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February 26, 2013

The Honorable Laurie Monnes Anderson
Chair, Senate Health Care and Human Services Committee
State Capitol
Salem, Oregon 97301

RE: Senate Bill (SB) 460, restrictions on biosimilar products

Dear Senator Monnes Anderson and members of the committee:

On behalf of Providence Health & Services and Providence Health Plan, thank you for the opportunity to provide our input regarding SB 460, as it relates to restrictions on substitution of biosimilar products for prescribed biological products. For reasons we will discuss in this letter, we believe the timing for state legislation is premature.

Biosimilars are not yet available to patients in the United States and many federal regulations are still not defined. We are concerned that state legislation enacted before the Federal Drug Administration releases its proposed protocol could conflict with national standards and patient safeguards. It is difficult to envision how a state bill at this juncture could be effective.

In a similar way to generics, biosimilars offer the promise of significant savings and should be an option for patients once national standards are in place. They will also increase access to much-needed therapies. Once on the market, these products will also be subject to existing state pharmacy laws and regulations that protect patients.

The FDA has said that the standards it develops for determining whether a branded biologic is interchangeable with an approved biosimilar – and therefore safe for substitution – will be rigorous. In addition, because of their complexity, we will continue to carefully evaluate biosimilar products using evidence-based information to ensure safety and efficacy for our patients. We do not see that the proposed legislation adds any strength or new approaches to what already is, and will be put into, place. Rather, this will only add expensive and unnecessary administrative burdens for providers and pharmacists at a time when we are looking for ways to reduce cost for patients.

We urge you to wait for pending FDA protocols before considering state legislation around biosimilar products.

Thank you for the opportunity to provide these comments. Should you have questions regarding this testimony, please contact 503-574-6568.

Sincerely,

David W. Robertson, RPh
Senior Pharmacy Manager
Providence Health Plans