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FOR IMMEDIATE RELEASE

National Health Council Urges Swift Passage of FDA User Fee Reauthorization

Washington, DC, March 22, 2017 - NHC Chief Executive Officer Marc Boutin urged swift passage of legislation to reauthorize the Food and Drug Administration (FDA) user fee programs:

"The current FDA user fee agreements were the culmination of months of negotiation between the FDA and the medical product industry, with significant input from the patient advocacy community. By listening to patients, the current agreements will benefit people with chronic diseases and disabilities by focusing the life sciences sector on the outcomes that matter most to patients.

"Above all, we are pleased to see that the Prescription Drug User Fee Act (PDUFA) calls for FDA to develop guidance for patient engagement in drug development, which will build on the Patient-Focused Drug Development Program to make patient input an integral part of drug development and regulation. Other provisions included in the agreement, such as increased emphasis on biomarkers and surrogate endpoints, advancing development of drugs for rare diseases, streamlining combination product reviews, studying the feasibility of incorporating real-world evidence (RWE) provided from clinical settings, and improving FDA hiring and retention practices, will lead to a more efficient FDA that is better equipped to review 21st Century treatments in a timely fashion. Similarly, the Medical Device User Fee Act (MDUFA) includes transformative provisions related to patient engagement and RWE.

"The National Health Council calls on Congress to reauthorize the user fees as currently negotiated to ensure patients are placed at the center of our life sciences ecosystem. Patients are waiting."

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