

Issue Brief

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Pro-Taxpayer Ways to Increase the Availability and Use of Biosimilars

Introduction

As policymakers and voters demand action to lower health care costs in America, a lot of attention has been focused on drug prices. While the share of total U.S. health expenditures spent on prescription drugs was [only around 10 percent](#) in 2017, the same share as in 1960, some high-profile price hikes have led Members of Congress to introduce a far-reaching set of proposals that purport to tackle drug costs.

National Taxpayers Union has drawn a clear line in the sand on some of these proposals:

- We are opposed to the importation or re-importation of prescription drugs from foreign countries, as [we believe such policies](#) “would undermine the entrepreneurial economy, introduce price controls, trample on property rights, abet protectionism, harm U.S. exports, encourage socialistic health care policies, and, ultimately, burden taxpayers.”

Key Facts:



Biosimilars, which are similar to generic drugs, offer promising savings to patients and taxpayers.



Regulatory barriers and a lack of information available on biosimilars have limited their potential.



Both Congress and the FDA have important roles to play in lowering barriers and promoting a robust biosimilar market.

- We [do not believe](#) the government should enact measures like an inflation cap for drug prices, since price controls ultimately lead to reduced innovation in the industry and price increases elsewhere in the health care system.
- And NTU is [opposed](#) to proposals that would allow Medicare to negotiate the cost of prescription drugs, noting that the Congressional Budget Office (CBO) has consistently expressed doubt that such a measure would bring significant cost savings to the federal government. In fact, CBO just [reiterated in May](#) its belief that “providing broad negotiating authority by itself would likely have a negligible effect on federal spending.”

As taxpayer advocates, NTU wants to see federal health programs slow their spending growth. As supporters of robust free markets, we also want to see competition and innovation drive down drug costs for patients. One trend that could contribute to both outcomes is increased access to and utilization of biosimilars. These drugs, complex biological products that are often injected instead of administered orally, are only used by a small portion of American patients. However, they make up a growing share of drug spending in the U.S.

One reason the Medicare Part D prescription drug program for seniors has been so successful is that the high rate of generic drug utilization has kept costs in check. From 2007 to 2016, generic drug utilization in Part D rose from [61 percent](#) of all prescriptions to [81 percent](#). NTU believes that policies encouraging the market entry and use of biosimilars will lower costs for patients and taxpayers. We lay out how policymakers can accomplish these goals below.

What Are Biosimilars?

The analogy often used to explain biosimilars is that they are to biological products (also known as biologics) what generic drugs are to brand-name drugs. While mostly true, it is not a perfect analogy, and the differences between biosimilars and generic drugs have consequences for policymakers.

The Biosimilars Council, a trade group that advocates for increased education on and patient access to biosimilars, [defines](#) them as “safe, effective alternative versions of existing biologic medicines (known as ‘reference products’) with scientifically comparable quality, safety and effectiveness.” The Congressional Research Service (CRS) offers an [even simpler definition](#): “A biosimilar, sometimes referred to as a follow-on biologic, is a therapeutic drug that is highly similar but not structurally identical, to a brand-name biologic.”

Biosimilars are distinct from generic drugs in that they are highly similar, but *not* identical, to their reference products. Given biological products are “relatively large and complex molecules,” biosimilars are not exact copies of brand-name biologics. As a result, both biologics and biosimilars are expensive to research and develop. According to a [2018 report](#) from the White House Council of Economic Advisors:

“Small molecule generics rely on easily replicated chemical ingredients and can be approved on the basis of relatively small and inexpensive studies to prove bioequivalence. In contrast, biosimilars and biologics are highly sensitive to the living systems used to manufacture them. Production is difficult and requires significant scientific expertise (Palmer 2013). Biosimilars can take 8-10 years and hundreds of millions of dollars to gain approval (FTC 2009).”

As a result, there are fewer biosimilars on the market now than there are generic drugs, and biosimilars are typically more expensive than generics as well. These factors have impacted biosimilar utilization in the U.S.

How Often Are Biosimilars Used?

According to [former Food and Drug Administration \(FDA\) Commissioner Scott Gottlieb](#), “[w]hile less than 2 percent of Americans use biologics, they represent 40 percent of total spending on prescription drugs.”

Despite low levels of utilization, the high proportion of prescription drug spending on biologics means that the potential cost savings from increased competition are significant. As Gottlieb also noted:

“Even without these policy changes, right now savings estimates from expected biosimilar competition are large. They range from \$54 billion from 2017 to 2026 according to a study by RAND, to as much as \$250 billion from 2014 to 2024 from just 11 biosimilars expected to be approved and marketed according to a survey by Express Scripts.”

The biosimilar market has been slow-going, though. The FDA [approved only 23 biosimilars](#) from March 2015 through July 2019. Compare that to [64 generic drug approvals](#) by the FDA in 2019 *alone*. Even some of the 23 biosimilars approved by the FDA are not available to the public. CRS [notes](#) that many biosimilars are not available to patients “primarily due to ongoing litigation and settlement agreements.”

Pro-Taxpayer Ways to Increase the Availability and Use of Biosimilars

Streamline FDA Review and Approval of Biosimilars

The FDA must constantly balance the need for competition in the drug market with the need for safe and effective drugs. Keeping that balance in mind, the agency itself has noted it can improve and streamline its review and approval process for biosimilars. FDA stated in its July 2018 Action Plan that it is:

“Developing and implementing new FDA review tools, such as standardized review templates that are tailored to marketing applications for biosimilar and interchangeable products, to improve the efficiency of FDA review and enhance the public information about FDA’s evaluation of these products.”

These moves offer promise to biological product manufacturers, taxpayers, and patients, so long as FDA’s guidance and tools make applying and receiving approval for a biosimilar easier, faster, more clear, and more efficient.

Allow for Reciprocal Drug Approval

Sen. Ted Cruz (R-TX) recently reintroduced the RESULT Act. [NTU sent a letter thanking](#) Sen. Cruz for his legislation, writing:

“The RESULT Act would be a strong first step to reforming the FDA’s outdated approach, by providing an expedited, reciprocal approval process for drugs, biologics, or medical devices that have been authorized to be lawfully marketed in a limited set of other countries. The legislation includes responsible limits to this expedited process, allowing the Secretary of Health and Human Services to decline a reciprocal approval if the Secretary determines a drug or device would not be safe and effective.”

Sen. Cruz's legislation allows for reciprocal approval of brand-name biologics approved in the European Union (EU). While the RESULT Act does not include reciprocal approval for biosimilars or interchangeable products, earlier U.S. market entry for brand-name biologics developed in the EU could, in turn, spur earlier U.S. market entry for biosimilars. As Sen. Cruz [noted](#) when introducing an earlier version of the RESULT Act:

“Health care providers and their patients who need critical and commonly used generic medications including cancer drugs, antipsychotic drugs for mental health emergencies, anesthetics and much more...will benefit from increased competition and a greater supply of drugs and devices.”

It's worth adding the EU is ahead of the U.S. on biosimilar approval - the European Medicines Agency (EMA) [approved the first biosimilar in 2006](#) (nine years before the first U.S.-approved biosimilar) and has [approved 68 to date](#) (compared to 23 in the U.S.).

Increase Practitioner and Patient Knowledge of Biosimilars

According to health care experts, several of the major barriers to increased uptake of biosimilars have to do with a lack of certainty and knowledge about these products. From a [2019 study in *Pharmacy & Therapeutics*](#), a peer-reviewed journal:

“Many reasons for this have been cited, including a lack of provider confidence in these similar biologics, potential minor differences from the reference products, uncertainty about substitution, certain financial incentives favoring the use of originator biologics (e.g., higher reimbursement limits for reference biologics), and a lack of patient awareness and education.”

...“Educational opportunities (e.g., data on approval requirements, clinical study regulations, immunogenicity considerations) for physicians, patients, and payers are needed to facilitate the incorporation of biosimilars into formulary decision-making. Without education to increase biosimilar familiarity, physicians may be less inclined to prescribe this new category of biologics and may not be aware of which biosimilars are available on a payer formulary.”

The Department of Health and Human Services (HHS) has [echoed](#) the need for physician and patient education, writing that “FDA intends to build on the momentum of past education efforts, such as the launch of its Biosimilars Education and Outreach Campaign in 2017, by developing additional resources for health care professionals and patients.”

Fortunately, existing legislation would help tackle the knowledge gap on biosimilars. The Advancing Education on Biosimilars Act of 2019 ([S. 1681](#)), sponsored by Sen. Michael Enzi (R-WY) and cosponsored by Sen. Maggie Hassan (D-NH), would require HHS to establish, maintain, and operate a website with educational materials on the use of biosimilars.

Update the “Purple Book”

Multiple stakeholders have expressed the need for updates to the FDA's “[Purple Book](#),” which lists licensed biological products along with FDA biosimilarity or interchangeability evaluations. This is similar to the FDA's “Orange Book” for prescription drugs, but the Purple Book does not include much of the information the Orange Book does. The Department of Health and Human Services' “American

Patients First” blueprint released in May 2018 said this about the Purple Book:

“The Purple Book provides information about these products that is useful to prescribers, pharmacists, patients, and other stakeholders. FDA is committed to the timely publication of certain information about reference product exclusivity in the Purple Book.”

S. 1895, the Lower Health Care Costs Act, also includes a provision on the Purple Book. NTU has expressed our [concern with some aspects](#) of the bill, but the Purple Book provision at least takes some important steps in modernizing the FDA’s Purple Book and codifying it into law.

According to the [section-by-section summary](#) published by the Senate Health, Education, Labor, and Pensions (HELP) Committee, Section 201:

- “Increases transparency of patent information for biological products by requiring information to be submitted to the Food and Drug Administration (FDA) and published in the ‘Purple Book.’”
- “Codifies the publication the ‘Purple Book’ as a single, searchable list of information about each licensed biological product, including marketing and licensure status, patent information, and relevant exclusivity periods.”
- “Requires the Secretary, in consultation with the Director of the U.S. Patent and Trademark Office, to publish a list of any holders of biological product licenses that failed to submit such information.”

NTU believes that making the Purple Book a single, searchable list, and adding exclusivity information, will provide manufacturers with the information and certainty they need to confidently develop and seek approval for biosimilar products.

Whether policy should go as far as S. 1895 in providing patent information deserves careful consideration. As former FDA official Kate Cook [wrote in May](#), listing patent information in the Purple Book may require FDA “to add new expertise and staff to fulfill this role, which could be a considerable drain on current agency resources.” Regardless, the provision requiring FDA to consult with the Director of the U.S. Patent and Trademark Office is a prudent one, given FDA’s functional gaps when it comes to mediating patent disputes between manufacturers of biological products and biosimilars.

Overall, a Purple Book that’s more like the Orange Book would make it easier for biosimilar manufacturers to bring their products to market, would introduce competition in the biological products industry, and ultimately offer patients more options and lower costs.

As Biosimilars Come to Market, Monitor Federal Reimbursement Policies

As noted above, only 23 biosimilars have been approved for marketing by the FDA. Some of those 23 products are not available to patients yet, due to ongoing litigation. However, as the FDA approves more biosimilars and the market begins to grow, the federal government should keep a close eye on its reimbursement policies. Tara O’Neill Hayes of American Action Forum (AAF) [points out](#) that the Centers for Medicare and Medicaid Services (CMS) have been inconsistent in how they treat biosimilars across Medicare Part B, Medicare Part D, and Medicaid.

Thanks to [recent changes from CMS](#), Medicare now provides a unique billing code to each biosimilar

for a given reference product (rather than grouping all biosimilars for a given reference product under the same billing code). Biosimilars are reimbursed in Medicare Part B based on the average sales price (ASP) of the biosimilar in question plus an add-on payment that is pulled from the reference product's ASP. This incentivizes biosimilar utilization, since the add-on payment will be higher (relative to the cost of the biosimilar) than it would for a brand-name biological product (relative to the cost of the biologic).

Medicare Part D biosimilar prices are negotiated by private plan sponsors, but the Bipartisan Budget Act of 2018 recently corrected a [disparity between biosimilars and brand-name biologics](#) in the Part D coverage gap (also known as the “donut hole”) that discouraged plan sponsors from covering biosimilars.

Medicaid treats biosimilars like brand-name drugs in its [Drug Rebate Program](#), meaning biosimilar manufacturers must rebate states at a higher rate than generic drug manufacturers do.

AAF's Hayes argues that the current inconsistencies attempt to strike a balance between encouraging biosimilar adoption by providers and patients, and keeping costs down for patients and for taxpayers:

“In terms of reimbursement, policies aim to reduce the government's and patients' costs, either directly through greater rebate requirements or indirectly by encouraging development and utilization of biosimilars over the brand-name reference product. Yet just as the biosimilar market is evolving, these policies could as well, and they are worth watching.”

These developments are worth watching, and should encourage policymakers to critically examine whether current reimbursement policies present barriers to the development of a robust, competitive biosimilars market that patients and providers can take advantage of. Care must be taken in this process to ensure an appropriate balance between innovation, access, and affordability.

Conclusion

Increased availability and use of biosimilars and interchangeable products will introduce competition in the health marketplace, lower costs for patients and taxpayers, and help slow the growth of health spending in the U.S. The savings could range from tens of billions of dollars to hundreds of billions over the next decade. While this is promising, NTU believes that any changes encouraging biosimilar availability and use should rely on market forces and not on government mandates. Any significant and costly mandates from lawmakers or regulators will only increase costs for patients and hamper innovation. The reforms outlined above are much more prudent, and will ultimately pay off for patients.

About the Author

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