

May 9, 2012

The Honorable Fred Upton, Chairman
The Honorable Henry Waxman, Ranking Member
The Honorable Joseph Pitts, Chairman, Subcommittee on Health
The Honorable Frank Pallone, Ranking Member Subcommittee on Health
United States House of Representatives
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Upton, Chairman Pitts, Ranking Member Waxman and Ranking Member Pallone,

On behalf of the Michigan Biosciences Industry Association (“MichBio”), we would like to offer our support for the reauthorization of the FDA user-fee programs. MichBio represents approximately 240 companies, the overwhelming majority of which are small businesses, dedicated to developing technologies that improve the quality of life for patients worldwide. We believe that both the user-fee proposals, especially the reauthorization of PDUFA and MDUFA, and the accompanying legislative reforms are steps in the right direction to ensure that patients are provided timely access to safe and effective products.

The user fee proposal represents the collective efforts of FDA, industry, patients, physicians and other stakeholders who all worked diligently over the past 18 months to craft a balanced approach which seeks to improve transparency and predictability of the review process. Patient access is enhanced when innovators develop new technologies under the assurance of a fair, predictable and transparent FDA. Our members also recognize that the success of this program will ultimately depend on the whether the goals outlined in the Commitment Letter will be realized in the coming years.

Finally, MichBio would like to thank the Committee for having an open and transparent process to comment on proposals and provide feedback throughout this process. We applaud the Committee for its efforts to advance the interests of patients and innovators. We encourage you and the Committee to support this bipartisan bill, and urge you to reject proposals that would upset its carefully negotiated balance. Additionally, we urge swift passage of the package, as it is essential that the process advances quickly, and we are committed to working with you to that end.

Sincerely,



Stephen T Rapundalo, PhD
President and CEO