National Health Council
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July 20, 2010

Joshua Sharfstein, M.D.
Principal Deputy Commissioner
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Re: Phase II FDA Transparency Report

Dear Dr. Sharfstein,

The National Health Council (NHC) appreciates the opportunity to submit comments to the Food and Drug Administration (FDA) on the Phase II Transparency Report released on May 19, 2010 by the FDA Transparency Task Force. The NHC commends the FDA for launching this important initiative to promote transparency throughout the FDA process. We are eager to work with the Agency to ensure that increased transparency promotes the development of new treatments for people living with chronic diseases and disabilities. With this in mind, we urge the Task Force to prioritize Proposal 12 of its Transparency Report.

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 living with chronic conditions have benefited from numerous medical advances over the last 20 years. Many diseases that were once fatal diagnoses are now managed by patients and their caregivers over a lifetime. Today, advances in science continue to hold promise for the development of new treatment strategies for many other conditions in the future. However, while billions of dollars are spent on research and development to develop new products, many patients with chronic disease still lack effective, disease-modifying, or life-saving treatments.

To ensure that advances in science translate into new treatments for patients, we urge the Task Force to prioritize the implementation of Proposal 12 (as transcribed below) regarding withdrawn or abandoned marketing applications. In implementing Proposal 12 and considering the data elements for disclosure, we encourage the FDA to weigh whether the disclosure of such information could inadvertently jeopardize investments in research and development.

Proposal 12: *When an application for a designated orphan drug or a designated minor use/minor species animal drug has been withdrawn, terminated, or abandoned, FDA should disclose, if it determines, based on its review, that the application was not withdrawn, terminated, or abandoned for safety reasons and the product, if approved, could represent a significant therapeutic advance for a rare disease or for a minor animal species. A disclaimer that provides that FDA's expressed views about the product do not reflect whether a subsequent application involving the product will be accepted for filing or will be approved by FDA should accompany the disclosure of this information.*

It is an unfortunate reality that many promising drugs in clinical development or undergoing the approval process are abandoned — not for safety and efficacy reasons, but for business decisions based on assessments of commercial viability or lack of sufficient resources to support a drug through the approval and post-marketing process. The patient community is acutely aware of and uniquely affected by this reality. The NHC has sought to shed light on this issue, particularly in relation to the impact that weak patent protections can have on a decision to pursue or continue development of a drug. Specifically, compounds in development for which patents are deemed to be too weak to generate a sufficient return on investments in clinical trials are often abandoned by their manufacturers. Once abandoned, these compounds may never again be pursued. This is especially problematic for drugs that may treat complex neurological and autoimmune conditions for which the development and approval process may exceed the patent life.

Far too often, potential treatments with tremendous value to patients and to society are never developed or are abandoned during the development and approval process. The NHC believes the lack of transparency on when and why a drug application is abandoned or withdrawn is a disservice to patients who are anxiously tracking progress on new therapeutics to treat their conditions. We believe disclosing information on withdrawn or abandoned applications would allow others to pursue the development of promising drugs, particularly of those that FDA believes could be a major therapeutic advance, or glean learnings that could inform and speed the development of other drugs. In addition, it would allow the patient community to take action in potentially engaging other potential funders to continue the development of a promising product.

As the Transparency Task Force notes in its draft report, patients and their caregivers often anxiously await the approval of new therapeutics. We believe the disclosure of information on when an application has been withdrawn or abandoned is an important step toward fostering innovation. At the same time, the patient community is sensitive to the potential consequences of disclosing nonpublic information. We recognize that disclosure of information that is deemed to be of competitive value by a manufacturer could undermine efforts to promote research and development. We rely on the FDA to strike the right balance between the need to protect proprietary information and the need for information to be shared in an effort to motivate the development of new treatments.

The NHC appreciates the opportunity to share our comments. 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 via 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

Myrl Weinberg, CAE
President