# Review of Biosimilar Legislation Activity at State and Federal Level in the United States between 2018 and 2022

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## Background & Objective

- The biosimilar market in the United States is forecasted to grow by roughly 26.1% between 2022 to 2027 and surpass over $60 Billion in market value. [1]
- This will be driven by patent expiration, market competition, increasing number of patients, and cost-saving initiatives from government and third-party payers. [1]
- North America currently holds the highest share of the biosimilar market in the world. [2]
- Biosimilar utilization is expected to rise for both cancer treatment and supportive care and as a result, regulatory challenges are anticipated. [3]
- With the anticipated challenges, the author conducted a superficial review of biosimilar legislation activity at both state and federal level in the United States between January 2018 and December 2022.

## Methods

- LegiScan was tool that was used to find biosimilar bills with the criteria stated below.
- The only search term used was "biosimilar".
- Inclusion criteria:
  - Bills affecting biosimilar that was on the floor between January 2018 and December 2022
  - Bills affecting biosimilar regulation that ultimately did not pass
  - Bills affecting biosimilar regulation
- Exclusion criteria:
  - Bills not affecting biosimilar regulation
  - Appropriation bills
- Data on the topic of each bill was not collected for the purpose of this presentation.

## Disclosures

The author has no relevant conflicts of interest to disclose for this presentation.

## Data

- The table below shows the data collected for this presentation.
- States that did not have any biosimilar bill activity between January 2018 and December 2022 were not included in this table and instead listed below the table.
- The number not in parentheses denotes bills that passed.
- The number in parentheses denotes bills that ultimately did not pass.

| Government | 2018 | 2019 | 2020 | 2021 | 2022 |
|---|---|---|---|---|---|
| Alabama | 0 | 1 (2) | 0 | 0 | 0 |
| Arizona | 0 | 0 | 0 (1) | 0 (2) | 0 (1) |
| California | 1 | 0 | 2 (1) | 0 | 1 |
| Colorado | 0 (1) | 0 | 0 | 0 | 0 |
| Connecticut | 1 | 0 (1) | 0 (2) | 0 (3) | 0 (2) |
| Idaho | 0 | 0 | 0 (1) | 0 | 0 |
| Illinois | 0 | 0 | 0 (1) | 0 (2) | 0 |
| Maine | 0 | 0 | 0 (1) | 0 | 0 (1) |
| Michigan | 0 (2) | 0 | 0 | 0 | 0 |
| Minnesota | 0 | 0 | 0 | 0 (3) | 0 (2) |
| Missouri | 0 | 0 | 0 (2) | 0 | 0 |
| Nebraska | 1 | 0 | 0 (1) | 0 | 0 |
| New Hampshire | 0 (1) | 0 | 0 | 0 | 0 |
| New York | 1 | 0 | 0 | 0 | 0 |
| Vermont | 0 (1) | 0 | 0 | 0 | 0 |
| Washington DC | 0 | 0 | 1 | 0 | 0 |
| Federal | 0 (2) | 0 (3) | 0 (4) | 1 (7) | 0 (3) |
| Total Bills Passed | 4 | 1 | 3 | 1 | 1 |
| Total Bills Introduced | 11 | 7 | 17 | 18 | 9 |

States with no activity: Alaska, Arkansas, Delaware, Florida, Georgia, Hawaii, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maryland, Massachusetts, Mississippi, Montana, Nevada, New Jersey, New Mexico, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, Washington, West Virginia, Wisconsin, Wyoming

## References

1. The International Market Analysis Research and Consulting Group (IMARC Group). Biosimilar Market: Global Industry Trends, Share, Size, Growth, Opportunity and Forecast 2022-2027. Published 2023.
2. Mordor Intelligence. Biosimilars Market – Growth, Trends, COVID-19 Impact and Forecasts (2023-2028). Published 2023.
3. Joshi D, Khursheed R, Gupta S, et al. Biosimilars in Oncology: Latest Trends and Regulatory Status. *Pharmaceutics*. 2022;14(12):2721. Published 2022 Dec 5.
4. LegiScan. Legiscan.com.

## Results

- Biosimilar legislation activity at the state level is minimal but there is a significantly more activity at the federal level every year in comparison to individual states.
- Out of 50 states and Washington DC, only 16 states had biosimilar legislation activity.
- 35 states did not have biosimilar legislation activity.
- Most bills that were introduced at both state and federal level ultimately did not pass.
- There was a higher than usual biosimilar legislation activity in 2020 and 2021. There was a decrease in 2022 however.

## Conclusion & Discussion

- There is minimal biosimilar bill activity at state level.
- At a federal level however, there have been increased efforts for biosimilar regulation.
- While there seems to be an overall decrease in activity in 2022, it is anticipated that there will be a surge in activity as biosimilars become more prevalent in the market.
- It should be noted that biosimilar regulation is complicated and that plays a role in state bills ultimately not being passed.
- As the United States enters into the uncharted territory of biosimilar regulation, the success of the European Union can be a guide.
- In the future, an in-depth review of the biosimilar bills should be completed.

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