BIO

BIOTECHNOLOGY
INDUSTRY
ORGANIZATION

January 12, 2006

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

Dear Mr. Secretary,

Enclosed is a letter from a broad coalition of organizations that support the Food and Drug Administration's Critical Path Initiative. Let me take this opportunity on behalf of BIO's members and the patient organizations listed to thank you, Deputy Secretary Alex Azar, and Acting FDA Commissioner Andy von Eschenbach for making this initiative a high priority. Critical Path is an initiative that holds great promise for improving the health of all Americans by accelerating the development of innovative safe and effective treatments, and by helping to usher in the era of personalized medicine. BIO looks forward to working with you, FDA and the patient and medical communities to implement the Critical Path Initiative and speed innovative medical therapies to those in need.

Sincerely,

James Greenwood
President & CEO

1225 EYE STREET, N.W., SUITE 400
WASHINGTON, D.C. 20005-5958

202-962-9200
FAX 202-962-9201
http://www.bio.org

January 12, 2006

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

Dear Mr. Secretary:

In March 2004, the Food and Drug Administration (FDA) released a white paper entitled "Innovation or Stagnation: Challenges and Opportunities on the Critical Path to New Medical Products" (available at http://www.fda.gov/oc/initiatives/criticalpath/). This paper was the result of FDA's investigation into the downward trend in applications for drugs, biologics, and medical devices. FDA concluded that reversing this downward trend will require modernization of the medical product development process – the Critical Path – to make product development more predictable and less costly.

The release of this white paper marked the launch of FDA's "Critical Path Initiative." FDA requested input from stakeholders on the best ways to modernize and better utilize the applied sciences to streamline the translation of innovative discoveries into new treatments and cures, i.e. "Critical Path Opportunities." FDA plans to release a list of such opportunities. Key opportunities could include, for example, new tools that help protect patient safety by predicting negative toxicological properties earlier in drug development, new clinical trial designs and computer models for evaluating product effectiveness, or new methods for manufacturing products quickly and reliably.

We support implementation of the Critical Path Initiative. We hope that it will play a vital role in helping FDA to fulfill its mission of protecting and advancing the public health by speeding access to safe and effective medical innovations. The Critical Path Initiative has the opportunity to be an important step toward realizing the promise of personalized medicine: getting the right medicine to the right patient, at the right time, and in the right dosage. Under the auspices of Critical Path, FDA and stakeholders will work together to develop the tools necessary to usher in the new era of personalized medicine, such as new validated safety and efficacy biomarkers and new ways to measure variation in patient responses.

For people with devastating diseases and disabilities, road blocks to getting new products developed and approved can be a matter of life or death. For patients who are still waiting for treatment options – such as a first-ever broadly-effective treatment for amyotrophic lateral sclerosis, and a first new treatment in four decades for lupus, and a

next generation treatment for multiple sclerosis, or the next miracle product for cancer – nothing is more important than seeing safe and efficacious products developed and approved as quickly as possible. The goal of the Critical Path Initiative is to streamline the translation of innovative discoveries into newer and better treatments that improve the lives of those living with disease and disability. Regardless of whether we are academic researchers, non-profit health advocates or private sector biotechnology, drug, device or diagnostic companies, we share this goal.

Whether one is living with a rare disease like spinal muscular atrophy or is among the many facing a future with Alzheimer's Disease, time is of the essence. We urge you to ensure that Critical Path programs receive the priority and resources within the Department needed for them to be successful. At the same time, resources for Critical Path should not result in underfunding of other crucial FDA programs.

We understand FDA will soon release the second Critical Path report and a Critical Path Opportunities White Paper. We welcome this progress in implementing the Critical Path Initiative, and look forward to working with FDA to foster the rapid development of new safe and effective therapies for patients. We very much appreciate your leadership on this issue, as well as that of Deputy Secretary Alex Azar and Acting FDA Commissioner Andrew C. von Eschenbach.

Sincerely,

Alliance for Aging Research
American Gastroenterological Association
The Amyotrophic Lateral Sclerosis Association
Arthritis Foundation
Biotechnology Industry Organization
Children's Tumor Foundation
The Christopher Reeve Foundation
Creutzfeldt-Jakob Disease Foundation
The Critical Path Institute
Crohn's & Colitis Foundation of America
Digestive Disease National Coalition
Foundation for Allergy & Immunology Research
Foundation for Collaborative AIDS Research
Foundation Fighting Blindness
Friends of Cancer Research
Huntington's Disease Society of America
Infectious Diseases Society of America
International Foundation for Functional Gastrointestinal Disorders
Lupus Foundation of America
National Kidney Foundation
National Organization of Rare Disorders
Parkinson's Action Network