

Client Alert

FDA & Life Sciences Practice Group

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President Obama's FY 2012 Budget Plan Includes Provisions that Impact Pharmaceutical and Device Manufacturers

On February 14, 2011, the White House released its proposed budget for Fiscal Year 2012. The budget projects a \$1.1 trillion reduction in the federal deficit over the next ten years, with two-thirds of the savings expected to come from spending cuts. The budget provides a high-level, generalized discussion of the intent behind various funding decisions. This client alert highlights the budget provisions for the Department of Health and Human Services (HHS) that are particularly relevant for drug and medical device manufacturers. The full budget is available from the Office of Management and Budget at: <http://www.whitehouse.gov/omb/budget/Overview/>

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- **Funds Programs to Reduce Fraud, Waste, and Abuse in Medicare, Medicaid, and the Children's Health Insurance Program (CHIP).** The President's budget provides \$581 million in discretionary program integrity funding to implement activities to reduce the payment error rate and enhance civil and criminal enforcement for Medicare, Medicaid, and CHIP.
- **Invests in Prevention.** The President's budget allocates \$1 billion within the Prevention and Public Health Fund (which was included in the Affordable Care Act (ACA) for activities that have demonstrated improved health outcomes and will help reduce health care costs.
- **Continues Funding for Health Centers.** The President's budget provides \$2.1 billion to expand health center services; this allocation builds on a \$500 million allocation under the Recovery Act, and \$2.2 billion investment under the ACA. Significantly, many in Congress are seeking reductions to this program.
- **Imposes User-Fee System for Providers Enrolled in the 340B Drug Discount Program.** The proposed budget includes the first-ever user fee for providers enrolled in the 340B drug discount program—a 0.1 percent levy on each purchase to pay for the 340B program's operating expenses. If adopted by Congress, the entire responsibility of paying for the Office of Pharmacy Affairs' line item in the federal budget would be shifted from the federal treasury to 340B covered entities.

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- **Reduces the Exclusivity Period for Biologics to Seven Years and Proposes Reverse Settlement Ban.** The proposed budget reduces from twelve to seven the number of years that drug manufacturers may exclusively market brand-name biological drugs. It also gives the Federal Trade Commission the authority to block arrangements under which brand-name manufacturers pay generic manufacturers to delay the entry of generic drugs into the market. The follow-on biologics legislation is not expected to advance in Congress, but reverse settlement legislation remains at issue.
- **Supports Reforming Medicare's Payments to Physicians to Improve Quality and Efficiency.** The proposed budget extends the "doc fix" by continuing the current levels of physician payments under Medicare for the next two years, preventing the scheduled 25% cut in physician payment rates. The proposed budget is premised upon an expectation that the cost of the extension of the doc fix will be offset by "specific health savings." These savings are not described in the budget document, but an accompanying fact sheet states that the White House expects \$62 billion in savings, which will be generated by recommendations from the Fiscal Commission and unspecified bipartisan proposals.
- **Maintains Coverage for Low-Income Individuals.** The budget provides for extended coverage for low-income Americans under two programs: Transitional Medical Assistance for welfare recipients who are transitioning to employment and the Qualified Individuals program, which pays Medicare Part B premiums for certain low-income senior citizens.
- **Supports Biomedical Research at the National Institutes of Health (NIH).** The President's budget allocates to NIH \$31.8 billion to support, in part, grants for basic and applied biomedical research. This is a \$1 billion increase in funding over the last fiscal year. Funds will specifically be allocated for the National Center for Advancing Translational Sciences and the Cures Acceleration Network (\$100 million). The budget document specifically describes research related to cancer, Alzheimer's disease, and autism, although there is no indication that the grants will be selectively applied to these areas.
- **Invests Monies in the Safety of the Nation's Food and Medicines.** Finally, the budget includes \$2.7 billion in budget authority (an increase of \$100 million) and \$4.4 billion (an increase of \$1.1 billion) in program resources for the Food & Drug Administration (FDA). The funds will be applied to a variety of areas, including the advancement of health care reform efforts to create a biosimilars approval pathway.

Many of the Administration's budget proposals will not advance in this Congress, but some of these initiatives may form the basis for selective bipartisan agreements in the future. We will continue to monitor the Fiscal Year 2012 budget process and alert you to further developments.

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