EXECUTIVE SUMMARY

This Executive Summary describes the fiscal year (FY) 2020 Budget for the U.S. Food and Drug Administration (FDA). FDA is the agency within the U.S. Department of Health and Human Services (HHS) responsible for protecting and promoting public health by ensuring the safety, effectiveness, and security of human and animal drugs, biological products, and medical devices; ensuring the safety of food and feed, cosmetics, and radiation-emitting products; and regulating tobacco products.

RECENT ACCOMPLISHMENTS

FDA delivers significant, quantifiable results that help Americans every day. Here is a selection of recent accomplishments.

Reducing the Burden of Addiction Crises that are Threatening American Families

New Actions to Confront the Opioid Crisis

FDA is committed to finding new approaches to address emerging issues of the opioid crisis facing the Nation. We redoubled that commitment by taking steps to help those currently addicted to opioids, while taking steps to help prevent new cases of addiction, through FDA's four priority areas:

- Decreasing Exposure and Preventing New Addiction
- Supporting the Treatment of Those with Opioid Use Disorder
- Fostering the Development of Novel Pain Treatment Therapies
- Improving Enforcement & Assessing Benefit-Risk.

In a public hearing held January 2018, FDA received stakeholder input on how FDA might, under its REMS authority, improve the safe use of opioid analgesics by curbing overprescribing to decrease the occurrence of new addictions and limit misuse and abuse of opioid analgesics.

Also, in January 2018, FDA took steps to address concerns regarding intentionally misusing and abusing high doses of loperamide (Imodium), an anti-diarrhea medicine. FDA issued a Drug Safety Communication and worked with sponsors to update drug labeling and packaging.

In 2018, FDA held two Patient Focused Drug Development (PFDD) public meetings on opioid use disorder and chronic pain. At the PFDD for Opioid Use Disorder held April 2018, FDA learned from patients' perspectives on OUD, including the effects on their health and well-being that have the greatest impact on daily life, their experience using prescription medical treatments and other treatments or therapies for OUD, and challenges or barriers to accessing or using medical treatments for OUD.

At the PFDD for Chronic Pain held July 2018, FDA heard patients' perspectives on chronic pain, views on treatment approaches, and challenges or barriers to accessing treatments for chronic pain. These meetings provided FDA with important insights on how to best take vigorous steps to confront addiction while also protecting the needs of these patients.

Furthermore, in June 2018, FDA convened internet stakeholders, government entities, academic researchers, and advocacy groups at a one-day Online Opioid Summit to discuss ways to

collaboratively take stronger action in combatting the opioid crisis by reducing the availability of illicit opioids online.

FDA approved the finalized Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS) to include immediate-release opioids, not already covered by another REMS program. The Opioid Analgesic REMS is one strategy among multiple national and state efforts to reduce the risk of abuse, misuse, addiction, overdose, and deaths due to prescription opioid analgesics. The REMS requires companies to provide health care providers with continuing education on the fundamentals of acute and chronic pain management and provides a contextual framework for the safe prescribing of opioid analgesics.

FDA also approved Lucemyra (lofexidine hydrochloride), the first non-opioid treatment for the mitigation of withdrawal symptoms associated with abrupt discontinuation of opioids.

In addition, FDA issued the draft guidance for industry, "Opioid Use Disorder: Endpoints for Demonstrating Effectiveness of Drugs for Medication-Assisted Treatment," which is intended to assist sponsors in developing drugs for medication-assisted treatment of opioid use disorder (OUD) and addresses the clinical endpoints acceptable to demonstrate effectiveness of such drugs. FDA also finalized the guidance, "Opioid Dependence: Developing Buprenorphine Depot Products for Treatment," which reflects the agency's current thinking regarding drug development and trial design issues relevant to the study of depot buprenorphine products (i.e. modified-release products for injection or implantation).

To help advance the development of evidence-based guidelines for appropriate opioid analgesic prescribing for acute pain resulting from specific conditions or procedures, FDA awarded a contract to the National Academies of Sciences, Engineering, and Medicine (NASEM) in August 2018. Currently, work is underway to understand what evidence is needed to ensure that all current and future clinical practice guidelines for opioid analgesic prescribing are sufficient, and what research is needed to generate that evidence in a practical and feasible manner.

In December 2018, FDA conducted an advisory committee meeting to discuss naloxone co-prescribing, where FDA asked for input and advice on strategies to increase the availability of naloxone products intended for use in the community. This meeting built upon past discussions regarding naloxone products and their availability in the community to reduce opioid overdose fatalities, which were held in 2012, 2015, and 2016. This year, FDA plans to announce the results of our Model Drug Facts Label (DFL) Comprehension Study for OTC Naloxone, including posting the model DFL and the supporting FDA review, to jumpstart the development of OTC naloxone products to promote wider access to this medicine. This is the first time FDA has proactively developed and tested a DFL for a drug to initiate the development of an OTC product.

Additionally, on May 30, 2018, the FDA announced the launch of the Devices to Prevent and Treat Opioid Use Disorder Challenge to spur the development of medical devices, including digital health and diagnostic devices, to help combat the opioid crisis and to help prevent and treat Opioid Use Disorder—a serious health condition which can be a devastating outcome of opioid drug use.

This challenge will provide those companies that are selected by the FDA under this new program with the opportunity to work closely with the agency to accelerate the development and review of their innovative products. The goal is to provide additional incentives for product

developers to invest in products that can address aspects of the addiction crisis and advance the development of promising technologies. FDA received more than 250 applications from medical device developers and based on these criteria, eight submissions were selected.

The engagement and participation from so many developers is indicative of the dire need we face for new ways to treat this disease, and that medical devices, including digital health technologies, like mobile medical apps, will play a critical role in the FDA's all hands on deck approach to confronting the opioid epidemic. In fact, in the past few years, FDA has cleared, granted, or approved more than 200 devices related to the treatment or management of pain, including 10 with new or novel technologies.

Tobacco Regulation

Tobacco product regulation represents one of FDA's greatest opportunities to save lives. FDA's comprehensive plan for tobacco and nicotine regulation serves as a multi-year roadmap to protect youth and significantly reduce tobacco-related disease and death. The approach places nicotine, and the issue of addiction, at the center of the agency's tobacco regulation efforts. The goal is to ensure that the FDA has the proper scientific and regulatory foundation to efficiently and effectively implement the Family Smoking Prevention and Tobacco Control Act. Key features of the comprehensive plan include:

- regulatory policies on addiction, appeal and cessation
- Youth Tobacco Prevention Plan: announced April 24, 2018, to reduce access to - and use of - tobacco products, particularly e-cigarettes
- science-based review of tobacco products.

According to new findings from the 2018 National Youth Tobacco Survey (NYTS), there has been a dramatic increase in youth use of e-cigarettes and other electronic nicotine delivery systems (ENDS): From 2017 to 2018, there was a 78 percent increase in current e-cigarette use among high school students and a 48 percent increase among middle school students.

Therefore, on November 15, 2018, Commissioner Gottlieb outlined updates to FDA's policy framework to address the large increase in youth use of tobacco products. Our focus is on what appear to be the central issues—youth appeal and youth access to flavored tobacco products. FDA will be taking steps on the following product categories:

- flavored ENDS products (other than tobacco, mint, and menthol flavors or non-flavored products) that are not sold in an age-restricted, in-person location;
- flavored ENDS products (other than tobacco, mint, and menthol flavors or non-flavored products) that are sold online without heightened age verification processes;
- flavored cigars;
- ENDS products that are marketed to kids; and
- menthol in combustible tobacco products, including cigarettes and cigars.

This policy reflects FDA's aim of striking the right balance between closing the on ramp for kids to become addicted to nicotine while maintaining access to potentially less harmful forms of nicotine delivery for adult smokers seeking to transition away from combustible tobacco products.

In the largest coordinated enforcement effort in the FDA's history, the agency announced in September it had issued more than 1,300 warning letters and civil money penalty complaints (fines) to retailers who illegally sold e-cigarette products to minors during a nationwide, undercover blitz of brick-and-mortar and online stores.

Leveraging Innovation and Competition to Improve Health Care, Broaden Access, and Advance Public Health Goals

Advancing Drug and Medical Device Safety and Innovation

In the area of drug safety, on May 23, 2018, FDA announced that over-the-counter (OTC) oral health products containing the pain reliever benzocaine for the temporary relief of sore gums due to teething in infants or children should no longer be marketed and is asking companies to stop selling these products for such use. If companies do not comply, the FDA will initiate a regulatory action to remove these products from the market. Also, the agency is requesting that companies add new warnings to all other benzocaine oral health products to describe certain serious risks.

To support continued innovation in gene therapy products and provide clear recommendations to sponsors and researchers of novel therapies, FDA issued six human gene therapy guidances in July 2018. These guidances serve as the building blocks of a modern, comprehensive framework to help advance the field of human gene therapy while making sure new products meet the FDA's standards for safety and effectiveness. Three of these guidances are disease specific and three provide comprehensive updates to existing guidances that address manufacturing issues related to gene therapy.

The July 2018 approval of TPOXX (tecovirimat), the first drug with an indication for the treatment of smallpox, illustrates FDA procedures for facilitating medical countermeasure product development as part of FDA's public health mission. Smallpox as a naturally occurring disease was eradicated decades ago, however there are concerns that the virus could potentially be used as a biothreat agent. During tecovirimat development and review, FDA utilized expedited development and review pathways to enhance efficiency to advance the product's development and approval. The expedited pathways include Fast Track and Orphan Drug designations, Advisory Committee consultation regarding Animal Rule studies, Priority Review, and a Material Threat Medical Countermeasures Priority Review Voucher.

For medical devices, FDA advanced several meaningful initiatives and policy proposals to enhance medical device safety, including the safety of devices cleared through the FDA's 510(k) review process. In April 2018, FDA released its Medical Device Safety Action Plan, and, on November 20, 2018, FDA set an important and ambitious new goal: Ensuring that the FDA remains consistently first among the world's regulatory agencies to identify and act upon safety signals related to medical devices.

FDA also continued to evolve beyond current, passive post-market surveillance system, working to build the National Evaluation System for health Technology (NEST), to effectuate active surveillance and help FDA fulfill its promise of ensuring safer devices for patients. The Agency also continued efforts to strengthen our Coordinated Registry Networks (CRN), as well as our focus on addressing clinical questions on device therapies that are unique to women.

FDA remains equally committed to advancing medical device innovation that can address unmet medical needs to reduce or prevent the adverse health effects from disease. Both objectives are

essential to meeting our public health mission, resulting in more lives saved and improved quality of life. Recent examples of this commitment to improving the safety and quality of life for patients include two novel device approvals from 2018 described below.

In June 2018, FDA expanded the approval of the MiniMed 670G hybrid closed loop system, expanding use of an artificial pancreas to include individuals aged 7 to 13 with Type 1 diabetes and approved a continuous glucose monitoring system with a fully implantable glucose sensor and compatible mobile app.

In March 2018, FDA expanded the approval of a heart valve to include a size small enough to be used in newborn pediatric patients to treat heart defects, making it the smallest mechanical heart valve approved in the world.

By continuing to enhance and implement the right tools and foster an environment that lets the FDA be innovative, while prioritizing patient safety, we'll continue to deliver on our public health mission.

Drug Competition

FDA plays a pivotal role in fostering drug competition through the approval of safe, effective, and lower-cost generic drugs and biosimilars.

FDA is finding innovative ways to help foster competition and provide patients with more access to affordable medications. In May 2017, FDA announced various actions as part of the agency's Drug Competition Action Plan to increase competition in the market for prescription drugs and facilitate entry of lower-cost alternatives.[1]

FDA is currently assessing these comments as it continues to actively identify new initiatives that can enhance efforts to provide more safe, effective, and high-quality generic medicines to the public, and address "gaming," including abuses of the patent system, that exploits rules and loopholes in our system to delay generic approval and thereby extend a drug's monopoly beyond what Congress intended.

To further encourage generic drug development, FDA has:

- Prioritized complex generic drug development and application review
- Published a list of off-patient, off-exclusivity branded drugs
- Enhanced efficiency of submission process for generic drug applicants
- Issued guidance to enhance regulatory certainty for generic drug development and review.

In August 2018, FDA approved the first generic version of the epinephrine EpiPen and EpiPen Jr. auto-injector for the emergency treatment of allergic reactions, including those that are life-threatening – anaphylaxis. This approval advances access to safe and effective generic alternatives once patents and other exclusivities no longer prevent marketing entry. The availability of a generic version of EpiPen means that patients living with severe allergies who require constant access to life-saving epinephrine should have a lower-cost option, as well as another approved product to help protect against potential drug shortages.

[1] Association for Accessible Medicines, 2017 Generic Drug Access and Saving Report in the U.S. (2017). Available at https://accessiblemeds.org/resources/blog/2017-generic-drug-access-and-savings-us-report

The path to developing generic drug-device combination products like this one is challenging. FDA remains committed to providing scientific and regulatory clarity for sponsors seeking to develop complex generics, as well as prioritize the approval of medicines with little or no generic competition as part of FDA's effort to remove barriers to generic development and market entry of critically important medicines. Many of these steps were outlined in the Drug Competition Action Plan.

Also, FDA intends to implement policies and actions to enhance the efficiency of FDA's review of marketing applications for biosimilar and interchangeable products to:

- Increase regulatory certainty for biosimilar manufacturers and other stakeholders
- Educate patients, providers, and payors about biosimilar and interchangeable products
- Reduce the gaming of FDA regulations or other attempts to unfairly delay market competition.

In July 2018, FDA released the Biosimilars Action Plan[2] (BAP). Biologics are used to treat many serious and life-threatening diseases, such as cancer and autoimmune conditions. While less than two percent of Americans use biologics, they represent 40 percent of total spending on prescription drugs. Forging a path to competition for biologics from biosimilars is key to reducing costs and to facilitating more innovation. FDA is also focused on advancing policies that make the process for developing biosimilars more efficient. The Biosimilars Action Plan outlines the steps FDA is taking to achieve these goals. This plan is an important piece of the Administration's bold Blueprint to Lower Drug Prices and demonstrates the progress being made against its deliverables.

DQSA Implementation

Title I - Compounding

In November 2013, after a fungal meningitis outbreak linked to contaminated compounded drugs caused more than 60 deaths and 750 cases of illness, the Drug Quality and Security Act (DQSA) was enacted, providing FDA with additional responsibilities to oversee compounding. Following the enactment of the DQSA, FDA has acted quickly to increase its drug compounding oversight though inspections and enforcement, develop policies regarding the compounding provisions of federal law, convene and obtain input from an advisory committee, collaborate and coordinate with state regulators, and conduct stakeholder outreach.

Since enactment of the DQSA, FDA has completed the following actions:

- Conducted over 600 inspections of compounders, including over 160 inspections of compounders registered as outsourcing facilities
- Issued over 220 warning letters to compounders
- Issued over 200 recall notices regarding compounded drug products
- Issued 23 draft and revised draft guidance documents regarding compounding and related activities (16 of which have been finalized)
- Issued three proposed rules (two of which have been finalized)
- Issued a Federal Register Notice regarding the list of bulk drug substances that may be used in compounding under section 503B

[2] For additional information visit https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm613761.pdf

- Issued a draft and revised draft memorandum of understanding
- Convened eight Pharmacy Compounding Advisory Committee meetings
- Held seven intergovernmental working meetings with state regulatory partners and six listening sessions with more than 75 stakeholders.

Title II - Drug Supply Chain Security Act

The Drug Supply Chain Security Act (DSCSA), outlines critical steps to build an electronic, interoperable system to identify and trace certain human, finished, prescription drug products as they are distributed within the United States by 2023.

Since enactment of the DSCSA, FDA has issued ten draft guidance documents and six final guidances, including two final guidances to assist stakeholders in understanding when a product without a product identifier is grandfathered and when requirements will be enforced. In addition, FDA has held six public meetings as well as multiple stakeholder meetings on various strategies and issues related to enhanced drug distribution security provisions of the DSCSA. FDA continues to develop regulations, standards, policies, and programs to implement the law.[3]

Empowering Consumers and Patients

Protecting Consumers through Modern Regulatory Approaches

FDA faces the challenge of regulating new areas of novel and emerging science, like gene therapy, targeted medicine, and digital health, where traditional approaches to product regulation may not be well suited for such products. To meet these challenges, FDA is taking a fresh look at how to adapt and modernize our approaches to make sure that we are enabling new technology to develop, while maintaining FDA's gold standard for product review and consumer protection.

FDA supports efforts to increase patient safety and the efficiency for manufacturers of medical devices to sell their products globally – while still following high internationally-accepted quality systems – by proposing a new regulation to the existing Quality Systems regulations. And FDA promotes transformational approaches that will enable it to use real-world data in its regulatory decision making.

In support of maintaining FDA's gold standard for product review and consumer protection, FDA took the following actions in 2018 to alert the public and raise awareness regarding safety concerns and violations:

- Took action against stem cell clinics marketing products without FDA approval, putting patients at risk;
- Warned companies making false claims that their unapproved products can treat or cure life-threatening diseases;
- Advanced a new framework for regulating homeopathic products based on consumer risk, and
- Alerted the public to the dangers of unproven and untested products.

[3] For more information on FDA's DSCSA-related activities, please visit https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/default.htm

Strengthening Science and Efficient Risk-Based Decision Making

Food Safety

In March 2018, the FDA Commissioner announced a comprehensive, multi-year Nutrition Innovation Strategy that focuses on reducing preventable death and disease related to poor nutrition. This new strategy gives consumers easier access to nutritious and affordable foods by providing them with information and by supporting industry innovation towards healthier foods.

Key elements of the strategy include modernizing health claims, modernizing ingredient labels and standards of identity, implementing the nutrition facts label and menu labeling requirements, and reducing sodium.

FDA is implementing menu labeling requirements and on May 7, 2018, finalized guidance to provide additional clarity and flexibility to covered establishments. Menu labeling regulations require the disclosure of certain nutritional information for standard menu items in chain restaurants and similar retail food establishments. The finalized guidance addresses concerns that were raised about challenges establishments faced in understanding how to meet their obligations under the new regulations. As of May 7, 2018, consumers now have consistent access to menu labeling information in covered eating establishments across the country.

FDA continues successful implementation of the FDA Food Safety Modernization Act (FSMA). FDA has published more than 20 draft and final guidances related to the FSMA rules including:

- Current Good Manufacturing Practices and Preventive Controls for Human Food;
- Current Good Manufacturing Practices and Preventive Controls for Animal Food;
- Produce Safety;
- Foreign Supplier Verification Program;
- Intentional Adulteration, Sanitary Transportation of Foods, and
- Registration of Food Facilities.

In 2018 FDA has strengthened oversight of imported foods by recognizing four accreditation bodies for the Third Party Accreditation Program and by launching FSMA's Voluntary Qualified Importer Program (VQIP). The Third Party Program and VQIP are two new FSMA tools FDA is using to help ensure that foods imported into the United States are produced in accordance with the same safety standards required of food produced domestically.

OVERVIEW OF THE BUDGET REQUEST

The FY 2020 Budget Request is $6.1 billion, an overall increase of 12 percent or $643.1 million compared to the FY 2019 Annualized Continuing Resolution (CR).[4] The request includes $3.3 billion for budget authority - or $361.9 million compared to the FY 2019 Annualized CR level - and $2.8 billion for user fees - or $281.1 million compared to the FY 2019 Annualized CR level.

All budget displays reflect the FY 2019 implementation of FDA's Working Capital Fund (WCF). As part of implementation, funds are realigned to shift service provider dollars and staff from FDA Headquarters to the Programs. This realignment results in a net reduction of $40.1 million ($18.8M BA / $21.3M UF) / 196 FTEs from FDA Headquarters and redistributes the funding to

[4] Includes a reduction to HHS OIG Transfer. See APT for details.

the Programs that will benefit from the services of the WCF. The APT and related tables have been comparably adjusted to reflect the realignment of: intergovernmental affairs (IGA) FTE to FDA HQ; operational support FTE from FDA HQ to the centers and offices as part of implementation of FDA's Working Capital Fund (WCF); and FDA HQ organizations as per the December 2018 Congressional Notification.

Budget Structure and Strategic Plan Framework

The Budget is described in terms of budget authority and user fees and is broken down into the following major activities.

- **Food Safety** – ensures the food and feed supply is safe, sanitary, wholesome, and accurately labeled, and that cosmetic products are safe and properly labeled.
- **Advancing Safe and Effective Medical Products** – ensures that safe and effective human and animal drugs, biological products, devices, and radiological products are available to improve the health and quality of life for the people in the U.S., including medical countermeasures - the drugs, vaccines, and diagnostic tests to diagnose, treat, and prevent the adverse health consequences associated with chemical, biological, radiological, nuclear (CBRN) agents, and emerging infectious disease threats, like pandemic influenza.
- **Tobacco Regulation** – protects Americans from tobacco-related death and disease by regulating the manufacture, distribution, and marketing of tobacco products, and by educating the public about tobacco products and the dangers their use poses.
- **Infrastructure: Facilities and Rent Investments** – ensures FDA staff have optimally functioning offices and labs across the country to execute the agency's vital public health mission.

The Budget focuses on four strategic priorities:

- *Reduce the burdens of addiction crises* that are threatening American families
- *Leverage innovation and competition* to improve health care, broaden access, and advance public health goals
- *Empower consumers and patients* to make better and more informed decisions about their diets and health; and expand the opportunities to use nutrition to reduce morbidity and mortality from disease
- *Strengthen science and efficient risk-based decision making*

FDA's *Healthy Innovation, Safer Families: FDA's 2018 Strategic Policy Roadmap* provides an overview of some of the key priorities the Agency is pursuing to advance FDA's public health mission.[5]

FY 2020 Request

The FY 2020 budget will invest in new initiatives focused on the most urgent priorities as well as support needed for infrastructure. The BA Crosswalk provides full details of each level. New initiatives are summarized in the following sections by major activity with funding levels identified in parentheses.

[5] https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm591993.htm

FOOD SAFETY (BA $1.4B; UF $0.04B)

The FY 2020 Budget provides $1.4 billion for food safety, an increase of $67 million compared to the FY 2019 Annualized CR. The request includes $1.4 billion for budget authority – an increase of $38.4 million compared to the FY 2019 Annualized CR – and $44.4 million for user fees – an increase of $28.6 million compared to the FY 2019 Annualized CR. The Budget provides funding for FDA priorities for food safety across human and animal products. This request aligns to FDA's Strategic Policy Roadmap priorities to strengthen food safety and empower consumers to make better and more informed decisions about their diets and health.

Strengthening Response Capabilities for Foodborne Outbreaks ($16.3M)

The FY 2020 budget includes $16.3 million to improve signal detection and response timelines for human and animal food contamination and outbreaks of foodborne illness so that contaminated food is detected and removed from the marketplace as quickly as possible, and implements recent OIG recommendations to strengthen FDA's food recall process.

Advancing FSMA ($16.5M)

The FY 2020 budget includes $16.5 million to support FSMA Cooperative Agreements with funding for animal and human foods preventive controls inspections and human foods produce safety inspections through the states cooperative agreement programs (CAPs).

Promoting Innovation and Emerging Technology While Maintaining Product Safety ($36.2M)

The FY 2020 budget includes $36.2 million to ensure that FDA keeps pace with how changes in the marketplace affect the human and animal food supply – including modernizing the regulatory framework for biotechnology products, assessing products in a risk-based manner, providing predictable pathways for commercialization, and enhancing the scientific review of human and animal food ingredients to foster innovative products getting to market and to improve nutrition. This funding level includes establishing new user fee program that would collect $28 million in its first year. FDA will invest $5.0 million in underfunded program areas in Center for Veterinary Medicine (CVM), including the premarket safety review of animal food ingredients to improve review times and eliminate unnecessary burdens to industry. FDA will make additional investments in CFSAN and FDA Headquarters (HQ) ($31.2M) to promote innovation and enhance FDA's ability to review plant and animal biotechnology products and other novel products.

ADVANCING SAFE AND EFFECTIVE MEDICAL PRODUCTS (BA $1.8B; UF $1.9B)

The FY 2020 Budget Request for medical product safety and availability is $3.8 billion, an increase of $428 million above the FY 2019 Annualized CR. The request includes $1.8 billion for budget authority – an increase of $316 million compared to the FY 2019 Annualized CR – and $1.9 billion for user fees – an increase of $112.1 million compared to the FY 2019 Annualized CR. The net BA increase is the result of $386 million in investments in new initiatives and -$70.3 million in adjustments.

The Budget provides funding for FDA priorities for medical product safety and availability. The request aligns to FDA's Strategic Policy Roadmap priorities to reduce the burden of the

addiction crises that are threatening American families and to leverage innovation and competition to improve healthcare, broaden access, and advance public health goals.

Integrated Pathogen Reduction of the Blood Supply ($20.0M)

The FY 2020 budget includes $20.0 million for a pilot program for pathogen inactivation technology which could help protect the blood supply from existing and emerging pathogens and potentially reduce or eliminate donor deferral and/or testing requirements.

Medical Countermeasures ($7.0M)

The FY 2020 budget includes $7.0 million for FDA review and regulatory science capacity to facilitate the development and availability of medical countermeasures to respond to chemical, biological, radiological, nuclear, and emerging infectious disease threats.

Modernize Generic Drug Reviews ($27.0M)

The FY 2020 budget includes $27.0 million to continue to modernize generic drug development by enhancing the efficiency of the review and approval of generic drug applications and by enabling more consistent regulatory decision making. This proposal would expand current efforts to streamline and automate the review of the drug quality section of the application to include other disciplines engaged in generic drug application assessments and would lead to faster generic drug approval.

Opioids ($55.0M)

The FY 2020 budget includes $55.0 million to support ongoing efforts to address the Opioids crisis, as well as support existing investments and additional lab needs for the International Mail Facilities initiative by increasing field and center operational capacity to review up to 100,000 packages annually.

Compounding ($13.5M)

The FY 2020 budget includes $13.5 million to catalyze development of policies and regulations for the outsourcing facilities, including advancement of the list of bulk drug substances that outsourcing facilities may use in compounding and current good manufacturing practice guidance and regulation specific to outsourcing facilities.

Promote Domestic Manufacturing: Advancing Modern Drug and Biological Product Manufacturing Technologies, Through the Development of Efficient Regulatory Pathways ($38.5M)

The FY 2020 budget includes $38.5M to promote domestic manufacturing. These technologies have great potential to accelerate new, more targeted therapies, enhance product quality, allow the vaccine supply to be more easily ramped up on short notice, and bolster stability in the U.S. drug supply to meet domestic and global needs. New manufacturing platforms contribute to development of personalized medicines and may help reduce the cost and uncertainty of adopting new manufacturing technologies.

Advance a New Domestic Drug Industry and Promote Access by Establishing the Outsourcing Facility Sector as a Robust and Reliable Source of Compounded Products ($12.0M)

The FY 2020 budget includes $12.0 million to create a "Center of Excellence on Compounding for Outsourcing Facilities" which will expand engagement with outsourcing facilities and states to help the pharmacy outsourcing industry grow to meet its intended function and adhere to higher quality standards to protect patient health.

Bring MedTech Manufacturing Home: Advance Medical Device Manufacturing and Quality ($12.0M)

The FY 2020 budget includes $12.0 million to establish a voluntary program for device manufacturers to receive certification for meeting objective manufacturing and product quality criteria. FDA will recognize third-party certifiers and offer regulatory incentives for those manufacturers who receive certification demonstrating their quality capability to increase manufacturing innovation, accelerate availability of high-quality devices to patients and foster a competitive marketplace.

New Medical Data Enterprise: Advance the Use of Real-World Evidence to Improve Human and Animal Health and Support Pre-Market Evaluation and Post-Market Safety ($60.0M)

The FY 2020 budget includes $60.0 million to advance the use of real-world experience to better inform patient care and provide more efficient, robust, and potentially lower-cost ways to develop clinical data that can inform product review and promote innovation. This capability will allow FDA to conduct near-real-time evidence evaluation down to the level of individual electronic health records for at least 10 million individuals in U.S. healthcare settings.

Transform Medical Device Safety, Cybersecurity, Review, and Innovation ($55.0M)

The FY 2020 budget includes $55.0 million to build an integrated knowledge management system and portal for medical devices using modern, agile information technology systems with secure cloud-based data storage that will enable safety issues to be monitored along the total life cycle of the device from bench testing to premarket clinical trials to postmarket adverse events and real-world evidence. This capability to better leverage pre-existing and new data in near-real-time is essential for implementing FDA's new approaches for digital health technologies, breakthrough devices, use of real-world evidence, and cybersecurity. Overall, it will make device reviews, postmarket surveillance, and cybersecurity efforts significantly more efficient and informative, which could shorten review cycles, quickly identify and address safety signals and cyber vulnerabilities, and spur the development of innovative, safer, more effective devices.

Create a New Platform for How the Agency More Efficiently Develops and Validates Modern Science-Based Principles for New Drug Development ($50.0M)

The FY 2020 budget includes $50.0 million to build a knowledge management system and portal to apply cutting edge science to advance drug development and review as well as to support a new model for team-based product review and collaboration within the FDA Oncology Center of Excellence (OCE).

Stimulate Investment In, and Innovation of, Medical Products Targeted to Rare Diseases ($20.0M)

The FY 2020 budget includes $20.0 million[6] to foster investment and innovation in, and medical product development for, rare diseases. FDA will develop clinical trial networks to create an understanding of the natural history and clinical outcomes of rare diseases.

Office of Laboratory Safety ($1.0M)

The FY 2020 budget includes $1.0 million for IT solutions, FDA-wide training programs, and maintaining the laboratory safety, biological safety, and industrial hygiene programs.

21st Century Cures - FDA Innovation Account (+$15.0M)

The 21st Century Cures Act (Cures Act) enacted into law on December 13, 2016, established an "FDA Innovation Account" for FY 2017 – FY 2025 and authorizes funding, subject to the annual appropriation process, to carry out designated provisions of Title III, which focus on medical product development activities regulated by FDA.[7]

For FY 2020, the Cures Act authorized $75.0 million for the FDA Innovation Account. These resources will help FDA implement provisions to accelerate medical product innovation, reduce regulatory burden, increase efforts for critical scientific and methodological research, and increase the involvement of patients and their perspectives in research and the medical product development process.

INFRASTRUCTURE: FACILITIES AND RENT INVESTMENTS

The FY 2020 Budget provides a Budget Authority increase of $30.7 million over the FY 2019 Annualized CR to ensure that FDA's offices and labs across the country and its fully integrated headquarters Campus are optimally functioning to enable FDA to carry out its mission and respond to food safety and medical product emergencies. This level supports increased FTE levels associated with medical product user fees and increased facility costs related to real estate taxes, rental rates, expiring leases, maintenance, utilities, repairs, and improvements. This level also supports inflationary increases for White Oak campus logistics management, facilities operations, security infrastructure, utility infrastructure capacity and reliability improvements, and the campus safety program.

The FY 2020 Budget addresses planned lease costs for increasing facility needs in the National Capital Region and FDA field locations and attempts to sustain the current condition of FDA's owned buildings at its six mission-critical sites. As FDA's owned buildings continue to age and equipment and systems failures occur, more demands will arise for repairs and non-standard maintenance requests.

[6] $10 million will support activities in CDER and $10 million will support policy related activities in FDA HQ.

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