

ONE HUNDRED ELEVENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
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June 8, 2009

The President
The White House
Washington, DC 20500

Dear Mr. President:

I am pleased that your FY 2010 Budget provides a substantial increase for the Food and Drug Administration (FDA) and includes a proposal to establish a pathway for FDA approval of generic biologics.

On March 11, 2009, my colleagues and I introduced H.R. 1427, the "Promoting Innovation and Access to Life-Saving Medicine Act," a bipartisan bill to allow the FDA to approve affordable generic biologic drugs. Biotech drugs, while often life-saving, are the fastest growing and most expensive components of the nation's prescription drug costs. Many of them cost tens and thousands of dollars a year and impose an unsustainable burden on patients, employers, and the federal and state governments. This legislation, which I believe is consistent with the principles outlined in your budget is one of my highest priorities this year.

When this legislation passes, it is important for FDA to begin implementing the program as soon as possible. I urge the Administration to consider what steps can be taken under existing authority to prepare and even begin to use a pathway for generic biologics. The speed of FDA's action will determine how quickly safe and effective generic biologics become available to patients.

In addition, I would be interested in your Administration's analysis of long-term savings generated from generic biologics not only for Medicare and Medicaid, but also for businesses, insurers, and families. Generic biologics are a significant way to control costs and I agree with you that controlling costs is integral to reforming our health care system.

With your support I am hopeful we can achieve our shared vision for Americans to get access to safe, effective, and affordable generic biologic therapeutics.

I thank you for your attention on this matter and look forward to working with you.

Sincerely,



Henry A. Waxman
Chairman

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June 8, 2009
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cc: Nancy-Ann DeParle
Counselor to the President and Director, Office of Health Reform

Peter Orszag
Director, Office of Management and Budget