Protecting Ourselves With Biosimilar Drugs

March 5, 2013 By David Mixner

Over the decades, the HIV/AIDS and LGBT communities have learned that they must accept responsibility to understand the variety of medical options open to us and to ensure our own safety. This valuable lesson we had to learn the hard way with a number of false starts and a trail of tears from our friends dying.

One of the gifts that came out of such darkness that has impacted all patient groups was reforming the Food and Drug Administration (FDA) to expedite promising therapies and ensure their safety at the same time.

Over the last few years, I have been personally involved with the healthcare system and never have I been more relieved for the work and vision of our pioneers.

The good news is that science is advancing by leaps and bounds in their ability to understand diseases and generate promising therapies within a reasonable time line. However that requires us to be even more vigilant by increasing our knowledge to embrace the rapid changes and to ensure our safety.

The FDA is swamped and has to rely on citizens to be their eyes and ears in the field. We have learned that lesson.

Such is the case with the breakthrough biologic drugs. Just what are Biologic medicines? Dr. Hary Gewanter offers a good description:

> The treatment of many serious and chronic medical conditions has been changed dramatically by a class of cutting-edge medications called “biologics.” These medications have produced clinical miracles for thousands of children and adults with arthritis, psoriasis, inflammatory bowel disease, multiple sclerosis, cancers and other diseases. Instead of facing death or significant disability, biologics have changed the course of these diseases and allowed patients to continue to work, attend school and have a more typical life.
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> What makes biologics distinct from traditional, chemical drugs is that they are made by or derived from cells and DNA. As a result, these medications are large and complex molecules that are subject to many potential problems during the manufacturing process.

Consequently, two companies making the same biologic drug will have similar - though not identical - products. Thus creating what we call biosimilar drugs which the name in itself describes the meaning.

Biosimlars drugs are new to many of us but they are very important and exciting. These drugs are more affordable versions of the new breakthrough biologic medicines. The reason these biolsimlar drugs are critical to the patient community is that they can save 20% to 30% of costs which is a huge amount especially if you have no insurance or high co-pays. New biologic therapies can cost some patients up to $100,000 annually.

This matters for patients because biosimilars will be on the U.S. market soon. And once these biosimilars are approved, the FDA will make an additional determination of whether or not a biosimilar product is “interchangeable” with its name-brand counterpart. This means that patients can be switched back and forth seamlessly between the name brand and imitative version without experiencing any health problems.

As with all new scientific advances are introduced into the market place there are always safety concerns. With our excitement, we have to guarantee that the minimum safety standards are adhered too before releasing these important new treatments. The FDA and various state legislators (Florida, Texas, Colorado and Utah) are coming to terms with this new field.

For us, the requirements are simple to ensure our safety and our patient rights. We must insist that there is protection for patients by establishing basic criteria for pharmacists who might give a patient a biosimilar drug when a name brand biologic drug is prescribed by the doctor. What we should ask for is actually quite simple and not a hindrance to the science of biologic drugs or companies ability to bring them to marketplace in a timely manner.

Three basic steps are required:

1. The FDA should have thoroughly reviewed the clinical data and other information available to ensure patients can reasonably presume that they won’t have any adverse reactions to the replacement biosimilar.
2. Pharmacists should let the patient and his or her doctor know that they are switching the drug to a biosimilar.
3. Pharmacists should keep a record of this switch in their files.

If you are a healthcare professional, run a patient organization or association, active in the HIV/AIDS community or care about patient rights and safety, then you must contact your legislators at both the state and federal levels.

Let our elected officials know:

1, You are excited about the breakthrough of biologics for treatment of people with cancer, HIV/AIDS and other diseases.

2. That you want to have access to the cost-saving biosimilars.

3. However you want to be sure that the three points covered above are guaranteed to the patient community.

Let’s do what we have always done and that is accept responsibility for our own healthcare, treatments and costs. With each new advance comes new responsibilities, Let’s step up to the plate.
