NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

Oregon State Senate Health Care and Human Services Committee
Testimony by Lis Houchen
February 28, 2013

Chain Pharmacy Opposes Senate Bill 460

Chair Monnes Anderson, for the record my name is Lis Houchen, NW Regional Director for the National Association of Chain Drug Stores (NACDS). I am here today on behalf of NACDS members who include: Costco, CVS Caremark, Genoa Healthcare, Good Neighbor Pharmacy, Haggen/Top Food & Drug, Health Mart Systems, Hi-School Pharmacy, Sears Holding Company (Kmart), Medicine Shoppe, Omnicare, Rite Aid, Safeway, Shopko, Supervalu (Albertsons), Target, Walgreens and Wal-Mart. These 17 companies operate 472 pharmacies in the state of Oregon and wish to convey their serious concerns with Senate Bill 460. We respectfully oppose this legislation, as it would impose unnecessary special requirements on the substitution of biosimilar products deemed interchangeable by the United States Food and Drug Administration (FDA).

Federal law directs FDA to develop standards for biosimilars that are appropriately rigorous to protect patient safety. The Biologics Price Competition and Innovation ("BCPI") Act of 2009 created an abbreviated pathway for FDA to approve generic biologics (termed "biosimilars"), and to further determine whether biosimilars meet even higher standards for "interchangeability," which would allow pharmacists to substitute these generic products for their brand counterparts. With the regulatory framework now in place, FDA is undergoing the process to establish standards for approval of biosimilars and for determining interchangeability.

The FDA approval and interchangeability standards for biosimilars will be rigorous. According to FDA Commissioner Margaret Hamburg who spoke at a conference on this topic

last week, "[t]he high standards for approval of biosimilar and interchangeable products [that FDA will establish] means that patients and health care professionals can be assured that when those products go to market, they will meet the standards of safety, efficacy and high quality that everyone expects and count [sic] on."[1] Moreover, as agency leadership made clear in an August 2011 article published in the New England Journal of Medicine, FDA is cognizant of the complexities inherent to biologic products and that the approval standards will ensure that FDA can perform an overall assessment that a biologic is biosimilar to an approved reference product. Only biosimilar products that meet FDA's standards for interchangeability will be designated as interchangeable. Once this designation is achieved, such products will be suitable for substitution for the reference product without the intervention of the prescribing health care provider, consistent with the intent of federal law.[2]

FDA has further indicated that the agency will look to Europe, where biosimilar products have been approved for use and on the market without any safety issues for seven years. Drawing from the experience of the European Medicine Agency, as well as the nearly 30 years of experience that FDA has in approving generic drugs, we are confident that FDA will develop approval and interchangeability standards for biosimilars that will be appropriate to protect patient safety.

Chain pharmacy opposes special requirements for the substitution of interchangeable biosimilars that would be inconsistent with federal law and serve only to limit dispensing of biosimilar products. NACDS members oppose the special requirements under Senate Bill 460 for pharmacists to notify prescribers upon substituting

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[1] Remarks by Food and Drug Administration Administrator Margaret Hamburg at the Generic Pharmaceutical Association's Annual Meeting on February 23, 2013

[2] 42 U.S.C.A. § 262 (i)(3)

biosimilar products deemed interchangeable by FDA. Imposing any such limitations on the substitution of biosimilars would be inconsistent with the intent of federal law and the standards under development at FDA to implement the BCPI Act. Further, these special requirements would undermine public perception of the safety and efficacy of biosimilar products as compared to other prescriptions drugs. Creating special practices for the substitution of biosimilars would serve no other purpose than to limit the dispensing of biosimilar products, reducing opportunities to expand patient access to these vital, live saving medications.

Barriers to dispensing of biosimilars ultimately impede potential healthcare savings while protecting the profits of innovator biotech firms. As noted in a recent New York Times article "Biotech Firms, Billions at Risk, Lobby States to Limit Generics," biologic medications account for roughly one-quarter of the nation's $320 billion in spending on drugs per year. If enacted, these requirements making the interchange of biosimilars more difficult and therefore less likely will impede greater savings for patients, health insurers and other third party payors, including Medicaid, while protecting the profits of innovator biotech firms. Biologics medications represent a growing category of products that, on average, cost the state Medicaid program $1,563 per prescription and represent 7.4% of the overall drug spend. As less expensive interchangeable biosimilars become approved for use in the United States, we can expect to see significant future healthcare savings in this area.

For the reasons discussed, we respectfully urge you to vote against Senate Bill 460. We appreciate the opportunity to present the viewpoints of our members in Oregon on this very important issue.