AMCP Academy of Managed Care Pharmacy®

April 27, 2016

The Honorable Lamar Alexander (R-TN)
*Chairman*
Senate Committee on Health, Education, Labor and Pensions
428 Dirksen Office Building
Washington, DC 20510

The Honorable Patty Murray (D-WA)
*Ranking Member*
Senate Committee on Health, Education, Labor and Pensions
428 Dirksen Office Building
Washington, DC 20510

***Re: S. 2700 - FDA and NIH Workforce Authorities Modernization Act***

Dear Chairman Alexander, Ranking Member Murray, and Members of the Senate HELP Committee:

The Academy of Managed Care Pharmacy (AMCP) is writing to express our concerns with Section 11 of S. 2700, the "FDA and NIH Workforce Authorities Modernization Act," which was considered by the Senate Health, Education, Labor and Pensions Committee and placed on the Senate calendar on April 18th. This section of the bill states that "provisions of the Federal Food, Drug, and Cosmetic Act that refer to an official compendium as defined under section 201(j) of such Act shall not apply to a biological product subject to regulation under this section."

AMCP is a national professional association of pharmacists and other health care practitioners who serve society by the application of sound medication management principles and strategies to improve health care for all. The Academy's nearly 8,000 members develop and provide a diversified range of clinical, educational, and business management services and strategies on behalf of the more than 200 million Americans covered by a managed care pharmacy benefit.

AMCP believes this provision would remove the current long-standing requirements in law for all biologics, including biosimilars, to meet public, transparent quality standards. This not only raises public health safety concerns, but has the potential to impede implementation of the biosimilars pathway, which AMCP views as critical to increasing consumer access to lifesaving treatments. Rather than enhancing innovation, this provision could limit competition and hinder the development of critical new biosimilars.

The United States Pharmacopeia's public health safety standards have served as recognized benchmarks for quality for over 100 years and are used by drug and biologics manufacturers to avoid the time and expense of developing individual measures. Such standards promote competition among multiple manufacturers by eliminating the need for follow-on manufacturers to invest in creating new standards.

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AMCP is concerned that this provision would also eliminate the critical role of current public health safety standards and have unknown, potentially negative consequences to patients and consumers. AMCP respectfully requests that this provision be removed from the legislation and that a process be initiated for a full and transparent review of the concerns of all stakeholders on this provision's potential effects on patient safety and access to treatments.

Thank you for your consideration of our views. AMCP appreciates your commitment to public health and the well-being of patients and looks forward to a continued dialogue on this critical issue. If you have any questions, please contact me at (703) 683-8416 or scantrell@amcp.org.

Sincerely,

Susan A. Cantrell, RPh, CAE
Chief Executive Officer

cc:
The Honorable Richard Burr (R-NC)
The Honorable Michael B. Enzi (R-WY)
The Honorable Johnny Isakson (R-GA)
The Honorable Rand Paul (R-KY)
The Honorable Susan Collins (R-ME)
The Honorable Lisa Murkowski, (R-AK)
The Honorable Mark Kirk (R-IL)
The Honorable Tim Scott (R-SC)
The Honorable Orin Hatch (R-UT)
The Honorable Pat Roberts (R-KS)
The Honorable Bill Cassidy, M.D. (R-LA)
The Honorable Barbara Mikulski (D-MD)
The Honorable Robert P. Casey (D-PA)
The Honorable Al Franken (D-MN)
The Honorable Michael Bennet (D-CO)
The Honorable Sheldon Whitehouse (D-RI)
The Honorable Tammy Baldwin (D-WI)
The Honorable Chris Murphy (D-CT)
The Honorable Elizabeth Warren (D-MA)
The Honorable Bernard Sanders (I-VT)