BIOSIMILARS 101:

FACTS, RISKS & OPPORTUNITIES

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BIOSIMILARS ARE THE BIGGEST COST SAVINGS OPPORTUNITY IN PHARMACEUTICALS SINCE GENERICS EMERGED IN THE 1980s.

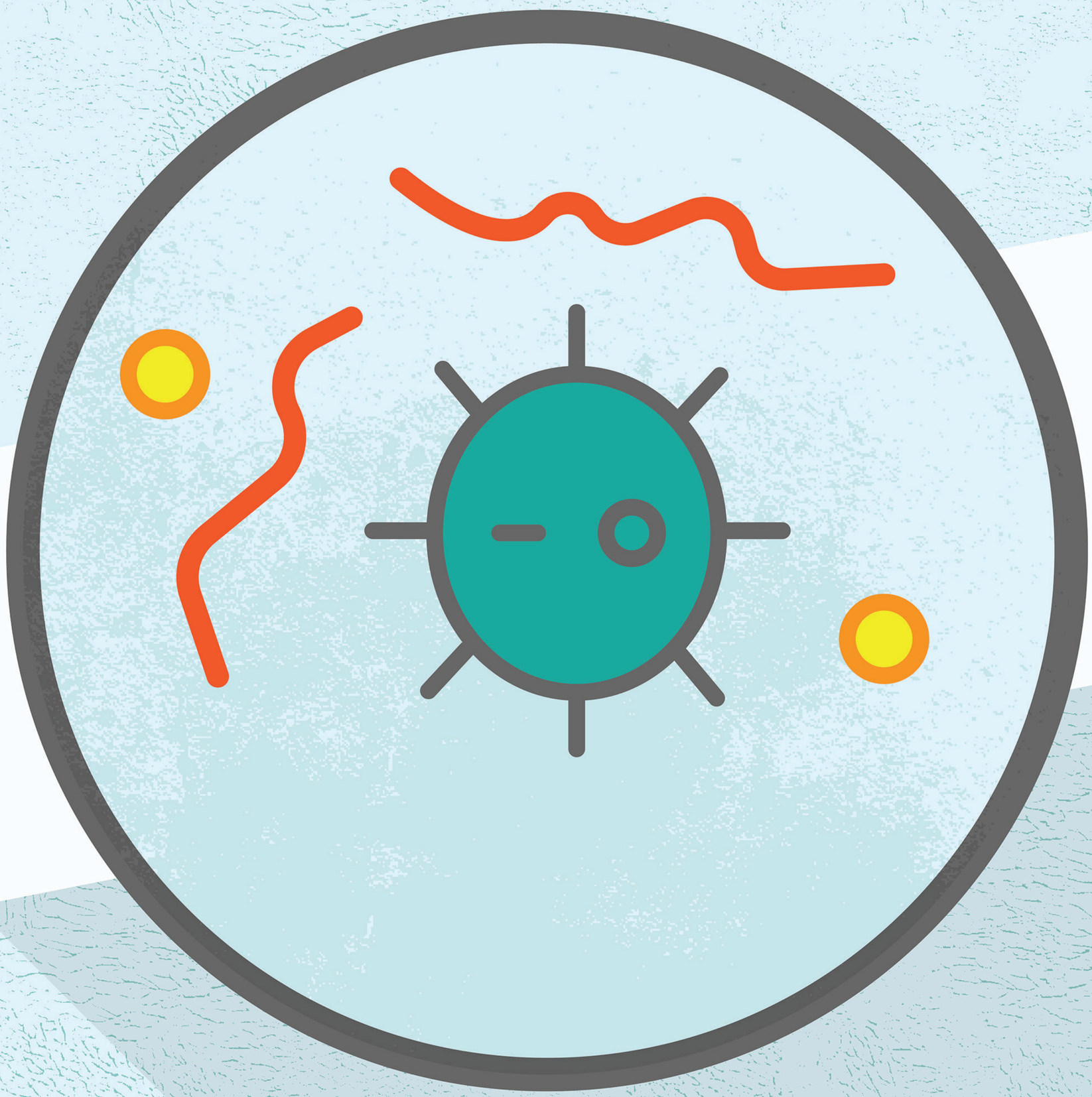
THE EMERGENCE OF BIOSIMILARS OVER THE LAST FEW YEARS HAS INTRODUCED A NEW COMPETITIVE SPECIALTY PHARMACEUTICALS MARKET TO COMBAT THE RISING PRICE TAGS ON EXPENSIVE BIOLOGICS.

DENISE JULIANO PRESENTS:
BIOSIMILARS 101: FACTS, RISKS & OPPORTUNITIES

DENISE JULIANO
IS THE GROUP VICE PRESIDENT,
LIFE SCIENCES OF PREMIER APPLIED SCIENCES

QUESTION #1

What are biosimilars?



There are many exciting developments in the pharmaceutical industry, from precision medicine to “smart pills” with embedded chips and beyond. One of the most interesting new developments is biosimilar medications.

To understand the ins and outs of biosimilars and how they are unique, first it is important to understand the difference between a small molecule drug and a biologic. Chemically manufactured molecules, or small molecule drugs, are simple to reproduce and are constructed from a controlled and predictable chemical reaction. Common painkillers such as aspirin and other medications that we ingest by mouth are examples of small molecule drugs.

On the flip side, there is another class of drugs called biologics. These medications are usually taken via shots, injections or infusions and are used to treat chronic and advanced illnesses such as some cancers, diabetes and rheumatoid arthritis. These large molecule drugs are highly complex and difficult to reproduce. Why? Unlike the predictable production process of a small molecule drug, biologics are created from living cells, such as plants, bacteria or yeast. This process is much more timely, expensive and complicated.

Because small molecule drugs are created by combining ingredients in a specific sequence, they can easily be replicated. Generic medications are identical copies of brand name small molecule drugs, such as Ibuprofen is the generic to Advil. Due to a complex production and patent process, it is difficult to make an exact copy of a biologic. That said, by following a similar production process, a close copy can be produced.

That’s where biosimilars come in. Biosimilars are defined as a biological product that is highly similar to the reference product notwithstanding minor differences in clinically inactive components. Similar to when generics first hit the market in the 1980s, the addition of biosimilars increases the number of options available to patients, creates healthy competition in the marketplace and contributes greatly to reducing the costs of medications.

CHECK OUT OUR BIOSIMILARS VIDEO.

QUESTION #2

What are some challenges with biosimilars?

While the benefits of biosimilars are substantial, there are also quite a few challenges and much confusion surrounding these medications. Biosimilars are still in their infancy in the United States due to several challenges in bringing these drugs to market, such as:

- **Changes to regulatory framework;**
- **Cautious policymakers and payers;**
- **Lack of patient and provider education;**
- **Competitive strategies to slow market uptake; and**
- **Legal disputes over patents and approvals.**

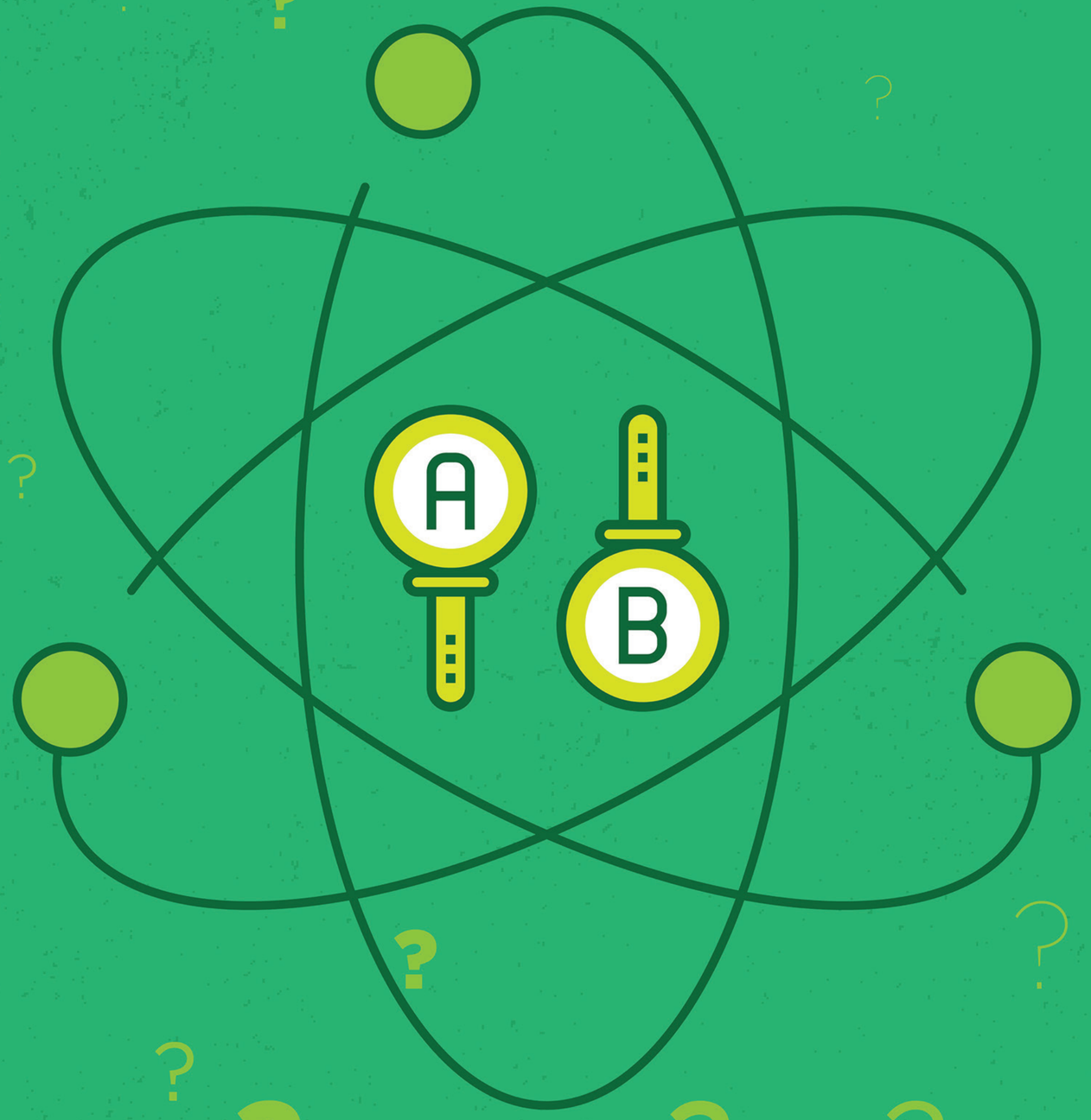
Manufacturing and pharmaceutical challenges are abundant. For example, comparability between the originator biologic and biosimilar may not be the same from lot to lot—drifts over time are certainly possible. The reference product, or originator biologic, could also differ in dosage form, concentration and mode of administration from the original.

To mitigate confusion and promote adoption of biosimilars, education is critical. Patient safety is the number one priority for providers, who may be hesitant to prescribe biosimilars without clinical data and ongoing educational opportunities.

THE FIRST BIOSIMILAR APPROVED IN THE U.S. WAS ALREADY AVAILABLE IN 60 OTHER COUNTRIES.

QUESTION #3

Are biosimilars a safe alternative for patients?



Drug safety is a priority for everyone involved: patients, pharmacists, prescribing physicians, manufacturers, insurance companies…the list goes on.

There have been several concerns raised regarding the safety and efficacy of biosimilars, particularly for those currently prescribed to a biologic who are considering switching to a biosimilar.

In most cases, biosimilars are going to be a perfectly safe alternative. They have been tested and are proven to produce the same clinical result as the reference product in any given patient. For a product administered more than once to an individual, the risk in terms of safety is no greater than the risk of using the original product. Subject to state laws, an interchangeable biosimilar may be substituted for the reference biologic without intervention of the prescribing healthcare provider.

That said, there are still potential risks to consider. The immunogenicity, or the ability of a particular substance to provoke an immune response in the body, could differ from the originator. Switching from a biologic to a biosimilar can also elicit unpredictable immune phenomena.

Non-inferiority trials, or clinical trials demonstrating that a new drug is not inferior to the reference drug, can sometimes be helpful in easing these concerns. However, the outcomes are not always as expected due to factors not often considered during these trials, such as age, sex, race, genomics and even whether or not the enrolled patient population is suitable. Study durations can also be too short to truly demonstrate value and produce real results and even finding patients willing to test these drugs can be challenging.

Patients considering biosimilars should consult their prescriber and pharmacist for more information on any potential risks and side effects associated with the medication.

JUST

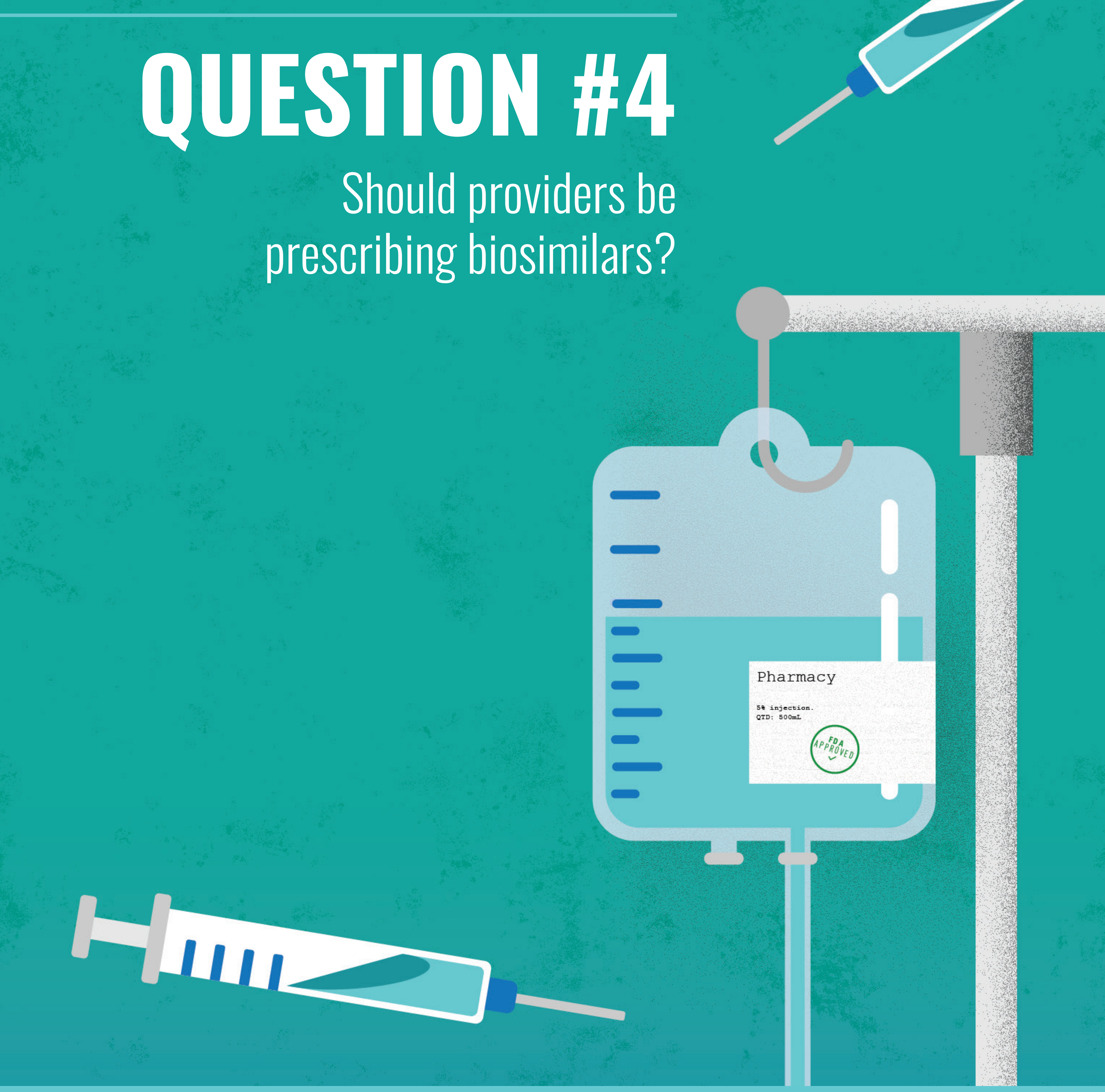
1-3PERCENT

OF THE POPULATION USES

BIOLOGIC DRUGS.

QUESTION #4

Should providers be prescribing biosimilars?



ONLY

19PERCENT

— IN THE INDUSTRY —

UNDERSTAND

BIOLOGICS.

While interest around less costly alternatives to biologics is high, providers are not yet familiar with biosimilars and thus have been hesitant to begin prescribing them. Many physicians would prefer to see more data comparing the efficacy of the drug versus the reference biologic before prescribing these medications. Because they are still so new in the United States, there is a lack of long term data that would help support providers making these decisions for their patients.

One possible solution is to use clinical evidence from other countries. This data could be leveraged as proof of concept for biosimilars, ultimately speeding approvals and easing provider concerns. Physician education is also crucial to driving adoption of biosimilars. Manufacturers are beginning to do a better job of educating around these products; however, there is still great opportunity to educate and inform clinicians who may be struggling to get up to speed.

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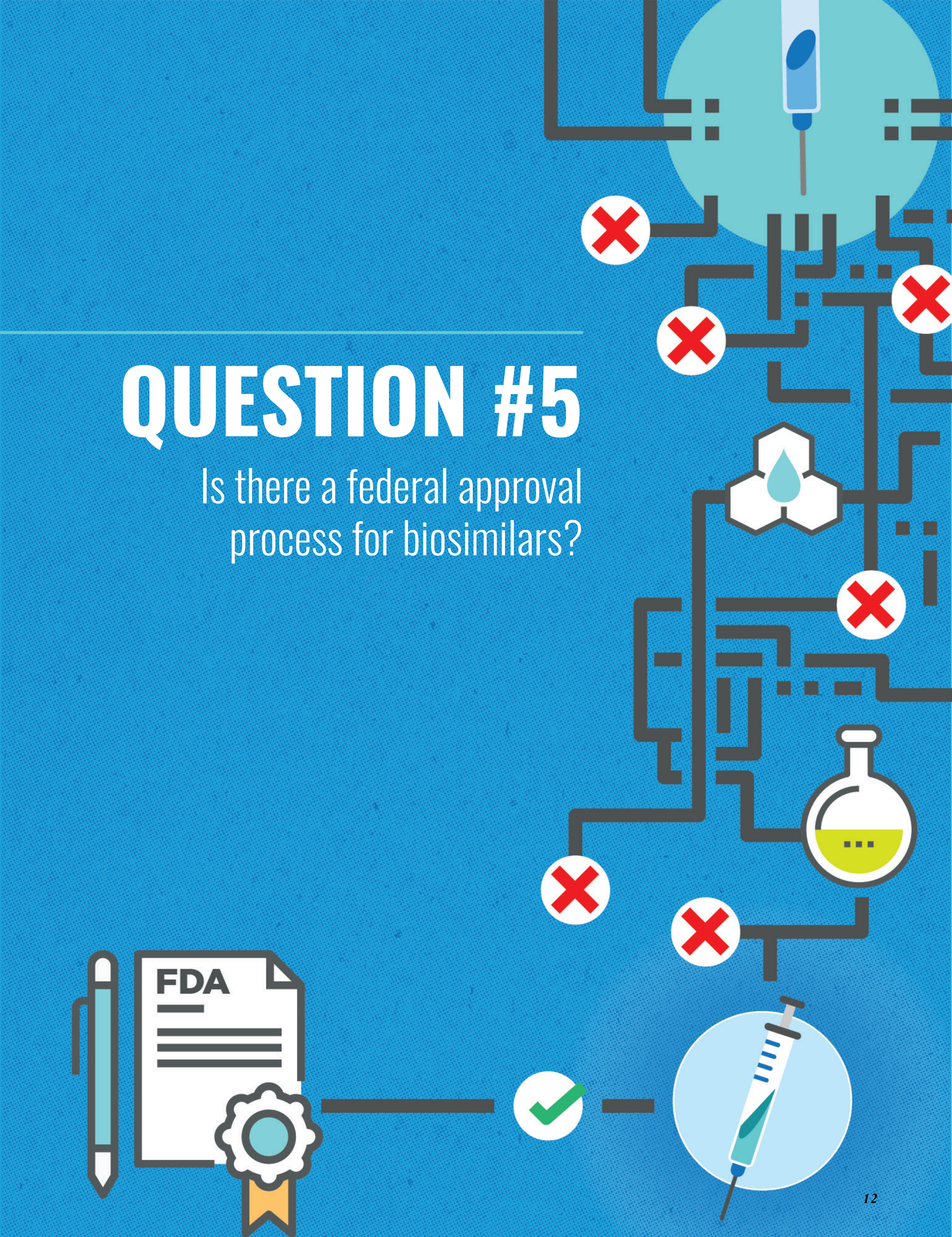
QUESTION #5

Is there a federal approval process for biosimilars?



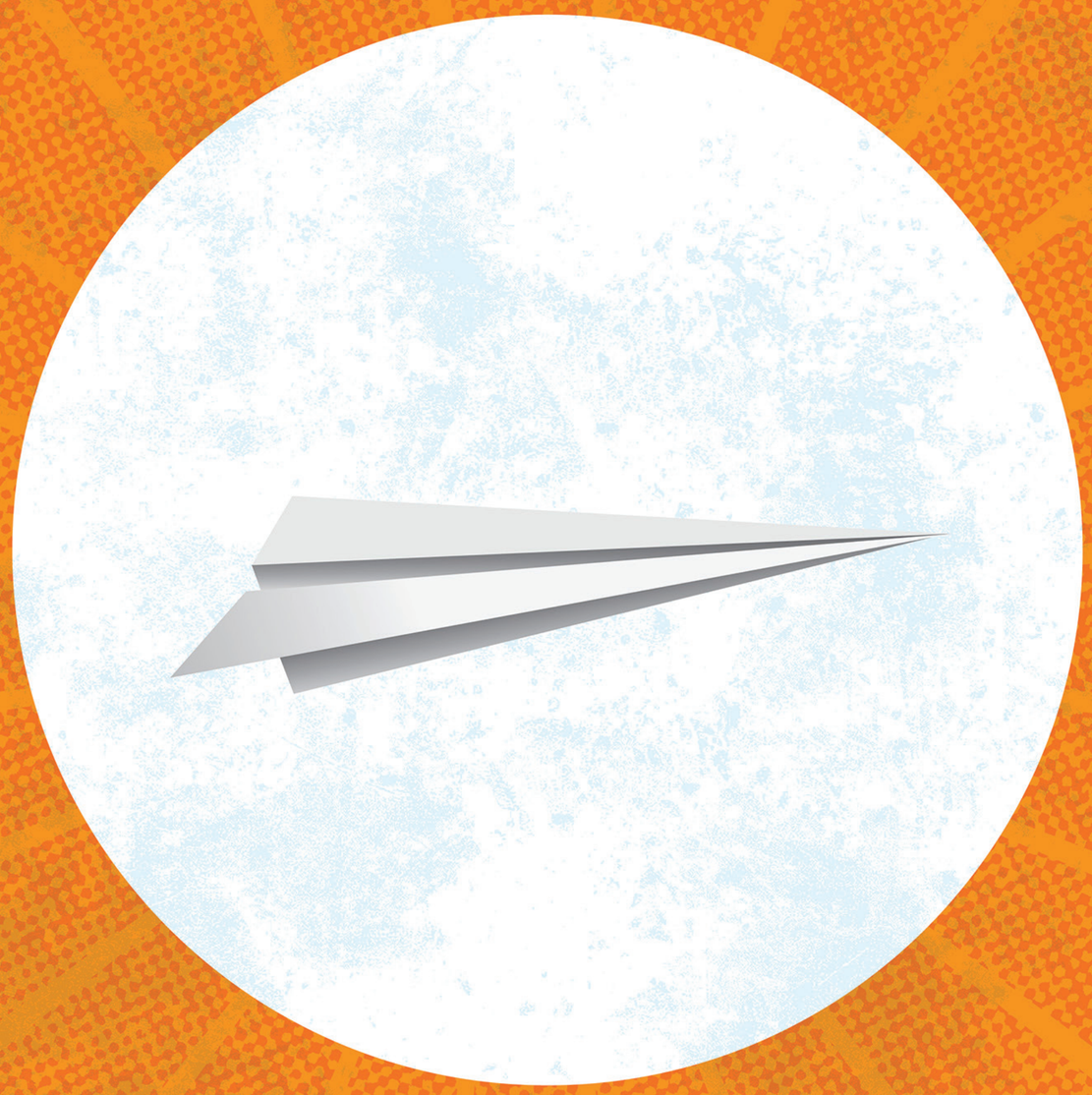
As part of the Affordable Care Act, the Biologics Price Competition and Innovation (BPCI) Act of 2009 amended sections of the Public Health Services (PHS) Act to create a pathway for biosimilars. Essentially, the BPCI Act creates an abbreviated licensure pathway for biologics shown to be biosimilar to or interchangeable with an FDA licensed product. This new pathway allows biosimilars to be licensed based on less product-specific clinical data. However, there are no abbreviated licensure pathways for related biologics not intended to be biosimilar to a reference product.

The application for this licensure includes information demonstrating the biosimilarity based upon data derived from analytics studies demonstrating biosimilarity to the reference product, animal studies including the assessment of toxicity and a clinical study demonstrating safety, purity and potency in one or more appropriate conditions of use for which the biologic is licensed and for which the licensure is sought for the biosimilar.

IT TAKES APPROXIMATELY SEVEN YEARS AND UP TO $150 MILLION TO BRING A BIOLOGIC TO MARKET.

QUESTION #6

What does the future look like for biosimilars?



Predictions for overall industry savings from newly approved biosimilars in the United States range from $5 billion to $250 billion over the next decade; however, this is largely dependent on pace of development of new biosimilars and subsequent FDA approvals. It will also depend on the number of products brought to market within each therapeutic category.

In Europe, biosimilars have already been available for ten years, where they typically sell for 30 percent less than the brand name alternative.

As of April 2019, there are 18 biosimilars in the US market; however, there are several currently under review in the United States, and with their approval, the pharmaceutical industry is certain to see lower costs, increased access to life-saving treatments and overall improved quality of care and patient outcomes.

$250 BILLION COULD BE SAVED IN THE NEXT DECADE IF 11 PENDING BIOSIMILARS ARE APPROVED.

CONCLUSION

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