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May 3, 2012

Dr. Margaret Hamburg
U.S. Food and Drug Administration Commissioner
10903 New Hampshire Avenue
Silver Spring, MC 20993

Dear Dr. Hamburg,

Approximately 1 million American myalgic encephalomyelitis / chronic fatigue syndrome (ME/CFS) patients endure decades of suffering due to medical ignorance, scant research funding and public bias. Additionally, no pharmacological treatment has been approved for this disease, leading to one of the largest unmet health needs of our time. Instead, clinicians can only offer palliative care. Many obstacles form barriers that stand in the way of relief coming to these patients.

In October 2011, you outlined a blueprint for "Driving Biomedical Innovation." According to the FDA website fact sheet of your blueprint: "The agency remains committed to continuing our dialogue with companies, innovators, and other stakeholders to identify barriers to progress and better define what steps need to be taken to overcome any obstacles to innovation."

We are asking that FDA meet with the stakeholders, including ME/CFS experts, clinicians, researchers, advocacy groups, patients and drug sponsors, to meet your goal to "bring effective treatments to American families" impacted by this debilitating disease draining $21 billion from the economy annually.

One proposed treatment has been in the FDA pipeline for over two decades. We hope FDA Center for Drug Evaluation and Research Director Janet Woodcock is aware of two recently published peer-review studies increasing the data on this drug. It is now in its fifth review division of the FDA (with four pivotal trials and a treatment protocol in place for 14 years).

In July 2011, Dr. Woodcock told the House Committee on Energy and Commerce Subcommittee on Health: “It should be noted that FDA assesses the benefit-risk of new drugs on a case-by-case basis, considering the degree of unmet medical need and the severity and morbidity of the condition the drug is intended to treat. This approach has been critical to increasing patient access to new drugs for cancer and rare and other serious diseases, where existing therapies have been few and limited in their effectiveness.”

We ask the same approach be taken on proposed ME/CFS treatments and a review be made on how to expedite the process to meet the large unmet health needs of these patients as they too lack existing therapies that are effective against their disease.

Sincerely,

Marly C. Silverman

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CC: Dr. Kathleen Sebelius, Secretary of Health and Human Services
Dr. Howard K. Koh, Assistant Secretary of Health and Human Services
Dr. Nancy C. Lee, Deputy Assistant Secretary for Health- Women’s Health, CFSAC Designated Federal Officer
Dr. Janet Woodcock, Director of FDA Center for Drug Evaluation and Research