



**EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503**

July 8, 2015
(House Rules)

STATEMENT OF ADMINISTRATION POLICY

H.R. 6 – 21st Century Cures Act
(Rep. Upton, R-MI, and 230 cosponsors)

The Administration appreciates the bipartisan support for medical research in H.R. 6, the 21st Century Cures Act, and looks forward to continuing to work with the Congress on strategies to prevent and cure disease and improve health.

In particular, the Administration appreciates the legislation's support for the President's Precision Medicine Initiative, which would advance a new model of participant-centered research to accelerate biomedical discoveries and provide clinicians with new tools and therapies tailored to individual patients' needs. This will also require enabling patients to access their data and accelerating interoperability between electronic health records. The Administration also believes we can build on our progress in improving the drug development and approval process by incorporating patients' voices into the Food and Drug Administration's (FDA) decision-making; encouraging the development and qualification of reliable biomarkers to accelerate work on important new therapies; and reducing barriers to initiating medical device trials. H.R. 6 takes meaningful steps on each of these important issues and includes provisions to pay for the new funding included in the bill.

While the Administration welcomes the additional support for biomedical research and innovation included in H.R. 6, the Administration has concerns about providing additional funding for the National Institutes of Health (NIH) and FDA without addressing sequestration more broadly. Sequestration funding levels threaten not only NIH research, but also other investments in innovation. They threaten health care access and quality, not only by underfunding biomedical research, but also by underfunding key public health and mental health programs. The President has proposed a plan to reverse sequestration and increase funding for NIH by \$1 billion in Fiscal Year 2016 while making other pro-growth investments. Separately, the new responsibilities for FDA outlined in H.R. 6 exceed the resources provided in the bill and the President's FY 2016 Budget and as such, FDA will be unable to fully implement the programs established in the bill, while maintaining its current performance levels.

H.R. 6 also proposes to sell oil from the Strategic Petroleum Reserve as a source of funding. The Administration reiterates the critical importance of making the investments necessary to modernize the Strategic Petroleum Reserve and ensure it continues to support U.S. energy security. The Administration remains concerned about extending drug exclusivity beyond current law and how this provision will affect drug costs. The Administration is also concerned that this bill would make funding subject to problematic ideological riders included in appropriations bills. The Administration believes funding should be free of such riders. The Administration also believes that H.R. 6 could undermine regulatory standards by allowing unproven uses of therapies to be marketed to health care payors as though such uses had been proven safe and effective.

Further, while the Administration supports strengthening the Government's ability to hire and retain qualified scientific experts, we look forward to working with the Congress to do this while promoting accountability. Finally, the Administration appreciates the bipartisan interest in advancing the interoperability of health information technology and remains focused on the need to strengthen this critical foundation for delivery system reform and precision medicine.

The Administration looks forward to working with the Congress on continuing to improve the bill as it moves forward.

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