

[H.R. 6, 21st Century Cures Act](#)

FLOOR SITUATION

On Thursday, July 9, 2015, the House will consider [H.R. 6](#), *the 21st Century Cures Act*, under a [structured rule](#). H.R. 6 was introduced on May 19, 2015, by Rep. Fred Upton (R-MI) and was referred to the Committee on Energy and Commerce, and in addition, to the Committee on Ways and Means. The Energy and Commerce Committee ordered the bill reported by a vote of 51 to 0 on May 21, 2015.

SUMMARY

H.R. 6 is designed to “modernize the health-care innovation infrastructure, incorporate a patient perspective into the drug and device approval process, support advances in personalized medicine, streamline clinical trials, and provide more resources to support cutting-edge research and help young scientists.”¹ The bill seeks to speed and improve the “discovery, development, and delivery of life saving and life improving therapies” and “transform the quest for faster cures” by:²

- Removing barriers to increased research capabilities;
- Incorporating the patient perspective into the drug development and regulatory review process;
- Measuring success and identifying diseases earlier through personalized medicine;
- Modernizing clinical trials;
- Removing regulatory uncertainty for the development of new medical apps;
- Providing new incentives for the development of drugs for rare diseases;
- Helping the entire biomedical ecosystem coordinate more efficiently to find faster cures; and,
- Investing in 21st Century science and next generation investigators.

The major provisions of the bill are as follows:

Section 2—NIH and Cures Innovation Fund

¹ See Chairman Upton’s Op-ed—“[How to Breathe New Life into America’s Health Care System](#),” June 4, 2015.

² See [Fact Sheet](#)—21st Century Cures Act (H.R. 6)

This section establishes the NIH and Cures Innovation Fund for the National Institutes of Health (NIH) and Food and Drug Administration (FDA) for research and researchers that plan to tackle the major challenges in biomedical research and have the potential to lead to breakthroughs.

The bill authorizes the appropriation of—and appropriates—\$1.86 billion per year for each of fiscal years 2016 to 2020 for the Fund. The funding would be required to come from funds in the Treasury not otherwise appropriated and shall be in addition to any amounts otherwise made available to NIH. The authorized and appropriated funding would sunset at the end of fiscal year 2020. This provision also maintains the Appropriations Committee’s role in allocating funding for specific activities.

For each fiscal year during this period, \$1.75 billion is designated from the Fund for biomedical research conducted through NIH, of which not less than \$500 million is for an Accelerating Advancement Program, which would provide matching funds (not derived from the NIH Cures and Innovation Fund) for NIH’s 27 institutes and centers to accomplish important biomedical research objectives.

Of the remaining funds, not less than 35 percent is for early stage investigators, and not less than 20 percent is for high-risk, high-reward research. The bill also provides that not more than 10 percent of the Fund will be used for intramural research.

The bill also requires the allocation of \$110 million annually from the Fund for FDA regulatory modernization activities required by the bill.

Section 2 also requires the NIH Director to ensure that scientifically-based strategic planning is implemented in support of research priorities, including through development, use, and updating of a research strategic plan. The section requires the plan to be updated not less than every 18 months.

Title I—Discovery

Title I reauthorizes and funds NIH for three years and authorizes various initiatives to promote medical research and discovery.

Specifically:

Subtitle A—National Institutes of Health reauthorization

Section 1001: This section reauthorizes NIH at a funding level of \$31.8 billion for Fiscal Year 2016, \$33.3 billion for Fiscal Year 2017, and \$34.9 billion for Fiscal Year 2018.

Subtitle B—National Institutes of Health Planning and Administration

Section 1021: This section requires the Director of NIH, in consultation with the directors of the national research institutes and national centers, researchers, patient advocacy groups, and industry leaders, to develop and maintain a biomedical research strategic plan that:

- Is designed to increase the efficient and effective focus of biomedical research in a manner that leverages the best scientific opportunities through a deliberative planning process;
- Identifies areas, to be known strategic focus areas, in which the resources of the NIH can best contribute to the goal of expanding knowledge on human health in the United States through biomedical research; and,
- Includes objectives for each such strategic focus area.

The plan would be used to identify research opportunities and develop individual strategic plans for the research activities of each national research institute and national centers that have a common template and identify strategic focus areas in which the resources of the national research institutes and national centers can best contribute to the goal of expanding knowledge on human health in the United States through biomedical research.

The initial five-year strategic plan must be developed within 270 days of enactment and updated every five years thereafter.

Section 1022: This section amends current law with regard to the appointment and terms of the Director of the National Cancer Institute and the directors of other NIH Institutes and Centers (ICs). Specifically, the section:

- Requires directors of ICs to be appointed by the NIH Director instead of the HHS Secretary, as required by current law;
- Establishes a five-year term of office for each IC Director and authorizes the NIH Director to remove a director prior to the expiration of his or her term, as well to reappoint a director for an unlimited number of successive five-year terms;
- Permits the NIH Director to fill a vacancy if the office of a director becomes vacant before completion of a five-year term with a successor to serve a new five-year term, as opposed to finishing the five-year term of the previous director; and,
- Deems current IC directors to have been appointed to new five-year terms as of the date of enactment.

Section 1023: This section directs the NIH to compile research and implement recommendations on how to streamline the grant process for researchers and reduce administrative burdens. Not later than two years after enactment, the Director is required to submit to Congress a report on the extent to which such measures have been implemented.

Section 1024: This section exempts certain NIH research activities from the Paperwork Reduction Act.

Section 1025: This section expresses the sense of Congress about the importance of scientific conferences and meetings to the mission of NIH.

Section 1026: This section provides the [National Center for Advancing Translational Science \(NCATS\)](#) at NIH with increased flexibility in the use of Other Transaction Authority (OTA), which provides flexible research authority to use other transactions to fund projects under certain conditions. Under the bill, unlike current law, the OTA would not be conditional on a determination that the goals and objectives of this section cannot be adequately carried out through a contract, grant, or cooperative agreement.

Section 1027: This section removes a restriction on the conduct of, or grants for, phase II and III clinical trials by NCATS.

Section 1028: This section requires the Director of each NIH institute to “establish programs to conduct or support research projects that pursue innovative approaches to major contemporary challenges in biomedical research that involve inherent high risk, but have the potential to lead to breakthroughs.” The NIH Director would determine a specific percentage of funding for each institute for such projects.

Section 1029: This section expresses the sense of Congress that the National Institute on Minority Health and Health Disparities (NIMHD) should include within its strategic plan ways to increase representation of underrepresented communities in clinical trials.

Subtitle C—Supporting Young Emerging Scientists

Section 1041: This section revises existing NIH loan repayment programs by increasing annual loan repayment limits from \$35,000 to \$50,000 and by permitting an annual adjustment of loan repayment amounts for inflation, beginning in Fiscal Year 2017. The section also authorizes a new loan repayment program based on the agency’s scientific and workforce needs, under which the Federal government would pay not more than \$50,000 per year on the principal and educational loans of health professionals who engage in research.

Section 1042: This section requires the NIH Director to submit a report to Congress, not later than 18 months after enactment, on programs for young emerging scientists at NIH.

Subtitle D—Capstone Grant Program

Section 1061: This section creates a ‘Capstone Award’ to support outstanding scientists who have received NIH funding. The purpose of the award would be to “facilitate the successful transition or conclusion of research programs.” The duration and amount of each award would be determined by the NIH Director in consultation with the IC Directors. Individuals who have received a capstone award would not be eligible to be the principal investigator on subsequent NIH awards.

Subtitle E—Promoting Pediatric Research through the National Institutes of Health

Section 1081: This section requires NIH to establish a national pediatric research network 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.

Section 1082: This section expresses the sense of Congress that NIH and the FDA should work with the European Union, industry, and others to establish a global pediatric clinical study network.

Section 1083: This section requires the NIH Director, within 180 days of enactment, to convene a workshop of experts on pediatrics and geriatrics and then publish guidelines regarding “appropriate age groupings to be included in research studies.” The Director would also be required to make available to the public, within 180 days after the end of the workshop, the findings and conclusions of the workshop. At least every other year, the Director would be

required to disclose to the public the number of children included in NIH-supported research, disaggregated by developmentally appropriate age group, race, and gender.

Subtitle F—Advancement of the National Institutes of Health Research and Data Access

Section 1101: This section requires NIH to standardize certain patient inclusion and exclusion information across all trials housed on clinicaltrials.gov. The section requires the NIH Director to ensure that (1) the registry and results data bank is easily used by the public; (2) the registry and results data bank entries are easily compared; (3) information is submitted to the registry and results data bank in a standardized format, including certain specified data; and (4) standard terminologies and code sets are used, to the extent possible, to facilitate electronic data matching. Within 90 days of enactment, the Secretary would be required to seek the advice of relevant stakeholders and experts on enhancements to the clinical trial registry data bank that are necessary to implement the provision. The Secretary would have to begin implementation of the provision within 18 months of enactment.

Subtitle G—Facilitating Collaborative Research

Section 1121: This section requires the HHS Secretary, acting through the FDA Commissioner and the Director of the NIH, to enter into a seven-year cooperative agreement, contract, or grant—the Clinical Trial Data System Agreement—with one or more eligible entities to implement a pilot program to enable registered users to conduct further research on reported clinical trial data. The section also requires GAO to conduct a study and issue a report to Congress and the Secretary on the pilot program not later than 6 years after the date on which the pilot program is established.

Section 1122: This section requires the Centers for Disease Control and Prevention (CDC) to establish a surveillance system for neurological diseases such as Parkinson’s disease and Multiple Sclerosis. Not later than 4 years after the date of the enactment, the Secretary is required to submit a report to Congress concerning the implementation of this section, which must include: (1) the development and maintenance of the National Neurological Diseases Surveillance System; (2) the type of information collected and stored in the System; (3) the use and availability of such information, including guidelines for such use; and (4) the use and coordination of databases that collect or maintain information on neurological diseases. The bill authorizes \$5 million for each of fiscal years 2016 to 2020 to carry out this section.

Section 1123: This section establishes a public-private partnership to establish or enhance and support an information technology system, including staffing, to collect, maintain, analyze, and interpret data on the natural history of diseases, with a particular focus on rare diseases. The bill authorizes \$5 million for each of fiscal years 2016 to 2020 to carry out this section.

Section 1124: This section requires the Secretary of HHS to revise several provisions in the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule to clarify certain permissible uses of protected health information.

Subtitle H—Council for 21st Century Cures

Section 1141: This section establishes a public-private partnership, the Council for 21st Century Cures, to accelerate the discovery, development, and delivery of innovative cures, treatments, and preventive measures for patients. The section provides for the organization

and administration of the Council and requires a report to Congress, not later than one year after the Council is established, on its performance. The authorization for the Council sunsets on September 30, 2023.

Title II—Development

Title II revises FDA regulations to modernize and streamline the development and approval process for prescription drugs, biologics, medical devices, and other health-related technologies. The Title also modifies certain surveillance activities of the Centers for Disease Control and Prevention.

Subtitle A—Patient-Focused Drug Development

Section 2001: This section requires FDA, during the new drug approval process, to implement a structured framework to incorporate patient experiences in the consideration of a drug’s benefits and risks. The section requires the Secretary to issue draft guidance on implementation not later than three years after enactment and final guidance not later than one year after the public comment period on the draft guidance closes. Not later than 90 days after the date on which the draft guidance is published, the Secretary must convene a public meeting to solicit input on the guidance.

Subtitle B—Qualification and Use of Drug Development Tools

Section 2021: This section codifies a structured framework at FDA for the submission, review, and qualification of biomarkers and other drug development tools for the specific contexts of use that, if qualified, can be relied on by any person for such purposes.

Section 2022: This section enables the sponsor of a drug that FDA determines may be eligible for accelerated approval to request voluntarily that FDA agree to an accelerated approval development plan.

Subtitle C—FDA Advancement of Precision Medicine

Section 2041: This section requires FDA to issue and periodically update guidance defining the term “precision drug or biological product” and authorizes the agency, in the case of a drug or biological product for the treatment of a serious or life-threatening disease or condition designated as a drug for a rare disease or condition, to rely on data or information previously submitted by the sponsor for a different drug or biological product that incorporates or utilizes the same or similar underlying approach. The Secretary is required to issue the guidance not later than 18 months after enactment.

Subtitle D—Modern Trial Design and Evidence Development

Section 2061: This section requires FDA to hold a public meeting and issue guidance documents that would assist sponsors in incorporating adaptive designs and Bayesian statistical modeling into their proposed clinical protocols and applications for new drugs and biological products. In recent years, some clinical and methodological researchers have looked to adaptive trial designs and statistical analyses using techniques (such as Bayesian statistics) that can provide mid-course feedback.

Section 2062: This section requires FDA to establish a program to evaluate the potential use of evidence from clinical experience to help support the approval of a new indication for a previously-approved drug and to help support or satisfy post-approval study requirements. The bill authorizes \$3 million for each of fiscal years 2016 to 2020 to carry out this section.

Section 2063: This section requires FDA to establish a program authorizing the holder of an approved application to submit a summary of clinical data intended to support the approval or licensure of the drug for a new indication for the treatment of cancer or other types of indications. FDA is required to issue guidance for implementation of the streamlined data review program not later than 24 months after enactment.

Subtitle E—Expediting Patient Access

Section 2081: This section reaffirms that FDA should continue to expedite the approval of drugs designated as breakthrough therapies as early as possible in the clinical development process, provided that the application for a drug meets the required evidentiary standards of safety and effectiveness.

Section 2082 and 2083: These sections require certain manufacturers or distributors of an investigational drug to make publicly available, such as through a manufacturer or distributor's website, basic information on their expanded access policy. The sections also require the FDA to expedite guidance providing clarity to sponsors seeking drug approval regarding the consideration during the drug review process of adverse events experienced by patients receiving a drug through an expanded access program.

Subtitle F—Facilitating Responsible Manufacturer Communications

Section 2101: This section clarifies the scope of health care economic information drug manufacturers can permissibly disseminate to payors, formulary committees, or other similar entities.

Section 2102: This section requires FDA to issue draft guidance, no later than 18 months from the date of enactment, to clarify how drug and device manufacturers can permissibly disseminate truthful and non-misleading scientific and medical information about a drug or device that is not included in the approved labeling for the product.

Subtitle G—Antibiotic Drug Development

Section 2121 to 2123: These sections include provisions to facilitate the development of new antibacterial or antifungal drugs through a new FDA approval pathway and creating economic incentives for new drug development.

Subtitle H—Vaccine Access, Certainty, and Innovation

Section 2141: This section ensures working groups convened by a CDC advisory committee (the Advisory Committee on Immunization Practices or ACIP) have sufficient time to review data and information to make an informed recommendation to ACIP and that ACIP votes on such recommendations in a timely manner to ensure patient access to these lifesaving vaccines.

Section 2142: This section requires the Director of the CDC to conduct a review of the process used by ACIP in order to evaluate ACIP's consistency in formulating and issuing recommendations pertaining to vaccines. Following such review, the CDC Director must publish a report, not later than 18 months after enactment, on the results of the review, including recommendations on improving the consistency of the process.

Section 2143: This section creates and formalizes processes for the making of vaccination scheduling recommendations by ACIP, for CDC review of ACIP recommendations, and for meetings between CDC and vaccine developers. These meetings will provide companies investing in vaccines more certainty and understanding when establishing investment and development plans.

Subtitle I—Orphan Product Extensions Now; Incentives for Certain Products for Limited Populations

Section 2151: This section incentivizes the repurposing of major market drugs for rare diseases, to advance safe and effective treatments and cures to patients with rare diseases. The provision would provide a one-time, six month extension of certain exclusivity periods and patent protection for an already-approved drug if the drug's sponsor obtains approval of a new indication for the drug for a rare disease or condition.

Section 2152: This section reauthorizes the Rare Pediatric Disease Priority Review Voucher (PRV) program through December 31, 2018, and broadens the definition of a rare pediatric disease to ensure that pediatric oncology drugs and treatments for sickle cell disease are eligible for designation. The section further requires the U.S. Government Accountability Office to complete a report, by not later than December 31, 2017, evaluating the effectiveness of the program for encouraging drug development for rare pediatric diseases.

Subtitle J—Domestic Manufacturing and Export Efficiencies

Section 2161: This section allows FDA to award grants to higher education and non-profit organizations to study and recommend improvements to the process of continuous manufacturing (and other similar innovative monitoring and control techniques) of drugs and biologics. The section authorizes \$5 million for each of fiscal years 2016 to 2020 for such grants.

Section 2162: This section allows U.S. pharmaceutical companies to re-export controlled substances similar to foreign pharmaceutical manufacturers, providing a level-playing field regarding controlled substances exports.

Subtitle K—Enhancing Combination Products Review

Section 2181: This section requires FDA to issue a final guidance document, not later than 18 months after enactment, describing the role of all agency centers when reviewing a combination product.

Subtitle L—Priority Review for Breakthrough Devices

Section 2201: This section requires FDA to establish a program to provide priority review for qualifying medical devices representing breakthrough technologies for diseases or conditions

for which no approved alternatives exist, offer significant advantages over existing approved or cleared alternatives, or the availability of which is in the best interest of patients.

Subtitle M—Medical Device Regulatory Process Improvements

Section 2221: This section establishes a voluntary third-party quality system assessment program where device companies could have their quality system certified by an FDA-authorized third party and, once certified, gain certain efficiencies in the FDA pre-market review process. This program sunsets on October 1, 2022.

Section 2222: This section clarifies that, in the context of FDA evaluation of medical devices, valid scientific evidence may include registry data, studies published in peer-review journals, and data collected in foreign countries if certain criteria are met.

Section 2223: This section ensures that each FDA employee involved in the review of medical device submissions receives adequate training in the meaning and implementation of the least burdensome means concept.

Section 2224: This section establishes a process at FDA for the submission, review, and recognition of standards established by a nationally or internationally recognized standard organization for purposes of medical device review.

Section 2225: This section requires the Secretary to identify and publish in the Federal Register any type of class I or II devices that the Secretary determines no longer requires a report currently required under current law to provide reasonable assurance of safety and effectiveness. The changes are designed to allow the FDA to focus its oversight on those devices that pose more risks to patients.

Section 2226: This section revises the medical device classification panel review process at FDA to ensure adequate expertise among panel members to assess the device and allow for presentation by the device sponsor to the panel, among other things.

Section 2227: This section provides FDA with the authority to apply the humanitarian device exemption to diseases and conditions that affect up to 8,000 individuals in the United States.

Section 2228: This section requires FDA to issue guidance, not later than 12 months after enactment, clarifying existing guidance regarding the regulation of clinical laboratories.

Subtitle N—Sensible Oversight for Technology Which Advances Regulatory Efficiency

Sections 2241 to 2243: These sections update regulatory laws around software to create clarity for developers and reviewers.

Subtitle O—Streamlining Clinical Trials

Section 2261: This section requires the Secretary to harmonize differences between the human subject regulations under the Common Rule and the Federal Food Drug and Cosmetic Act (FFDCA). The section also streamlines the institutional review board (IRB) process for trials that are being conducted at multiple sites.

Section 2262: This section removes the limitation on the use of central IRBs in medical device trials.

Section 2263: This section amends certain provisions governing the informed consent process for enrolling patients in medical device trials that pose no more than minimal risk and include appropriate safeguards to protect the rights, safety, and welfare of the participants.

Subtitle P—Improving Scientific Expertise and Outreach at FDA

Section 2281: This section enables FDA to hire more efficiently and ensure that the agency has the staff required to ensure they keep up with the pace of innovation. Not later than 3 years after enactment, the HHS Secretary is required to submit, and publish on the HHS website, a report on the implementation, including whether the revisions have improved the ability of the Food and Drug Administration to hire and retain qualified experts to fulfill obligations specified under user fee agreements.

Section 2282: This section expresses congressional support for eliminating barriers that prevent agency staff from attending scientific conferences and meetings.

Section 2283: This section ensures that the [Reagan-Udall Foundation](#) has access to the expertise and human capital it needs to fulfill its statutory mission of advancing FDA's scientific priorities.

Section 2284: This section exempts FDA from the Paperwork Reduction Act with respect to the collection from patients, industry, academia, and other stakeholders of voluntary information through voluntary surveys and questionnaires to enable the agency to more easily and efficiently receive patient input.

Section 2285: This section gives the FDA broad and flexible new authority to recruit and retain the staff required to ensure that the agency keeps up with the pace of innovation and includes the ability to offer salaries competitive with those in the private sector and in academia. Not later than September 30, 2021, the Secretary must submit a report to Congress that examines the extent to which the authority to appoint and retain personnel under this section enhanced the FDA's ability to meet the agency's critical need for highly qualified individuals for scientific, technical, or professional positions.

Subtitle Q—Exempting From Sequestration Certain User Fees

Section 2301: This section permanently exempts the following FDA user fees from sequestration: fees for medical devices, prescription drugs, generics drugs, biosimilars, animal drugs, and generic animal drugs.

Title III—Delivery

Title III is designed to improve and personalize health care delivery to empower patients to make informed choices and ensure care is provided as efficiently and effectively as possible.

Subtitle A—Interoperability

Section 3001: This section makes a series of changes to the Public Health Service Act to:

- Promote the adoption of new interoperability standards;
- Strengthen the existing certification process to ensure that EHR systems and other HIT meet those standards; and,
- Establish new enforcement authority and penalties to discourage HIT vendors, health care providers, and health care systems from blocking the exchange and use of electronic health information.

The changes are designed to refocus national efforts on making systems interoperable and holding individuals responsible for blocking or otherwise inhibiting the flow of patient information throughout the health care system.

Subtitle B—Telehealth

Section 3021: This section would require, within a year of enactment, the Centers for Medicare and Medicaid Services (CMS) and the Medicare Payment Advisory Commission (MedPAC) to submit certain information to Congress on telehealth. CMS must provide such information not later than one year after enactment. MedPAC must provide such information not later than March 15, 2017.

Subtitle C—Encouraging Continuing Medical Education for Physicians

Section 3041: This section broadens the exclusions from a reporting requirement under the Social Security Act for certain education-related payments or transfers of value between industry and providers that providers have reported discourage their engagement in continuing medical education activities. The exclusion applies with respect to transfers of value made on or after the date of the enactment.

Subtitle D—Disposable Medical Technologies

Section 3061: This section is designed to ensure that seniors receiving care in the home setting are not denied access to certain durable medical items, if they are medically necessary and would otherwise be available to them, based simply on the location in which they seek care. The changes apply to devices furnished on or after January 1, 2017.

Subtitle E—Local Coverage Decision Reforms

Section 3081: This section increases transparency around the Local Coverage Determination (LCD) process and begins the process of bringing greater accountability to the actions of those contracting with CMS to manage the operation of the Medicare program. The section requires the Secretary to require Medical Administrative Contractors (MACs) to display on their websites at least 45 days prior to the effective date the following information for each LCD developed by a MAC for its jurisdiction:

- the entire LCD;
- where and when the LCD was first made public;
- links to the proposed LCD and responses to comments submitted to the MAC on the proposed LCD;

- a summary of evidence considered by the contractor during the LCD development, as well as a list of sources of evidence; and,
- an explanation of the rationale in support of the proposed LCD.

The provision would be effective for LCDs proposed or revised 180 days after enactment.

Subtitle F—Medicare Pharmaceutical and Technology Ombudsman

Section 3101: This section requires the Secretary, within 12 months of enactment, to create a new technology ombudsman within the Centers for Medicare and Medicaid Services to address problems relating to coverage of new and life-saving technologies.

Subtitle G—Medicare Site-of-Service Price Transparency

Section 3121: This section establishes new requirements "to facilitate price transparency with respect to items and services for which payment may be made either to a hospital outpatient department or to an ambulatory surgery center." Beginning in 2017, and in each year thereafter, the Secretary would make information available to the public on a searchable website regarding (1) the estimated Medicare payment amount for the items and services provided under both the hospital outpatient prospective payment (OPPS) fee schedule and the ambulatory surgical center payment system, and (2) the estimated amount of the beneficiary's liability (for the item or service). The changes are designed to give seniors the ability to shop among certain sites of service for certain services so that they can identify the most cost effective treatments.

Subtitle H—Medicare Part D Patient Safety and Drug Abuse Prevention

Section 3141: This section authorizes prescription drug plans in Medicare Part D to:

- Institute a drug management program limiting the number of prescribers and pharmacies that could provide frequently abused drugs to Part D beneficiaries at risk for drug abuse:
- Require Part D plans to implement drug utilization management tools; and,
- Expand the authority of Medicare Drug Integrity Contractors (MEDICs).

The changes would take effect for Part D plan years beginning more than one year after the date of enactment.

Title IV—Medicaid, Medicare, and Other Reforms

Title IV makes various reforms to Medicare and Medicaid and includes requirements regarding the sale of crude oil from the Strategic Petroleum Reserve.

Subtitle A—Medicaid and Medicare Reforms

Section 4001: This section limits federal Medicaid reimbursement to states for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) to Medicare reimbursement rates.

Section 4002: This section excludes authorized generic drugs from Average Manufacturers' Price calculations for determining Medicaid brand name rebates.

Section 4003: This section implements a differential Medicare reimbursement for film x-ray and computed radiography to incentivize the transition to digital radiography.

Section 4004: This section would set payment amounts for Part B drugs infused through DME items using the methodology used for most physician-administered drugs: Average Sales Price plus 6 percent.

Section 4005: This section improves CMS's use of prior authorization for DME. This section creates a new safe harbor for suppliers who receive a prior authorization approval for medical necessity, so that such suppliers would not be unduly burdened by duplicative audits, although they could still be subject to audit in cases of suspected fraud. This policy would also expand the geographic scope and extend the duration of CMS's current DME power mobility device (PMD) demonstration.

Section 4006: This section clarifies and expands the HHS Office of the Inspector General's authority to use civil monetary penalties (CMPs) in cases of proven HHS grant or contract fraud. This tool would help save the federal government millions of dollars and penalize proven bad actors.

Subtitle B—Other Reforms

Section 4041: This section requires the Secretary of the Department of Energy to draw down and sell crude oil from the Strategic Petroleum Reserve. The Secretary is prohibited from drawing down and selling crude oil under this section in amounts that would result in a Strategic Petroleum Reserve that contains an inventory of petroleum products representing less than 90 days of emergency reserves, based on the average daily level of net imports of crude oil and petroleum products in the previous calendar year. The proceeds from a sale under this section are to be deposited into the general fund of the U.S. Treasury.

Subtitle C—Miscellaneous

Section 4061: This section would help to accelerate improved methods for prevention, diagnosis, and treatment of Lyme disease. It would establish a working group to prepare a report that would summarize federal research efforts related to Lyme disease and other tick-borne diseases. The HHS Secretary would develop a strategic plan to improve health outcomes that would be informed by the working group's report.

BACKGROUND

Although science and technology have made tremendous advances in recent years, “our regulatory system has not kept pace with the innovation that is happening both in labs and in Silicon Valley.”³ The 21st Century has seen enormous advances in mobile medical apps and other technological tools, but the current regulatory system was established before many of these technologies even existed. Consequently, the approval process for new drugs, therapies, and medical devices has lagged, while

³ See Chairman Upton [op-ed](#)

funding limitations have constrained medical and scientific research. Today, there are only 500 treatments for 10,000 known diseases, 7,000 of which are considered rare.⁴

The National Institutes of Health (NIH), which is part of the Department of Health and Human Services (HHS), “is the nation’s medical research agency—making important discoveries that improve health and save lives.”⁵ NIH is made up of 27 Institutes and Centers, each with a specific research agenda, often focusing on particular diseases or body systems. NIH leadership plays an active role in shaping the agency’s research planning, activities, and outlook.⁶

According to NIH, more than 80 percent of its budget “goes to more than 300,000 research personnel at over 2,500 universities and research institutions. In addition, about 6,000 scientists work in NIH’s own Intramural Research laboratories, most of which are on the NIH main campus in Bethesda, Maryland. The main campus is also home to the NIH Clinical Center, the largest hospital in the world totally dedicated to clinical research.”⁷ Click [here](#) for an NIH primer on the clinical trials process.

Congress doubled funding for NIH between Fiscal Year 1998 and 2003, raising its budget from \$13.6 billion to \$27.1 billion. During that period, annual budget increases of about 14 to 15 percent were common. However, increases through the regular appropriations process have been between about 1 to 3 percent annually since. The growth rate of NIH’s budget has been at or below the rate of inflation, which for biomedical research in fiscal year 2015, is estimated to be 2.2 percent.⁸ In constant 2012 dollars, “NIH funding in Fiscal Year 2015 is 22 percent lower than the Fiscal Year 2003 level.”⁹

The Food and Drug Administration (FDA), also part of HHS, has regulatory authority over foods, drugs, cosmetics, biologics, medical devices, electronic products that emit radiation, livestock feeds, pet food, and tobacco products.¹⁰ Within the FDA, there is an Office of the Commissioner and four directorates overseeing the core functions of the agency: Medical Products and Tobacco, Foods and Veterinary Medicine, Global Regulatory Operations and Policy, and Operations.¹¹

The [Federal Food, Drug and Cosmetic Act](#) (FFDCA) is the “central federal law regulating the safety of most foods, food additives, color additives, dietary supplements, prescription and non-prescription drugs, medical devices, cosmetics, and tobacco products.”¹² The FDA, in its mission to assure that the products it regulates are safe and truthfully labeled, enforces the Act “through a series of administrative mechanisms, such as pre-market reviews of certain products, examinations and investigations, and the dissemination of information to the public.”¹³ Click [here](#) for a Congressional Research Service (CRS) report on the FDA’s drug approval process and [here](#) for a CRS report on the Agency’s regulation of medical devices.

⁴ Id.

⁵ <http://nih.gov/about/>

⁶ Id.

⁷ Id.

⁸ See CRS Report—“[H.R. 6: The 21st Century Cures Act](#),” June 11, 2015 at 3.

⁹ Id.

¹⁰ <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194879.htm>

¹¹ <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm192695.htm>

¹² See CRS Report—“[Enforcement of the Food, Drug, and Cosmetic Act: Select Legal Issues](#),” June 19, 2014 at Summary.

¹³ Id.

COST

The Congressional Budget Office (CBO) [estimates](#) that implementing H.R. 6 would authorize the appropriation of \$100.9 billion during the fiscal year 2016 to 2020 period, resulting in estimated outlays of about \$97.9 billion during that time, assuming the appropriation of authorized amounts. CBO further estimates that changes in direct spending required by the bill will reduce the deficit by about \$524 million through the fiscal year 2016 to 2025 period.

ADDITIONAL INFORMATION

The following additional information has been provided by the Committee on Energy and Commerce:

- [Summary](#)
- [Section-by-section](#)
- [Summary of major changes to H.R. 6](#)
- [Frequently Asked Questions](#)

AMENDMENTS

- 1) [Rep. Dave Brat \(R-VA\)](#)—The amendment reforms the NIH and Cures Innovation Fund to make it a discretionary spending program.
- 2) [Rep. Todd Young \(R-IN\)](#)—The amendment creates authority within NIH to conduct a prize program. The intent of the program would be to incentivize health innovation by offering competitors the chance to win a prize for creating breakthrough research and technology.
- 3) [Rep. Barbara Lee \(D-CA\)](#)—The amendment strikes the provision that applies any policy riders included in the annual LHHS Appropriations Bill to NIH funds in H.R. 6. Also strikes the provision that applies any policy riders applied to the FDA in the annual Agriculture Appropriations bill to FDA funding in H.R. 6.
- 4) [Rep. Joaquin Castro \(D-TX\)](#)—The amendment ensures underrepresented individuals, such as women and minorities, are included in the Supporting Young Emerging Scientists Report.
- 5) [Rep. Louise Slaughter \(D-NY\)](#)—The amendment directs the CDC to conduct a study to determine how the additional payments are affecting the development of drug resistance.
- 6) [Rep. Michael Fitzpatrick \(R-PA\)](#)—The amendment expresses a sense of Congress 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.
- 7) [Rep. Jared Polis \(D-CO\)](#)—The amendment directs the Food and Drug Administration 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.
- 8) [Rep. Sheila Jackson Lee \(D-TX\)](#)—The amendment directs the Secretary of Health and Human Services to conduct outreach to Historically Black Colleges and Universities; Hispanic Serving

Institutions; Native American Colleges; and rural Colleges to ensure that health professionals from underrepresented populations are aware of research opportunities under this Act.

STAFF CONTACT

For questions or further information please contact [Jerry White](#) with the House Republican Policy Committee by email or at 5-0190.