THE REPUBLICAN STUDY COMMITTEE
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H.R. 6— 21st Century Cures Act (Upton, R-MI)

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FLOOR SCHEDULE: JULY 10, 2015 UNDER A STRUCTRED RULE THAT WAIVES ALL POINTS OF ORDER AGAINST THE BILL AND MAKES IN ORDER EIGHT AMENDMENTS.

TOPLINE SUMMARY: H.R. 6 would reauthorize the National Institutes of Health (NIH), focus efforts to increase strategic investments and medical research at the NIH, and modernize the approval and regulatory process for new drugs, biologics and medical devices at the Food and Drug Administration (FDA).

COST: The Congressional Budget Office (CBO) estimates enacting H.R. 6 would decrease the deficit by $525 million over the 2016-2025 period.

CONSERVATIVE CONCERNS: Some conservatives are concerned about the inclusion of a new mandatory funding stream created for the NIH Cures Innovation Fund. Although the committee reported bill contained an innovation funding stream that was scored by CBO as subject to appropriations, the manager's amendment moved the funding stream to the mandatory side of the budget ledger. The Budget Committee has warned that classifying this program as mandatory—rather than subjecting the fund to discretionary spending—would reduce congressional oversight and exacerbate our long-term budget challenges. Over the last 50 years, mandatory spending has grown from just one-third of the annual budget to over two-thirds of federal spending, totaling $2.5 trillion in FY 2015. This uncontrolled increase in mandatory spending has been the primary driver of our $18 trillion national debt. While the bill contains permanent entitlement reforms and asset sales to offset the new mandatory spending, some conservatives are concerned that these savings are back-loaded. Finally, some have expressed concerns that proceeds from sale of portions of the Strategic Petroleum Reserve should be used for deficit reduction rather than an offset for new spending.

- **Expand the Size and Scope of the Federal Government?** This bill would create a new mandatory funding program for the NIH and FDA.
- **Encroach into State or Local Authority?** No.
- **Delegate Any Legislative Authority to the Executive Branch?** No.
- **Contain Earmarks/Limited Tax Benefits/Limited Tariff Benefits?** No.

DETAILED SUMMARY AND ANALYSIS:

- **NIH and Cures Innovation Fund**– The secretary of Health and Human Services (HHS) would be directed to establish a NIH Cures Innovation Fund in the U.S. Treasury to support biomedical research through the funding of basic, translational, and clinical research while ensuring coordination among the research institutes to avoid duplication. The NIH director would establish a program known as the Accelerating Advancement Program where the director would partner with national research institutes and research centers to accomplish biomedical research objectives. In addition, director of the NIH would ensure scientifically based strategic planning is implemented in support of research priorities. Funding for this section would be directly appropriated for five years at a total of $1.86 billion for each of FY 2016

through 2020. Of that amount, $1.75 billion would be directed to the NIH for biomedical research, and $110 million would be directed to the FDA. It is important to note current pro-life policy limitations found in appropriations bills such as the Hyde (abortion funding) and Dickey-Wicker (treatment of embryos) amendments would apply to this fund.

Title I

- The National Institute of Health (NIH) would be reauthorized for fiscal years (FY) 2016-2018. According to CBO, reauthorizing the NIH would cost $97.1 billion over the 2016-2020 period.
- **NIH Research Strategic Plan** – The director would be instructed to develop and maintain a biomedical research plan that is designed to increase the efficient and effective focus of biomedical research and includes objectives for each area of strategic focus. This plan would be used for identifying research opportunities and for developing individual strategic plans for each of the research institutes and national centers.
- **Reducing Administrative Burdens of Researches** - The director would prepare a plan to implement measures to reduce the administrative burdens of researches and submit a report to Congress detailing to the extent the recommendations have been implemented.
- **Other Transaction Authority** – The National Center for Advancing Translational Science (NCATS) would be given increased flexibility on the use of Other Transaction Authority (OTA) to enter into transactions other than contracts, grants or cooperative agreements.
- **Supporting Young Emerging Scientists** – Updates would be made to the NIH grant repayment program to allow researchers $50,000 a year for their education loans.
- **Capstone Grant Program** – An award, called the Capstone Award, would be created to support outstanding scientists funded by the NIH. The duration and the amount of the award would be determined by the director.
- **National Pediatric Research Network -** This section would require the NIH to establish a national pediatric research network. It would be composed of research institutions that would operate as a consortium in order to pool resources and coordinate activities related to pediatric rare diseases or birth defects.
- **Clinical Trial Data System** – The secretary would enter into a cooperative agreement known as the Clinical Trial Data System Agreement, to implement a pilot program to create a scientific research sharing program to allow the use and analysis of data beyond each individual research project.
- **Tracking Neurological Diseases** – The secretary would be required to enhance and expand infrastructure to track the epidemiology of neurological diseases and incorporate that data into an integrated surveillance system, known as the National Neurological Diseases Surveillance System.
- **Accessing and Sharing Health Data for Research** – This section would amend a several provisions in the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule to allow for the use of protected health information by a covered entity for research purposes. In addition, the secretary would be required to clarify the rule so that research activities related to the quality, safety, or effectiveness of a product or activity that is regulated by the Food and Drug Administration (FDA) are included as public health activities for the purposes of which a covered entity may disclose protected health information.
- **Council for 21st Century Cures** – This section would establish a nonprofit corporation known as the Council for 21st Century Cures to accelerate the discovery, development and delivery of innovative cures and treatments in the United States. This council would terminate on September 30, 2023. For each of FY 2016 through 2023, there is authorized to be appropriated $10,000,000 to the council.

Title II

- **Patient Experience Data** – The secretary would be directed to implement a structured risk-benefit assessment framework into the drug approval process. In order to enhance the assessment, the secretary could take into consideration patient experience data, which includes data collected by

patients, caregivers, and patient advocacy organizations that intend to enhance the risk-benefit assessments.

- **Accelerated Approval Development Plan** – This section would allow the secretary to determine drugs that are eligible for an accelerated approval process, and work with the sponsor of the drug to create an approval plan.
- **Utilizing Evidence from Clinical Experience –** The secretary would establish a program to evaluate the use of evidence from clinical experience, such as data regarding usage or the potential risks and benefits, to help support the approval of a new indication for a drug or to help support post-approval study requirements. In parallel to the clinical experience program, the secretary would identify and execute pilot demonstrations to extend existing use of the Sentinel System to support these efforts.
- **Streamlined Data Review Program** – This section would establish a streamlined data review program within the FDA that would make use of submitted clinical data summaries to support the approval or licensure of specified new indications of drugs and biologics if certain qualifying criteria are met.
- **Expanded Access for Investigational Drugs** – This section would require the manufacturer or distributer of investigational drugs for serious diseases to make publically available their policy on expanded access programs. Although the policy would be posted, it does not guarantee access to any specific investigational drug.
- **Drug Approval for Use in Limited Populations** – This section would allow for the sponsor of an antibacterial or antifungal drug used to treat a life-threatening infection to work with the secretary to develop data to support use in a limited population of patients with an unmet medical need. The drug sponsor and secretary would work together to help expedite the development and review of the drug through early consultation meetings, assessment meetings and post approval meetings.
- **Increased Payment for new Antimicrobial Drugs in Medicare** – For each FY beginning in 2018, this bill would require the publication of a new list of antimicrobial drugs eligible for a higher reimbursement under Medicare. These antimicrobial drugs would meet unmet needs and intended to treat infections with which are associated with high rates of mortality.
- **Vaccine Policy Updates** – This section would require the timely review of vaccines by the Advisory Committee on Immunization Practices (ACIP). The CDC would conduct a review of the process used by the ACIP to evaluate consistency in formulating and issuing recommendations pertaining to vaccines.
- **Extension of Exclusivity Periods for Rare Disease Drugs** – This provision would incentivize drug manufactures through longer market exclusivity (six months) for approved drugs that are repurposed for new indications to prevent or treat rare diseases.
- **Rare Pediatric Disease Priority Review Voucher (PRV)** – This section would reauthorize the PRV through December 31, 2018. This program encourages development of new drug and biological products for prevention and treatment of certain rare pediatric diseases.
- **Grants for Studying Continuous Drug Manufacturing** – The section would establish grants to institutions of higher education and nonprofit organizations to study and recommend improvements to the process of continuous manufacturing of drugs and biological products. $5,000,000 for each of FY 2016 through 2020 would be authorized to carry out this section.
- **Priority Review for Breakthrough Devices** – To provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions, the FDA would establish a priority review for devices which: (1) are breakthrough technologies; (2) no approved alternatives exists; (3) there is a significant advantage over existing alternatives; or (4) the availability is in the best interest of the patient.
- **Medical Device Third-Party Quality System Assessment** – This section would establish a third-party quality system assessment program to review and certify if a device company's quality system can reasonably assure the safety and effectiveness of in-scope devices subject to device related changes. If certified, it would gain certain efficiencies in the FDA pre-market review process.

- **Easing Regulatory Burdens on Class I & II Devices** – This section would allow certain Class I and II devices, as determined by the secretary, to be exempt from certain reporting requirements. This would allow the FDA to focus its oversight on riskier devices.
- **Exclusion of Definition of Device** – This section would clarify that health software is not considered to be a medical device. This would provide regulatory clarity for researchers and developers.
- **Improving Scientific Expertise and Outreach at FDA** – This section would make changes to the Silvo O. Conte Senior Biomedical Research Service. The purpose of the service would be to recruit and retain competitive and qualified scientific and technical experts in biomedical research, clinical research evaluation and biomedical product assessment. In addition, the secretary would be given additional hiring authority and flexibility in the pay schedule to appoint qualified candidates to specific centers within the FDA.
- **Exempting Certain User Fees from Sequestration** – This section would add FDA salaries and expenses to the list of budget accounts and activities exempt from reduction under sequestration.

Title III

- **Ensuring Interoperability of Health Information Technology** – In order for health information technology (HIT) to be considered interoperable, it must: (1) allow for the secure transfer of the entirety of a patient's data for authorized use; (2) allow for complete access to a patient's available data for authorized use; and (3) is not configured to engage in information blocking. The secretary would enter into contracts with health care standards development organizations to provide recommendations for interoperability standards.
- **Adoption of Initial Interoperability Standards** – This bill would require the secretary, in consultation with the National Coordinator for Health Information Technology, to review the standards and implementation specifications. A recommendation would then be made on whether or not to adopt the standards which would be made public in the Federal Register. No later than July 1, 2017, the secretary would submit to Congress and for publication the initial set of interoperability standards and any strategies or barriers for achieving widespread interoperability. Beginning January 1, 2018, EHR technology would have to comply with the new interoperability standards in order to obtain certification. In addition, vendors of such technology would have to attest to a series of conditions and requirements in support of interoperability.
- **Telehealth Services under Medicare**–This section would require CMS to provide information on how implementing telehealth services in the Medicare program would be beneficial for beneficiaries.
- **Medicare Pharmaceutical and Technology Ombudsman** – This section would create a new pharmaceutical and technology ombudsman within CMS who would receive and respond to complaints and requests from entities that manufacture pharmaceutical, biotechnology, medical devices or diagnostic products.
- **Medicare Site-of-Service Price Transparency** – For 2017 and each year thereafter, the secretary would be required to make publically available the estimated payment amount for items and services made either to a hospital outpatient department or to an ambulatory surgical center and the estimated amount of beneficiary liability.
- **Programs to Prevent Prescription Drug Abuse under Medicare Parts C & D** – This section would allow prescription drug plans in Medicare Part D to develop a safe prescribing and dispensing program for beneficiaries that are prescribed a high volume of controlled substances.

Title IV

- **Limiting Federal Medicaid Reimbursement for Durable Medical Equipment (DME)** – This section would limit the federal Medicaid reimbursement to states for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) to Medicare reimbursement rates. CBO estimates that enacting DME payment limits in the remaining states beginning January 2020 would reduce direct spending for Medicaid by approximately $2.5 billion over the 2016-2025 period.

- **Excluding Authorized Generics from Calculation of Average Manufacturer Price** – This section would exclude authorized generics from Average Manufacturers' Price (AMP) calculations for determining Medicaid brand name rebates. This would have the effect of increasing the AMP of brand drugs and thus increasing the rebates drug manufacturers would owe to the states and federal government.
- **Transitioning from Traditional X-Ray to Digital Radiography** – This section would reduce Medicare's payment rates under the physician fee schedule for x-ray and other imaging services that do not use digital imaging technology beginning in 2017.
- **Civil Monetary Penalties for Grant and Contract Violations** –This section would clarify and expand the HHS Office of the Inspector General's authority to use civil monetary penalties (CMPs) in cases of proven HHS grant or contract fraud.
- **Strategic Petroleum Reserve (SPR) Drawdown** – This section would direct the Secretary of Energy to draw down and sell:
    - 4 million barrels of crude oil in FY 18;
    - 5 million barrels of crude oil in FY 19;
    - 8 million barrels of crude oil in FY 20;
    - 8 million barrels of crude oil in FY 21;
    - 10 million barrels of crude oil in FY 22;
    - 15 million barrels of crude oil in FY 23;
    - 15 million barrels of crude oil in FY 24; and
    - 15 million barrels of crude oil in FY 25.
- **Lyme Disease and Other Tick Borne Diseases** –The secretary would establish a permanent working groups to review all efforts within HHS concerning Lyme disease and other tick-borne illnesses to reduce duplication and increase coordination. No additional funds are authorized to be appropriated for the purposes of carrying out this section.

AMENDMENTS MADE IN ORDER:

#29 Brat (R-VA); McClintock (R-CA); Garrett (R-NJ); Stutzman (R-IN); Perry (R-PA): This amendment would amend the NIH and Cures Innovation Fund to make it a discretionary spending program instead of a mandatory spending program. BIO opposes this amendment.

#13 Young (R-IN); Harris (R-MD): This amendment would establish an Innovation Prizes Program at the NIH with the goal of funding areas of biomedical research that could realize significant advancements through the creation of a prize competition, and improving health outcomes for diseases in which public and private investment in research is disproportionately small relative to expenditures on prevention and treatment.

 # 11 Lee (D-CA); Schakowsky (D-IL); Clarke (D-NY): This amendment would remove all prolife policy limitations normally found in appropriations bills, such as the Hyde and Dickey-Wicker amendments, from the NIH and Cures Innovation Fund. Family Research Council will score against this amendment.

#19 Castro (D-TX): This amendment would require the NIH to report on their efforts to attract, retain, and develop emerging scientists which include underrepresented individuals such as woman and other minorities.

#21 Slaughter (D-NY): This amendment would instruct the CDC to conduct a study to determine how the additional payments are affecting the development of drug resistance.

#8 Fitzpatrick (R-PA): This amendment would express a sense of Congress that that recording Unique Device Identifiers at the point-of-care in electronic health record systems could significantly enhance the availability of medical device data for post-market surveillance purposes.

#35 Polis (D-CO): This amendment would direct the FDA to issue a report on the risks and benefits associated with a two-tiered approval process that would permit certain medical devices to provisionally come to market if they have demonstrated safety but not efficacy.

#15 Jackson Lee (R-TX): This amendment would direct the HHS to conduct outreach to historically black colleges, Hispanic-serving institutions, Native American colleges, and rural colleges to ensure that health professional from underrepresented populations are aware of the research opportunities under this act.

OUTSIDE GROUPS SUPPORT:

- Ad Hoc Group for Medical Research
- Association of American Cancer Institutes
- American Academy of Ophthalmology
- American Association for Cancer Research
- Association of American Medical Colleges
- American Cancer Society Cancer Action Network
- American Gastroenterological Association
- American Heart Association
- Arthritis Foundation
- American Society of Clinical Oncology
- Biotechnology Industry Organization (BIO)
- Cures Alliance
- Epilepsy Foundation
- Frontiers of Freedom
- Health IT Now
- Houston Methodist
- Infectious Diseases Society of America
- National Health Council
- National Organization for Rare Disorders
- One Voice Against Cancer
- PhRMA
- Physician Clinical Registry Coalition
- Parent Project Muscular Dystrophy
- United for Medical Research

OUTSIDE GROUPS OPPOSE:

- Heritage Action – Key vote no
- Citizens' Council for Health Freedom

COMMITTEE ACTION: This bill was introduced by Representative Upton on May 19, 2015, and referred to the Committee on Energy and Commerce and the Committee on Ways and Means. The Committee on Energy and Commerce held a mark-up and the bill was reported out by a vote of 51-0.

Click here for additional background materials provided by the Energy and Commerce Committee.

ADMINISTRATION POSITION: 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 and to improve the bill as it moves forward

CONSTITUTIONAL AUTHORITY: According to the sponsor, Congress has the power to enact this legislation pursuant to the following: "Article I, Section 8, Clause 1."

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