



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

November 29, 2016
(House Rules)

STATEMENT OF ADMINISTRATION POLICY
House Amendment to the Senate Amendment to H.R. 34 – 21st Century Cures Act
(Rules Committee Print)

The Administration strongly supports passage of the bipartisan House Amendment to the Senate Amendment to H.R. 34, the 21st Century Cures Act, which dedicates more than \$6 billion to implement key priorities such as the President's proposal to combat the heroin and prescription opioid epidemic; the Vice President's Cancer Moonshot; and the President's signature biomedical research initiatives, the Precision Medicine and Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiatives. It also takes important steps to improve mental health, including provisions that build on the work of the President's Mental Health and Substance Use Disorder Parity Task Force, and includes policies to further modernize the drug approval process.

The legislation includes \$1 billion over two years, including \$500 million in Fiscal Year 2017, to combat the prescription opioid and heroin epidemic, consistent with the President's budget request. More Americans now die every year from drug overdoses than they do in motor vehicle crashes, and the majority involve opioids. The opioid epidemic is devastating families and communities and straining the capacity of law enforcement and the healthcare system. The resources included in the bill will allow states to expand access to treatment to help individuals seeking help to find it and to start the road to recovery, with preference given to states with an incidence or prevalence of opioid use disorders that is substantially higher relative to other states.

The Administration is committed to taking immediate action to lay the groundwork to ensure that the funds in the bill would be disbursed quickly and effectively so we can begin to address these important public health challenges.

The bill also includes \$1.8 billion, including \$1 billion over the next three years, to support the Vice President's Cancer Moonshot. The Moonshot aims to accelerate research efforts and make new therapies available to more patients, while also improving our ability to prevent cancer and detect it at an early stage. The resources in this legislation will support investment in promising new therapies like cancer immunotherapy, new prevention tools, cancer vaccine development, novel early detection tools, and pediatric cancer interventions. As the Vice President and scientific experts have said, we are at an inflection point in cancer research and this investment could help seize this opportunity.

The legislation also dedicates support for other key research initiatives. In 2013, the President launched the BRAIN Initiative with the goal of helping researchers find new ways to treat, cure, and prevent brain disorders, such as Alzheimer's disease, epilepsy, and traumatic brain injury. In 2015, he launched the Precision Medicine Initiative to pioneer a new model of patient-powered research that promises to accelerate biomedical discoveries and provide clinicians with new tools, knowledge, and therapies to select which treatments will work best for which

patients. The bill creates dedicated funding of \$1.5 billion for the BRAIN initiative and \$1.4 billion for the Precision Medicine Initiative to continue these signature Presidential Initiatives, which have broad bipartisan support, over the next decade.

The legislation also includes bipartisan mental health reforms. These include a renewed emphasis on evidence-based strategies for treating serious mental illness, improved coordination between primary care and behavioral health services, reauthorization of important programs focused on suicide prevention and other prevention services, and mental health and substance use disorder parity provisions that build on the work of the President's Mental Health and Substance Use Disorder Parity Task Force.

In addition, the bill takes multiple steps to further the progress made in this Administration in improving the drug development process. It enhances the ongoing efforts to better incorporate patients' voices into the Food and Drug Administration's (FDA) decision-making processes; supports FDA's efforts to modernize clinical trial design; and improves FDA's ability to hire and retain scientific experts. The legislation includes strong protections for individuals' health data, as well as provisions preventing unnecessary restrictions on the sharing of health information technology data with patients and providers.

There are also provisions in the bill that raise concerns, but that have been modified from previous versions to help address concerns, such as provisions that allow for the marketing of drugs to payors for off-label uses. In addition, a number of effective dates will be challenging to meet, especially without additional administrative funding. The requirement to sell additional inventory from the Strategic Petroleum Reserve, when added to the sale requirements of the Bipartisan Budget Act and the FAST Act, continues a bad precedent of selling off longer term energy security assets to satisfy near term budget scoring needs.

That said, this legislation offers advances in health that far outweigh these concerns. As such, the Administration strongly supports passage of the House Amendment to the Senate Amendment to H.R. 34, the 21st Century Cures Act.

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