



PRESIDENT OBAMA PROPOSES REDUCING THE EXCLUSIVITY PERIOD OF BRAND-NAME BIOLOGICAL PRODUCTS

President Obama, in his new budget plan, proposes reducing the exclusivity period for brand-name biologics from 12 years to seven. The President would also limit the ability of manufacturers to obtain additional periods of exclusivity.

Under the Biologics Price Competition and Innovation Act—enacted in 2010 as part of President Obama’s efforts to reform health care—a product that is “biosimilar” to an already approved biological product can obtain approval from the Food and Drug Administration (“FDA”) without the full effort required of a pioneer product. This biosimilar approval pathway is limited by an exclusivity provision, which prohibits the FDA from approving a “biosimilar application” “until the date that is 12 years after the date on which the reference [pioneer] product was first licensed” An additional exclusivity period may be available for “a modification to the structure of the biological product” that results “in a change to safety, purity, or potency.” Public Health Serv. Act, § 351(k)(7).

Under the President’s new budget proposal, which he announced on September 19, 2011:

Beginning in 2012, this proposal would award brand biologic manufacturers seven years of exclusivity rather than 12 years under current law and prohibit additional periods of exclusivity for brand biologics due [to] minor changes in product formulations, a practice often referred to as “evergreening.”

The stated reason for this change is to “encourage faster development of generic biologics,” which the administration forecasts will reduce the cost of federal health programs by \$3.5 billion over 10 years. No details are provided as to how a new law might restrict the ability to obtain additional periods of exclusivity.

The President’s current budget plan echoes proposals he made in February 2011, in his proposed budget

for Fiscal Year 2012. The proposed reduction in the exclusivity period does not appear to reflect a consensus in Congress. Over the summer, separate groups of lawmakers wrote to President Obama on this issue, with one group advocating support for the current 12-year exclusivity period, and with others advocating that it be reduced to seven years.

The President's budget is, of course, a long way from being enacted into law. However, if enacted, the change to the exclusivity period would be very important to the pharmaceutical industry. Interested parties will want to closely monitor developments.

LAWYER CONTACTS

For further information, please contact your principal Firm representative or one of the lawyers listed below. General email messages may be sent using our "Contact Us" form, which can be found at www.jonesday.com.

Jonathan Berman

Washington
+1.202.879.3669
jberman@jonesday.com

Laura A. Coruzzi

New York
+1.212.326.8383
lacoruzzi@jonesday.com

Anthony M. Insogna

San Diego
+1.858.314.1130
aminsogna@jonesday.com