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Senator Laurie Monnes Anderson, Chair
Senate Health Committee
900 Court St. NE, Room 453
Salem, OR 97301

Re: Senate Bill 460: Oppose
Senate Health Committee: February 28, 2013 3pm

Dear Senator Monnes Anderson:

I am writing to inform you that Express Scripts respectfully opposes Senate Bill 460, which seeks to restrict the use of biosimilars. Express Scripts administers prescription drug benefits on behalf of our clients – employers, health plans, unions and government health programs — for approximately 109 million Americans. Headquartered in St. Louis, we provide integrated pharmacy benefit management services including pharmacy claims processing, home delivery, specialty benefit management, benefit-design consultation, drug-utilization review, formulary management, medical and drug data analysis services, as well as extensive cost-management and patient-care services. As such, we have serious concerns with this legislation as its underlying goal is to create confusion and fear in patients over biosimilars by creating numerous rules around their use.

In 2010, The Biologics Price Competition and Innovation Act (BPCIA) authorized the FDA to develop an approval pathway for biosimilars in the U.S. The FDA pathway will classify some biosimilars as `interchangeable' — meaning (1) the substitute is expected to produce the same clinical result as the brand biologic, and (2) switching between the brand and the biosimilar carries neither health risk nor decreased efficacy. The single most important fact in this debate is that the FDA is still developing their health and safety guidance for biosimilars. Until this is complete, there is no way that states can responsibly develop new regulations governing their use. As the FDA has not yet issued all of the final guidelines for approval of biosimilars, no applications have yet been approved. Once the FDA develops this regulatory pathway for biosimilars and interchangeable biosimilars, then states will have the information needed to make informed decisions.

Last week, Politico reported, “FDA Commissioner Margaret Hamburg, in a speech at the annual meeting of the Generic Pharmaceutical Association, stated that the FDA has not yet received an application for a biosimilar drug. The agency has received 50 requests for meetings regarding 12 “reference products,” the often costly biologic drugs with which cheaper biosimilar drugs would compete. Hamburg said the FDA was working toward finalizing draft guidances to the industry on biosimilar development but provided no timeline. Hamburg also took a swipe at efforts from some drugmakers to raise questions about the safety of the biosimiliars that will eventually hit the market. “The high standard for approval of biosimilar and interchangeable products mean ... they will meet the standards of safety, efficacy and high quality that everyone expects and can count on. Efforts to undermine trust in these products is worrisome and represents a disservice to patients who could benefit from these lower-cost treatments.”

As with generics today, the availability of biosimilars will give patients greater access to life-saving medications and reducing their costs by and estimated 10-40%. It is in the interests of the proponents of this legislation to up-end the FDA’s role and expertise in this area and to intentionally create confusion and fear around the use of biosimilars.

States enacting any law that addresses biosimilars would be premature and may conflict with the national standards the FDA is working to create. For these reasons, we are opposed to this legislation and respectfully seek your “No” vote.

Sincerely,

CYNTHIA M. LAUBACHER