October 2, 2014

The Honorable Mike Turzai
Pennsylvania House of Representatives, Majority Leader
110 Main Capitol Building
PO Box 202028
Harrisburg, PA 17120-2028

**Re: NCPA OPPOSES S.B. 405 AS UNNECESSARY AND COSTLY**

Dear Leader Turzai:

On behalf of the National Community Pharmacists Association (NCPA) I write to express strong opposition for S.B. 405 in its current form. If enacted, S.B. 405 would place unreasonable and unnecessary requirements on pharmacies for the interchange of interchangeable biological products (biosimilars), while increasing overall costs to the healthcare system and decreasing access to care. The proposed legislation will severely limit access to more affordable medications, vastly increase overall healthcare costs to Pennsylvania businesses and citizens, add cumbersome reporting requirements on healthcare providers and add unneeded regulation over a proven medication delivery process. NCPA's concerns are shared by many stakeholders and the United States Food and Drug Administration (FDA).

According to section 351(i)(3) of the Public Health Service (PHS) Act, interchangeable products may be substituted for the reference product without the intervention of the prescribing healthcare provider. Pennsylvania should trust the FDA's knowledge and its 15 plus years of experience comparing biologics and determining interchangeability. When a biosimilar is approved by the FDA as being interchangeable to its reference product, all should be confident that the FDA made this decision after thorough consideration. Therefore, NCPA believes that if the FDA allows interchangeability between products, pharmacists should be able to automatically substitute a biosimilar.

The proposed legislation undermines a process that has historically proven to save the healthcare industry significant money. From 1999-2010, reports show generic substitution saved the U.S. health care system more than $1 trillion[1] and, according to the Congressional Budget Office, generic drugs save consumers an estimated $8 to $10 billion a year at retail pharmacies[2]. FDA has extensive experience with reviewing safe and affordable medication alternatives and is developing even more extensive standards for biosimilars. Enacting legislation such as S.B.405 simply undermines an agency and industry that is charged with protecting public health and has done so successfully for many years.

The FDA itself has also expressed concerns about the effects of state biosimilar substitution legislation on access to lower-cost treatments. FDA has also stated the state biosimilar legislation is premature and publically stated that "Efforts to undermine trust in these products [interchangeable biological products] are worrisome and represent a disservice to patients who could benefit from these lower cost treatments. It is important for everyone to approach these issues with an understanding of both FDA's expertise in this area and what the 2010 law requires for approval of biosimilar and interchangeable products." [3]

[1] Savings: An Economic Analysis of Generic Drug Usage in the U.S. (September 2011); GPhA, Savings Achieved through the Use of Generic Pharmaceuticals, 2000-2009 (July 2010); GPhA, Economic Analysis: Generic Pharmaceuticals 1999-2008-$734 Billion in Health Care Savings (May 2009). GPhA 2011
[2] "Generic Drugs: Questions and Answers." FDA.gov. Page last updated August 24, 2011. Accessed June 27, 2012.
[3] FDA spokeswoman Lisa Kubaska, 2013 in response to state biosimilar legislation


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When reviewing S.B. 405 it is clear that it does little more than allow pharmaceutical manufacturers to drive patients to higher cost products while decreasing the ability to interchange extensively reviewed and approved interchangeable cost saving versions of those products, and therefore NCPA respectfully requests your opposition of S.B. 405.

Please feel free to contact me at matt.diloreto@ncpanet.org or 703-600-1223 should you have any questions.

Sincerely,

Matthew J. DiLoreto
Senior Director, State Government Affairs

CC: Honorable members of the Pennsylvania House of Representatives
Krystjan Callahan, Chief of Staff, Leader Mike Turzai
Karen Coates, Director of Legislative Affairs, Leader Mike Turzai
Whitney Krosse, Executive Director, House Health Committee
Abdoul Barry, Executive Director, House Health Committee