



March 26, 2026

Re: SB 1094 Prescription Drugs (OPPOSE)

Dear Members of the California Senate Health Committee:

On behalf of the Alliance for Safe Biologic Medicines (ASBM), we write to respectfully urge you to reconsider SB 1094, which would amend California's pharmacy practice framework to inappropriately permit third-party pharmacy level substitution of non-interchangeable biosimilars. Formed in 2010, ASBM is a coalition of physicians, pharmacists, patients, researchers, and manufacturers working together to ensure that patients have access to biologic medicines without compromising safety or effectiveness. We strongly support the use of biosimilars, which are safe and effective therapies that expand access and reduce costs. However, biosimilars are not generics, and policies governing their use must reflect their scientific complexity.

Biosimilars are highly similar (but not identical) versions of biologic drugs used to treat serious and chronic conditions like cancer, rheumatoid arthritis, Crohn's disease, psoriasis, and cancer. They offer patients essential, lower-cost treatment options, which they may not have access to otherwise, and have saved the U.S. health system an estimated \$36 billion.

But, as the FDA states, "biosimilars are not generics, and there are important differences between biosimilars and generic drugs." These differences can meaningfully impact patient lives and their health outcomes; and physicians are cautious not to switch patients unnecessarily or inappropriately. Recognizing this, Congress authorized the FDA to create an "interchangeable biosimilars" category, which requires additional evidence-based data from manufacturers to demonstrate that switching between a biosimilar and its reference biologic won't compromise safety or effectiveness.

However, SB 1094 would inappropriately apply a generic substitution paradigm to biologic medicines—products that, by their nature, cannot be identical copies. For this reason, since 2015, California (like all 50 states and U.S. territories) has permitted only biosimilars that meet the FDA's higher standard for interchangeability to be substituted at the pharmacy level without prescriber involvement.

Importantly, the current framework reflects a broad consensus among patients, physicians, pharmacists, and policymakers in California and nationwide. Support from medical societies and patient advocacy organizations for any biosimilar substitution has always been contingent on the assurance that **ONLY** interchangeable biosimilars may be substituted by someone other than the patient's physician. SB 1094 would depart from that longstanding consensus, potentially jeopardizing treatment stability for many California patients and eroding patient and physician confidence in biosimilars as a class.

Further, survey findings make clear that physicians—who are ultimately responsible for patient outcomes—**do not support the generic-style biosimilar substitution policy in SB 1094:**

- 58% of U.S. physicians strongly oppose biosimilar substitution by anyone other than the prescriber for non-medical reasons such as cost or profitability.
- Majorities of physicians say they are more comfortable prescribing an interchangeable (57%) and with one being substituted (59%) precisely because the manufacturer provided the additional data demonstrating the switch will not impact safety and efficacy.
- Like their U.S. counterparts, European physicians (73%) strongly oppose pharmacy substitution of biosimilars. Unsurprisingly, automatic substitution is rare—and often banned—in advanced European countries.
- 85% of physicians believe biosimilars should be considered interchangeable only if they have been specifically evaluated in switching studies
- **Only 11% support treating all biosimilars as interchangeable (i.e., substitutable by an insurer or pharmacy) - as SB 1094 would do.**

SB 1094 would expand the ability of third parties like insurance companies and pharmacy benefit managers to drive substitution decisions based on profitability and without adequate clinical justification (non-medical switching). This risks disrupting the treatment of stable patients and diminishing the role of clinicians in managing complex biologic therapies.

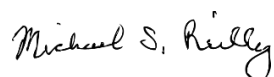
We respectfully urge the Committee to maintain the existing, evidence-based framework for biosimilar substitution and to reject the changes proposed in SB 1094.

Thank you for your consideration. We would welcome the opportunity to serve as a resource to you or your staff.

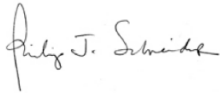
Sincerely,



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