



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health

Office of Technology Transfer
National Institutes of Health
6011 Executive Boulevard
Rockville, MD 20852

December 3, 2010

C. Allen Black, Jr., Ph.D.
1579 Montgomery Road
Allison Park, Pennsylvania 15101

Subject: Request to HHS to Exercise its Bayh-Dole March-In Authority

Dear Dr. Black:

I have attached NIH's determination of your request for HHS to exercise its Bayh-Dole march-in authority.

While NIH determined at this time not to exercise its march-in authority because any licensing plan that might result from such a proceeding would not, in our judgment, remedy the current problems associated with access to Fabrazyme®, NIH has not closed this request and will continue to monitor the shortage of Fabrazyme®.

We remain very concerned about the health of Fabry patients and their access to Fabrazyme. If at any time new information relevant to a march-in decision becomes available, we will evaluate it as quickly as possible to determine whether further action is warranted.

Sincerely,

A handwritten signature in black ink, appearing to read "Mark L. Rohrbaugh", with a large, stylized flourish at the end.

Mark L. Rohrbaugh, Ph.D., J.D.
Director

MLR:sf
Attachment: March-In Determination