Please join us in opposing SB 147

America's Health Insurance Plans (AHIP)
Elise Brown

Associated Oregon Industries
Betsy Earls

Cambia Health Solutions
Tom Holt
Elizabeth Remley

CVS Health
Maral Farsi

Health Net Health Plan of Oregon, Inc.
Lisa Trussell

Kaiser Permanente
Jeremy Vandehey
Inga Deckert

Mylan Pharmaceuticals
Fawn Barrie

National Association of Chain Drug Stores
Lis Houchen

Northwest Grocery Association
Shawn Miller

Moda
Fawn Barrie
Mike Dewey

Oregon Community Pharmacy Council
Shawn Miller

Oregon Society of Health System Pharmacists
Bill Cross

Oregon State Pharmacy Association
Bill Cross

PacificSource Health Plans
Marian Blankenship
Pam Leavitt

Pharmaceutical Care Management Association (PCMA)
Greg Peden
Kelsey Wilson

Providence Health Plan
Jessica Adamson

Providence Health and Services
Jessica Adamson

Fred Meyer, Safeway and Rite Aid
Evyan Jarvis Andries
Gary Oxley

United Health Group
Dan Jarman

Walgreens
Michael Smith

Vote NO on SB 147

What are biologics, biosimilars, and interchangeable biologics?

Biologic is a term used to describe complex pharmaceutical products that are generally produced using a living system or organism. This is in contrast to small molecule pharmaceutical drugs that are manufactured from chemical processes. A biosimilar is a biological product that is highly similar to a reference product notwithstanding minor differences in clinically inactive compounds. An interchangeable biologic can have **no clinically meaningful differences** from the biologic product in terms of safety, purity and potency, similar to requirements for generic substitution of name brand drugs. Interchangeable biologics must also complete clinical trials in order to receive their interchangeable status by the FDA.

Current Status

The U.S. Food and Drug Administration (FDA) is working to create a process for the approval of interchangeable biologics. The FDA is fully cognizant of the complex nature of biologics and has made clear that the standards they develop for determining whether a biosimilar is interchangeable with an approved biologic reference product will be rigorous. While there have been 5 applications filed for biosimilars, there have been no applications filed for interchangeable biologics since the FDA guidance still does not exist.

Unnecessary Requirements in SB 147

The new notification requirements in SB 147 are redundant and unnecessary. According to existing OR law, a pharmacist may not make a substitution if the biologic drug has not been deemed interchangeable by the FDA and/or the prescriber indicates on the prescription that he/she wishes for the patient to take the brand biologic medication. Therefore, the practitioner, at the point of issuing a prescription to the patient, has the ultimate authority to determine if the patient should be dispensed a specific biologic or biosimilar medication or if substitution of an interchangeable biologic is permitted. The practitioner always retains control of what medication the patient will be dispensed.

Bottom Line

Big biotechnology drug companies do not want to wait for the FDA to provide official guidance on interchangeability despite the federal definition clearly stating that an interchangeable biologic is one that "may be substituted for the reference product **without the intervention of the health care provider** who prescribed the reference product." They are pushing legislation in states all over the country, including in Oregon, in order to limit competition by promoting fear in patients and creating artificial barriers to their use. The availability of biosimilars and interchangeable biologics will give patients greater access to life-saving medications while saving significantly on the cost of their health care. A recent study from RAND finds that biosimilars and interchangeable biologics are expected to save as much as $66 billion in direct spending on biologic drugs from 2014 to 2024. Legislation that impedes or limits interchangeable biologic substitution is nothing more than an attempt by brand manufacturers to preemptively protect profit margins at the expense of consumers and payers.