

EXECUTIVE OFFICE OF THE PRESIDENT
WASHINGTON, D.C. 20503

June 24, 2009

The Honorable Henry A. Waxman
U.S. House of Representatives
Washington, D. C. 20515

Dear Chairman Waxman:

Thank you for your letter to the President of June 8, 2009 regarding the establishment of a pathway for the Food and Drug Administration (FDA) to approve generic biologics. Biologic medicines are improving and saving the lives of patients everyday. Safe, affordable and effective generic biologics are a vital element to lowering costs for American consumers and businesses, as well as the Federal government. Making certain that Americans have access to these therapies is an important goal in reforming our health care system.

As you know, the Administration's FY 2010 Budget proposes to establish a new regulatory pathway for FDA approval of generic biologics. The policy in the FY 2010 Budget strikes the appropriate balance between innovation and competition by providing for seven years of exclusivity. Innovation is driven by appropriate competition, and the Administration's policy will spur that competition.

The Federal Trade Commission recently released a report, "Emerging Health Care Issues: Follow-on Biologic Drug Competition" that found innovation and investment will be sustained even without this level of exclusivity. The FTC directly assessed the arguments that the pharmaceutical industry has made regarding their need for 12-14 years of exclusivity; the FTC rejected those arguments. They found that giving such lengthy periods of exclusivity will harm patients by diminishing innovation and unnecessarily delaying access to affordable drugs. Therefore, the seven year policy in the FY 2010 Budget is a generous compromise between what the FTC research has concluded and what the pharmaceutical industry has advocated.

The Administration is working closely with the FDA to ensure the agency is prepared to implement an abbreviated approval pathway for generic biologics. As part of this effort, a serious review of FDA's existing authorities is underway to ensure that we are effectuating this critical policy as quickly as possible. In addition, we continue to analyze the impact of generic biologics on national healthcare expenditures and the potential for additional Federal savings over the long-term, as well as the potential impact of generic biologics on patients, businesses, and insurers. As you know, the President is focused on health care cost containment – generic biologics are a key element to reducing both our federal health care spending and national health care expenditures.

The President is greatly encouraged by the progress you and your colleagues in Congress have made in developing legislation that will provide American consumers with access to safe, affordable and effective generic biologics.

Sincerely,



Nancy-Ann DeParle
Director,
Office of Health Reform



Peter Orszag
Director,
Office of Management and Budget