National Health Council

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January 10, 2010

PDUFA Reauthorization
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

On behalf of the member organizations of the National Health Council (NHC), I would again like to thank you for the opportunity to comment on the proposed enhancements to the Prescription Drug User Fee Act (PDUFA).

The NHC is the only organization of its kind that brings together all segments of the health care community to provide a united voice for the more than 133 million people with chronic diseases and disabilities and their family caregivers. Made up of more than 100 national health-related organizations and businesses, its core membership includes approximately 50 of the nation's leading patient advocacy groups, which control its governance. Other members include professional societies and membership associations, nonprofit organizations with an interest in health, and major pharmaceutical, medical device, biotechnology, and insurance companies.

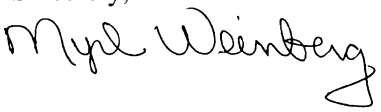
The NHC commends the FDA on its thorough consideration of the needs of the patient community as well as all of the other stakeholders that have been participating in the monthly stakeholder meetings. Your responsiveness to the stakeholders' concerns and effort to incorporate our respective requests into the agenda of the meetings has been exemplary.

As you know, the NHC has requested greater clarity on three of your proposed enhancements. We look forward to hearing more about how a patient-focused drug development program would seek and incorporate patient input into the development process, particularly in the context of benefit-risk evaluations (proposal #3). We also welcome the opportunity to learn more about what guidance on biomarker usage in clinical trials might look like (proposal #12). Finally, we look forward to discussing regulatory policies related to rare diseases and how these policies might be expanded to other conditions which lack adequate treatments (proposal #13).

We are delighted to know that you intend to share the FDA's views on these three topics in further detail during your January 11 meeting. We look forward to participating in a robust dialogue in which we can discuss ways to ensure that these three issues are incorporated into the PDUFA reauthorization in a way that best serves people living with chronic diseases and disabilities.

If you have any questions, please do not hesitate to contact Eric Gascho, our Associate Director of Government Affairs. He is reachable by e-mail at egascho@nhcouncil.org or by phone at 202-973-0545.

Sincerely,



Myrl Weinberg, CAE
President