



LEGISLATIVE POSITIONS

Biosimilars Bill Sheet

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Category	PRN's Position	Bill	Title	Summary	Sponsor	Cosponsors	Status
Transparency	Support	HR1873/S164	Advancing Education on Biosimilars Act of 2021	To educate health care providers and the public on biosimilar biological products, and for other purposes	Rep. Larry Bucshon [R-IN-8] Sen. Maggie Hassan [D-NH]	[1 D (H) 1 R (S)]	03/12/2021 Introduced in House 04/23/2021 Became Public Law No: 117-8.
Access	Support	HR2855	Star Rating for Biosimilars Act	To amend title XVIII of the Social Security Act to require the Secretary of Health and Human Services to add a new set of measures to the 5-star rating system under the Medicare Advantage program in order to encourage increased access to biosimilar biological products	Rep. Paul Tonko [D-NY-20]	1 R	04/26/2021 Introduced in House
Transparency	Support	S.3478	GAIN TOOLS Act of 2022	A bill to provide for the designation of biological products as qualified infectious disease products.	Sen. Robert P. Casey, Jr. [D-PA]	2 B	01/11/2022 Referred to the Committee on Health, Education, Labor, and Pension
Access	Monitor	S1427/HR2869	Increasing Access to Biosimilars Act of 2021	To require the Secretary of Health and Human Services to establish a demonstration project to increase access to biosimilar biological products under the Medicare program	Sen. John Cornyn [R-TX] Rep. Tony Cardenas [D-CA-29]	[1 D (S) 2 D (H)]	04/28/2021 Introduced in Senate 04/28/2021 Introduced in House
Transparency	Monitor	S4303	Interchangeable Biologics Clarity Act	A bill to provide for a period of exclusivity for first interchangeable biological products.	Sen. Tim Kaine [D-VA]	2 B	05/25/2022 Referred to the Committee on Health, Education, Labor, and Pensions
Access	Monitor	HR8877	Biologics Competition Act of 2022	To direct the Secretary of Health and Human Services to evaluate the extent to which the substitution of interchangeable biological products may be impeded by differences between the system for determining a biological product to be interchangeable and the system for assigning therapeutic equivalence ratings to drugs, and for other purposes	Rep. Mariannette Miller-Meeks, [R-IA-2]	4 B	09/19/2022 Introduced in House
Access	Monitor	S1644/HR3761	Promising Pathway Act	A bill to amend the Federal Food, Drug, and Cosmetic Act to establish a time-limited provisional approval pathway, subject to specific obligations, for certain drugs and biological products, and for other purposes	Sen. Mike Braun [R-IN] Rep. Mike Gallagher [R-WI-8]	[6 R (S) 9 B (H)]	05/13/2021 Introduced in Senate 06/09/2021 Referred to the Subcommittee on Health (H)
Transparency	Monitor	HR7035	Biologics Market Transparency Act of 2022	To amend the Federal Food, Drug, and Cosmetic Act to require prompt reports of marketing status by holders of approved applications for biological products, and for other purposes.	Rep. Kathy E. Manning [D-NC-6]	1 R	03/10/2022 Referred to the Subcommittee on Health
Transparency	Monitor	HR7473	Generic Substitution Noninterference Act	To prohibit pharmaceutical manufacturers from interfering with therapeutically equivalent or interchangeable substitution decisions by health care providers to limit competition from a generic drug or biosimilar biological product, and for other purposes.	Rep. Carolyn B. Maloney [D-NY-12]	7 D	04/07/2022 Referred to the House Committee on the Judiciary

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Transparency	Monitor	HR7473	Generic Substitution Noninterference Act	To prohibit pharmaceutical manufacturers from interfering with therapeutically equivalent or interchangeable substitution decisions by health care providers to limit competition from a generic drug or biosimilar biological product, and for other purposes.	Rep. Carolyn B. Maloney [D-NY-12]	7 D	04/07/2022 Referred to the House Committee on the Judiciary