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Secretary Kathleen Sebelius  
The U.S. Department of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

RE: Petition to use authority under Bayh-Dole Act to end rationing of Fabrazyme®, an invention supported by and licensed by the National Institutes of Health under grant no. DK-34045

Dear Secretary Sebelius:

Enclosed is a petition for Bayh-Dole march-in rights under 35 U.S.C. § 203 for an open license to the patents covering Fabrazyme® (agalsidase beta), which was developed under NIH grant no. DK-34045 and exclusively licensed to Genzyme, Inc. for the treatment of Fabry disease. Fabrazyme® is currently the only effective treatment for Fabry disease approved by the FDA and is currently being rationed by Genzyme. The rationing has led to a public health crisis for all Fabry victims.

The petitioners, Mr. Joseph M. Carik (resident of Nevada), Ms. Anita Hochendoner (resident of Pennsylvania), and Ms. Anita Bova (resident of Pennsylvania) are U.S. citizens with Fabry disease and receive Fabrazyme® treatment. However, they and all other Fabry patients on treatment have had their drug dose cut to only 30% of the recommended dose in accordance with Genzyme's rationing plan which is a direct result of its inability to manufacture sufficient drug to meet the needs of the Fabry disease community. Genzyme is currently under an FDA consent decree for violations in manufacturing Fabrazyme®.

The petitioners are representative of the entire class of Fabry disease victims and upon rationing have suffered a return of symptoms including neuropathy, proteinuria, digestive disorders, heart disease, renal disease, morbidity, and increased risk of premature death. Moreover, no newly diagnosed Fabry patients are eligible to receive therapy until the supply of drug is restored. Consequently, the petitioners respectfully request that an open license be granted to restore the supply of Fabrazyme® so that Fabry patients can again receive their recommended dosage and new patients can be treated. Petitioners further request that this petition be expedited so that treatment can be restored as quickly as possible.

Sincerely,

**Law Office of C. Allen Black, Jr., Ph.D.**

August 2, 2010

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