



March 1, 2015

The Honorable Laurie Monnes Anderson
Chair, Senate Committee on Health Care
Oregon State Senate
900 Court Street NE, #S-413
Salem, OR 97301

RE:SANOFI SUPPORTS SB 147

Dear Senator Monnes Anderson:

Sanofi, a global, diversified healthcare and life sciences company, supports SB 147.

Our primary policy concern as a manufacturer of originator biological products, as well as a potential manufacturer of biosimilars, is patient safety. SB 147 enhances patient safety at the state level by putting into place clear guidelines for addressing biosimilar products that will continue to protect patients as biosimilars begin to be marketed.

The legislation will cover all biologic products and in order to do so the definitions of biosimilar biologic product and interchangeable should reference the appropriate FDA approval pathways that will govern these definitions. Specifically, we urge full inclusion in the legislation of the two different regulatory pathways by which biological products are approved. One pathway is known as a *Biologics License Application* (BLA) governed by Section 351 of the Public Health Service Act; the other is known as a *New Drug Application* (NDA) governed by Section 505 of the Food, Drug and Cosmetic Act (FDCA). While the BLA pathway was intended to cover the approval of biologics, for procedural reasons at the FDA a small number of biologics, including insulin products, were approved under the NDA pathway. In SB 147 both pathways are included which will avoid confusion and differing provisions for substitution of the two types of biologics. While we are still evaluating the process in Oregon of directed definitions to the Board of Pharmacy in this area, we are supportive of the current draft and will continue working with you and other interested parties.

We urge you to support this bill and ensure its passage as soon as possible. If I can assist you or your staff with any questions, please contact me at 206.465.6987 or e-mail me at Deanne.Calvert@sanofi.com

Thank you for your consideration.

Sincerely,

A handwritten signature in black ink that reads "Deanne Calvert".

Deanne Calvert
Director, State Government Affairs
US Corporate Affairs
Sanofi, US