

A NEW FEDERAL BUDGET THAT WORKS FOR THE AMERICAN PEOPLE

The President's first Budget laid the foundation for an era of American greatness. The Budget enshrined fiscal responsibility and fiscal restraint while prioritizing spending to programs Americans need most. The Budget rights the wrongs of previous administrations by

reprioritizing spending to protect the American citizen and the homeland, bringing dignity back to the American worker, and strengthening national defense. By building on policies laid out in the President's first Budget, the 2019 Budget provides the gateway to America's future.

KEEPING AMERICA SECURE

As described in the National Security Strategy, the Government's fundamental responsibility is to protect the American people, the homeland, and American way of life. The National Security Strategy recognizes that an America that is strong and prosperous at home is an America capable of defending its interests and advancing its influence abroad. By leading abroad in concert with allies and partners, the United States can help create a world that is aligned with America's interests and values. Such a world makes us more secure and prosperous here at home. While America possesses enduring national strengths, the Nation now faces an era of increased strategic competition, global disorder, and erosion of the U.S. comparative military advantage. To effectively compete, deter, and win in this challenging new era, the United States must continue to invest in and adapt U.S. national security programs.

The Budget invests in protecting America and the homeland, including through a layered missile defense system to defend the homeland against missile attacks. The Budget also requests funds to pursue threats to their sources, so that jihadist terrorists and transnational criminals are stopped before they ever reach the Nation's borders. The Budget supports efforts by

the Department of State, Department of Energy, and Department of Defense (DOD) to strengthen international partnerships to stop the proliferation of the materials, technologies, weapons, and delivery systems necessary to build and deploy weapons of mass destruction; DOD capabilities to disrupt efforts to produce weapons of mass destruction; efforts by the Departments of State of the Treasury to hold accountable those that engage in proliferation activities or support these illicit programs; Department of Homeland Security (DHS) initiatives to identify weapons of mass destruction and their components before they reach the U.S. homeland or can be used on U.S. soil; and Federal Bureau of Investigation and DOD capabilities to thwart terrorists that attempt to use weapons of mass destruction.

The Budget advances the goal of preserving peace through strength by rebuilding the U.S. military so that it remains preeminent, deters adversaries, and if necessary, is able to fight and win. By investing in the capacity, capabilities, and modernization of America's Armed Forces, the Budget would continue to strengthen America's full spectrum of military capabilities and associated personnel—including in space and cyberspace.

To maintain the advantages America's Armed Forces enjoy and build upon its strengths, the Budget requests \$716 billion for national defense. These investments fund a military that protects America's vital national interests in an increasingly competitive world. However, America and its allies cannot be defended if the Nation is not both strong and solvent. Recognizing the importance of solvency, the Budget proposes to pay for increases for the military with \$65 billion in reductions from the non-Defense discretionary caps in 2019 under current law. DOD will also pursue an aggressive reform agenda to achieve savings that it will reinvest in higher priority needs.

The U.S. military cannot expect success fighting tomorrow's conflicts with yesterday's weapons or equipment. Rather, it will shift to a more lethal, resilient, and agile force able to take on and prevail against any foe, even in the face of aggressive military modernization campaigns on the part of potential adversaries.

To that end, the Budget makes significant investments in the capability of the joint force, and especially in its lethality, resilience, and agility to better deter and, if necessary, fight and prevail against any opponent. In particular, the Budget focuses on improving the joint force's capability to take on potential great power adversaries. At the same time, the Budget invests to recover full-spectrum readiness while acquiring new and improved capabilities, enabling the United States to meet security challenges now and into the future. The Budget ensures U.S. forces are ready to fight by providing critical funding for training, munitions, logistics, and maintenance while also enabling America's forces to recover readiness against high-end adversaries. The Budget also requests funds to selectively increase the size of the Army, Air Force, Navy, and Marine Corps and requests funds for the modernization of equipment, including armored vehicles, artillery, new warships, stealthy fighter aircraft, and the next generation of bombers. These investments would strengthen deterrence by ensuring the military is ready to confront even the most capable adversaries. Deterring adversaries from choosing

a military option would support a peaceful and open international order that underpins the prosperity of the United States and its allies.

Although the U.S. military will remain second to none, adversaries and competitors are increasingly challenging the United States across the political, economic, and military arenas. To that end, the Budget supports the missions of the Department of State, U.S. Agency for International Development, and other international programs to help America compete against hostile actors and ideologies and advance American interests. The Budget builds upon key reforms begun in last year's Budget to prioritize civilian activities that support more resilient, democratic, and prosperous societies, leading to a more secure and peaceful world. The Budget prioritizes efforts to ensure that the burden of responding to global crises is borne globally, rather than disproportionately by the people and economy of the United States. By focusing on programs and policies that catalyze other countries' economic and political development, America can help aspiring partners become economic and security partners, shield them from competitors, and promote a stable world reflecting these principles.

In recognition of the dedication and sacrifice of the men and women who have served in the Armed Forces, and those who continue to serve today, the Budget also reflects a renewed commitment to honor the service of veterans. The Budget supports veterans spanning multiple generations including during periods of conflict and peace. Specifically, the Budget would build upon the Veteran's Choice program to improve healthcare and implement a modernized appeals system to provide veterans with better medical options. The Budget would also provide enhanced access to education benefits through the Forever GI Bill signed into law by the President in August 2017. In addition, the Budget funds long-term efforts to improve infrastructure and modernize the Department of Veterans Affairs (VA) to ensure it is positioned to support future generations of veterans.

HELPING AMERICANS MOVE FROM WELFARE TO WORK

More than 20 years have passed since the Congress implemented significant reforms to America's safety net. In 1996, the Congress passed the Personal Responsibility and Work Opportunity Reconciliation Act (PRWORA), and transformed the way Government provided support to low-income families. Recognizing the value of State innovation, and promoting work as the best pathway out of poverty, PRWORA ushered in an era where success was no longer measured by how many people received welfare assistance but instead by how well Government helped families progress toward self-sufficiency. Building off of this framework, the Budget empowers States to develop innovative strategies to help welfare recipients achieve economic independence through work, while preserving the basic safety net necessary to help those most in need.

Promoting the Value of Work

Work is a fundamental element in moving welfare recipients toward self-sufficiency and economic security. This plan proposes to reinforce one of the original principles of welfare reform—able-bodied people should be required to work or prepare for work in order to receive Government assistance. The Budget, therefore, requires States to ensure that work-capable individuals are on a pathway to work. In addition, an abrupt end to welfare assistance is often an impediment to sustained employment, creating churn on the welfare rolls. To further increase employment outcomes, the Budget also encourages States to provide the support necessary to ease this transition.

Improving Food Assistance

The Budget proposes a bold new approach to administering the Supplemental Nutrition Assistance Program (SNAP) that combines traditional SNAP benefits with 100-percent American grown foods provided directly to households and focuses administrative reforms on outcome-based employment strategies. The Budget expands on previous SNAP proposals to strengthen expectations for work among able-bodied adults, preserves benefits for those most in need, promotes

efficiency in State operations, and improves program integrity. Combined, these reforms would maintain the commitment to ensure Americans in need of assistance have access to a nutritious diet while significantly reducing the cost to taxpayers.

Encouraging State Innovation

Today, there are still more than 80 single-purpose welfare programs that comprise a Federal safety net intended to help those living in poverty. This complex and bureaucratic system has proven to be ineffective. The Budget proposes to streamline, simplify, and improve the efficiency of the welfare system by proposing a new approach to assisting low-income Americans rise to their potential.

The Administration recognizes that States and local communities best understand the conditions and circumstances of their economically vulnerable citizens. Therefore, the Budget offers States the opportunity to propose Welfare to Work Projects that streamline funding from multiple welfare programs, and provide services that are tailored to their constituents' specific needs, helping them progress from welfare to work. Reducing burdens and inefficiencies in overlapping—or at times competing—program requirements would remove barriers to employment and self-sufficiency for families dependent on welfare programs.

This new opportunity would be accompanied by a strong accountability framework. Specifically, plans to combine safety net programs would be subject to rigorous, random-assignment evaluations, measuring achievement in targeted outcomes that focus on fostering employment, reducing welfare dependency, and promoting child and family well-being. These projects would serve to build the evidence base of best practices to help low-income individuals and families achieve self-sufficiency, and would inform the design of more comprehensive welfare reform efforts in the future.

Altogether, the Budget offers a bold new vision for America's safety net, and reinforces this Administration's commitment to helping all Americans achieve their full potential.

PROTECTING AMERICANS WHILE ENHANCING LEGAL IMMIGRATION

Since taking office, the President has made clear that he would restore order and integrity to the U.S. immigration system. There are three primary efforts underlying this goal: strengthening border security; ensuring enforcement of immigration laws; and reforming the legal immigration system, while recognizing that legal immigration is an important driver of a thriving economy. The Budget requests more than \$28.2 billion for the agencies that have primary responsibility for carrying out immigration programs at DHS and the Department of Justice (DOJ). This includes funding for U.S. Customs and Border Protection (CBP), U.S. Immigration and Customs Enforcement (ICE), and U.S. Citizenship and Immigration Services within DHS, and the Executive Office for Immigration Review (EOIR) within DOJ.

Within the Administration's proposal for \$18 billion to fund the border wall, the Budget invests \$1.6 billion to support CBP efforts to gain operational control of the Southwest border. Until the porous borders are closed to the criminals, terrorists, and gang members that exploit it, America remains at risk. Furthermore, since most of the illegal drugs that enter the United States come through the Southwest border, a border wall is critical to combating the scourge of drug addiction that leads to thousands of unnecessary deaths. The border wall would stop smugglers in their tracks and help make America safe.

The Budget also requests \$211 million for 750 additional Border Patrol agents in 2019, continuing the President's commitment to increase the ranks of the Border Patrol by 5,000 new agents. Funding would be used to recruit, hire, and train new agents, and for staff to support the men and women on the front line of America's border defenses. These new personnel would supplement investments in the border wall by guarding the border and apprehending and swiftly removing illegal aliens at the border.

The Budget furthers investment in CBP technology and targeting systems such as the National

Targeting Center (NTC) and the Biometric Entry-Exit System. The Budget requests a total of \$253 million for NTC, an increase of \$79 million, for its overall mission, including the background vetting of individuals seeking to enter the United States before they arrive. These programs would enable the Government to better identify terrorists and other criminals and prevent their entry into the United States. Completion of the long-required Biometric Entry-Exit System would increase law enforcement's ability to identify and remove those who overstay their visas. Future investments in enhanced vetting and targeting programs would further the Administration's goal of shifting such costs to visa and immigration applicants while continuing to facilitate legitimate travel to the United States.

The Budget makes major investments in immigration law enforcement in the interior of the Nation, focusing on efforts to identify, arrest, prosecute, and remove illegal aliens. Within ICE, the Budget proposes \$571 million to hire and support 2,000 new officers and agents, which directly supports the President's order for ICE to arrest all illegal aliens it encounters. Since the President's inauguration, ICE arrests have increased by 42 percent and the Agency has increased requests to local law enforcement to transfer custody of illegal aliens to ICE by 81 percent during the same time period in the previous fiscal year.

As ICE increases its arrests and deportations of illegal aliens, it also requires additional detention and removal capacity. The Budget requests more than \$2.5 billion for these critical law enforcement functions, funding an average daily detention capacity of 47,000 illegal aliens in facilities across the United States. To ensure immigration cases are heard expeditiously, the Budget also requests an increase of \$40 million for 75 new immigration judge teams at EOIR and nearly \$40 million for 338 new prosecuting attorneys at ICE. These investments are critical to the prompt resolution of newly-brought immigration charges and to reduce the 650,000 backlog of cases currently pending in the immigration courts.

The Budget requests \$208 million in new funding for 300 additional ICE Special Agents, support staff, and other activities for the Agency's Homeland Security Investigations' (HSI) mission. HSI staff lead efforts to ensure only those with legal permission to work in the United States are employed here, investigate and disrupt transnational criminal organizations (TCOs) that perpetuate human smuggling and trafficking, and stop immigration fraud, which directly facilitates illegal immigration. Because these investigations protect the integrity of the legal immigration system, the Budget proposes collecting the \$208 million for these purposes from the immigration applicants who want to come to the United States and benefit from the Nation's opportunities.

The integrity of the immigration system relies upon everyone in the United States doing their part to follow the law. The Budget invests \$23 million to expand the E-Verify Program for mandatory nationwide use, ensuring that businesses employ only those authorized to work in the United States. Further, the Budget proposes to amend the Illegal Immigration Reform and Immigrant Responsibility Act to condition DHS and DOJ grants and cooperative agreements

on States and local governments agreeing to cooperate with immigration enforcement activities. This proposal takes important steps to mitigate the risk that sanctuary cities pose to public safety and ensures appropriate alignment between State and Federal immigration enforcement.

The Budget supports efforts to reform the legal immigration system by ending family chain migration and the diversity visa lottery and replacing them with a merit-based regime that selects immigrants based on their skills, likelihood to assimilate, and ability to contribute to the economy. This is similar to the approach used by Canada and Australia and would reduce overall immigration while limiting low-skilled and unskilled labor entering the United States. The Budget requests the resources needed to adjudicate immigration and visa applications and identify and counter fraud in the immigration process, ensuring that businesses and individuals petitioning for foreign workers and relatives do so in a manner consistent with the Nation's immigration laws, while ensuring that the American economy continues to access the labor force critically needed for growth.

REBUILDING AMERICA THROUGH THE INFRASTRUCTURE INITIATIVE

America's infrastructure is a key component to its historic success. With the world's most efficient rail and interstate highway systems, America was a fierce global competitor. Local roads and water systems provided a clean and safe environment for communities and families.

In recent decades, however, we have chronically under-invested in public infrastructure, leading to the frustration of long commutes and the loss of life when a lack of maintenance creates safety hazards. The challenge of restoring this infrastructure is complicated by the fact that virtually all public infrastructure is owned by State and local governments, not the Federal Government. Interstate highways, drinking and waste water systems, commuter railroads, airports, power lines, telecommunications, and ports are all non-Federal. While the Federal

Government has co-invested in State and local infrastructure, using Federal dollars to pay for non-Federal infrastructure projects has created an unhealthy dynamic in which State and local governments delay projects in the hope of receiving Federal funds.

The Administration's infrastructure initiative would address the imbalances between infrastructure investment, ownership, and responsibility and generate \$1 trillion in total infrastructure investment through a combination of direct Federal funding and incentivized non-Federal funding. The Budget requests \$200 billion dedicated to this effort, as follows:

- **Incentive Grants**—\$100 billion is requested to encourage increased State, local, and private infrastructure investment

by awarding incentives to project sponsors for demonstrating innovative approaches that would generate new revenue streams, prioritize maintenance, modernize procurement practices, and generate a social and economic return on investment. Incentives would be provided in the form of competitive grants.

- **Rural Formula Funds**—\$50 billion is requested for this program, which would address the significant need for investment in rural infrastructure, including broadband internet service. Federal funding would be made available to States via formula distribution, along with a bonus competition based on State performance in achieving goals outlined in State-developed rural infrastructure plans. Within this amount, funding is set aside for federally recognized Tribes and U.S. Territories.
- **Transformative Projects**—\$20 billion is requested to support bold, innovative, and transformative infrastructure projects that can significantly improve existing infrastructure conditions and services. Funding would be awarded on a competitive basis for commercially viable projects that are capable of generating revenue, provide net public benefits, and would have a significant positive impact on the Nation, a region, State, or metropolitan area.
- **Existing Credit Programs**—\$14 billion is requested in additional subsidy funding for the key Federal credit programs providing financing to infrastructure projects. This funding would significantly increase Federal credit assistance to infrastructure via the Department of Transportation's Transportation Infrastructure Finance and Innovation Act (TIFIA) and Railroad Rehabilitation and Improvement Financing programs, the Environmental Protection Agency's Water Infrastructure Finance and Innovation Act program, and the Department of Agriculture's Rural Utilities Service program. For example, historically the TIFIA program has leveraged about \$40 in transportation infrastructure improvement for each \$1 of TIFIA assistance provided. The initiative would also expand eligibility for these credit programs to include other governmental infrastructure such as airports and ports.
- **Federal Capital Revolving Fund**—\$10 billion is requested to establish a mandatory revolving fund to finance purchases, construction, or renovation of federally owned civilian real property. The Federal Government is currently utilizing inefficient leases to access necessary property. Leases are being used due to the unavailability of the large upfront capital needed to acquire real property projects. Upon approval in annual appropriations acts, the revolving fund would transfer money to agencies to finance large-dollar real property projects. Purchasing agencies would then be required to repay the Fund using discretionary appropriations.
- **Private Activity Bonds (PABs)**—the initiative would expand flexibility and broaden eligibility for PABs, which play an important part in delivering many large, regionally- and nationally-significant projects. PABs provided for this broadened definition of "core public infrastructure projects" would not be subject to volume caps, but would require the projects to be available to the public and either Government-owned or privately-owned but subject to Government regulatory or contractual control and approval. The Budget requests \$6 billion related to this expansion.
- **Real Property Reforms**—the Budget supports several proposals to streamline and improve the Federal real property disposal processes, Government-wide, including the retention of sales proceeds.

These proposals would increase the opportunities to sell off real property no longer needed by the Federal Government, thereby generating revenue to improve other mission critical Federal facilities. Disposal of unneeded Federal facilities would also allow the disposed buildings to be returned to private use, potentially spurring local economic development. The Budget also supports flexibilities for VA to leverage existing assets to continue its efforts to reduce the number of vacant buildings in its inventory, leverage VA assets for the construction of needed new facilities to serve veterans, and align the VA lease prospectus threshold with the General Services Administration threshold.

- **Reduce Deferred Maintenance on Public Lands**—the Budget also proposes a new Public Lands Infrastructure Fund for the Department of the Interior to

support infrastructure investments in national parks, refuges, and Bureau of Indian Education schools. The Fund would be supported by half of the incremental receipts from expanded energy development that exceed previous projections and are not allocated for other purposes.

- **Streamline Permits**—in addition, the infrastructure initiative includes several proposals to streamline permitting decisions to accelerate project delivery while maintaining environmental safeguards. For example, the initiative proposes creating a new “One Federal Decision” structure that includes firm deadlines for completing environmental reviews, eliminating redundant agency reviews, delegating responsibilities to States where appropriate, and pilot programs to experiment with innovative approaches to environmental reviews.

COMBATTING THE DRUG ABUSE AND OPIOID OVERDOSE EPIDEMIC

The drug abuse and overdose epidemic, particularly related to opioids, is tearing apart America’s families and devastating communities. Last year, more people died from drug overdoses than traffic accidents. The two million people who are addicted to opioids, a class of drugs that includes both legal and illicit drugs such as certain prescription painkillers, heroin, and synthetic opioids such as fentanyl, are especially at risk. In 2016, approximately 64,000 people died from drug overdoses, 174 lives per day.

In 2017, the President said: “I made a promise to the American people to take action to keep drugs from pouring into our country and to help those who have been so badly affected by them.” The Administration has taken a number of significant actions to address the crisis. The President created the Commission on Combating Drug Addiction and the Opioid Crisis and the Administration declared the opioid epidemic a nationwide public health emergency. The Administration provided nearly \$500 million in new resources to States to prevent and treat opioid abuse and addiction in

2017, in addition to last year’s Budget that requested another \$500 million.

As the President noted: “Ending the epidemic will require mobilization of Government, local communities, and private organizations. It will require the resolve of our entire country.” The Budget requests more than \$30 billion in drug control funding in 2019, of which the Office of National Drug Control Policy estimates that more than \$7 billion combats the opioid crisis, with efforts spanning prevention, treatment, interdiction, international operations, and law enforcement across 14 Executive Branch Departments, the Federal Judiciary, and the District of Columbia.

The Budget requests \$5 billion in new resources for the Department of Health and Human Services (HHS) over the next five years, including \$1 billion in 2019, to combat the opioid epidemic by preventing opioid abuse and helping those who are addicted get access to overdose reversal drugs, treatment, and recovery support

services. The Budget request includes: \$50 million for a media campaign; \$625 million for States to respond to the crisis; \$50 million to improve first responder access to overdose-reversal drugs; \$100 million for surveillance and opioid abuse prevention activities, including improving State-based Prescription Drug Monitoring Programs (PDMPs); \$20 million for drug courts; \$10 million for pregnant and post-partum women treatment programs; \$10 million for the Food and Drug Administration's (FDA) regulatory science activities to develop tools to stem the misuse and abuse of opioids; \$65 million to support multi-sector, county-level teams in high-risk rural communities to improve access to care, and expand treatment and recovery services; \$45 million for supplemental grants for opioid abuse prevention, treatment, and recovery services in American Indian and Alaska Native communities; and \$25 million to evaluate the impact of medication assisted treatment on reducing overdose deaths.

In addition to the requested \$5 billion, the Budget also continues and expands existing activities in HHS that specifically address key strategies to combat the opioid crisis. The Budget requests \$100 million for the National Institutes of Health to support a public-private partnership with the pharmaceutical industry to develop prevention and treatments for addiction, overdose-reversal, and non-addictive therapies for pain. The Budget requests \$123 million in the Substance Abuse and Mental Health Services Administration for opioid abuse prevention, treatment, recovery support, and overdose reversal. The Budget also requests \$126 million in the Centers for Disease Control and Prevention to support opioid abuse prevention and surveillance activities, including support to States to improve the capabilities and use of State-based PDMPs.

Further, the Administration supports more rigorous research to better understand how existing programs or policies might be contributing to or mitigating the opioid epidemic.

For Medicaid, the Budget calls for expanding coverage of comprehensive and evidence-based medication assisted treatment options, previews

forthcoming guidance from the Centers for Medicare and Medicaid Services that would set minimum standards for State Drug Utilization Reviews to reduce clinical abuse, and requires States to track and act on prescribers that do not adopt best practices.

For Medicare, the Budget proposes to test and expand nationwide a bundled payment for community-based medication assisted treatment, including Medicare reimbursement for methadone treatment for the first time. The Budget also proposes to prevent prescription drug abuse in Medicare Part D and protect beneficiaries from potentially harmful drugs by requiring plan participation in a program to prevent prescription drug abuse. In addition, the Budget proposes to authorize the Secretary of HHS to work with the Drug Enforcement Administration (DEA) to revoke a provider's certificate (which allows a provider to prescribe controlled substances) when that provider is barred from billing Medicare based on a pattern of abusive prescribing. Cutting off Medicare funding for abusive prescription practices not only helps bring premiums down for seniors, it promotes sound public health policy.

The President also recognizes that combatting the opioid crisis means not only helping those suffering from drug addiction but also dismantling drug trafficking organizations profiting from this deadly scourge. The Budget requests \$2.2 billion for the DEA, including an additional \$41 million to enhance efforts to target the illicit drug traffickers that prey on communities. In addition, the Budget requests \$103 million within DOJ for opioid-related State and local assistance including: \$20 million for the Comprehensive Opioid Abuse Program to support a variety of activities such as treatment and recovery support services, diversion, and alternative to incarceration programs; \$59 million for Drug Courts, Mental Health Courts, and Veterans Treatment Courts; \$12 million for Residential Substance Abuse Treatment; and \$12 million to support PDMPs, in tandem with HHS efforts.

The Budget also requests a range of investments that would strengthen efforts at DHS to

identify, screen, and interdict drug shipments coming into the United States, and to investigate those responsible for bringing illegal drugs into the United States. The Budget request increases funding for CBP's NTC by \$79 million, for a total of \$253 million, which would also allow the Agency to better target its efforts to stop illicit goods, including illicit drugs, from entering the United States. The Budget also requests a \$44 million investment in new Non-Intrusive Inspection technology at Ports of Entry, which is used to examine cargo and conveyances for contraband and weapons of mass effect. The Budget requests an increase of \$42 million, funded by both fees and discretionary appropriations, to enable CBP to screen inbound packages at express consignment carrier facilities such

as FedEx, UPS, and DHL. The Budget continues investments in presumptive testing devices to improve customs officers' capability to detect and interdict fentanyl and other opioids, and requests an additional \$1.2 million, for a total of \$46 million, for scientific support to CBP officers for rapid identification of suspected illicit materials, in particular suspected opioids. In addition, the Budget fully supports all 57 ICE Border Enforcement Security Task Force units around the United States, which are the Agency's primary platform to investigate opioid smuggling, and continues support for DHS's Joint Task Force—Investigations, which works to identify, disrupt, and dismantle TCOs that seek to import opioids and other drugs into the United States.

RETHINKING DRUG PRICING TO PUT AMERICAN PATIENTS FIRST

Many drugs are too expensive for Americans and too many patients continue to be priced out of the medicines they need. Lowering prescription drug prices is one of the most important issues facing the Nation. Recent well-publicized instances of price manipulation and the disparity between U.S. drug prices and prices overseas also add to the growing frustration Americans feel. While American innovators bring life-saving pharmaceutical products to the world, drugs are purchased through an inefficient, opaque maze of segmented channels and a poorly understood network of pricing schemes. Complex regulations and barriers to entry for suppliers drive up drug costs for Americans. Americans unfairly shoulder a disproportionate amount of burden for research and development, allowing foreign governments to achieve better deals for their citizens at the expense of the American people. The goal of the Administration's comprehensive strategy is to address the problem of high drug prices, provide greater access to lifesaving medical products, and to ensure that the United States remains the leader in biomedical innovation.

The Administration has already taken a number of significant administrative steps to reduce drug costs. For example, in 2017, FDA approved the highest annual total number of generic drugs (1,027) in the Agency's history.

FDA is also increasing competition in the market for prescription drugs, and facilitating entry of lower-cost alternatives, by providing greater transparency and expediting the review of generic drug applications for products with limited competition. CMS modified payment policies for biosimilars to encourage innovation and a robust market, which should encourage competition and innovation and help lower prices in the long run. The Administration also took steps to lower the costs seniors pay for certain drugs in the hospital outpatient setting, so that patients could benefit from the discounts hospitals receive under the 340B Program. This action is expected to save seniors an estimated \$320 million on drug co-payments in calendar year 2018 alone. In addition, the Budget once again proposes reforms to improve 340B Program integrity to ensure that the benefits derived from participation in the program are used to benefit patients, especially low-income and uninsured populations, and to require entities to report on use of 340B Program savings.

The Budget proposes new strategies to address high drug prices and increase access to lifesaving medicines by: rationalizing the current incentive structure; fostering greater competition; and extending American leadership in innovation to put American patients first.

The Budget calls for new Medicaid demonstration authority for up to five States to test drug coverage and financing reforms that build on private sector best practices. Participating States would determine their own drug formularies, coupled with an appeals process to protect beneficiary access to non-covered drugs based on medical need, and negotiate drug prices directly with manufacturers.

Within the Medicare program, the Budget modernizes the Part D drug benefit, based upon 12 years of program experience, to improve plans' ability to deliver affordable drug coverage for seniors and reduce their costs at the pharmacy counter. Seniors would benefit from the Budget's proposals, which are designed to better protect beneficiaries from high drug prices, give plans more tools to manage spending, and address the misaligned incentives of the Part D drug benefit structure. The proposed changes enhance Part D plans' negotiation power with manufacturers, encourage utilization of higher value drugs, discourage drug manufacturers' price and rebate strategies that increase spending for both beneficiaries and the Government, and provide beneficiaries with more predictable annual drug expenses through the creation of a new out-of-pocket spending cap. The Budget also modifies payment for Part B drugs to discourage

manufacturers from increasing prices faster than inflation and improves payment accuracy. In addition, the Budget also modifies hospitals' payment for drugs acquired through the 340B drug discount program by rewarding hospitals that provide charity care and reducing payments to hospitals that provide little to no charity care.

The Budget also proposes to give FDA greater ability to bring generics to the market faster by incentivizing more competition among generic manufacturers. The Budget proposes to ensure that first-to-file generic applicants who have been awarded a 180-day exclusivity period do not unreasonably and indefinitely block subsequent generics from entering the market beyond the exclusivity period.

The Administration is updating a study from 2004 to analyze drug prices paid in countries that are a part of the Organization for Economic Cooperation and Development. HHS, working in conjunction with the Department of Commerce and the U.S. Trade Representative, will develop the knowledge base to understand the unfair disparity between the drug prices in America and other developed countries. The Administration is committed to making the regulatory changes and seeking legislative solutions to put American patients first.