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June 8, 2009

Committee on Health, Education, Labor and Pensions
428 Dirksen Senate Office Building
Washington, DC 20510-6200

Dear Senators:

On behalf of Americans living with chronic diseases and disabilities, 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 groups which together represent approximately 133 million Americans afflicted with chronic diseases, each of whom is dependent on modern drug therapies to battle the harmful effects of their conditions. A number of patient groups represented in 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), while other 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.

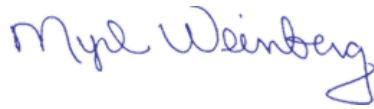
Our own nationwide focus groups of people with chronic diseases and their family caregivers clearly demonstrate their support for government initiated incentives to develop new and better treatments. This research has led us to strongly support additional exclusivity periods for modifications to biologics or new methods of administering such treatments, including use with devices or diagnostic tests that offer significant clinical benefit by providing more reliable assessments and/or predictions of patient outcomes and/or improving patient compliance.

To that end, we are concerned about proposed changes to S. 1695 intended to protect against "evergreening" that would preclude new exclusivity periods for products that differ significantly from the original reference product. As you know, many in the health care community believe that improvements that produce significant clinical advancement should be rewarded with additional exclusivity periods. From the patient perspective, it makes no difference what company manufactures a product that results in a new indication, improved compliance and adherence, or improved efficacy. Instead, our sole concern is that better treatments be advanced. The proposed legislative language, as currently drafted, would discourage innovator companies from engaging in novel research that could lead to breakthrough treatments. Typically innovator companies are most equipped to immediately engage in such research. Thus, precluding exclusivity periods for innovator companies will likely delay the development of potential life-changing or even life-saving new drug therapies. Accordingly, we believe that additional data exclusivity periods for improved biologics should apply to all manufacturers.

¹ The National Health Council is made up of 115 member organizations from across the health care community which together represent 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.

Again, we appreciate the bipartisan efforts to design biosimilars legislation that carefully balances access to healthcare 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 with a large, stylized "M" and "W".

Myrl Weinberg, CAE
President