

Support CO HB 1121
Ensure Patient Access to Safe, Affordable Biosimilars

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Dear Members of the Colorado General Assembly:

It is vitally important during this term of the state legislature that Colorado lawmakers take steps to address the health care needs of citizens with serious chronic illnesses—including our children, seniors and veterans—and bring state law into alignment with the current state of medical innovation.

The issue concerns biologic medicines—drugs created from living cells—and biosimilars, copies of the original brand-name biologics that are authorized under the Affordable Care Act and will be available to consumers in the near future. While Congress and the FDA will regulate and implement the approval pathway for biosimilars, it will fall to the states to create standards under which biosimilars can be substituted for their original counterparts without endangering patient safety. It is imperative that the legislature act on this issue before biosimilars enter the Colorado marketplace.

The best approach to this matter lies in HB 1121, and we strongly urge its passage. The core component of this bill is the standard that biosimilars must meet before they can be substituted for brand-name biologic drugs. Such a substitution cannot be made unless the FDA has certified that a biosimilar has been designated as interchangeable. FDA's expertise in this matter is irreplaceable. Because biologic drugs are made from living cells, a biosimilar cannot be an exact copy, but can only be similar to the innovator product. FDA scientists must certify that the biosimilar can be interchanged without causing harm to the patient or reducing treatment effectiveness.

HB 1121 also requires complete transparency in the substitution process. Whenever a pharmacist substitutes an interchangeable biosimilar for its original biologic counterpart, both the prescribing physician and the patient must be notified. Patients receiving biologic medications tend to have one or more severe chronic illnesses and their doctors take great care in determining which drugs will be the most effective in treating their conditions, and also must be able to track any adverse reactions should they occur. It is critical, especially for these patients, that both the physician and patient are aware of the substitution.

The measure also requires that records of biosimilar substitutions be maintained by the pharmacy so that it is possible to track medication decisions in the event the patient suffers an adverse health event.

HB 1121 is a necessary, common sense bill for the Colorado legislature to adopt. It aligns Colorado law with the state of 21st century medicine, creating a pathway for biosimilar substitutions and greater medication access for patients. And it does so without creating higher costs or undue burdens for taxpayers or the state's health care system. In fact, there is nothing in this bill that would restrict the ability of insurance companies or pharmacy benefit management firms from incentivizing the use of biosimilars through co-payments or formulary controls.

Colorado patients need access to safe, affordable medicines that will treat their conditions and alleviate their symptoms. Because biosimilars will be available to Colorado patients at any time in the near future, it is essential that the legislation allows and promotes their safe usage.

We strongly encourage you to pass HB 1121 in its entirety.