



BIOTECHNOLOGY  
INDUSTRY  
ORGANIZATION

October 1, 2001

The Honorable Michael Bilirakis  
United States House of Representatives  
2269 Rayburn House Office Building  
Washington DC 20515

Dear Representative Bilirakis:

We understand that the Subcommittee will soon mark up the "Best Pharmaceuticals for Children Act" (H.R. 2887) that would continue the authority of Food and Drug Administration (FDA) to grant six months of market exclusivity to products on which FDA-approved pediatric studies have been conducted. The Biotechnology Industry Organization (BIO) enthusiastically supports continuation of this important initiative, which has resulted in significantly improved scientific and medical information on the safety and effectiveness of drugs in the pediatric population. BIO also supports applying user fees to supplemental applications for pediatric studies.

We understand that several controversial amendments may be offered during markup. In particular, BIO opposes any amendments that would involve so-called "generic biologics" and amendments that would codify the pediatric rule now in litigation.

Attached is BIO's position paper on "generic" biotechnology products. It has been approved by BIO's Board – consisting of large and small biotech companies. It is a scientifically based position. It concludes that currently, the science does not exist to provide an alternative to appropriate clinical evidence to demonstrate safety and effectiveness for biotechnology products.

BIO believes that the House Energy and Commerce Committee should adopt

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no provision on the issue of "generic" biotech products without hearings and careful deliberation. BIO looks forward to contributing to the debate on this complex set of scientific and legal issues.

BIO also believes that any amendment codifying the pediatric rule would resolve inappropriately a controversial matter currently in litigation. Codifying the current pediatric rule would grant the FDA unprecedented authority to compel companies to conduct studies on indications that the sponsor has not otherwise chosen to pursue.

Thank you for the opportunity to present BIO's position. In sum, we enthusiastically support the pediatric studies incentive, and oppose unrelated amendments. Should you or your staff have questions, feel free to call Steve Lawton, BIO's General Counsel at (202) 857-0244.

Sincerely,

A handwritten signature in black ink, reading "Carl B. Feldbaum". The signature is fluid and cursive, with a long horizontal line extending from the end.

Carl B. Feldbaum  
President

Attachment