

BIOSIMILAR DRUGS: PANACEA FOR HEALTH CARE COSTS? NOT EXACTLY

By David Beier

Food and Drug Administration Commissioner Scott Gottlieb has shined a spotlight on an important policy matter: biosimilar drugs. Gottlieb said, “we have a lot of finger-pointing that ignores shared complicity for pricing practices that are eroding trust in both payers and innovators.”ⁱ

Missing from Gottlieb’s remarks, unfortunately, was a complete set of concrete recommendations to move utilization of biosimilars forward based on sound patient-centric principles. We will need this if we are to convert the promise of biosimilars into tangible healthcare improvements for the American people.

Background

First, a step back to define biosimilars: what are they, and why are they important?

A biosimilar is a close cousin of an originator biologic drug, a class of drugs made using living cells, not synthesized from chemicals. Some of the world’s most expensive drugs are biologics, which is why biosimilars are so important – they stand to increase competition and thus broaden access to lifesaving healthcare interventions for millions of Americans.

Generic confusion

It is important not to confuse the relationship between biosimilars and originator biologics with that between generic drugs and their brand-name counterparts. There are significant differences.

The US generic drug industry grew from the 1984 Hatch-Waxman Act,ⁱⁱ which established a regulatory pathway for the approval of copies of brand-name medicines. This pathway was possible because with chemical drugs (as opposed to biologics), the FDA could verify an exact match – without expensive and time-consuming clinical trials – between the physical identities of the two drugs.

After an initial hesitance about the use of generics, the market eventually accepted them as reliable substitutes for their name-brand counterparts. And because they did not require separate clinical trials or complex new manufacturing, they would be much cheaper. Today, generic drugs make up nearly 90 percent of all prescriptions written in the US.ⁱⁱⁱ By 2020, the global generic market will exceed \$100 billion.^{iv}

Biosimilars decoded

In the 1980’s, the biotechnology industry began producing something completely unlike traditional chemical drugs. Using living cells, they created complex, mostly injectable products: biologics.

As the biologics industry evolved, it became possible to create products that were similar – but not identical to – biological drugs. In 2003, Europe – followed by the US in 2010 – introduced regulatory pathways to permit the approval of “biosimilars.”^v

This is where the story often veers into confusion. In contrast to the relationship between generic and brand-name drugs, the difference between a biosimilar and its counterpart requires clinical trials. Furthermore, both Europe and the US provide a form of intellectual property protection that bars biologics from being approved on the basis of the original drug’s underlying data for a period of years.^{vi} In the United States, an additional regulatory feature prevents automatic substitution, unless a biosimilar has been determined to be “interchangeable” by the FDA.^{vii}

Not surprisingly, biosimilars have not produced the massive shift seen in the generic drug market. In Europe, which is many years ahead of the US, biosimilars tend to lower prices by less than generic drugs.^{viii} While there is substantial variation between pricing decisions within the nations of the European Union, the price reduction upon entry of a first biosimilar is roughly 30-40 percent, and biosimilars frequently garner less than a majority of market share.^{ix}

Even in countries with more favorable biosimilar rules, the savings from biosimilars is modest compared to generic drugs.^x In the United States, nine biosimilars have been approved by the FDA,^{xi} but intellectual property litigation arising from a confusing federal law, the rules for patents, trade secrets and other forms of intellectual property, have kept all but three biosimilars from the market.^{xii}

Looking ahead

Recent policy debates^{xiii} suggest some commentators want to jumpstart biosimilar competition by ignoring laws on substitution and treating biologics like generic drugs. Even more troubling is the push^{xiv} to use insurance coverage as a way to encourage increased use of biosimilars. Another problem is the apparently inadvertent creation of a Gordian knot policy mandating higher prices for biosimilars in certain safety net hospitals.^{xv}

There is a consensus that biosimilars will play a vital role in creating competition, lowering prices and offering more choices of safe and effective biologics. Savings from biosimilars in the United States are estimated at \$54 billion from 2017 to 2026, with a range of \$24 to \$150 billion.^{xvi} While we would all like these savings, we should not make the mistake of viewing biologics through an economic lens alone.

The following four points must guide our policy decisions:

1. Biosimilars are not like generic drugs, and a public policy of automatic substitution is inappropriate
2. The FDA must make a scientific determination that biosimilars are “interchangeable” with the original product before automatic substitution occurs and that doctors must be informed or notified if substitution has occurred for such interchangeable products.
3. In the end, it is the patients who are at risk for the rare adverse event when it comes to biosimilars. Any savings from rebates or discounts by either the originator or the biosimilar company should flow directly back to benefit the patient
4. More biosimilar products would get to the market faster if Congress took up and passed a more rational and implementable set of litigation rules concerning patents for such products. Europe has not struggled with these issues and has much more competition. As FDA Commissioner Gottlieb has said, “We’ll know that we’ve been successful when there’s a biosimilar market that can sustain multiple competing biosimilar and biologic options.”^{xvii}

Conclusion

Insurance and payments for biosimilars are important parts of the equation, and we need to make these drugs more available. Recent changes to Medicare Part B’s insurance rules encourage physicians in safety net hospitals to prescribe more expensive biosimilars. We need to do more, including educating doctors on the similarity of biosimilars and why trying them could be a useful option for new patients. Insurers should work with the FDA, patient groups, medical specialty societies, pharmacists and manufacturers on efforts to overcome hesitance from doctors not used to prescribing biosimilars.

Finally, the FDA can accelerate consideration of biosimilars by using the newly enacted user fee resources. The FDA can also make clear the science-based rules for determining drug interchangeability, which is the first step toward biosimilar-originator biologic substitution.

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ⁱⁱ Thayer, Ann M. “30 years of Generics: The door that legislation unlocked for generic drugs three decades ago has blown wide open.” Chemical and Engineering News, 2014. URL: <https://cen.acs.org/articles/92/i39/30-Years-Generics.html>

ⁱⁱⁱ Scutti, Susan. “How to pay less for your prescription drugs, legally.” CNN, 2016: URL:

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^{iv} Thayer, “30 years of Generics.”

^v The FDA has said: “Unlike conventional medications, biologics can’t be made following a chemical “recipe”. Because biologics come from living organisms, they are variable in nature and their structures are generally more complex and not as easy to define and characterize. In turn, developing biologics generally is a far more difficult process than manufacturing conventional drugs ... A biosimilar is not like a generic drug. It is not the exact duplicate of the reference product.”

“Biosimilars: More Treatment Choices and Innovation.” FDA, 2017. URL:

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^{vii} “Prescribing Biosimilar and Interchangeable Products.” FDA, 2017. URL:

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^{ix} “The Impact of Biosimilar Competition in Europe.” QuintilesIMS, 2017. URL: https://ec.europa.eu/growth/content/impact-biosimilar-competition-price-volume-and-market-share-update-2017-0_en

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^{xi} “Biosimilar Product Information.” FDA, 2017. URL:

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^{xii} “US 351(k) Biosimilar Filings: Biosimilar Drug Status in the US: FDA Filing Dates and Actions.” BR&R: Biosimilars Review & Report, 2018. URL: <https://biosimilarsrr.com/us-biosimilar-filings/>

^{xiii} Frank, Richard. “Friction in the Path to Use of Biosimilar Drugs.” The New England Journal of Medicine, 2018. URL:

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^{xiv} While the impatience of some authors about pace of biosimilar adoption approvals (7 to date) and the modest impact of biosimilar competition (Frank in the NEJM) (about 3% of biologics face competition – in large part because of intellectual property protection. Some have proposed using similar billing codes for both the innovator biologic and the biosimilar. A valid concern about this approach is that such equalization could lead to thwarting the protection of patients in a surveillance system that is necessary to determine which product could have caused in adverse event. More importantly, insurance rules should not imply scientific identity when biosimilars are per se different.

“State Laws and Legislation Related to Biologic Medications and Substitution of Biosimilars.” National Conference & State Legislators, 2018. URL: <http://www.ncsl.org/research/health/state-laws-and-legislation-related-to-biologic-medications-and-substitution-of-biosimilars.aspx>

^{xv} To insiders this is known as the 340B conundrum caused by a reduction from ASP of 22.5% for originator biologics coupled with pass through status and higher prices for newly approved biosimilars. The law itself is not very clear. Even worse by mistakenly combining these two complex policy schemes patients will end up paying more out of pocket.

Recently, big pharmaceutical and biotech companies like Johnson & Johnson, Amgen, and Genentech are lobbying Congress to add a provision in the forthcoming appropriations package that ensures that one Medicare program does not pay more for newer “biosimilar” drugs than it does for their products.

The small eye drug company, Omeros, is also pushing for a policy-add on that would allow it to maintain a higher Medicare reimbursement for its drug for five years, instead of the two to three years allowed under the current laws.

^{xvi} Mulcahy, Andrew W., Jakub P. Hlavka, and Spencer R. Case. “Biosimilar Cost Savings in the United States: Initial Experience and Future Potential.” Santa Monica, CA: RAND Corporation, 2017. URL:

<https://www.rand.org/pubs/perspectives/PE264.html>

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