COLORADO CENTER on LAW & POLICY

HB 1121: Biosimilar drugs bill would limit access to safe, effective, and less costly medications.

CCLP Position: Oppose

FACT SHEET

Bill title: Biosimilars
Bill No.: HB 1121
Sponsor: Rep. Schafer, Rep. Murray, Sen. Heath, Sen. Roberts,
Our position: Oppose

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HB-1121 will discourage the use of safe, effective, and therapeutically equivalent biosimilar drugs that can help lower health care costs for low-income Coloradans and the state Medicaid program.

Like the use of generic drugs, substituting biosimilar drugs for branded biologics would reduce health care costs.

- Generic drugs have saved the American health care system more than $1 trillion since 1999. These savings include $157 billion in 2010 alone[i].
- Generic drugs are 75 to 85 percent cheaper than their brand name counterparts[ii].
- Biologics are among the most expensive drugs, costing tens of thousands of dollars per patient per year (e.g. Avastin: $100,000 per year, Humira: $20,000 per year, Enbrel: $18,000 per year)[iii].
- Four of the top 10 selling drugs in 2012 were biologics, totaling more than $18.4 billion in sales[iv].
- While not yet on the market, biosimilar drugs are expected to begin saving money for consumers and Medicaid in the next few years.

Biosimilar drugs, like generic drugs, are not inherently less safe than their branded reference products

- Generics must meet rigorous safety and efficacy standards, just like their branded counterparts. Generics are cheaper, in part, because they must compete with other manufacturers to produce the drug at the lowest price[v].
- The Federal Food and Drug administration (FDA) tracks adverse events from all drugs and biologics, including generics to address any safety issues that may arise.
- Federal law requires that a biosimilar must be as safe, pure and potent as the branded biologic[vi].

HB13-1121 would discourage pharmacists and doctors from using biosimilars.

- Onerous record keeping requirements would discourage pharmacists from substituting biosimilars for branded biologics. The bill requires pharmacists to keep records of any substitution for at least five years. There is no similar requirement for generic drugs in

Colorado law[vii].

- Physician notifications create a presumption that biosimilars are inherently unsafe**.** The law requires pharmacists to notify the prescribing physicians within 3 days of making a substitution. This requirement is more burdensome what is required in current Colorado law for generic drugs.

Discouraging or preventing the use of biosimilars would cost consumers and the state money.

- Prescription drug plans can require patients to pay thousands of dollars out-of-pocket for the most expensive drugs, like many biologics.
- Preventing the use of biosimilars in Medicaid would require the state to pay for needlessly expensive drugs. HB13-1121's fiscal note does not assess the long term financial impact of failing to encourage the use of biosimilars. The patents of top selling, expensive biologics are set to expire within the next 6 years[viii]. These biologics have become the standard of care for cancer, rheumatoid arthritis, and other diseases and substituting biosimilars for these biologics would save the state Medicaid program money in coming years.

By requiring biosimilars to be "interchangeable," HB13-1121 may limit access to safe, effective biosimilars that produce similar clinical results.

- The bill requires a biosimilar meet a difficult legal standard and be deemed "interchangeable." The FDA approval process is still being developed and it is unclear what may be required to establish interchangability.
- FDA acknowledges that "it would be difficult as a scientific matter for a prospective biosimilar applicant to establish interchangeability."[ix] The scientific requirements for proving "interchangeability" may be so high that few products will be called "interchangeable," even if they produce similar clinical results.
- At this premature stage, limiting substitutions only to "interchangeable biosimilars" may limit access to lower cost, therapeutically similar biosimilars.

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[i] Research on Savings from Generic Drug Use. GAO-12-371R. http://www.gao.gov/products/GAO-12-371R

[ii] See FDA Fact sheet: http://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/understandinggenericdrugs/ucm167991.htm

[iii] Avastin: http://www.nytimes.com/2008/07/06/health/06avastin.html?pagewanted=all; Humira: http://articles.latimes.com/2011/jun/02/business/la-fi-humira-20110602; Enbrel: http://seattletimes.com/html/health/2008120449_drugs18m.html

[iv] See list of top selling drugs: http://www.drugs.com/stats/top100/2012/sales

[v] See ii above

[vi] Public Health Service Act, Section 351(k), as well as 42 USC 262(i).

[vii] Colorado revised statutes 12-42.5-122

[viii] http://gabionline.net/Biosimilars/General/US-67-billion-worth-of-biosimilar-patents-expiring-before-2020

[ix] See FDA Guidance for Industry. "Biosimilars: Questions and Answers Regarding the implementation of the Biologics Price Competition and innovation act of 2009." http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM273001.pdf