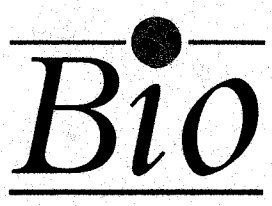

BIOTECHNOLOGY
INDUSTRY
ORGANIZATION

July 22, 2002

The Honorable Edward Kennedy
United States Senate
317 Russell Senate Office Building
Washington, DC 20510

Dear Senator Kennedy:

Thank you for your prompt response to my letter of July 15 objecting to several new provisions of S. 812, the Schumer-McCain legislation. No one was more surprised than members of the biotechnology industry at these last-minute changes, which pose significant problems for our companies. At this stage in the debate, we must strongly object to these provisions and urge that they be deleted from the bill under consideration on the floor of the Senate.

The Biotechnology Industry Organization quite intentionally took no position on the particulars of the original version of the Schumer-McCain bill, leaving debate on the practices described in your letter to others. But the bill has been changed radically, without opportunity for members of our industry to provide legal and policy reaction to the new provisions on bioequivalence, loss of rights to sue for patent infringement, and a right of action for generics to sue our companies to "correct" patent information filed with the Food and Drug Administration.

In BIO's July 15 letter, I pointed out the potentially damaging consequences to our emerging industry that could result from these provisions – carte blanche authority of FDA to determine testing methods applicable to full NDAs, loss of the ability to protect our intellectual property because of failure to meet new filing deadlines under food and drug law, and an unwarranted private right of action afforded generic companies to sue members in efforts to "delist" patents or

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

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

"correct" patent information. Whatever the purposes of these provisions, we fundamentally disagree with their consequences – perhaps the result of producing totally new provisions only 36 hours before markup.

We also point out that we were assured by committee staff that the bioequivalence provision was intended only to confirm FDA's authority to craft tests for bioequivalence for products not easily absorbed in the bloodstream. We were also assured that this provision (section 7) would be worked out before floor consideration. This has not occurred, despite the fact that BIO provided draft language that accomplishes precisely the stated purposes of the bioequivalence section.

BIO retains its admiration for you and your staff and appreciates very much your past efforts to respond to challenges that confront our industry in Massachusetts and across the nation. We have no doubt that you did not intend that the bill's new provisions pose threats to BIO companies, and look forward to an opportunity to work with you to remove from S. 812 the provisions on bioequivalence, loss of rights to sue for infringement and the private cause of action during its consideration on the Senate floor.

Sincerely yours,

Carl B. Feldbaum
President
Biotechnology Industry Organization

CBF:SL:fc