



## **Therapeutic Proteins, Inc**

---

26 December 2008

President-elect Barack Obama  
Chicago Transition Office  
Kluczynski Federal Building, 38<sup>th</sup> Floor  
230 S. Dearborn St. Chicago, IL, 60604

Dear Mr. President-Elect:

During your campaign, you and your health advisors frequently stated your commitment to increasing access to generic medicines to help Americans obtain safe and effective medicines at affordable prices. This included your support for legislation to create a biogenerics approval pathway with as short an exclusivity period as possible to ensure timely consumer access.

Several biogeneric bills have been introduced in the Senate and House. The Senate bill (S. 1695), which was approved unanimously by the Health, Education, Labor, and Pensions Committee in June 2007, includes a provision that gives an innovator company 12 years of data exclusivity during which a generic version of the brand biologic product could not be approved by the FDA. Meanwhile, three biogeneric bills also have been introduced in the House that differ on data exclusivity. Rep. Henry A. Waxman (D-CA), along with Rep. Frank Pallone Jr. (D-NJ), introduced a bill (H.R. 1308) in February 2007 that offers no data exclusivity. A more recent bill (H.R. 6529) introduced March 13 by Reps. Anna G. Eshoo (D-CA) and Joe Barton (R-TX), the ranking Republican on the Energy and Commerce Committee, includes 12 years of data exclusivity like the Senate bill.

What is vital here is the savings of billions of dollars by Medicare if the FDA allows the approval of biogeneric products as has been done in Europe and elsewhere worldwide. While you have many timely issues to take care of, the urgency to approve a biogenerics bill arises from the lag time of 3-4 years between the passage of the bill and the entry of affordable drugs into the market.

While the FDA awaits passage of a bill to give it the authority to approve equivalent forms of biological drugs, we believe the FDA has the right to accept these applications even under its current purview as established by case law. A copy of the Citizen Petition filed is enclosed.

We at Therapeutic Proteins ([www.theraproteins.com](http://www.theraproteins.com)) are proud to be part of this commitment of yours to make drugs more affordable, which we are doing by establishing the manufacturing of these drugs as an independent, small-business company investing heavily right here in Chicago within the campus of the Illinois Institute of Technology (University Technology Park: [www.universitytechnologypark.com](http://www.universitytechnologypark.com)), supported by Wexford Investments, fully trusting that the US will follow suit. We request you to make this a high priority of your administration. Your choice of Tom Daschle to head the HHS

is remarkable in that Mr. Daschle is also committed to this timely cause.

We congratulate you on your success and hope that we would be allowed to make a small contribution to your broader goals by producing safe biogeneric drugs within the boundaries of the US and by keeping high-end jobs in Illinois.

Sincerely,

*Sarfaraz Niazi*

Sarfaraz K. Niazi, Ph.D.

CSO and Chair, Therapeutic Proteins Inc

111 Pfingsten Road, Suite 105, Deerfield, IL 60015

(847) 205-7800 phone; (312) 297-0000 direct; (312) 803-1868 fax

Cc:

Tom Daschle, Secretary-designate HHS

Alston & Bird LLP

The Atlantic Building, 950 F Street, NW, Washington, DC 20004-1404

(202) 756-3156; tom.daschle@alston.com

Kathleen Jaeger, President and CEO, Generic Pharmaceutical Association (GPhA)

2300 Clarendon Blvd., Suite 400, Arlington, VA 22201

(703) 647-2480, (703) 647-2490; kjaeger@gphaonline.org