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H.R. 6 - The 21st Century Cures Act Rules Committee Print

Prepared by the Democratic Staff of the House Energy and
Commerce Committee

The 21st Century Cures Act, a version of which passed the Energy and Commerce Committee by a vote of 51-0, encourages biomedical innovation and the development of new treatments and cures.

Below are highlights of the legislation:

Provides \$8.75 billion in mandatory funding for NIH over the next five years

- Creates the NIH and Cures Innovation Fund, which will deliver \$8.75 billion in mandatory funding over the next five years, is meant to spur scientific innovation and discovery by providing an additional, supplementary funding stream to NIH.
- Directs funds towards high-risk high reward research and research performed by early stage investigators. NIH is also encouraged to use the new influx of dollars to address areas of unmet medical needs, including but not limited to, biomarkers, precision medicine, infectious diseases, and antibiotics.
- Increased funding will serve as an effective tool to further strengthen our economy. It has been estimated that every \$1 of NIH funding generates about \$2.21 in local economic growth, and, in 2012, NIH-funded research supported an estimated 402,000 jobs all across the U.S.

Promotes the maintenance of the best biomedical workforce in the world, including increasing the diversity of the biomedical workforce

- Through the increased funding provided in the Innovation Fund, NIH will also be able to increase the number of research projects it supports. Since 2003, the total application success rate for research project grants has declined by nearly 14 percent. The new Innovation Fund will help to reverse that trend.
- Increases the cap for NIH's loan repayment programs, including a repayment program for clinical scientists who do research in health disparities and for clinical scientists from disadvantaged backgrounds, from \$35,000 per year to \$50,000 per year plus a yearly inflation adjustment.
- Strengthens NIH's focus on diversifying the biomedical workforce through requiring NIH to focus on ensuring participation from scientists from underrepresented communities.

Modernizes clinical trials and supports inclusion of diverse populations in clinical research

- Allows for the use of new and creative adaptive clinical trials designs, while also harmonizing clinical trial regulation and reducing any regulatory duplication.
- Expresses the sense of Congress that the National Institute on Minority Health and Health Disparities should include strategies for increasing representation of minority communities in its strategic plan.
- Directs NIH to issue guidance identifying when it is appropriate to consider age as an inclusion or exclusion criteria for participation in clinical trials.
- Requires NIH to publically report the number of children broken out by race and gender who participate in clinical trials funded by NIH. This would help ensure that children are adequately represented in clinical trials and that we can determine the safety and effectiveness of drugs on children at the subgroup level.

Encourages the development of next generation treatments

- Supports the development of precision medicine through funding in the NIH and Cures Innovation Fund. FDA will also be directed to issue guidance to help sponsors with the development of precision drugs and biologics.
- Gives HHS the authority to participate in public-private partnerships to foster better utilization of patient registries to gather information on the natural history of diseases, particularly rare diseases.

Makes improvements to how FDA approves new drugs and devices

- Provides FDA with additional tools for the testing and review of drugs and medical devices, such as, streamlined data review, the use of biomarkers, evidence from clinical experience, and the establishment of a priority review program for breakthrough devices. These tools will make the drug and device development and review process more efficient, helping new treatments reach patients more quickly.
- Enhances incorporation of the patient experience into the drug development and regulatory process, which will help advance treatments that will improve the quality of life for patients. Patients understand better than anyone else the impact a treatment has on their daily lives, and have a unique perspective to add as industry and regulators consider the benefits and risks of different therapies.
- Facilitates the development of important antimicrobials for limited patient populations, incentivizes the development of new treatments for rare diseases, and clarifies FDA's regulatory pathway for software for medical applications.

Provides FDA with Resources to Keep Pace with Innovation

- Allocates \$550 million to FDA through the NIH and Cures Innovation Fund over five years to support the development of biomarkers, collection of data on natural history of diseases, development and use of patient experience data and evidence from clinical experience, advancement of continuous manufacturing, the priority review of breakthrough medical devices, creation of a third-party quality system assessment program for medical devices, the training and oversight in least burdensome means concept for medical device review, and the establishment of the new regulatory framework for software for medical applications.
- Ensures that user fees paid by industry are protected from sequestration and available for use for the review and approval of drugs and devices. This will enable the agency to continue to meet the goals laid out in user fee agreements, and ensure timely access to safe and effective medical treatments.
- Provides FDA with direct hiring authority and the ability to offer more competitive salaries so as to be able to attract and retain the highly qualified scientists and engineers necessary to review the most innovative drugs and devices.

Reduces Unnecessary Administrative Burdens on NIH and FDA

- Exempts certain activities of FDA and NIH from the Paperwork Reduction Act facilitating their ability to collect valuable information that can aid the research and development of medical products.
- Includes a sense of Congress that traveling to scientific conferences is essential to the missions of NIH and FDA. It is critical we make such travel less burdensome, so government scientists can fully participate in acquiring and disseminating cutting edge science, along with their academic and industry colleagues.

Interoperability of Health Information Technology

- Requires the Secretary to contract with standards development organizations to acquire mature interoperability standards that technology must meet, which will help to ensure that the health information technologies our health care system uses share information among them. Enforcement of interoperability will be through meaningful use decertification, HHS Inspector General investigations, or civil monetary penalties.
- Includes a patient empowerment section, which clarifies that patients also have a right to access their health information.
- Interoperability of our health system will lead to better access to electronic information, more coordinated care, increased efficiency, and improved health outcomes.

Offsets the Cost of the Bill

- Directs the Department of Energy (DOE) to draw down and sell crude oil from the Strategic Petroleum Reserve (SPR), as the SPR is well in excess of required reserves. (*\$7.05 billion*)
- Limits Federal matching funds for Medicaid fee-for-service payments for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) to Medicare fee schedule rates, and where applicable, the market-based rates paid by Medicare under its competitive bidding program (CBP). Modeled after the proposal in the President's fiscal year (FY) 2016 budget, this policy would take effect beginning January 1, 2020. (*\$2.525 billion*)
- Incentivizes the transition from traditional x-ray imaging to digital radiography by setting differential Medicare payments for film x-ray and computed radiography to encourage providers' to transition to modern digital technologies and away from older film-based technology, which often produce less detailed images. (*\$257 million*)
- Allows Medicare Part D plans to develop a safe prescribing and dispensing program for beneficiaries that are prescribed a high volume of controlled substances by assigning high-risk beneficiaries to one or more pharmacies for purposes of filling controlled substances. This policy also includes extensive beneficiary notification and appeals protections, does not apply to beneficiaries in long-term care facilities, and allows for emergency situations as well as multiple residences. (*\$116 million*)
- Expands Medicare coverage for certain devices that are disposable and thus less expensive, but are not covered currently under the definition for "durable medical equipment." (*\$200 million*)
- Excludes authorized generic drugs from average manufacturer price (AMP) calculations for purposes of determining manufacturer rebate obligations for brand-name drugs. Authorized generics are generally priced less than the branded drug, but still notably higher than true generics. Inclusion of authorized generics artificially lowers AMP calculations, resulting in lower Medicaid rebates paid by manufacturers to state Medicaid programs and the federal government. Removing the authorized generic from the calculation will raise the AMP back to a true reflection of the brand-name cost, and will allow the federal government to better maximize drug rebate savings in Medicaid. (*\$165 million*)
- Sets payment amounts for Part B DME infusion drugs using the ASP plus six percent methodology used for most other physician-administered drugs, as was recommended by the Health and Human Services Office of the Inspector General (HHS OIG), to better reflect actual transaction prices. (*\$617 million*)