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Kaiser Permanente Health Plan of the Northwest

To: The Honorable Laurie Monnes Anderson
Chair, Senate Committee on Health Care and Human Services

From: Steve Logan, R.Ph.
Senior Director, Regional Pharmacy Services
Kaiser Permanente Northwest

Date: February 28, 2013

Re: Opposition of Senate Bill 460– Dispensing of Biosimilars

Thank you for the opportunity to present testimony on behalf of Kaiser Permanente in opposition to SB 460. I am a pharmacist and serve as the Senior Director of Regional Pharmacy Services for Kaiser Permanente's Northwest Region.

Kaiser Permanente is supportive of the advancement of both biologics and biosimilars due to the potential use in the effective treatment of diseases and chronic conditions, as well as the ability to improve the quality of life for patients. SB 460 would create unnecessary limits on the use of biosimilars.

The Biologics Price Competition and Innovation Act of 2009, passed as part of the Patient Protection and Affordable Care Act, created a pathway for the Food and Drug Administration (FDA) to approve biologic medications that are "biosimilar" to approved biologic "reference products." The FDA is in the process of establishing criteria for the approval of these biosimilar drugs and interchangeable biosimilars.

The approval process for biosimilars 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. There should be no meaningful differences in terms of safety, purity, and effectiveness of the product between the interchangeable biosimilar and the original biologic drug. Thus, biosimilars deemed interchangeable can be substituted without the prescriber's intervention.

The FDA's process to approve biosimilars and interchangeable biosimilars is ongoing and there are currently no approved biosimilars on the market. We believe enacting state law at this time which creates limits on biosimilars is ***premature*** and can potentially conflict with the standards that federal standard developed by the FDA.

Enacting barriers that make substitution of biosimilars more difficult can drive up prescription drug costs for all payers, including state Medicaid programs. Biologic drugs are costly. The

Kaiser Permanente
Regional Pharmacy Services
5725 NE 138th Ave
Portland, OR 97230

average treatment costs for biologic drugs are estimated to be $16,000 per year, though some treatments can cost more than $10,000 per month.[1] This growing category of drugs represents an area of the drug spend where the state stands to achieve much greater savings once less expensive biosimilars come onto the market. A recent report notes that in the European Union, where biosimilars have been introduced, reference product prices have fallen 30 percent.[2]

For the foregoing reasons, we oppose SB 460 and ask that it not move forward. I would be happy to discuss this legislation at any time. Thank you for your consideration.

[1] "What you need to know about the Follow-On Biologic Market in the U.S.: Implications, Strategies and Impact," Thompson Reuters, Jan. 2011 (available: http://thomsonreuters.com/content/science/pdf/ls/newport-biologics.pdf.)

[2] "The New Biosimilar Era: The Basics, the Landscape, and the Future," Bloomberg Law (available: http://about.bloomberglaw.com/practitioner-contributions/the-new-biosimilar-era-the-basics-the-landscape-and-the-future/