



May 28, 2009

The Honorable Anna Eshoo  
U.S. House of Representatives  
205 Cannon Office Building  
Washington, DC 20515

Dear Representative Eshoo:

On behalf of the more than 1,100 state and local affiliates of the National Alliance on Mental Illness (NAMI), I am writing to offer our strong support for the Pathways for Biosimilars Act of 2009 (HR 1548). As the nation's largest organization representing people living with serious mental illness and their families, NAMI is pleased to offer our support for this important legislation.

While there are few biologics currently approved by the FDA to treat severe mental illnesses such as schizophrenia, bipolar disorder and major depression, there is emerging evidence that treatments for these illnesses that move beyond palliative care toward disease modification and actual cures are on the horizon and may be achievable in biologic forms. NAMI wants to ensure that any effort to make generic biologics or biosimilars available does not hinder this innovation before it ever emerges from the lab.

HR 1548 represents an important step forward in allowing generic versions of biologics and biosimilar versions of brand name products currently available on the market. Your legislation strikes a careful balance to ensure that generic meet strict standards for safety, purity and potency in accordance with data requirements relevant to therapeutic class specific guidelines. It also requires a biosimilar product to meet standards of equivalence to a reference product based on data from analytical studies and other clinical data and requires the FDA to publish guidance on scientific feasibility and data requirements necessary to support a claim of interchangeability. Finally your legislation subjects biosimilars to post-marketing clinical studies and safety monitoring by the FDA.

Thank you for your leadership in bringing this legislation forward. NAMI looks forward to working with you to ensure passage in 2009.

Sincerely,

Michael J. Fitzpatrick, MSW  
Executive Director

cc: Steve Way, President, NAMI San Mateo County  
Carol Williamson, President, NAMI Santa Cruz County  
John Mitchem, President, NAMI Santa Clara County