Why Colorado's Health Care Experts Oppose Physician Notification for Interchangeable Biologics (SB15-071)

Background:
The Biologics Price Competition and Innovation Act of 2009 created an abbreviated pathway for FDA to give approval to biologic medications that are interchangeable with already approved biologic "reference products." With this framework now in place, FDA is working to implement the drug approval pathway for interchangeable biologics. The agency has issued guidance around the development and approval of interchangeable products and is undertaking development of standards for determining interchangeability. According to FDA, the approval process for interchangeable biologics will ensure that any product deemed interchangeable can be expected to produce the same clinical result in any given patient, who will experience **no greater risk from alternating or switching between the two products** than if the patient were to continue to use the reference product.

Why Colorado's Health Care Professionals OPPOSE Physician Notification:

- The FDA standards for interchangeables will be rigorous. The agency is cognizant of the complexities inherent to biologic products and has made clear that the standards will ensure that FDA can perform an overall assessment that a biologic is interchangeable to an approved reference product. Only interchangeable products that meet FDA's standards for interchangeability will be approved and designated as interchangeable.

- The FDA's work in the area of interchangeable biologics is ongoing. Considering that industry consensus is that we are likely years away from FDA making determinations around interchangeability, enacting laws that would impede such substitution in the future creates an unfair marketplace by creating an advantage for the name-brand reference products currently being prescribed.

- Prescribers ALREADY have the ability to track patient medications through "Dispense as Written" and/or "Notify of Interchange". This bill would take current language that is purposely designed to be permissive and turn it into a blanket mandate, tying the hands of providers and patients who do not feel notification is warranted in every single occasion.

- Since pharmacists would not substitute interchangeable biologics except where a prescriber would expressly authorize the substitution on the prescription, the special notification requirements in these bills would be redundant and serve no other purpose than to perpetuate the notion that biologic and interchangeable products warrant special treatment as compared to other types of prescription drugs, ultimately undermining prescriber confidence in interchangeable products in particular.

- Pharmacists are ALREADY required by law to notify patients of a substitution orally AND in writing, and records are kept for at least two years afterwards. The patient always has the right to refuse a substitution. The patient's safety and knowledge of his or her medicine will never be at risk.

- The current bill is written so that pharmacists would have to notify prescribers of filling a prescription, **even if it is filled as written**, and even if there was a Dispense as Written order. Such regulations are unnecessary, confusing, and redundant

- Moreover, **the special notification requirements would create otherwise unnecessary distractions from the important communications already initiated by pharmacists when there are pressing healthcare issues to address**. For example, pharmacists commonly reach out to prescribers regarding potential drug interactions, patient allergies to medications, and formulary issues. It is important to maintain focus on patient care issues that need resolution, and not to inundate prescribers with irrelevant information.

- When the FDA reclassifies insulin as a biologic, this bill would require pharmacists to undertake the same notification requirements. **There were over 3 million insulin prescriptions filled in Colorado in 2013** – that has the potential for creating an enormous amount of unnecessary work.

- Compared to other types of prescription drugs, biologic drugs that currently are without any generic competition in the US market cost on average 22 times more per day[i]. Considering how costly biologic products are and that there are a growing number of biologic products expected to enter the market, **enacting special requirements that make substitution of interchangeables more difficult and therefore less likely will unnecessarily drive up prescription drug costs for all payors, including state Medicaid.** Notably, a Recent RAND report expects interchangeable biologics to save US healthcare system $44.2 billion from 2014 to 2024.This growing category of products represents an area of the drug spend where the state stands to achieve much greater savings once less expensive interchangeable products come onto the market.

Notification is OPPOSED by: Colorado Chain Pharmacy Committee, RxPlus Independent Pharmacies, Colorado Pharmacists Society, Pharmaceutical Care Management Association, National Association of Chain Drug Stores, CVS Health, Walgreens, Mylan, Kaiser Permanente, Anthem Blue Cross Blue Shield, United Health Group, Aetna, Colorado Association of Health Plans, Optum Rx, National Community Pharmacists Association, Academy of Managed Care Pharmacy, America's Health Insurance Plans, Pharmacy Choice and Access Now

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[i] Generics and Biosimilars Initiative. http://www.gabionline.net/Biosimilars/Research/Small-molecule-versus-biological-drugs