



National Health Council

1730 M Street NW, Suite 500, Washington, DC 20036-4561 ■ 202-785-3910 ■ www.nationalhealthcouncil.org ■ info@nhcouncil.org

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June 23, 2009

The Honorable Edward M. Kennedy
Chairman, Committee on Health,
Education, Labor and Pensions
317 Russell Senate Building
Washington, DC 20510

The Honorable Michael B. Enzi
Ranking Member, Committee on Health,
Education, Labor and Pensions
379A Russell Senate Building
Washington, DC 20510

Dear Chairman Kennedy and Ranking Member Enzi:

On behalf of the more than 133 million Americans living with chronic diseases and disabilities and their family caregivers, the National Health Council¹ (NHC) takes this opportunity to thank you for your commitment to improving health care in this country. Members of the NHC are ready to work with you to seize this opportunity to create a pathway for the approval of biosimilars that meets the needs of people with chronic conditions.

The core membership of the National Health Council is made up of 50 patient advocacy groups. The patients these organizations serve are dependent on modern drug therapies to battle the harmful effects of their conditions. A number of patient groups represented in the NHC's membership are focused on diseases that rely on biologic drugs currently on the market as a predominant method of treatment (e.g. multiple sclerosis, arthritis, psoriasis). Other member organizations are focused on conditions that currently have no treatment, and biologic drugs are thought to be the best hope for a cure (e.g. ALS, lupus). Accordingly, we remain attentive to matters of improved access to existing drug therapies, but also remain concerned about unintended consequences of legislation that could delay the advancement of new treatments. We thank the Committee for its efforts to balance those two interests.

Nationwide focus groups of people with chronic diseases and their family caregivers have clearly articulated their support for government-initiated incentives to develop new and better treatments. This research has led us to strongly support exclusivity periods for biologics that drive innovation in basic and clinical sciences to create new treatments, especially for conditions with limited or non-existent treatments.

In order to achieve this objective for people with chronic conditions, our extensive work with NHC member organizations on this topic has led to the consensus-driven conclusion that a minimum of ten years of data exclusivity must be offered along with one additional year of data exclusivity for new indications that offer significant clinical benefit (as determined by the FDA)². Further, there should be an additional two years of data exclusivity to encourage the development of treatments for autoimmune or neurological disorders with limited or non-existent treatments and other disorders with limited or non-existent treatments, as determined by the FDA, including but not limited to rare disorders, or pediatric disorders. To facilitate the advancement of biologic therapies, there should also be an additional two years of exclusivity for new methods of administering biologics, including use with devices or diagnostic tests that offer significant clinical benefit by providing more reliable assessments and/or predictions of patient outcomes or improving patient compliance as determined by the FDA.

¹ The National Health Council is made up of 115 member organizations from across the health care community which together represents approximately 133 million Americans. The National Health Council is the only organization of its kind that brings together all segments of the health care community to provide a united voice for people with chronic diseases and disabilities. Together, we work to bring about a health care system that puts patients first.

² The ten years of data exclusivity includes eight years of exclusivity during which no follow-on product may be applied for and two years of data exclusivity where a follow-on product may be applied for with reference to the innovator's data, but not approved.



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Again, we appreciate the bipartisan efforts to design biosimiliars legislation that carefully balances access to health care while fostering innovation. We are anxious to work with you and your colleagues to formulate this legislation and bring the voice of patients to this debate. Please do not hesitate to contact Kevin Cain, our Assistant Vice President for Government Affairs and Programs, if you or your staff would like to discuss these issues in greater detail. You may also reach me on my direct, private line at 202-973-0546 or via e-mail at mweinberg@nhcouncil.org.

Sincerely,

A handwritten signature in blue ink that reads "Myrl Weinberg". The signature is written in a cursive style.

Myrl Weinberg, CAE
President