MEMORANDUM

TO: Sen. Jake Corman, Senate Appropriations Committee Chairman
Sen. Vincent Hughes, Senate Appropriations Committee Chairman

FROM: Coalition Opposed to Biologic/Biosimilar Legislation

DATE: February 26, 2014

The undersigned entities representing vast and varying stakeholders - **pharmacists, insurance companies, PBMs, and drug manufacturers** – write to you to clarify that we remain opposed to SB 405/HB 746 and the new version of the legislation being promoted by pharmaceutical manufacturers as a "compromise." The "compromise" was solely between a group of drug manufacturers and does nothing to alleviate the strong concerns of the majority of the stakeholders. **In fact, this version is actually more burdensome, as it makes the physician notification provisions of SB 405 apply even in cases when a brand-name biologic is dispensed as directed by a physician when there was no substitution**. In addition, the option for "electronic" notification is simply not possible at this point, so it is merely window dressing.

SB 405/HB 746 and the new proposal being floated create an entirely new and highly bureaucratic notification system for only one class of drugs: biologic medications. It is a marked departure from how states decided to treat generics when they became available in the marketplace. The current drug substitution practices were purposefully crafted to encourage competition in the marketplace in order to provide patients with less-costly alternatives to brand medications.

As brand innovator products, biologics are extremely expensive. In fact, the average daily cost of a biologic medication is 22 times greater than traditional drugs.[1] Humira costs approximately $50,000 a year while Cerezyme costs $200,000 annually.[2] According to the Centers for Medicare and Medicaid Services (CMS**), PA Medicaid spent $523 million, with an average cost of nearly $1650 per prescription on biologic medications in 2012**. As these drugs grow in popularity, those numbers will continue to increase exponentially. As health care providers and payors, we believe competition is essential in this market to drive down costs so that biologics become more affordable for patients and payors, including Medicaid, PACE and PEBTF. This legislation is in direct conflict with that goal.

The attached article published on Feb 5 in Drug Industry Daily highlights concerns expressed at a recent Federal Trade Commission (FTC) workshop by Commissioner Edith Ramirez that proposes to require pharmacists to notify patients or doctors of interchangeable biosimilar substitutions may squelch biosimilar usage, while not improving adverse events reporting. According to the Commissioner, "[t]he FTC believes competition from [biosimilars] can help patients by lowering prices and expanding access to biologics."[3]

Brand Biologic medications such as Embrel and Humira have been on the market since the 1990s and are regularly dispensed by pharmacies. These medications have a proven track record for safety and efficacy, providing life-saving treatments for patients with chronic illnesses. Notification has never been required

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[1] "Why Biologics Remain Expensive**,"** Forbes, 2009
[2] Biotechnology Healthcare, Spring 2012
[3] http://www.fdanews.com/articles/162194-ftc-says-biosimilar-naming-dispensation-should-mirror-generics-model?v=preview Drug Industry Daily, Feb. 5, 2014

on these drugs (or any other medications). Both biologics and biosimilars are manufactured from the same materials, yet legislation was not proposed in any state when brand biologics came to the marketplace years ago.

Now, as we are approaching the patent cliff for brand biologic medications, representing $60 Billion in market value, we need pharmacists to notify physicians that they filled a prescription for a biologic medication, as the physician had directed on the prescription? This provision would even apply in cases where the prescription was filled with a brand biologic as directed and no substitution was made! Notably, it would also apply to insulin which has been on the market for more than 30 years and in some cases can be sold without a prescription. With 1.3 million insulin prescriptions filled in Pennsylvania last year, this provision alone would subject pharmacies to potentially making tens of thousands to hundreds of thousands of unnecessary notifications per year if an Interchangeable Biosimilar for insulin is approved.

Though proponents are now arguing that this legislation is needed to track adverse events reporting, we remain skeptical. **The FDA has a system in place that is regularly used to track adverse drug events. Why do we need to create an additional adverse event reporting system for biologics in Pennsylvania?** We have no reason to believe that the current system is not working. The volume of redundant paperwork this proposal would mandate may only serve to distract pharmacists and physicians from the important work they do with patients. Generating a piece of paper for every biologic prescription dispensed is inefficient and bureaucratic. Pharmacies maintain robust and extensive dispensing records that physicians can and do reference on an as-needed basis. **If it can be demonstrated that improvements are needed to the FDA's adverse events reporting system, the proponents of this bill should be looking for ways to better educate prescribers on how to correctly complete and file adverse event forms.**

Moving forward with this legislation now is premature. It is important to note that the FDA is still working on finalizing multiple guidances on these issues and, to our knowledge, have yet to even receive even one application for approval of a Biosimilar. We see no reason for Pennsylvania to move ahead without the benefit of this guidance from the scientists and experts at the FDA. There is no risk in waiting, but great risk in passing a law that sets up a Pennsylvania-specific system that runs counter to federal guidance.

Other states have shared our concerns. Though this legislation was introduced in multiple states in 2013, only one state – North Dakota – passed legislation similar to SB 405/HB 746. The others significantly amended it by removing the physician notification provision or added sunset language that effectively made the issue moot. **Notably, Florida adopted it without physician notification provisions with the support of both BIO and PhRMA**. The legislation was also vetoed in California. In addition, no state has passed a law that included insulin.

Thank you for your attention to our concerns. Please do not hesitate to reach out to us for more information or to discuss further.

Enclosure

Cc: Senate Appropriations Committee
Senate Republican Leadership
Senate Democratic Leadership

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