

S 659

Biologic Patent Transparency Act

Congress: 116 (2019–2021, Ended)

Chamber: Senate

Policy Area: Commerce

Introduced: Mar 5, 2019

Current Status: Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

Latest Action: Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (Mar 5, 2019)

Official Text: <https://www.congress.gov/bill/116th-congress/senate-bill/659>

Sponsor

Name: Sen. Collins, Susan M. [R-ME]

Party: Republican • **State:** ME • **Chamber:** Senate

Cosponsors (8 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Braun, Mike [R-IN]	R · IN		Mar 5, 2019
Sen. Kaine, Tim [D-VA]	D · VA		Mar 5, 2019
Sen. Portman, Rob [R-OH]	R · OH		Mar 5, 2019
Sen. Shaheen, Jeanne [D-NH]	D · NH		Mar 5, 2019
Sen. Stabenow, Debbie [D-MI]	D · MI		Mar 5, 2019
Sen. Hawley, Josh [R-MO]	R · MO		Apr 3, 2019
Sen. Paul, Rand [R-KY]	R · KY		May 1, 2019
Sen. Murkowski, Lisa [R-AK]	R · AK		May 6, 2019

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Mar 5, 2019

Subjects & Policy Tags

Policy Area:

Commerce

Related Bills

Bill	Relationship	Last Action
116 S 4796	Related bill	Oct 5, 2020: Read twice and referred to the Committee on Finance.
116 HR 8527	Related bill	Oct 2, 2020: Referred to the Committee on Energy and Commerce, and in addition to the Committees on Ways and Means, Education and Labor, the Judiciary, Oversight and Reform, House Administration, Rules, the Budget, and Armed Services, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.
116 HR 4850	Identical bill	Dec 18, 2019: Referred to the Subcommittee on Courts, Intellectual Property, and the Internet.
116 S 1895	Related bill	Jul 8, 2019: Placed on Senate Legislative Calendar under General Orders. Calendar No. 133.

Summary (as of Mar 5, 2019)

Biologic Patent Transparency Act

This bill requires the holder of a license to market a biologic drug to disclose all patents believed to be covering that drug. The bill also directs the Department of Health and Human Services (HHS) to make such information publicly available. (Biologics are drugs produced through natural processes or isolated from natural sources.)

The holder of a market approval license for a biologic product shall submit a list to HHS of all patents that the holder reasonably believes would be infringed by an unauthorized person making, using, offering to sell, selling, or importing that product. The license holder shall update HHS as to any relevant patents granted after the initial submission and as to listed patents that were later invalidated or rendered unenforceable.

If a patent that should have been listed was not timely disclosed to HHS, the patent holder may not sue for infringement of that patent.

HHS shall publish an easily searchable list of all biologics that have received market approval or for which an application for approval has been filed. The list shall contain information including (1) the official and proprietary name of the product, (2) the patents the license holder has listed under this bill, (3) whether various market exclusivity periods apply to the product, and (4) information about whether the product is interchangeable with another biologic product.

Actions Timeline

- **Mar 5, 2019:** Introduced in Senate
- **Mar 5, 2019:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

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