

Patient Organization Urges Senate to Advance the Development of Modern Medicines & Pass User Fee Legislation

Washington, DC (April 25, 2012) -- The National Health Council (NHC) today urged the Senate Committee on Health, Education, Labor, and Pensions (HELP) to approve legislation covering four Food and Drug Administration (FDA) user fee programs and for the full Senate to pass the user agreements.

The HELP Committee is scheduled this morning to consider a bill that incorporates the following agreements worked out by the FDA and industry representatives: reauthorization of the Prescription Drug User Fee Act (PDUFA), reauthorization of the Medical Device User Fee Act (MDUFA), and the establishment of generic drug and biosimilar user fee programs.

NHC President Myrl Weinberg urged the Senators to act quickly on the legislation, which includes elements proposed by the patient advocacy community.

“These agreements demonstrate that the FDA and industry listened to patients, understood our concerns, and developed agreements 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,” Weinberg said.

“Under the PDUFA and MDUFA agreements, the FDA would develop an objective, qualitative benefit-risk framework that includes robust patient input. In addition, the PDUFA agreement would help advance new therapies through the expanded use of biomarkers and patient-reported outcomes in clinical trials, and it would create 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.

“The National Health Council calls on Congress to reauthorize the user fee agreements as quickly as possible in order to create a 21st Century regulatory process for 21st Century discoveries.”

Related Links:

NHC congressional testimony, comment letters, and statements on PDUFA:
<http://www.nationalhealthcouncil.org/pages/page-content.php?pageid=80>

About the National Health Council:

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. For more information about the NHC, visit www.nationalhealthcouncil.org.

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