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The Obama Administration Stakes Out Positions on Generic Biologics, Hatch-Waxman Settlements and Evergreening in Its First Budget

March 4, 2009

President Barack Obama's first budget proposals highlight the role of generic drugs as a key part of a series of spending curbs aimed at helping to reduce costs in the health care system and also pay for expanded coverage to all Americans. The biggest impact may come from the administration's goal of establishing a regulatory pathway for FDA approval of generic versions of biologic drugs. "The administration will accelerate access to make affordable generic biologic drugs available through the establishment of a workable regulatory, scientific and legal pathway for generic versions of biologic drugs," the President said. The Budget also addresses settlements in Hatch-Waxman patent litigation and the practice by branded drug companies of "evergreening."

President Obama's budget aims to foster generic competition for biotech drugs used to treat cancer , rheumatoid arthritis, multiple sclerosis and other ailments. The Hatch-Waxman Act provides for the approval of generic versions of traditional small molecule pharmaceuticals, but the FDA currently has no process for approving generic biologic drugs, also called "biogenerics," "follow-on biologics" or "biosimilars." Generally, biogenerics have more complex and variable structures than traditional chemically-synthesized pharmaceutical drugs because they are made from living cells or bacteria, and even small variations in manufacturing can lead to pharmacological and clinical differences. With Americans now spending more than $40 billion each year on such medications, however, the budget calls on Congress to set up a framework for regulators to approve generic versions, cutting costs for government programs, employers and patients. This change is projected to save the government about $9.2 billion over a ten-year period, according to the budget. The regulatory pathway will be most likely modeled on the current Hatch-Waxman Act but incorporate a standard of "biosimilarity" and/or "interchangeability" rather than "bioequivalence."

Generic Biologics Pathway

One of the key issues in any biogeneric regulation will be the length of the exclusivity period before the FDA can approve any follow-on biologic. The generic industry has proposed FDA approval of follow-on biologics after three to five years, similar to rules for approval of conventional drugs under the Hatch-Waxman Act. The administration's proposal suggests the time frame would be "consistent with" Hatch-Waxman, though administration officials have not been more specific. Biotechnology companies have been pushing for a longer exclusivity period such as twelve to fourteen years of exclusivity. Herein lays the major legislative battle.

Hatch-Waxman Settlement Limitations

The administration's budget indicates support of limitations on agreements between brand-name drug companies and their generic competitors that delay the entry of low-cost copies onto the market. The U.S. Federal Trade Commission has been recently rebuffed by the courts in its efforts to block some agreements as anti-competitive, and supports legislation against the agreements..

Evergreening Limitations
The administration's budget also indicated an objective of ending "evergreening," a practice in which brand-name pharmaceutical makers reformulate existing products to extend the life of their market exclusivity.

For more information, please contact the professional(s) listed below, or your regular Crowell & Moring contact.

Keith J. Harrison
Partner – Washington, D.C.
Phone: +1.202.624.2560
Email: kharrison@crowell.com