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May 7, 2012

Representative Fred Upton
Chairman
House Energy & Commerce Committee

Representative Henry Waxman
Ranking Member
House Energy & Commerce Committee

Dear Chairman Upton and Representative Waxman:

On behalf of the members of the Personalized Medicine Coalition (PMC), I am writing to urge passage of legislation to reauthorize FDA's authority to collect user fees that will help the Food and Drug Administration (FDA) meet specified performance goals.

This legislation, and the related performance goals for FDA, will benefit patients by providing the agency with tools and resources necessary to make new personalized medicines and diagnostic tests available to patients in a timely manner. With the current authorities expiring on September 30, 2012, it is imperative that the bill pass quickly so that FDA can continue to implement its mission without an interruption to its funding.

PMC is an educational and advocacy organization with more than 200 member institutions from across the health care spectrum dedicated to advancing the understanding and adoption of personalized medicine concepts, services and products to benefit patients and the health system.

"Personalized Medicine" refers to the tailoring of medical treatment to the individual characteristics of each patient and to the classification of individuals into subpopulations that differ in their susceptibility to a particular disease or their response to a specific treatment. Preventative or therapeutic interventions can then be concentrated on those who will benefit, sparing expense and side effects for those who will not.

In addition to supporting the legislation, we applaud the language contained in the “Drug Approval and Patient Access” section of the bill. We believe it will improve the regulatory process for personalized medicines and ultimately benefit patients.

The section creates an expedited approval process for drugs developed using biomarkers that will be used to treat serious or life-threatening ailments. It will also allow FDA to designate a drug as a “breakthrough therapy” when a sponsor has preliminary clinical evidence to indicate that it may demonstrate substantial improvement over existing therapies and outlines how the agency can expedite review. Also, it outlines a process for FDA to consult with external experts on the genetic targeting of treatments and innovative trial designs, among other topics that would enhance FDA’s ability to evaluate the safety and effectiveness of personalized medicine products.

We appreciate the bipartisan effort that has produced this bill and urge you to work with your colleagues in the Senate to pass the legislation as quickly as possible.

Sincerely,

A handwritten signature in cursive script that reads "Amy M. Miller". The signature is written in black ink and is positioned below the word "Sincerely,".

Amy M. Miller, Ph.D.
Vice President, Public Policy
Personalized Medicine Coalition