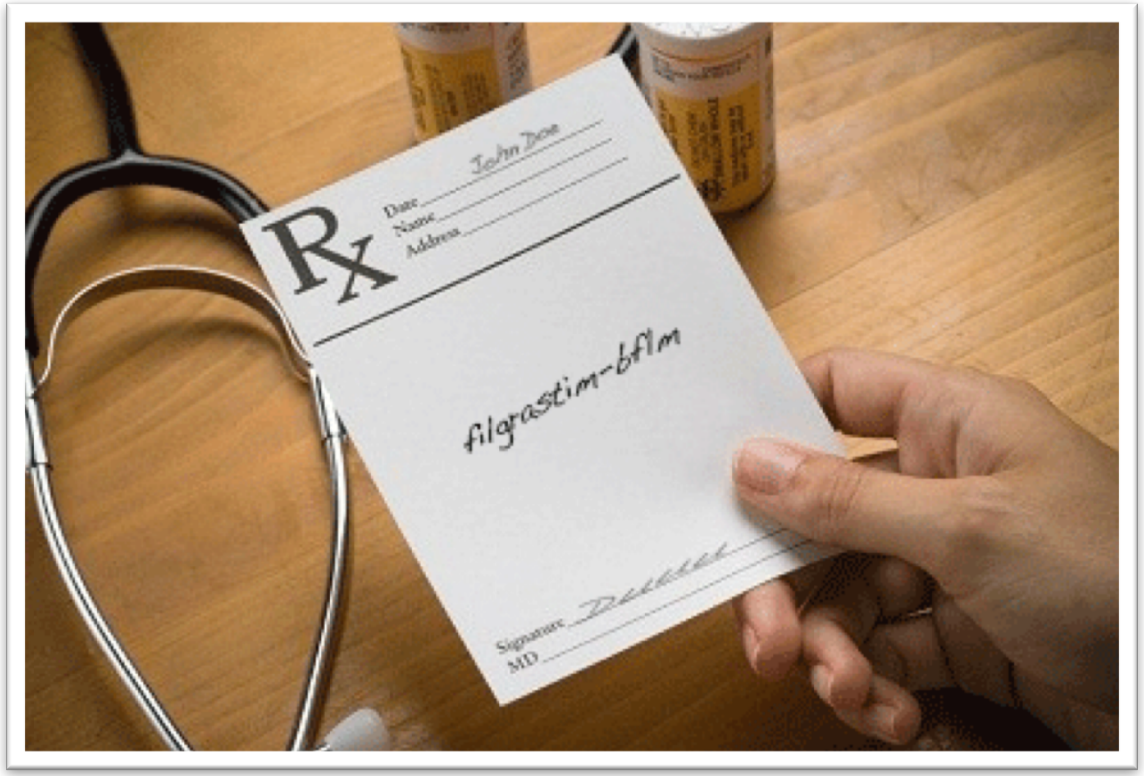
Treatment choices should be made by the patient and his or her healthcare team- not by third parties such as insurance companies.

This includes the decision if and when to switch to a biosimilar.

5) Robust Pharmacovigilance

Biosimilars have an easier approval pathway; we expect **accurate post-market tracking and comparison of the effects of similar products.**

The FDA's use of **unique nonproprietary names** is critical to this effort.



6) International Leadership

As a leading regulator that recognizes the pharmacovigilance benefits of unique naming, FDA should lead the way in working with the WHO to extend these benefits to patients worldwide.

Additional areas for potential harmonization include safety and approval standards.

Thank You for the Opportunity to Comment