



National Health Council

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Patient Requests Included in PDUFA Proposed Agreement

Washington, DC (September 1, 2011) – The National Health Council (NHC) has learned that three proposals it put forth on behalf of the patient advocacy community have been included in the proposed agreement for the reauthorization of the Prescription Drug User Fee Act (PDUFA).

The agreement was published today by the Food and Drug Administration (FDA), and NHC President Myrl Weinberg issued the following statement:

This agreement demonstrates that the FDA and the pharmaceutical industry listened to patients, understood our concerns, and developed an agreement that will greatly help in the creation of new treatments and cures that provide hope for the millions of Americans with chronic diseases and disabilities.

The National Health Council applauds the FDA for agreeing to include in its recommendations three proposals championed by patients: the development of an objective, qualitative benefit-risk framework that includes robust patient input; the advancement of new therapies through the expanded use of biomarkers and patient-reported outcomes in clinical trials; and the creation of regulatory policy, procedures, and guidance to encourage the development of treatments for rare diseases.

All three of these components are necessary for advancing access to desperately needed treatments and cures. To exclude any one of these elements would be to offer a reauthorization package that would not meet the needs of patients – particularly those with few or no treatment options.

We now call on Congress to adopt the agreement as presented by the FDA in order to create a 21st Century regulatory process for 21st Century discoveries.

After a public comment period, it is expected the agreement will be submitted to Congress by January 2012.

Related Links:

- PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2013 through 2017: <http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM270412.pdf>
- NHC congressional testimony, comment letters, and statements on PDUFA: <http://www.nationalhealthcouncil.org/pages/page-content.php?pageid=80>

About the National Health Council – www.nationalhealthcouncil.org

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.

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