Pharmacovigilance through Patient and Provider Education

Presented by
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PBSA Principles

- Patients must have access to safe and effective biologic and biosimilar medicines.
- Prescribers and patients should have all the information necessary to make a fully informed choice about whether to use an innovative biologic or biosimilar.
- Steps must be taken to assure appropriate tracking of adverse events for all biologics, including biosimilars, so that safety problems are promptly and accurately identified.
- Biosimilars should have unique nonproprietary names to eliminate confusion, allow prescribers to accurately track the therapeutic agent in a patient’s medical record and quickly trace a product to an adverse event.
- Biosimilar pathways should support innovation and ensure incentives remain to bring new therapies to market for patients.
Issues of Importance to Patients

• Initial studies show there may be more to learn about switching between non-interchangeable biosimilars and biologics – the risk to patient health over the long term is still unknown.

• FDA has yet to issue guidance on what evidence is needed to assure patient safety for switching stable patients to and from biosimilars.

The Patient Voice

It is critical that the FDA have clear review standards and processes in place to protect patient safety and ensure efficacy of biosimilar medicines prior to making decisions about these applications.
Issues of Concern to PBSA

- Unique Non-proprietary Naming and Pharmacovigilance
- Labels should indicate that the drug is a biosimilar and have access to safety data
- Guidances should be published as soon as possible
- Prevention of non-medical switching
- Patients need to be at the table

The Patient Voice

It is critical that the FDA have clear review standards and processes in place to protect patient safety and ensure efficacy of biosimilar medicines prior to making decisions about these applications.
Patient Protection through “Interchangeability”

• Biosimilar must be “highly similar”, but Congress established a higher standard of evidence to be approved by FDA as “interchangeable.”

• Must also demonstrate that it “can be expected to produce the same clinical result as the reference product in any given patient; and for a product that is administered more than once..., the risk in terms of safety or diminished efficacy of alternating or switching between use of the product and its reference product is not greater than the risk of using the reference product without such alternation or switch.”

• Congress felt the interchangeability standard was needed to allow automatic substitution by a pharmacist.
Across the country, insurance companies and pharmacy benefit managers (PBMs) are making health plan changes, sometimes in the middle of a plan year, which effectively force stable patients off their treatments without a designation of interchangeability in order to cut costs.

This practice is known as non-medical switching. In most cases, the patient has little recourse or ability to fight the change.

As a result of this practice, patients who have been stabilized on one therapy, as determined by their physician, are switched to an alternative therapy – regardless of the health impact.
How Does Non-Medical Switching Happen?

Non-Medical Switching

**Higher Out-of-Pocket Costs**
Insurers raise patient out-of-pocket costs, often mid-plan year, for previously covered medications - making these critical treatments financially inaccessible.

**Restrictive Formulary Tiers**
Insurers move previously covered medications, often mid-plan year, to a more prohibitive formulary tier – often with higher costs and additional clinical restrictions, such as step therapy or prior authorization.

**Coverage Removal**
Insurers remove previously covered medications (even mid-plan year), leaving patients who are stabilized on these treatments with nowhere to turn.
# Why is Non-Medical Switching Harmful?

## Why it's Harmful

Non-medical switching particularly harms patients living with complex conditions such as cancer, mental illness, arthritis, lupus, hemophilia, chronic pain and HIV/AIDS.

It can take years to find a stabilizing treatment. Any disruption in treatment that is not medically necessary can put a patient's health at risk.

## What it Truly Costs

Changing a stable patient’s medication can not only cause adverse reactions and side effects, it can also cause patients to no longer respond to the therapy on which they were previously stable.

These devastating health consequences translate to increased hospitalizations, physician visits, and lab tests – which drive up overall health care costs.

The impact of non-medical switching...
Patient Groups Are Speaking Up

Patient groups have been published multiple times in key Washington DC publications to raise awareness about their concerns on biosimilars issues.
Need for Patient Education

• The need for understanding biosimilars is great if there is to be acceptance and confidence

• Patients who use biologics are more sophisticated – especially those who use them on a regular and on-going basis

• Patients know their bodies and tolerances
Need for Patient Education

• Understand extrapolation:
  – What it is
  – How it works
  – How it doe or soesn’t assure safety and effectiveness

• Understand labels

• Effectiveness of adverse event monitoring system
What Patients Think about Biosimilars

Policy Issues – Need for Education

Global Healthy Living Foundation Patient Survey

• **93 percent** of respondents who have tried multiple biologics said they **do not believe all biologics are equally effective**

• **68 percent** of respondents **tried at least one other biologic medicine** before finding their current effective medication

Retire Safe Member Survey

• **92 percent** of respondents wanted a requirement that drug companies **test the safety of biosimilars for all conditions** the drug will be used to treat

• **86 percent** of respondents wanted a requirement that drug companies that are developing biosimilars **conduct human clinical trials** to ensure a given biosimilar is safe

American Autoimmune and Related Diseases Association Patient Survey

• **52 percent** did not understand how biologics **differ** from chemical drugs.
Need for Provider Education

• The need for understanding biosimilars is great if there is to be acceptance and confidence
• Providers who prescribe biologics are skeptical of biosimilars because of the reliance on analytics rather than scientific data derived from clinical studies
What Providers Think about Biosimilars

- A recent survey of the membership of the US’s Coalition of State Rheumatology Organizations found more than **82 percent of respondents believe that the FDA approval standards for designating a biosimilar as "interchangeable" must be very rigorous to ensure patient safety**

- An ASCO survey of physicians throughout the U.S. found 80 percent of American physicians believe it is highly important when a patient is switched to a biosimilar.

- The same survey also found that American doctors “lack technical knowledge of about the effects of biosimilars and biologics sharing the same non-proprietary name.”
Questions?