UPDATED: MARCH 2020

U.S. Public Policies Impacting Biosimilar Drugs

This overview offers insights on known legislation as of March 19, 2020. Given that the policy landscape is dynamic and changes often, this overview is a limited snapshot in time.

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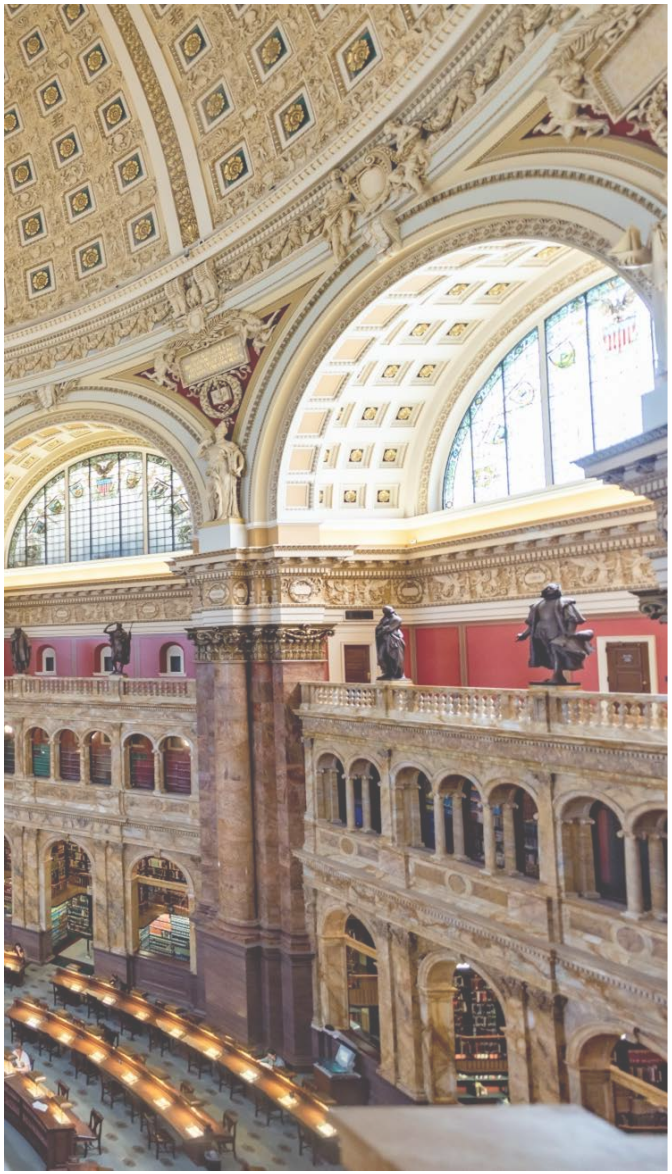
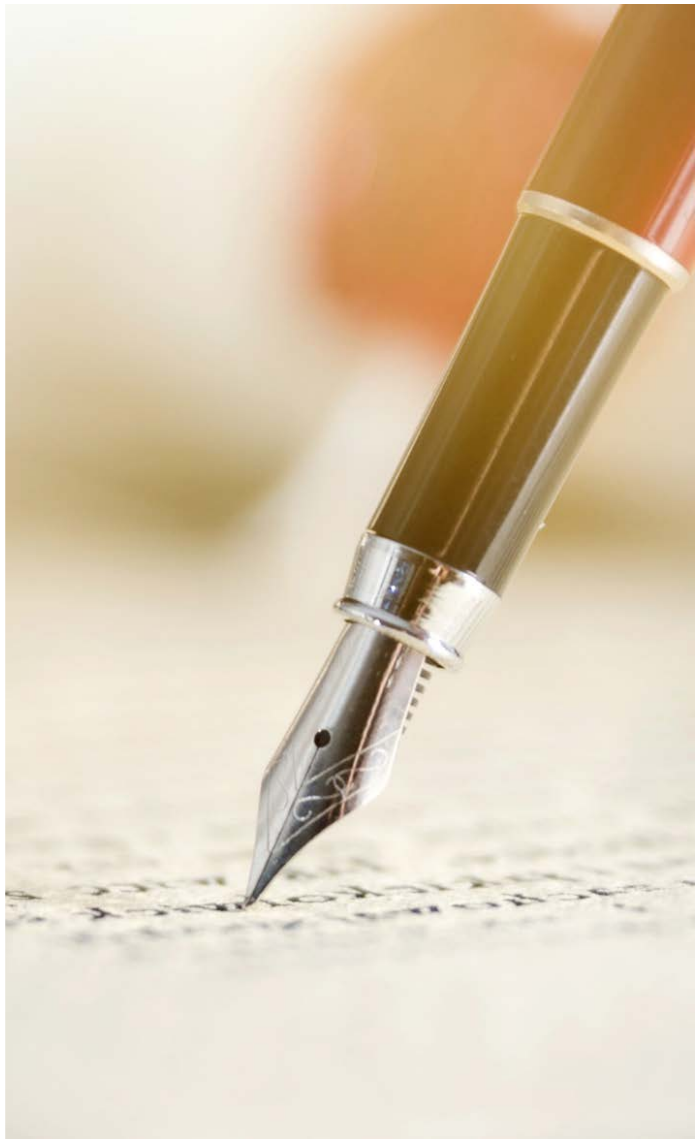
INTRODUCTION

One of the key drivers of the health care policy debate is the rising costs of prescription drugs – and principally products that are known as "biologics." Biologics have been available for many years; however, our scientific knowledge of cells, tissues, blood, and other complex substances has led to discoveries in the treatment of cancers, rare diseases, and complex health care problems. Congress has already recognized the need for competitive products in the marketplace to obtain more options for patients and reduce pricing. The Affordable Care Act created a pathway for biosimilars so that similar products can be approved by the U.S. Food and Drug Administration (FDA) and made available to patients. There are many other policy changes that Congress and state policymakers are evaluating that would make biosimilars more available and accessible, lowering the cost of care for everyone and improving health for the larger population.



Many of these proposed ideas are identified in this summary with a focus on key areas to ensure patients can access affordable products; that physicians can have full information on the availability of biosimilar products that are similar to other products; that FDA will move toward implementing a final process for interchangeable products (i.e., generic products); that biologics, biosimilars, and interchangeable biologic products can be available and administered in the lowest cost setting; and that employers can have transparent information on the availability and appropriate uses of these products in evaluating coverage and payment.

Policymakers must align their interests to ensure patients have access to affordable prescription medications. The federal regulatory process for introducing biosimilars and interchangeable products can be improved to provide prescription drug companies with assurances of the requirements. State lawmakers should also evaluate their rules and



policies to ensure that physicians are notified when alternative and more affordable products are available for their patients, and to provide physicians with the discretion needed to determine the most appropriate course of treatment for patients. Aligning access to affordable biologics and promoting improved patient outcomes should be priorities.

This compilation was prepared for The ERISA Industry Committee (ERIC), which is a Washington, DC-based trade association that advocates exclusively for federal, state, and local public policies that support the ability of large employers to provide health, retirement, and compensation benefits to their nationwide workforces. Regarding prescription drug costs, ERIC advocates on the federal level for a competitive marketplace with full transparency of cost and quality information. On the state level, ERIC has drafted model legislation that could help streamline state regulation and improve the flow of biosimilar drugs into the market and patients' hands.

THE REGULATORY OUTLOOK? SLOW MOVING.

The Biologics Price Competition and Innovation Act (BPCI Act) of 2009 (passed as part of the Affordable Care Act) created an expedited FDA licensure pathway for biological products. Since 2015, the FDA has approved 19 biosimilars in the U.S., but only seven are currently on the market, and none have been deemed "interchangeable."[1] An interchangeable product is a biosimilar product that meets additional requirements outlined by the BPCI Act (see below).

In 2019, the FDA released a set of guidelines intended to spur the market for biosimilars. The new guidelines set testing standards for a biosimilar to be declared interchangeable, allowing pharmacists to replace a branded drug with a generic biologic in the same way they currently do for small-molecule drugs, without having to talk with a doctor first.[2]

The FDA plans to use insulin as a test case for the new guidance. "Anything the FDA can do to encourage competition in this space is very useful to the consumer," says Michael Carrier, a professor at Rutgers Law School who specializes in pharmaceutical patent law." As helpful as it is, though, there are still many hurdles to biosimilar competition," he warns.[2]

Physicians and patients need to be aware of their state regulations since this may affect their treatment choices. At the state level, automatic substitution laws and requirements for notifying physicians can vary.

WHAT CAN CONGRESS AND THE ADMINISTRATION DO NOW?

Federal policymakers have proposed laws to strengthen the spirit of patent exclusivity, reform FDA processes, expand negotiation and financial incentives for payers, institute pricing and cost caps, and broaden consumer education. Some of these bills are described below.

Patent Related Proposals

Bill #	Bill Name	Co-Sponsors	Summary	Status
S. 659	**The Biologic Patent Transparency Act**	Sens. Collins (R-ME), Kaine (D-VA)	Requires the manufacturers of approved products to disclose and list patents covering their products with the FDA. By requiring patent information to be published in FDA's "Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations," commonly referred	Referred to Senate HELP Committee

Bill #	Bill Name	Co-Sponsors	Summary	Status
			to as the "Purple Book," the bill imposes transparency requirements that are similar to what are required for small molecule drugs under the Hatch-Waxman framework, which has proven successful in promoting the development and use of generic drugs. The bill also targets competition-stymieing patent thickets that delay competition without providing meaningful product improvements by restricting enforcement of patents that are issued after a biosimilar application has been submitted to the FDA. It will encourage manufacturers to apply for patents sooner, allowing prospective biosimilar manufacturers to challenge weak or invalid patents earlier in the product development process. The bill will also standardize publication of the "Purple Book" and require that the FDA make enhancements to it that will promote competition.[3]	
S. 64	**The Preserve Access to Affordable Generics and Biosimilars Act**	Sens. Grassley (R-IA), Klobuchar (D-MN)	Aims to strengthen the Federal Trade Commission's (FTC) ability to challenge settlement agreements ("pay for delay" deals) between large brand drug companies and generic drug companies in court, which will help lower prescription drug prices for Americans.[4]	Referred to Senate Judiciary Committee
H.R. 2375		Reps. Nadler (D-NY), Collins (R-GA)		

Bill #	Bill Name	Co-Sponsors	Summary	Status
H.R. 1499	**The Protecting Consumer Access to Generic Drugs Act**	Democratic proposal sponsored by Rep. Rush (D-IL)	Prohibits the practice of "pay-for-delay," in which brand name drug companies compensate generics for delaying the entry of generic drugs into the market. This practice leads to decreased competition and increased drug prices for Americans.[5]	Referred to House Energy & Commerce Committee, House Judiciary Subcommittee on Antitrust, Commercial, and Administrative Law
S. 1895	**The Lower Healthcare Costs Act**	Sens. Alexander (R-TN), Murray (D-WA)	Aims in a broad bipartisan Senate bill to reduce the prices of prescription drugs, prominently featuring biosimilars' role in doing so.[6] "The legislation would require updates to the FDA's Purple Book, which provides stakeholders with information on biologics. It would codify the Purple Book as a single, searchable list of information that would include, among other information, materials related to patents on biologics. It also proposes updates to the Orange Book, which addresses small-molecule drugs. The FDA would be required to remove patent information if a patent is found to be invalid."[7]	Introduced by Senate HELP Committee Chair & Ranking Member
S. 1140 H.R. 2011	**The Protecting Access to Biosimilars Act**	Sens. Cassidy (R-LA), Smith (D-MN) Reps. DeGette (D-CA), Reed (R-NY)	Amends federal law regarding licensing for biological products (targets Insulin, specifically).[8]	Referred to Senate HELP Committee Referred to House Energy & Commerce Committee

Bill #	Bill Name	Co-Sponsors	Summary	Status
S. 1209	**The Reforming Evergreening and Manipulation that Extends Drug Years ("REMEDY") Act**	Sens. Cassidy (R-LA), Durbin (D-IL)	Amends the FDA statute to remove incentives for drug manufacturers to file excessive patents, and would lift onerous legal barriers that delay generic market entry. Under this policy, once the substance patent and all exclusivities expire, generic manufacturers would be allowed to enter the market more easily. The REMEDY Act also increases transparency and removes hurdles for generic drug companies by ensuring that when a patent is invalidated by a ruling at the U.S. Patent and Trademark Office and upheld on appeal, the FDA's listing of relevant drug patents would be updated. The bill would lower prescription drug prices and promote competition by removing barriers to FDA approval for lower-cost generic drugs. Many high-cost, brand-name drugs are shielded from competition because of the ability to manipulate the system by "evergreening" or filing numerous additional patents to their product in an attempt to forestall generic competition. The REMEDY Act would crack down on pharmaceutical monopolies and lower patient costs.[9]	Referred to Senate HELP Committee
H.R. 3812		Reps. McKinley (R-WV), Welch (D-VT)		Referred to Energy & Commerce Committee

Reforming FDA Processes

Bill #	Bill Name	Co-Sponsors	Summary	Status
S. 1169	**The Ensuring Timely Access to Generics Act**	Sens. Cassidy (R-LA), Shaheen (D-NH)	Provides direction to the FDA on how to curb the number of unnecessary citizens petitions, a tactic brand drug manufacturers can use to delay generic medications from accessing the market. Under the bill, the FDA would gain the authority to deny citizens petitions if they deem their primary purpose is a way to delay the approval of a drug's transition to the generic marketplace. The legislation aims to reduce the costs of prescription drugs by making generic medicine more quickly accessible to consumers.[10]	Referred to Senate HELP Committee
H.R. 2455		Reps. Joyce (R-PA), Brindisi (D-NY)		Referred to House Energy & Commerce Committee
	American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs	President Trump's May 2018 proposal to lower drug prices.	Accelerates FDA approval of generic drugs. Studies show that greater generic competition is associated with lower prices. FDA is publishing the names of drugs that have no competitors to spur new entrants and bring prices down. Over 1,000 generic drugs were approved in 2017, which is the most in FDA's history in a calendar year by over 200 drugs. These generic approvals saved American consumers and taxpayers nearly $9 billion in 2017. Also, in 2017, President Trump's FDA established a Drug Competition Action Plan to enable patients to access more	Certain proposals included in this package can be achieved via regulation, though other proposals would require Congressional action.

Bill #	Bill Name	Co-Sponsors	Summary	Status
			affordable medications by focusing the agency's efforts in three key areas: (1) improving the efficiency of the generic drug development, review, and approval process; (2)maximizing scientific and regulatory clarity for complex generic drugs; and (3)closing loopholes that allow brand-name drug companies to "game" FDA rules in ways that forestall the generic competition Congress intended. The agency also has taken steps to prioritize its review of generic drug applications; issued guidance to improve efficiencies in the development, review, and approval processes for generic drugs, including complex generic drugs; and issued guidance to streamline the submission and review process for shared system Risk Evaluation and Mitigation Strategies (REMS), and to allow collective submissions to streamline the review of shared REMS. Also, speeds access to more affordable generics by spurring competition. Today, a generic manufacturer that has been awarded 180-day exclusivity for being the first generic to file can "park" its application with FDA, preventing additional generic manufacturers from entering the market. The President's FY2019 Budget proposes to prevent companies from using their 180day exclusivity to indefinitely delay real competition and savings for consumers by seeking a legislative change to start a company's 180-day exclusivity clock in certain instances when another generic application is ready for approval but is blocked solely by such a first applicant's 180-day exclusivity.	

Bill #	Bill Name	Co-Sponsors	Summary	Status
			Finalizes a policy in which each biosimilar for a given biologic gets a billing and payment code under Medicare Part B to incentivize the development of additional lower-cost biosimilars. Prior approaches to biosimilar coding and payment would have created a race to the bottom of biosimilar pricing, while leaving the branded product untouched, making it an unviable market that few would want to enter.[11]	
N/A	**Office of the White House, "A BUDGET FOR A Better America PROMISES KEPT. TAXPAYERS FIRST.** Budget for Fiscal Year 2020.[12]	Included in President Trump's proposed Department of Health & Human Services (HHS) Budget for FY 2020	Gives the FDA more authority to address abuses of citizen petitions. The budget proposes to give FDA the authority to summarily deny citizen petitions and eliminate the 150-day response timeframe for addressing such petitions. Citizen petitions have come under fire as methods used to delay generic or biosimilar competition.[13]	The President releases an annual proposed budget for the federal government. It rarely advances in Congress, but rather is viewed as a roadmap for where the administration recommends focusing resources.
N/A	**Office of the White House, "A BUDGET FOR A Better America PROMISES KEPT. TAXPAYERS**	Included in President Trump's proposed Department of Health & Human	Amends the Public Health Service Act to state that biologics do not have to meet the same United States Pharmacopeia standards as non-biologic drugs. According to the budget, this revision will make it easier for biosimilars to enter the market.	The President releases an annual proposed budget for the federal government. It rarely advances in

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	FIRST. Budget for Fiscal Year 2020.[14]	Services (HHS) Budget for FY 2020		Congress, but rather is viewed as a roadmap for where the administration recommends focusing resources.
S. 340	**The Creating and Restoring Equal Access to Equivalent Samples ("CREATES") Act**	Sens. Leahy (D-VT), Grassley (R-IA)	"Allows a biosimilar or generic developer to bring a civil action against an innovator drug company if the latter refuses to make available enough samples of a product for testing. It would also explicitly empower the FDA to approve alternative REMS, programs if a generic or biosimilar developer and the innovator company are unable to arrive at a single shared system. Both objectives are intended to allow biosimilar and generic competition to enter the market sooner, thereby driving down drug prices for US patients."[15]	Enacted into law in December 2019 as part of a broader government spending bill (H.R. 1865).
H.R. 965		Reps. Cicilline (D-RI)		
H.R. 2374	**Stop STALLING Act**	Reps. Jeffries (D-NY), Sensenbrenner (R-WI)	Enables the Federal Trade Commission to deter the filing of sham citizen petitions to cover an attempt to interfere with the approval of a competing generic drug or biosimilar, to foster competition and facilitate the efficient review of petitions filed in good faith to raise legitimate public health concerns.[16]	Marked up by House Judiciary Committee

Bill #	Bill Name	Co-Sponsors	Summary	Status
S. 1224		Sens. Klobuchar (D-MN), Grassley (R-IA)		Reported out of Senate Judiciary Committee
Budget for Fiscal Year 2017 (p. 66)	**Office of the White House, "Meeting Our Greatest Challenges: Opportunity for All,"** Budget for Fiscal Year 2017	President Barack Obama	Proposes to reduce biologic exclusivity to seven years in the Obama Administration budget for fiscal year 2017. Biologics approved by the FDA are granted 12 years of exclusivity —substantially longer than the five years typically granted to traditional, small-molecule pharmaceuticals. Other high-income countries grant biologics fewer years of exclusivity than the U.S., and many provide small-molecule drugs and biologics the same period of exclusivity. This proposal also included a prohibition on "additional periods of exclusivity for brand biologics due to minor changes in product formulations." According to the Office of Management and Budget, these proposals together would have generated federal savings of $6.96 billion over 10 years.	The President releases an annual proposed budget for the federal government. It rarely advances in Congress, but rather is viewed as a roadmap for where the administration recommends focusing resources.
H.R. 3379	**Price Relief, Innovation, and Competition for Essential Drugs Act**	Democratic proposal sponsored by Schakowsky (D-IL) and 22 others.	Amends the Public Health Service Act to shorten the exclusivity period for brand name biological products from 12 to 5 years.[17]	Referred to the House Committee on Energy & Commerce Committee.

Expanding Negotiation/Financial Incentives for Payers

Bill #	Bill Name	Co-Sponsors	Summary	Status
H.R. 3	**The Lower Drug Costs Now Act**	Democratic proposal sponsored by Rep. Pallone (D-NJ)	Provides the Department of Health and Human Services (HHS) the authority to "directly negotiate prices on the top 250 drugs with the greatest total cost to Medicare and the entire US health system without competition from at least two generic, biosimilar or interchangeable biologics on the market."[18] Each year, the most expensive 250 drugs would be subject to review. Not only that, but the price would be available to all payers—not just Medicare.[19]	Referred to House Energy & Commerce Committee, House Ways & Means Committee, House Education & Labor Committee
H.R. 4455	**BIOSIM Act**	Reps. Schrader (D-OR), Gianforte (R-MT)	Provides for a temporary payment increase under the Medicare program for certain biosimilar biological products to encourage the development and use of such products.[20]	Referred to House Energy & Commerce Committee, House Ways & Means Committee
H.R. 4629	**Star Rating for Biosimilars Act**	Reps. Tonko (D-NY), Gibbs (R-OH)	Requires HHS to add a new set of measures to the 5-star rating system under the Medicare Advantage program to encourage increased access to biosimilar biological products.[21]	Referred to House Energy & Commerce Committee, House Judiciary Committee
S. ___		Sens. Cassidy (R-LA), Menendez (D-NJ)		Unknown

Bill #	Bill Name	Co-Sponsors	Summary	Status
H.R. 4597	**The Acting to Cancel Copays and Ensure Substantial Savings ("ACCESS") for Biosimilars Act**	Reps. King (R-NY), Peters (D-CA)	Eliminates cost-sharing for biosimilar biological products furnished under Part B of the Medicare program.[22]	House Energy & Commerce Committee, House Ways & Means Committee
	"FAILURE TO LAUNCH": Barriers to Biosimilar Market Adoption (Part 2)	Proposal from the Biosimilars Council	Reduces rebate and discounting schemes when a new biosimilar enters the market, especially if exclusionary contracting to obstruct price competition is involved.[23]	Published September 2019

Instituting Pricing Caps/Mandated Cost Caps

Bill #	Bill Name	Co-Sponsors	Summary	Status
S. 102	**The Prescription Drug Price Relief Act**	Democratic proposal sponsored by Sen. Sanders (D-VT)	Establishes a series of oversight and disclosure requirements relating to the prices of brand-name drugs. Specifically, the bill requires HHS to review at least annually all brand-name drugs for excessive pricing; HHS must also review prices upon petition. If any such drugs are found to be excessively priced, HHS must (1) void any government-granted exclusivity; (2) issue open, nonexclusive licenses for the drugs; and (3) expedite the review of corresponding applications for generic drugs and biosimilar biological products. HHS must also create a public database with its determinations for each drug.[24]	Referred to Senate HELP Committee
H.R. 465		Democratic proposal sponsored by Rep. Khanna (D-CA)		Referred to House Energy & Commerce Subcommittee on Health, House Judiciary Subcommittee on Antitrust, Commercial, and Administrative Law

Broadening Consumer's Education

Bill #	Bill Name	Co-Sponsors	Summary	Status
S. 1681	**The Advancing Education on Biosimilars Act**	Senators Enzi (R-WY) and Hassan (D-NH)	Requires HHS to establish, maintain, and operate an internet website consisting of educational materials regarding the meaning and use of biosimilar biological products and interchangeable biological products.[25]	Referred to the Senate HELP Committee
H.R. 4400		Reps. Bucshon (R-IN) and Engel (D-NY)		Referred to the House Energy & Commerce Committee, House Ways & Means Committee

This overview offers insights on known legislation as of March 19, 2020. Given that the policy landscape is dynamic and changes often, this overview is a limited snapshot in time.

HOW ARE STATES GETTING INVOLVED?

While there are solutions that can be implemented at the federal level, many states have taken it upon themselves to pass certain policies to diminish the burden on consumers and increase access to effective treatments. For several decades, every state has regulated the use of brand-name and generic prescription drugs through statutes and agency or board rules with varying rules across the country. In the past five years at least 45 states have considered legislation establishing state standards for substitution of a "biosimilar" prescription product to replace an original biologic product.[12]

Many states have taken it upon themselves to pass certain policies…

Recent state legislation also includes efforts to promote provider discretion in determining the best course of treatment for patients. On April 1, 2019, Arkansas enacted HB 1269, permitting prescribers to limit biosimilar substitution, so it can be within the provider's discretion to decide what treatment is in a patient's best interest. Maine enacted similar legislation in the same month and included language that lends a reasonable time period (five business days) for a pharmacist to notify the prescriber of a biosimilar substitution.

Several active state bills would impact access to biosimilars. In D.C., policymakers are considering legislation (B30-0430) that would authorize licensed pharmacists to dispense interchangeable biological products and to require reasonable notifications to physicians when such interchangeable biological products are dispensed. Maryland has also recently introduced HB 664, requiring pharmacists to inform consumers when there is a less costly therapeutically equivalent drug or device, or interchangeable biologic.

CONCLUSION: WHAT SHOULD POLICYMAKERS DO?

It's vitally important to increase competition and streamline the approval framework for getting biosimilars to market as these important and more affordable drugs will expand access for patients and lower costs for all. Policymakers must recognize that private-sector employers pay, on average, 80 percent of health coverage for their workers and families, including for the cost of drugs, and that biologic spending is the fastest-growing part of their health care costs. Making biosimilars more available and accessible to patients will lower health care costs for all and improve health and wellbeing. Employers can use their health plan design to accelerate the use of biosimilars in their plans, but the federal and state governments hold the keys to making these life-saving medications more accessible and available to employees and families across the country.

LEARN MORE

For more information about this topic, please contact ERIC at www.eric.org or call 1.202.789.1400.

About ERIC

ERIC is the only national association that advocates exclusively for large employer plan sponsors on health, retirement, compensation, and paid leave public policies at the federal, state, and local levels. With member companies that are leaders in every sector of the economy, ERIC promotes uniformity and flexibility for nationwide benefit plans.

About Fidelity Workplace Consulting

Fidelity Workplace Consulting is a dedicated business unit that focuses on solving workplace challenges for clients. From analysis to change management and measurement, Fidelity consultants help employers assess and improve the effectiveness of their benefit programs, engage employees, and design and implement successful workforce planning strategies.

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