



NATIONAL HEALTH COUNCIL

NEWS

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Statement by NHC President Myrl Weinberg on modifications to FDA 'Revitalization Act'

WASHINGTON, April 18 — Following is a statement by National Health Council (NHC) President Myrl Weinberg regarding markup of S. 1082, the "Food and Drug Administration (FDA) Revitalization Act" by the Senate Committee on Health, Education, Labor and Pensions (HELP):

"The National Health Council appreciates efforts to craft a bill that recognizes the needs of patients. We look forward to working with members of congress to ensure access to safe and effective medications."

"A balance between access and safety has been achieved in this legislation. People living with chronic diseases and disabilities are well served by an enhanced post-market surveillance system that gleans drug safety data from federal and private health databases. It provides a more accurate picture about drug usage in patient populations, who often suffer from co-morbidities, and allows the FDA to respond in a timelier manner."

"The Council also applauds changes made to the risk-evaluation and mitigation strategies (REMS) to ensure that they only will be imposed when serious risks have been identified and assessed prior to approval — as opposed to requiring REMS for all drugs and biologics. We are pleased that the bill clarifies the specific FDA authorities to apply these tools if and when new information about serious risks arise after approval."

"The Council thanks Senator Edward Kennedy, chairman of the Senate HELP Committee, and his staff, for being responsive to the needs of people with chronic conditions."

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The National Health Council is a private, nonprofit organization of 115 national health-related organizations working to bring quality health care to all people. Its core membership includes more than 50 of the nation's leading voluntary health agencies representing approximately 100 million people with chronic diseases and/or disabilities. Other Council members include professional and membership associations, nonprofit organizations with an interest in health, and major pharmaceutical and biotechnology companies. The Council serves as a place for diverse health-related groups to build

consensus with a focus on patients and their needs.

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