President's Latest Budget Proposal Seeks Decrease of Data Exclusivity Period and Elimination of Pay-for-Delay Agreements

By Donald Zuhn – February 21, 2012

Last week, President Obama unveiled his 2013 budget, and at least with respect to aspects of the budget proposal that would impact drugmakers, the President's 2013 proposal looks a lot like his 2012 proposal. In a section of the budget proposal entitled "Health Savings," the Administration sets forth eighteen proposals, the final two of which concern pay-for-delay agreements and the biosimilar regulatory pathway. With respect to pay-for-delay agreements, the budget seeks to:

Prohibit "Pay for Delay" Agreements to Increase the Availability of Generic Drugs and Biologics. The high cost of prescription drugs places a significant burden on Americans today, causing many to skip doses, split pills, or forgo needed medications altogether. The Administration proposes to increase the availability of generic drugs and biologics by authorizing the Federal Trade Commission to stop companies from entering into anti-competitive deals, known also as "pay for delay" agreements, intended to block consumer access to safe and effective generics. Such deals can cost consumers billions of dollars because generic drugs are typically priced significantly less than their branded counter-parts. These agreements reduce competition and raise the cost of care for patients both directly, through higher drug and biologic prices, and indirectly through higher health care premiums. The Administration's proposal facilitates greater access to lower-cost generics and will generate $11 billion over 10 years in savings to Federal health programs including Medicare and Medicaid.

As for biosimilars, the budget proposes to:

Modify the Length of Exclusivity to Facilitate Faster Development of Generic Biologics. Access to affordable lifesaving medicines is essential to improving the quality and efficiency of health care. The Administration's proposal accelerates access to affordable generic biologics by modifying the length of exclusivity on brand name biologics. Beginning in 2013, 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." Reducing the exclusivity period increases the availability of generic biologics by encouraging faster development of generic biologics while retaining appropriate incentives for research and development for the innovation of breakthrough products. The Administration's proposal strikes a balance between promoting affordable access to medications and encouraging innovation to develop needed therapies. The proposal will result in $4 billion in savings over 10 years to Federal health programs including Medicare and Medicaid.

The Administration's 2013 proposals remain unchanged from its 2012 proposals (*see* "President's Budget Proposal Increases Funding for Basic Research But Seeks to 'Trim' Data Exclusivity Period and Pay-for-Delay Agreements"). Of the 2012 budget, a document posted on the White House website at the time noted that:

The Administration is proposing to give consumers more access to affordable pharmaceuticals by: 1) reducing the exclusivity period for brand biologics to encourage faster development of generic biologics; and 2) giving the Federal Trade Commission the authority to prohibit brand and generic drug companies from entering into anticompetitive or "pay-for-delay" agreements intended to keep more generics off the market.

The Administration attempted to justify its proposals as follows:

Generic Biologics. Under current law, innovator brand biologics have 12 years of exclusivity and broad "evergreening" authority, whereby innovator manufacturers are able to make relatively minor changes to the "potency, purity, and safety" of their products to receive an additional 12 years of exclusivity.

Under the Administration proposal, beginning in 2012, innovator brand biologic manufacturers would have 7 years of exclusivity and would be prohibited from receiving additional exclusivity by "evergreening" their products. According to the Federal Trade Commission, 12-year exclusivity is unnecessary to promote innovation by brand biologic drug manufacturers and can potentially harm consumers by directing scarce research and development funding toward developing low-risk clinical data for drug products with proven mechanisms of action rather than toward new products to address unmet medical needs. The Administration policy strikes a balance between promoting affordable access to medication while at the same time encouraging innovation to develop needed therapies.

Pay-for-Delay. In these agreements, a brand name company settles its patent law suit by paying the generic firm to delay entering the market. Such deals can cost consumers billions of dollars because generic drugs are typically priced significantly less than their branded counterparts. The Administration proposal would give the Federal Trade Commission the authority to prohibit pay-for-delay agreements in order to facilitate access to lower-cost generics.

With respect to the specific savings that would be derived from each of the renewed proposals, the Administration predicts in the 2013 budget that by "[p]rohibiting brand and generic drug companies from delaying the availability of new generic drugs and biologics," $4.333 billion and $10.991 billion would be saved over the next five and ten years, and that if the Administration were to "[m]odify [the] length of exclusivity to facilitate faster development of generic biologics," $667 million and $3.825 billion would be saved over the next five and ten years. The Administration's predicted cost savings this time around are higher than its 2012 budget projections -- when it estimated 10-year savings of $8.79 billion for eliminating pay-for-delay agreements and $2.34 billion for reducing the data exclusivity period -- which is perhaps not too surprising given that the Administration was unable to realize either objective last year.