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Cancer patients may soon be hearing about and offered new treatment options called biosimilars.

This quick guide will explain what biosimilars are and how they are being used to treat certain types of cancer.

There are different types of drugs used to treat cancer. Some, like chemotherapy, are made from chemicals.

Others, called biologics, use living organisms.

A biologic can be made from living cells or tissues, like a vaccine. Or it can be made by living cells or tissues, like many of the newest cancer therapies.

Biologic drugs are complex. Because they are made by living organisms, it is impossible to make an exact copy of one. In fact, even different batches made of the same biologic drug aren’t exactly identical.

Biologic drugs (also called biological drugs or biopharmaceuticals) aren’t only used to treat cancer.

Vaccines and insulin used to treat diabetes are made with living organisms. Some treatments for arthritis, psoriasis, Crohn’s, and colitis are too.
One of the most well-known biologic drugs used to treat cancer is Trastuzumab (brand name Herceptin®), which is used for HER2-positive (her-two positive) breast cancer and gastric cancer.

Another biologic that treats cancer is rituximab (brand name Rituxan®), which is used for blood cancers. Bevacizumab (brand name Avastin (R)) may be used to treat breast, colorectal, lung, and other cancers. Cetuximab (brand name Erbitux (R)) is used for colorectal and head and neck cancers.

So now that we know what biologic drugs are, what are biosimilars?

A “biosimilar drug” is a copy version of a biologic drug. It is given at the same dose, for the same purpose, and works in the same way as the original biologic drug.

But unlike generic drugs (which are exact copies of chemical drugs), biosimilars are not exact copies.

They are so similar to the original biologic, that biosimilars work the same way in your body. But because biologic drugs are made by or from living organisms, it is impossible to make an exact copy of one. Instead, biosimilars are made to be very similar copies of biologic drugs.

The Food and Drug Administration (FDA) is the federal agency responsible for protecting public health and ensuring that drugs are safe and effective. It oversees the approval of all drugs, biological products, and medical devices in the U.S. – including generics and biosimilars.

Before the FDA will approve using a biosimilar, it must undergo a series of tests. These tests make sure that the biosimilar has the same overall structure and function as the original drug. The FDA also requires biosimilars to be made at the same dose and strength as the original biologic product.

The biosimilar product must:

· Meet FDA’s rigorous standards,
· Be made in licensed facilities, and
· Be monitored to ensure quality.

Biosimilars must work just as well (they cannot be worse…or better) and be just as safe as the original biologic product.

To know if a drug is a biosimilar, it helps to understand the way drugs are named.

Every drug that’s offered to a patient has a trademarked brand name and a generic name. Let’s use Tylenol as an example. Tylenol is a brand name for a chemical drug whose “generic” name is acetaminophen.

The “generic” name is what is used by the medical industry to define what the drug does and how it reacts within the body. No matter what company makes this drug, the “generic” name will always be “acetaminophen,” even though only one company can use the brand name “Tylenol.”
A biosimilar drug will have the same “generic” name as the original drug – but it will be followed by a dash and a series of four letters.

In 2015, the FDA approved the first biosimilar drug for use in the U.S.. It is called Filgrastim SNDZ (brand name Zarxio®), and it is a biosimilar to the drug filgrastrim (brand name Neupogen®).

Both Zarxio and Neupogen are used to help patients produce the white blood cells they need to fight infection. They are both approved for cancer patients receiving chemotherapy, a stem cell transplant, or who have severely low levels of white blood cells for other reasons. They both work the same.

Your doctor will prescribe Zarxio OR Neupogen. Pharmacists can switch out a generic drug for a brand name drug. But they can’t give you a biosimilar instead of a prescribed biologic product, without getting your provider to write a new prescription.

This means if your insurance company will only pay for the biosimilar and the original drug is prescribed, the pharmacist must ask your provider to change the prescription to the specific drug that your insurance will cover.

You can ask your doctor or pharmacist whether you are receiving an original reference (or “brand name” product), a generic product, or a biosimilar.

When you become more familiar with how treatments work and how drugs are named, you can feel more confident about the care you receive.

Although biosimilars are fairly new in the US, they have been approved and used safely in Europe since 2006.

In the United States, the price savings of using biosimilars over the original product are still somewhat unclear.

The hope is that biosimilars may improve a patient’s access to care, increase treatment options, and possibly offer price savings, as we’ve seen happen with generic drugs.

Let’s hear Dr. Leah Christl from the FDA talking about the future of biosimilars in cancer treatment.

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