

Senate Health and Human Services Committee

Sophie Walsh 271-3469

HB 117, relative to the substitution of biological products.

Hearing Date: April 2, 2025

Time Opened: 9:45 a.m.

Time Closed: 9:58 a.m.

Members of the Committee Present: Senators Rochefort, Birdsell, Prentiss and Long

Members of the Committee Absent: Senator Avard

Bill Analysis: This bill modifies the definition of "interchangeable biological product" and allows for interchangeable biological products to be provided by pharmacists subject to certain restrictions.

Sponsors:

Rep. Layon

Rep. Burroughs

Rep. Spier

Rep. Kofalt

Rep. Potucek

Rep. Wheeler

Sen. Prentiss

Who supports the bill: 56 people signed in support of the bill. Full sign in sheets are available upon request by contacting the Legislative Aide, Sophie Walsh (Sophie.Walsh@gc.nh.gov).

Who opposes the bill: 1 person signed in opposition of the bill. Full sign in sheets are available upon request by contacting the Legislative Aide, Sophie Walsh (Sophie.Walsh@gc.nh.gov).

Who is neutral on the bill: No one signed in neutral to the bill. Full sign in sheets are available upon request by contacting the Legislative Aide, Sophie Walsh (Sophie.Walsh@gc.nh.gov).

Summary of testimony presented:

Representative Erica Layon, Rockingham – District 13

- Representative Layon explained that she took over sponsoring this bill when the original prime sponsor was not re-elected.
- One of the most significant challenges facing constituents in New Hampshire is the high cost of medications, particularly biologics.
- While biologics can be life changing, their costs often impose a substantial financial burden on patients.

- Representative Layon emphasized that this initiative will benefit taxpayers.
- She referenced a handout from the Prescription Drug Affordability Board that shows some of the most expensive retail prescription drugs include those covered in New Hampshire under various programs, including Medicaid.
- Approved biosimilars must have essentially identical safety and benefit risks to the referenced biologic.
- The intent of this bill is to standardize language regarding biosimilars.
- The U.S. Food and Drug Administration (FDA) is currently evaluating how to address the interchangeable designation, which was initially created as a safety measure to facilitate the acceptance of these products.
- Globally, studies have demonstrated that biosimilars do not introduce any new, unique side effects. Any side effects observed are consistent with those of the original referenced biologic.
- Standardizing the language in state statute will allow New Hampshire to be prepared when policy is changed at the federal level.
- Representative Layon emphasized that this initiative will help lower healthcare costs for those who choose to utilize biosimilars.
- Senator Rochefort noted that the bill does not explicitly define biosimilars. He suggested implementing a definition and noted that the FDA definition may be incorporated, as lines 14-18 of the bill reference the federal law that this definition is in.
- Senator Rochefort also noted that the bill refers to biological drugs, which are large molecule drugs. However, on lines 16-18, the bill references the Orange Book, which is a standard for small molecule drugs. He suggested correcting the language to reference the Purple Book instead.
- Senator Rochefort proposed amending the bill to address these concerns and asked if Representative Layon would be open to that.
- Representative Layon said she would be open to making those changes.
- Senator Rochefort asked if this bill will be incorporated into HB 2.
- Representative Layon explained that she heard that might happen, as this initiative could generate approximately \$2.5 million in savings for the State.

Chris Kent, Amgen

- Mr. Kent stated that Amgen is a biotech company that currently has 11 biosimilars in their portfolio.
- Amgen advocates for effective policies to promote success in the marketplace with biosimilars, so that biosimilars may bring in competition and meaningful cost savings to the healthcare system.
- Amgen believes this bill is unnecessary because it seeks to preemptively address a hypothetical change in federal law.

- The Red Tape Elimination Act, which has been introduced at the federal level in previous years, amends federal law to make all biosimilars interchangeable with their referenced products.
- This legislation has not been reintroduced yet this year. It remains unclear if it will be introduced, or if it will garner sufficient support to become law.
- Mr. Kent explained that regulatory changes may be further delayed by the reduction in staff and resources in federal agencies.
- Mr. Kent noted that this bill contains some inconsistencies and ambiguous language. If the Committee proceeds with this legislation, Amgen is willing to collaborate on refining the language to streamline the bill while preserving its intent.
- Mr. Kent addressed Senator Rochefort's earlier comment about the definition of biosimilars and said Amgen could be supportive of including the FDA definition.
- Senator Rochefort noted that the bill's sponsor is attempting to anticipate potential federal policy shifts and align state statute accordingly.

Michael Layon

- Mr. Layon stated that he is speaking in support of this bill.
- This bill seeks to address both the needs of patients and fiscal responsibility.
- While the projected savings for the State are currently modest, the number of biologics is consistently growing.
- The potential cost savings for patients, particularly those on fixed incomes, is substantial.
- Mr. Layon emphasized that there are no safety concerns any reasonable person would have with this bill. In nearly two decades of global use, no new adverse effects have been reported that were not already associated with the referenced biologic.