National Health Council
1730 M Street NW, Suite 500, Washington, DC 20036-4561 ■ 202-785-3910 ■ www.nationalhealthcouncil.org ■ info@nhcouncil.org

August 31, 2010

Margaret Hamburg, M.D.
Commissioner
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2010-N-0284, "Risk Evaluation and Mitigation Strategies: Public Meeting"

Dear Dr. Hamburg:

The National Health Council (NHC) takes this opportunity to submit comments to the Food and Drug Administration (FDA) on the development and implementation of risk evaluation and mitigation strategies (REMS) for drugs. We appreciate the FDA's efforts to address drug safety issues related to patient monitoring, medication dispensing, and settings of use through the implementation of REMS. As the FDA continues to refine its REMS initiative, the NHC urges the FDA to consider the impact of REMS on access to treatments for those living with chronic diseases and who may have few or no treatment alternatives. Also, in addition to evaluating the effectiveness of REMS, we encourage the FDA to establish mechanisms to evaluate the impact of REMS on patient care.

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.

People with chronic diseases depend on modern drug therapies to treat their conditions. Many patients rely on medications that have REMS programs in place or could be subject to a REMS requirement in the future. As the FDA further refines the REMS program, we believe an essential consideration should be the impact of REMS on patient access to medications. The NHC is concerned that the implementation of REMS thus far has inadequately balanced the risks of medications relative to their benefits.

Consider Benefit-Risk Balance from the Perspective of Patients

When evaluating the risk of drugs and deciding whether to implement REMS, we urge the FDA to not only take into consideration the size of the population affected, but also the range of existing treatment alternatives available to those patients. The NHC believes it is

important to recognize the varying perceptions of risk among patients and consumers and to consider that the acceptability of risk for a patient living with a serious chronic condition may be higher than that of a more healthy person. To ensure this perspective is incorporated in decision making, the NHC believes it is imperative that patients are consulted before developing a REMS. For patients with a rare or incurable condition and for whom treatment options are nil or few, a REMS requirement could have a devastating impact on access. For example, patients with systemic lupus erythematosus (SLE) rely on corticosteroids to alleviate flares. Despite significant side effects, such as osteoporosis, hepatoxicity, glaucoma, artery damage, weight gain, and serious skin irritation, corticosteroids remain an essential component of the treatment regimen for a patient with lupus because their use can substantially reduce the symptoms associated with inflammation.

Minimize Burden on Providers

In addition, we urge the FDA to consider ways to reduce the administrative burden of meeting REMS requirements on physicians and pharmacists. For example, certain drugs with REMS programs in place require physicians to enroll in additional training or receive special certification from manufacturers. Such requirements place demands on already-constrained time and resources, and the NHC is concerned that this may ultimately lead clinicians to avoid prescribing particular drugs. Retail pharmacists, too, may bear burdensome documentation requirements, which may slow or impede patient access to needed medications. Further, we are concerned that complex REMS requirements will add to the cost of certain therapeutics and may cause formulary decision makers to avoid these drugs.

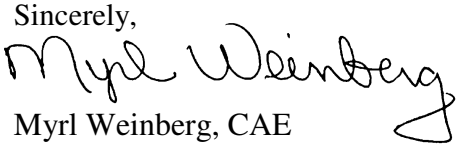
Implement Mechanisms to Evaluate Impact of REMS on Patient Care

As stated above, the NHC agrees that REMS should be monitored and assessed to determine the program's effectiveness. However, we believe it is also important to monitor and assess REMS in relation to its impact on patient care. For example, the drug Letairis, used to treat pulmonary arterial hypertension, includes elements to assure safe use and an implementation system. It can take a patient ***eight*** weeks to receive the medication from the date of prescription because of the lengthy process to obtain and approve the use of the drug under REMS requirements. As the FDA considers the metrics that should be used to determine the effectiveness of REMS, we urge the FDA to also establish criteria and metrics that would allow for an evaluation of the impact of REMS programs on patient care. In addition, we believe the reauthorization of PDUFA V could be an appropriate vehicle for commissioning the U.S. General Accountability Office to conduct a study of the impact of REMS on patient care.

The NHC appreciates the opportunity to provide our comments and to share the perspective of the patient community as the FDA continues to refine REMS. The NHC recognizes the tension the FDA faces in balancing its mission to protect the nation's health with the need to provide access to new, life-saving drugs to people with chronic conditions. We encourage the FDA to maintain a transparent and collaborative process in its refinement of this initiative.

Please do not hesitate to contact Kevin Cain, our Assistant Vice President of Government Affairs, if you or your staff would like to discuss these issues in greater detail. He is reachable by phone at 202-973-0542 or by e-mail at kcain@nhcouncil.org. You may also reach me on my direct, private line at 202-973-0546 or via e-mail at mweinberg@nhcouncil.org.

Sincerely,



Myrl Weinberg, CAE
President