Proposed FDA Work Plan for 21st Century Cures Act Innovation Account Activities

Prepared for Review by the FDA Science Board
As Required by Section 1002 of the 21st Century Cures Act (Public Law 114-255)

Introduction

Title I, section 1002 of the 21st Century Cures Act (Cures Act) establishes an "FDA Innovation Account" for Fiscal Year (FY) 2017 – FY 2025 and authorizes funding, subject to the annual appropriation process, to be used by the Food and Drug Administration (FDA or the Agency) to carry out the requirements of designated provisions of Title III of the Cures Act. Section 1002 also requires FDA to develop a work plan for the allocation of any Innovation Account funds that may be provided through appropriations. Prior to submitting the work plan to Congress, FDA must seek recommendations from the FDA Science Board on the proposed allocation of funds and contents of the work plan. Such recommendations are to be included in the work plan when submitted to Congress. This work plan is due to Congress within 180 days of enactment of the Cures Act (June 11, 2017). In future years, FDA is required to submit annual updates on the activities conducted using any Innovation Account funds that may be appropriated. This document provides the Science Board with background on the Cures Act and explains the mandated scope of the work plan. Part II of this document presents, for the Science Board's review, the proposed work plan, including FDA's proposed allocation of authorized Innovation Account funds, if appropriated.

Background

The Cures Act was enacted into law on December 13, 2016, after a bipartisan, multi-year effort. The Cures Act primarily affects activities of the Department of Health and Human Services (HHS) and its agencies. Included in the Cures Act are provisions to help accelerate medical product innovation while reducing regulatory burden; to increase efforts for critical scientific and methodological research; and to increase the involvement of patients and their perspectives in research and the medical product development process. The law also aims to lessen administrative burdens for researchers supported by the federal government; to improve the provision of mental health services; and to provide direct financial support for states addressing opioid abuse.

Title III of the Cures Act is specifically focused on medical product development activities regulated by FDA, with all but a few of the fifty-seven sections under Title III directly requiring FDA action or involvement.[1] This title includes authorities FDA can use to help modernize drug, biological, and

[1] In other Cures Act titles not focused on FDA, the Agency is required to provide consultation and serve on working groups, headed by other HHS agencies. These include, among others, consultation with the National Institutes of Health (NIH) on

device product development and review, and to create greater efficiencies and predictability in product development and review. The Cures Act also improves FDA's ability to hire and retain scientific, technical, and professional experts in specialized areas. As preventive, diagnostic, therapeutic, and analytical methods become more complex, these experts will help FDA approve products and patients access products more quickly with continued assurance from high quality evidence that medical products are safe and effective for their intended uses.

Scope of This Work Plan

Congress authorized annual funding amounts for the Innovation Account as shown in the following table, and specified that such funds, if appropriated, may be used to support FDA's efforts to implement subtitles A through F and section 3073 of the Cures Act (described below).

Title I, Section 1002 of the Cures Act[2]

FDA Innovation Account Funds Authorized – Subject to Yearly Appropriation									
Fiscal Year (FY):	2017	2018	2019	2020	2021	2022	2023	2024	2025
$ (*in millions*)	20	60	70	75	70	50	50	50	55

The work plan in Part II identifies the proposed allocation of potential funds for projects that fall within the subtitles and sections identified in the Cures Act as eligible for any Innovation Account funds. Among these, Agency leadership identified a set of principles (see Charge to the Science Board, Part I) and set priorities. Each medical product center and other affected FDA offices identified funding needs to carry out the statutory requirements and activities within the eligible subtitles and sections. The resulting proposals were evaluated and prioritized collectively to identify those projects with the greatest need for innovation funds, the highest priority for action, and to ensure the total of the funding requests did not exceed the authorized Innovation Account levels. The proposed work plan also reflects the Agency's top priorities and balances various funding streams available to implement the Cures Act, including medical product user fees and any Innovation Account funds that Congress may provide through appropriations.

The resulting proposed work plan, contained in Part II, provides the list of subtitles and sections for which Innovation Account funds could be allocated, if appropriated, and includes a description of the necessary work and justification for the allocation of funds. The Cures Act includes provisions that have the potential to have far-reaching effects on scientific advancements in medical product development. The speed at which science is evolving is unprecedented – creating an era of biomedical discovery and innovation. Given the significant changes in medicine and science and other factors, including the Agency's other mission-critical work, FDA believes it is prudent for the work plan to preserve the Agency's ability in future years to take a flexible approach to implementing the Cures Act. However, if innovation funds are appropriated on an annual basis, FDA is committed to undertaking a yearly planning and prioritization exercise to identify activities eligible for the Innovation Account funds.

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research on pregnant and lactating women, tick-borne diseases, animal care and research, and certain activities related to the NIH ClinicalTrials.gov data bank.

[2] Details in the Tables in this document may not add to the totals due to rounding.

Cures Act Implementation

The Agency proposes to allocate the authorized Innovation Account amounts to the activities that represent the best opportunity to achieve the goals of the Cures Act in conjunction with other funding sources subject to their availability. Consequently, FDA's proposed allocation does not spread the Innovation Account funds across all eligible sections. Some eligible provisions may assist FDA in carrying out its responsibilities but do not require any specific investment in new or expanded program activities. Others complement projects and commitments under current or anticipated reauthorized user fee programs and could be funded in part through some user fee resources subject to the availability of funds. Still others dovetail with on-going work supported by budget authority. For example:

- Section 3003 exempts certain voluntary surveys from the Paperwork Reduction Act, and thus does not require implementation funds.

- Implementation of some provisions related to regenerative advanced therapies (sections 3034, 3035) is well underway and being accomplished without a request for innovation funds.

- The work plan does not include a proposed allocation of innovation funds for FDA related activities in Subtitle E such as Antimicrobial Resistance Monitoring (section 3041) (primarily handled by the Centers for Disease Control and Prevention) or the Limited Population Pathway (section 3042), because work on these activities will be conducted using other resources subject to their availability.

- Under the Medical Device Innovation subtitle, the provisions on Classification Panels (section 3055) and Cleaning Instructions and Validation Data Requirement (section 3059) are not included in the work plan because the Agency anticipates using other resources subject to their availability.

- FDA is not requesting innovation funds to help support the GAO (Government Accountability Office) review of FDA priority review programs required by section 3014, because this effort will be incorporated in the Agency's regular work with GAO.

Since the FDA work plan is mandated by section 1002 to cover only proposed uses of any Innovation Account funds, the above Cures Act sections are not part of the proposed work plan allocations. The full list of Cures Act Title III activities eligible for Innovation Account funds is in the Appendix. FDA remains committed to responsibly implementing the Cures Act, regardless of whether or not particular provisions are covered by this work plan. Further, the proposed allocations of any Innovation Account funds will not necessarily cover the cost of full implementation. In many cases, a mixed funding model (Innovation Account funds plus other funds) may best support implementation. As required by section 1002, any proposed use of Innovation Account funds, even if such funds would only provide partial support for implementation of a particular section, appears in the work plan.

The eligible activities and allocation plan are contingent upon the Innovation Account funds being appropriated each year at the levels authorized.

Part I: Charge to FDA Science Board

In the Cures Act, Congress requested "recommendations from the Science Board to the Food and Drug Administration, on the proposed allocation of funds … and on the contents of the proposed work plan."

The Cures Act requires FDA to allocate Innovation Account funds for identified eligible activities. Innovation Account funds are authorized, but only available to FDA if appropriated every year by Congress. Each medical product center and other affected FDA offices identified proposed activities and associated potential Innovation Account resources needed to carry out the Cures Act statutory requirements in the eligible subtitles and sections. The resulting proposals were evaluated and prioritized according to the following criteria:

- Provisions that present the greatest opportunity for FDA to foster innovation and integrate advances in biological sciences, engineering, information technology, and data science, to most directly improve the Agency's product review tools and processes.
- Provisions that address the greatest need for scientific modernization.
- Provisions that have the most immediate impact on delivery of services to patients, the medical product industry, academia, and health professionals.
- Provisions for which other funds may not be available.

Together, these criteria were used to prioritize activities that could better equip FDA to advise sponsors on, and otherwise facilitate, the efficient development of new products, and to more effectively and efficiently review them. The proposals were reviewed and prioritized collectively to ensure the total proposed allocations did not exceed the annual Innovation Account amounts authorized to be appropriated FY 2017- FY 2025.

FDA requests that the Science Board review the proposed work plan and provide recommendations for FDA's consideration in preparing the final work plan that the Agency is required to submit to Congress.

In conducting its review and preparing recommendations, FDA requests that the Science Board address the following questions within the context of the information provided above:

1. Are the criteria used by FDA to prioritize the proposed allocation of funds appropriate?
2. Are the proposed activities reasonably likely to contribute to successful achievement of the Cures Act requirements?

Part II. Proposed FDA Work Plan Activities and Allocations

Subtitle A – Patient-Focused Drug Development

Section 3001. Patient Experience Data
Section 3002. Patient-Focused Drug Development Guidance
Section 3004. Report on Patient Experience Drug Development

The Cures Act emphasizes the need for patient engagement and directs the Agency to include the patient's voice in drug development and review. Section 3001 requires FDA to make public a brief statement regarding whether and how patient experience data and related information that was submitted, if any, was used in the review of a drug or biologic marketing application. Section 3002

requires FDA to issue one or more guidances for the purposes of drug development and regulatory decision making. Guidance should address such issues as acceptable methodological approaches for collecting, measuring, and analyzing patient experience data. Section 3004 directs FDA to issue reports at specified intervals assessing the use of patient experience data in regulatory decision making, especially focusing on the review of patient experience data and information on patient-focused drug development tools as part of approved applications. In implementing these provisions FDA aims to facilitate a more systematic gathering and use of patients' perspectives on their disease/condition and available therapies to treat their disease/condition. The work plan proposes to use Innovation Account funds to implement certain elements of these provisions.[3]

FDA Innovation Account Proposed Allocation – Subject to Yearly Appropriation Subtitle A – Patient-Focused Drug Development Sections 3001, 3002, 3004									
Fiscal Year (FY):	2017	2018	2019	2020	2021	2022	2023	2024	2025
$ (*in millions*)	-	2.3	2.5	3.2	3.6	3.3	3.3	3.4	4.2

Subtitle B – Advancing New Drug Therapies

Section 3011. Qualification of Drug Development Tools

This section requires FDA to establish a qualification process for drug development tools (DDTs) (e.g., biomarkers, clinical outcome assessments) for proposed contexts of use. FDA must develop a new regulatory process under the Cures Act to qualify DDTs in order to facilitate timely and consistent review of DDT qualification submissions and publicly disseminate broader information about DDTs under review and following a qualification determination. Once a DDT is qualified under this new process, any sponsor may use it for its qualified context of use to support an application for approval or licensure of a drug or to support the investigational use of a drug.

Expert FDA staff and contractors will help develop evidentiary criteria needed to support qualification, develop regulatory informatics platforms, and integrate new review processes. This must occur quickly to ensure FDA can meet its obligations under this section within statutory timeframes, including developing and issuing guidance outlining procedures for the qualification process, holding public meetings, and posting public reports. Once fully implemented, this section has the potential to transform drug development and review.

Section 3012. Targeted Drugs for Rare Diseases

This section is intended to facilitate the development, review, and approval of genetically targeted drugs and variant protein targeted drugs intended to address an unmet need in one or more patient subgroups

[3] The Agency will strengthen its staff with clinical, statistical, psychometric, and health outcomes research expertise, incorporating these staff into review teams during drug development and application review where sponsors intend to use patient input as part of the development program. The guidance development work under section 3002 is a top priority for the Secretary and for the Agency, both to fulfill the statutory mandate and meet the needs of patients. In view of the close alignment of the content of these statutory requirements and the commitments for guidance proposed under the Prescription Drug User Fee Act (PDUFA) VI, FDA anticipates relying on PDUFA VI fee funding to support the majority of this work.

with respect to rare diseases or conditions that are serious or life-threatening. Under this authority, and consistent with applicable statutory standards related to drug and biological products, a sponsor of an application for a genetically targeted drug or a variant protein targeted drug may rely upon data and information previously submitted by the same sponsor (or by another sponsor who has given the applicant a contractual right of reference to such data and information) in another application. Expert FDA staff will support review activities associated with this section.

Section 3013. Reauthorization of Program to Encourage Treatments for Rare Pediatric Diseases

This provision extends the priority review voucher program for sponsors of approved rare pediatric diseases product applications that meet certain criteria intended to encourage the development of safe and effective products for rare pediatric diseases. The voucher can be redeemed by the sponsor to receive a priority review of a subsequent marketing application for a different product or the voucher can be transferred to another sponsor. "Rare pediatric disease" means a disease that is a serious or life-threatening disease in which the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years (including neonates, infants, children, and adolescents) and the disease is a rare disease or condition, meeting the definition within section 526 of the Federal Food, Drug and Cosmetic (FD&C) Act.

For FY 2018-FY 2020, expert FDA staff will develop draft and final guidance; review rare pediatric disease designation requests; improve IT and other systems; and manage the administration of the program which has seen increasing requests for designations and is expected to continue to increase.

Section 3016. Grants for Studying Continuous Manufacturing

This section allows FDA to issue grants to study continuous manufacturing of drugs and biological products and similar innovative monitoring and control techniques. Continuous manufacturing is a new and exciting technology that is being used in the pharmaceutical industry instead of "batch" technology, a process that involves many stops and starts in a series of manufacturing steps. Not only can these breaks cause inefficiencies and delays, they also can increase the risk of introducing human error into the manufacturing process and defects in the finished product.

Continuous manufacturing has significant potential to improve the agility, flexibility, cost, and robustness in the development of manufacturing processes for both small-molecule drugs and biotechnology products. In contrast to batch technology, continuous manufacturing uses an uninterrupted process, eliminating the breaks between manufacturing steps, thereby decreasing the possibility of introducing human error during the stops and starts of the batch process. For this reason, continuous manufacturing is generally thought to be more reliable and safer. In addition, more efficient production of quality drug and biological products can drive down manufacturing costs, potentially resulting in lower drug prices. Likewise, continuous manufacturing can allow manufacturers to both prevent and respond to drug shortage and recall events.

Expert FDA staff will issue grants to enhance knowledge of novel continuous manufacturing technologies, and develop well-defined scientific standards and policies for clearly articulating how the Agency will evaluate these technologies as part of regulatory submissions for new drugs, generic drugs, biotechnology products, and biosimilars.

FDA Innovation Account Proposed Allocation – Subject to Yearly Appropriation Subtitle B – Advancing New Drug Therapies Sections 3011, 3012, 3013, 3016									
Fiscal Year (FY):	2017	2018	2019	2020	2021	2022	2023	2024	2025
$ (*in millions*)	4.0	14.2	13.1	11.2	11.3	9.7	9.8	10.3	10.7

Subtitle C – Modern Trial Design and Evidence Development

Section 3021. Novel Clinical Trial Designs

This section directs FDA to assist sponsors in incorporating complex adaptive and other novel trial designs into proposed clinical protocols and applications for new drugs and biological products in order to facilitate more efficient product development. To accomplish this FDA must hold a public meeting 18 months after the date of enactment of the Cures Act and issue guidance on, among other things, how to use such novel trial designs, how they can help to satisfy the substantial evidence standard, and recommended analysis methodologies.

FDA expert staff will plan and conduct the public meeting, further develop novel clinical trial designs and approaches, and draft the required guidance.

Section 3022. Real World Evidence

This section directs FDA to establish a program to evaluate the potential use of real world evidence to help support the approval of a new indication for an already approved drug or to help support or satisfy post approval study requirements. Real world evidence is defined as data regarding the usage, or the potential benefits or risks, of a drug derived from sources other than randomized clinical trials. Real world evidence can be derived from a variety of sources relating to the delivery of healthcare and its outcomes, including electronic health records, claims and billing data, and product and disease registries. Use of such evidence has the potential to allow researchers to answer questions about treatment effects and outcomes efficiently, saving time and money while yielding answers relevant to broader populations of patients than would be possible in a specialized research environment. This could help streamline clinical development and help inform the safe and effective use of products. Expert FDA staff with expertise in statistics, data science, meta-analysis, clinical outcomes research, and other areas will develop the framework and methodologies for evaluating the use of real world evidence, draft guidance, and hold a workshop on using real world evidence in regulatory decision making.

Section 3023. Protection of Human Research Subjects

Within three years of enactment of the Cures Act, FDA's human subject regulations are required to be harmonized, to the extent practicable, with HHS's Common Rule (human subject regulations applicable to certain federally conducted or supported research). These harmonization activities will be designed to, among other things, increase efficiencies of the clinical trial system, reduce ambiguity in interpretation of FDA and HHS regulations, protect vulnerable populations, and alleviate burden on clinical investigators. After the rulemaking is effective, and as a result of the harmonization, FDA will be required to conduct periodic updates and reviews of its regulations on various provisions because of certain requirements of the new Common Rule regulations. Subsequent to the rulemaking it will be

necessary to revise or create relevant guidance (currently estimated to include at least five guidance documents), forms, training, and assistance regarding the revised regulations. To accomplish this rulemaking, including contractual work and other necessary work subsequent to the effective date of the rule, FDA will use experienced staff familiar with the rulemaking and harmonization process.

Section 3024. Informed Consent Waiver or Alteration for Clinical Investigations

This provision changes the law and enables FDA regulations to allow for Institutional Review Board (IRB) waiver of informed consent for certain minimal risk research. The ability to waive informed consent for certain minimal risk research is important to the conduct of studies that could contribute substantially to the development of products to diagnose or treat diseases/conditions or address unmet medical needs. The waiver also would help enable the conduct of certain comparative effectiveness research in cluster randomized trials, as well as other types of analyses of large identifiable data sets, including some patient centered data.

To implement this provision FDA will need to issue proposed and final rules to revise FDA's regulations; and issue guidance. FDA will use highly experienced expert FDA staff with regulation and guidance development expertise to lead these efforts.

FDA Innovation Account Proposed Allocation – Subject to Yearly Appropriation Subtitle C – Modern Trial Design and Evidence Development Sections 3021, 3022, 3023, 3024									
Fiscal Year (FY):	2017	2018	2019	2020	2021	2022	2023	2024	2025
$ (*in millions*)	2.9	4.6	8.2	10.8	8.0	6.0	6.1	5.9	6.3

Subtitle D –Patient Access to Therapies and Information

Section 3031. Summary Level Review

This section allows FDA to rely on qualified data summaries to support approval of a supplemental application for a qualified use of a drug. Data summaries may be used if the drug has existing safety data that is available and acceptable to FDA as part of the supplemental application and if the full data used to develop the qualified data summaries are submitted in the application. This may save considerable time and reviewer resources because Agency reviewers may not need to reexamine the primary raw datasets or conduct additional analyses of the data. The initial focus of FDA's implementation of this provision will be on supplemental applications for cancer drugs.

Expert FDA staff in the Oncology Center of Excellence will develop policies and procedures for implementation of summary level review for appropriate oncology applications for drugs and biologics products.

Section 3033. Accelerated Approval for Regenerative Advanced Therapies

This section allows FDA to build on existing expedited programs available to regenerative medicine products by establishing a new program to foster their development and approval through the new Regenerative Medicine Advanced Therapy (RMAT) Designation. Upon RMAT designation, sponsors

of such products are eligible for increased and earlier interactions with FDA to help facilitate an efficient development program, including discussion of which approval pathways would be appropriate and the size of clinical trials. In order to support effective development and review of these products, the Center for Biologics Evaluation and Research (CBER) will provide continual regenerative medicine advanced therapies training for all Center staff who may work on these products. Robust training is crucial to ensure that FDA reviewers are well versed in the latest practices in this rapidly evolving field of medicine.

Section 3036. Standards for Regenerative Medicine and Regenerative Advanced Therapies

This section requires the establishment of standards and consensus definitions to support the development and review of regenerative medicine therapies, including with respect to the manufacturing processes and controls of such products.

In order to meet the requirements of the Cures Act, CBER will use innovation funds to facilitate a public process with the National Institute of Standards and Technology and other stakeholders to coordinate and prioritize the development of standards and consensus definitions of terms. Such standards and terms will help foster the development, evaluation, and review of regenerative medicine therapies, including with respect to the manufacturing processes and controls for such products. Innovation funds will support expert FDA staff engaged in this work, as well as help facilitate long-term engagement with stakeholders on regenerative medicine standards development and consensus definitions through the creation of a public-private partnership.

Section 3038. Combination Product Innovation

This section updates and modernizes FDA's regulation of combination products. It requires FDA to provide clear rationales for combination product designations, ensure timely inter-center coordination and work with sponsors to help clarify establish clear premarket and postmarket expectations. Under this legislation, a sponsor can request engagement with FDA including a combination product agreement meeting to discuss, among other things, standards and requirements for market approval or clearance. FDA must issue guidance to help facilitate such meetings.

The legislation authorizes combination product sponsors, in certain circumstances, to rely on FDA's prior findings of safety or effectiveness or substantial equivalence. It also mandates that FDA develop, publish, and maintain a listing of efficiencies for complying with current good manufacturing requirements for combination products. Additionally, the legislation enhances existing oversight functions for the program within FDA and adds additional elements for FDA's annual reports to Congress about the program.

FDA expert staff will conduct assessments of existing policies, procedures, and information technology systems and to make necessary modifications; establish new tracking systems; and support program implementation. Staff also must develop and revise guidances, rules, notices, SOP's, training, and other tools necessary to implement the section.

These changes will facilitate efficient, consistent, and predictable combination product designation and regulation.

FDA Innovation Account Proposed Allocation – Subject to Yearly Appropriation Subtitle D – Patient Access to Therapies and Information Sections 3031, 3033, 3036, 3038									
Fiscal Year (FY):	2017	2018	2019	2020	2021	2022	2023	2024	2025
$ (*in millions*)	7.8	23.9	26.8	29.5	27.9	16.6	17.0	17.0	18.7

Subtitle F – Medical Device Innovation

Section 3051. Breakthrough Devices

This section writes into law and expands FDA's Expedited Access Pathway program, which allows for expedited development and review of devices that represent breakthrough technologies for life threatening or irreversibly debilitating diseases/conditions. The Breakthrough Devices program requires frequent and extensive interactions between device companies and FDA staff during the device development phase, as well as priority review for breakthrough medical devices.

FDA estimates that this program will grow at a rate as high as 20 percent per year over the next 10 years. FDA expert staff will accommodate the increased workload and will need to acquire the IT systems needed to fully implement the program. The program will accelerate patient access to these lifesaving therapies.

Section 3052. Humanitarian Device Exemption

This section raises the eligibility cap for a humanitarian device exemption, which allows devices intended to benefit patients with a rare disease/condition to be marketed by demonstrating, among other things, safety and probable benefit (rather than safety and effectiveness), from 4,000 to not more than 8,000 individuals in the United States. FDA must issue guidance that defines the criteria for establishing "probable benefit."

FDA expert staff will accommodate the increased workload, and will need to acquire the IT systems needed to implement and track the impact of this change on the development of devices for rare diseases/conditions. This change will expand patient access to needed devices, and is expected to encourage development of more devices for rare diseases/conditions.

Section 3053. Recognition of Standards

This provision requires FDA to make a determination on requests for recognition of all or part of standards established by nationally or internationally recognized standards organizations for the purposes of conducting device reviews, within 60 days. FDA's rationale for these decisions must be made public, as appropriate, and relevant FDA employees must be trained in use of recognized standards in premarket device review.

FDA expert staff will coordinate review of submitted standards across review divisions, and respond to external information requests regarding the recognition of new standards. FDA will also expand its participation in national and international standard setting organizations across all device areas (e.g., cyber security, robotics, software, and additive manufacturing). This standards recognition work will require operating funds to support travel for FDA participants. Greater use of nationally and

internationally recognized standards will promote more efficient and consistent device review, and will reduce the burden on manufacturers from inconsistent standards in use by different international regulatory authorities.

Section 3056. Institutional Review Board Flexibility

This section eliminates the requirement that device trial sponsors always use a local Institutional Review Board (IRB). This change will provide flexibility and promote efficiencies in the clinical trial system. This also will help to reduce burden on investigators. Several key guidance documents will be developed related to the use of centralized IRBs.

Section 3058. Least Burdensome Device Review

This provision requires FDA to train relevant employees on application of the "least burdensome" principle in device review, audit the training, and periodically assess implementation of the "least burdensome" principles.

FDA will use both expert staff and contractors to conduct these audits. More consistent and meaningful application of the "least burdensome" principle in device review will improve review efficiency and consistency, and will reduce the regulatory burdens on manufacturers.

Section 3060. Clarifying Medical Device Software

This provision exempts specific categories of medical software from FDA regulation based on their low levels of risk to patients. However, the provision provides a process by which exempted software will not be excluded from FDA's jurisdiction based on a finding from the Secretary that such software function would be reasonably likely to have serious adverse health consequences. FDA expert staff will implement a system for surveillance of the exempted products or functions. Surveillance capabilities would benefit the public by ensuring that exempted software products or functions do not pose safety concerns or contribute to serious adverse health consequences.

FDA Innovation Account Proposed Allocation – Subject to Yearly Appropriation Subtitle F – Medical Device Innovations Sections 3051, 3052, 3053, 3056, 3058, 3060									
Fiscal Year (FY):	2017	2018	2019	2020	2021	2022	2023	2024	2025
$ (*in millions*)	5.3	12.3	15.6	16.1	14.9	11.0	10.9	10.7	12.2

Subtitle G - Improving Scientific Expertise and Outreach at FDA

Section 3073. Intercenter Institutes

This section requires FDA to establish one or more intercenter institute(s) to help develop and implement processes for coordination of activities in major disease areas between the drug, biologics, and device centers.

FDA has established the Oncology Center of Excellence (OCE) to create a unified policy approach and clinical review for all drugs, biologics, and devices used in medical oncology. It will leverage the combined talents and skills of all FDA regulatory scientists and reviewers who work in medical oncology product review. OCE will also serve as a single point of contact for external stakeholders for our work in cancer, including professional societies and patient advocacy groups.

FDA medical and professional staff will coordinate review of oncology product applications across the medical product centers, policy development, and collaboration with external stakeholders. This Center of Excellence will help expedite the development of oncology and hematology medical products and support an integrated approach in the clinical evaluation of drugs, biologics, and devices for the treatment of cancer.

FDA Innovation Account Proposed Allocation – Subject to Yearly Appropriation Subtitle G – Improving Scientific Expertise and Outreach at FDA Section 3073									
Fiscal Year (FY):	2017	2018	2019	2020	2021	2022	2023	2024	2025
$ (*in millions*)	-	2.8	3.7	4.1	4.3	3.4	2.9	2.8	3.0

Conclusion

The proposed FDA work plan describes activities that are intended to successfully achieve the Cures Act requirements in areas that are a high priority for any Innovation Account funding that is appropriated. Together with other funding sources, as available, FDA's proposed Innovation Account funding allocations can help chart a path for advancing medical product development and reviews and help bring innovative new therapies and products to patients and health care providers in a more timely and efficient manner.

Appendix

Complete List of Cures Act Title III Activities Eligible for FDA Innovation Account Funds	
Subtitle A - Patient Focused Drug Development	
Sec. 3001	Patient experience data.
Sec. 3002	Patient-focused drug development guidance.
Sec. 3003	Streamlining patient input.
Sec. 3004	Report on patient experience drug development.
Subtitle B - Advancing New Drug Therapies	
Sec. 3011	Qualification of drug development tools.
Sec. 3012	Targeted drugs for rare diseases.
Sec. 3013	Reauthorization of program to encourage treatments for rare pediatric diseases.
Sec. 3014	GAO study of priority review voucher programs.
Sec. 3015	Amendments to the Orphan Drug grants.
Sec. 3016	Grants for studying continuous drug manufacturing.
Subtitle C - Modern Trial Design and Evidence Development	
Sec. 3021	Novel clinical trial designs.
Sec. 3022	Real world evidence.
Sec. 3023	Protection of human research subjects.
Sec. 3024	Informed consent waiver or alteration for clinical investigations.
Subtitle D - Patient Access to Therapies and Information	
Sec. 3031	Summary level review.
Sec. 3032	Expanded access policy.
Sec. 3033	Accelerated approval for regenerative advanced therapies.
Sec. 3034	Guidance regarding devices used in the recovery, isolation, or delivery of regenerative advanced therapies.
Sec. 3035	Report on regenerative advanced therapies.
Sec. 3036	Standards for regenerative medicine and regenerative advanced therapies.
Sec. 3037	Health care economic information.
Sec. 3038	Combination product innovation.
Subtitle E - Antimicrobial Innovation and Stewardship	
Sec. 3041	Antimicrobial resistance monitoring.
Sec. 3042	Limited population pathway.
Sec. 3043	Prescribing authority.
Sec. 3044	Susceptibility test interpretive criteria for microorganisms; antimicrobial susceptibility testing devices.
Subtitle F - Medical Device Innovations	
Sec. 3051	Breakthrough devices.
Sec. 3052	Humanitarian device exemption.
Sec. 3053	Recognition of standards.
Sec. 3054	Certain class I and class II devices.
Sec. 3055	Classification panels.
Sec. 3056	Institutional review board flexibility.
Sec. 3057	CLIA waiver improvements.
Sec. 3058	Least burdensome device review.
Sec. 3059	Cleaning instructions and validation data requirement.
Sec. 3060	Clarifying medical software regulation.
Subtitle G - Improving Scientific Expertise and Outreach at FDA	
Sec. 3073	Establishment of Food and Drug Administration Intercenter Institutes.