GPhA
Generic Pharmaceutical Association

Written Comments of the Generic Pharmaceutical Association to the Senate Committee On Health Care and Human Services Re Senate Bill 460

Submitted by
Brynna Clark, Sr. Director of State Affairs

Dear Chair Monnes Anderson, Vice Chair Kruse, and Honorable Senators of the Committee:

The Generic Pharmaceutical Association (GPhA) represents the manufacturers and distributors of finished dose generic pharmaceuticals. Generic pharmaceuticals fill 80 percent of the prescriptions dispensed in the U.S. but account for only 27 percent of total drug spending. GPhA's members provide more than 90 percent of the generic medicines dispensed in the U.S.

GPhA respectfully requests that you oppose SB 460. This bill allows for substitution of biosimilars and requires the pharmacist to notify the prescriber of the substitution. This creates a new pharmacy practice and is a typical brand ploy to thwart competition. Legislation like this is being pushed across the U.S. by two bio-tech companies who stand to lose $60 billion dollars in patent expiry between 2012-2020. Their motives and end-game must be questioned as they do not have a compelling interest in allowing competition to their marketplace. Senate Bill 460 is premature, it erects substitution barriers, implements a new pharmacy practice, and creates doubt about the safety and effectiveness of affordable biosimilar drugs.

Biologics and biosimilar drugs currently treat a variety of diseases such as cancer, HIV, rheumatoid arthritis. Biosimilar leaders in the generic industry have been successfully producing safe and effective biosimilars for sale outside the U.S. since the early 2000s. This marketplace has opened up competition, lower costs, and more importantly, access.

A biosimilar is a product that is highly similar to a U.S.-licensed reference biological product notwithstanding minor differences in clinically inactive compounds, **and for which there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.** The Biologics Price Competition and Innovation Act (BPCIA) of 2009, part of the Affordable Care Act, created an abbreviated pathway for the Food and Drug Administration to review and approve biologic medications that are biosimilar to already approved "reference products." FDA is currently establishing standards for approval of "biosimilars."

Once approved, FDA will separately make a determination if a biosimilar can be designated as "**interchangeable**." According to FDA, a biosimilar deemed interchangeable will produce the same clinical result in a patient as the reference biologic. The patient will experience no greater risk from alternating or switching between the two products than if the patient was to continue using the reference product. Therefore, interchangeability = substitutability. The federal statute explicitly states: [Interchangeable biologic products] ***"may be substituted for the reference product without the intervention of the prescribing healthcare provider."*** (U.S.C. §262(i)(3)).

For years, FDA has reviewed and approved biologic reference products and the FDA will use the most rigorous standards to approve a biosimilar product and determine interchangeability. The agency has the

skills and expertise to understand the complex nature of biologic products. The strict statutory standard for interchangeability, will render any additional state barriers to substitution completely unnecessary for patient protection. In addition to being unnecessary, these burdens would chill biosimilar substitution, and lead to increased health care costs for consumers and for the state of Oregon.

Since the FDA has not issued guidance, and biosimilars will not be on the marketplace before 2015, legislation at this stage premature. The FDA has not fully implemented the law, reviewed a biosimilar application, or deemed a product interchangeable. This legislation is being introduced before a single biosimilar is on the marketplace, making it impossible to put an accurate fiscal note on this legislation. However, the fiscal impact will no doubt be significant.

When biologics go off patent, the generic industry is ready to make them widely accessible to consumers. The biosimilars market is primed to take off, as the small molecule generic drug market did after the 1984 Hatch-Waxman Act. Brand-backed legislation like SB 460 has been introduced in 15 states and is rumored in over 20 more, but has not been signed into law anywhere. This type of legislation was rampant in the 1980s when generic drugs first came on the market and we see the same types of bills every time a blockbuster drug is about to go off patent. "Carve Out" legislation not only treats a certain class of drugs differently, but it also undermines confidence in their safety and effectiveness.

Oregon stands to benefit greatly from the introduction of lower-cost biosimilars. Biologics will be a major cost driver for your state Medicaid program. Interchangeable biosimilars have the potential to reduce prices by 40 or 50 percent. The average daily cost of a brand name biologic product is approximately **22** times greater than a small-molecule drug and this area of drugs is growing. By 2016 it is estimated that 8 of the top 10 drugs in the United States will be biologics. In 2011 Oregon's portion of Medicaid costs for biologics was over $2.6 million dollars. As more biologics are prescribed, this number will increase exponentially – with potentially dire budget consequences.

Across the nation this legislation has been sold under the guise of "patient safety" but we at GPhA do not understand how prescriber notification would serve patient safety. GPhA is dedicated to preserving the patient/prescriber relationship and has every interest in insuring patients using our biosimilars are safe. As currently written, SB 460 places additional burdens of notification and record keeping on the pharmacist and prescriber for no compelling reason. Unnecessary burdens on substitution is a brand-ploy to chill biosimilar substitution. A larger concern and a trend we have seen before, is that this language is being pushed now as a vehicle for more onerous language in the future.

GPhA has always opposed legislation that creates special prescriber notification and/or consent for the substitution of products the FDA has deemed interchangeable, because it is bad public policy. There is no need for such as it is already in Oregon law. Under current Oregon law, prescribers have the ultimate authority to determine whether it is appropriate for a pharmacist to substitute biosimilars when issuing a prescription, by specifying "in writing, by a telephonic communication or by electronic transmission that there may be no substitution for the specified brand name drug in a prescription." ORS 689.515(3).

The FDA is aware of these issues in the states and Dr. Hamburg, the FDA Commissioner commented that, *"The high standard for approval of biosimilar and interchangeable products mean that patients and healthcare professionals can*

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be assured that when those products go to market, they will meet the standards of safety and 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."[1]

In a time where employers are struggling to provide health benefits to their employees and states are looking for ways to balance Medicaid budgets, and implement exchanges, policymakers should focus on encouraging the use of safe and cost-effective medications and opening up competition in the biologics sector. SB 460 would do just the opposite and GPhA respectfully requests that you oppose this legislation.

Please let us know if we can provide any additional information. Thank you for your consideration.

Sincerely,

Brynna McClark

Brynna Clark
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[1] Dr. Margaret Hamburg, M.D. Commissioner of the FDA, February 22, 2013, http://www.gphaonline.org//gpha-media/press/gpha-feb-2013-webcast