

The Promise of Biosimilars: A Patient Advocate's Perspective

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Introduction

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- Patient Advocate (pan-tumor) since joining ICAN in 2009
- Oncology and biomarkers expert from Columbia University and Oncostem Biotherapeutics
- Chairman, ICAN Biomarkers Council



About ICAN

- The International Cancer Advocacy Network (formerly IFADD) was launched in February, 1997 as a tribute to the many hundreds of thousands of people who prematurely die of cancer every year.
- ICAN has worked with biologics in the direct navigation of Stage IV cancer patient cases since the late nineties.
- ICAN has been very involved in the passage of biosimilar substitution legislation in 45 states that contains pharmacist-prescriber communication provisions. Dr. Schneider will discuss state substitution policies for biosimilars later today.



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.

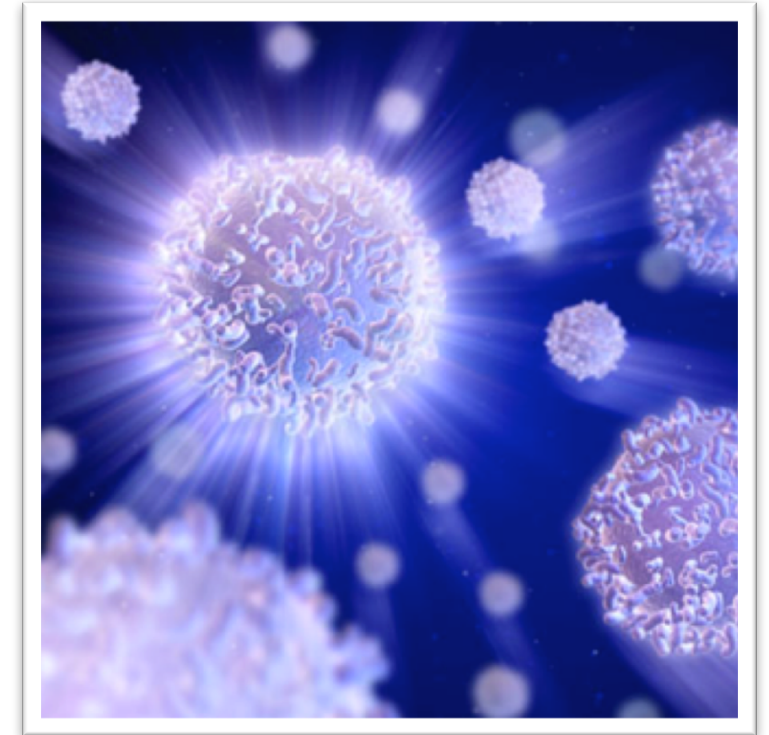
Improved Treatments For Colorectal Cancer Patients

- Access to new medicines have given our patients TIME and HOPE.
- We've gone from one drug to more than ten in a decade, half of these are 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

- Patients are Excited about Biosimilars; they offer many benefits:
 - Greater access to biologic therapies
 - New therapeutic choices
 - Lower-cost alternatives
 - But we want to make sure that biosimilar policies work for patients...



Example: Non-Medical Switching

Switching a patient's medicine, often by a third party such as an insurer, PBM, or government agency, for reasons other than that patient's health and safety.



Concerns 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 and/or PBMs 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 can actually increase costs for the individual and the health care system because of an increase in hospitalizations, doctor visits and other health care services.

What Patients Expect Regarding Biosimilars:

- 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.

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.





Thank You for Your Attention.

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