



**BIOTECHNOLOGY  
INDUSTRY  
ORGANIZATION**

September 11, 2003

The Honorable C.W. Young  
Chairman  
Committee on Appropriations  
2407 Rayburn House Office Building  
United States House of Representatives  
Washington, DC 20515

Dear Chairman Young:

As President of the Biotechnology Industry Organization (BIO), I am writing to express BIO's views with regard to specific priorities on funding for federal agencies as well as several legislative issues you will confront as you move to conference on the Fiscal Year 2004 appropriations bills.

**BIO Federal Agency Funding Priorities**

Adequate funding of key government agencies such as the Food and Drug Administration (FDA), the National Institutes of Health (NIH), the Department of Agriculture (USDA), the Patent and Trademark Office (PTO), and the Department of Energy (DOE) is crucial to creating the necessary pipeline for continued advancement in cutting-edge biotechnologies. There are currently more than 130 biotechnology drugs and vaccines approved by the FDA, but with more than 371 innovative products in the pipeline, these agencies must be fully funded to help advance the next scientific breakthrough to the market. A product that proves its value in rigorous clinical trials but is held up in the regulatory process

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

FAX 202-962-9201

## 2. Human Patenting Provision

On July 23, the House passed the Commerce-Justice-State appropriations bill (H.R. 2799) that includes an amendment on human patenting offered by Representative Weldon. The amendment states,

*"None of the funds appropriated or otherwise made available by this act may be used to issue patents on claims directed to or encompassing a human organism."*

BIO objects to the inclusion of the provision in the bill because the language does not define "human organism," and it could prevent patenting of many biotechnology inventions and impede the development of new and potentially life saving products. We believe the amendment is unnecessary because current PTO policy states, "A claim directed to or including within its scope a human being will not be considered to be patentable subject matter." BIO has long supported this view. Moreover, this amendment would preclude the U.S. Patent and Trademark Office (PTO) from granting patents on an organism of human species at any stage of development produced by any method, a living organism made by human cloning, and a process of human cloning. We urge you to remove the Weldon human patenting language from the Commerce/Justice/State appropriations bill.

We look forward to working with you throughout the appropriations process. Once again, thank you for taking the time to consider our concerns and please don't hesitate to contact us if you have any questions.

Sincerely,



Carl B. Feldbaum  
President  
Biotechnology Industry Organization