

drugs where there is little or no market competition, called the Competitive Generic Therapies pathway, as part of the FDA Reauthorization Act of 2017.

Since August 2018, FDA has approved five new generic drugs under this pathway and has designated over 140 generic drug applications as qualifying for this pathway.

Dr. Gottlieb also announced a new plan, called the Biosimilar Action Plan, to bring generic versions of biologic drugs, called biosimilars, to help improve competition for biologics by increasing market entry of biosimilars and providing more treatment options for patients.

FDA has approved a total of 18 biosimilar products since 2010, when the biosimilar pathway was created, 13 of which were approved under Dr. Gottlieb's watch.

At his confirmation hearing, Dr. Gottlieb described the opioid crisis as "having staggering human consequences. I think it's the biggest crisis facing the agency. . . . I think it's going to require an all-of-the-above approach . . ."

Last year, 72 senators worked on legislation to combat the opioid crisis.

Dr. Gottlieb provided us with crucial advice as we worked on this legislation and has begun to take advantage of the new law.

He has taken steps to help prevent illicit fentanyl, which is 100 times more powerful than heroin, from coming across the border.

He worked with Congress to clarify his authority to require opioids to be packaged in blister packs, such as a 3 or 7-day supply, to encourage doctors to prescribe responsibly; and clarified FDA's authority to require safe disposal options to accompany opioid packaging.

Dr. Collins, who leads the NIH, has predicted a nonaddictive opioid in the next decade, which really is the Holy Grail for fighting the opioid crisis and for helping the 50-100 million Americans living with pain.

I believe Dr. Gottlieb has laid groundwork to encourage the development of nonaddictive and nonopioid medicines and therapies to treat pain.

Dr. Gottlieb was integral to Congress's ability to reauthorize the animal drug user fees, which authorize the FDA to collect user fees to speed the review and approval of new drugs that farmers, families, and veterinarians rely on to keep their animals healthy and the food supply safe.

The 21st Century Cures Act created the Regenerative Medicine Advanced Therapy Designation, which is similar to the very successful breakthrough drug pathway that safely shortened the development and review time for certain drugs, to get them to patients who need them more quickly.

While we worked on that law, I heard the story of Nashville resident Doug Oliver.

In 2007, Doug began to have trouble seeing and, after a near accident, had

his driver's license taken away and was declared legally blind.

The culprit was a rare form of macular degeneration.

His doctor at the Vanderbilt Eye Institute told him that while there were no cures, Doug could search online for a clinical trial.

Doug found a regenerative medicine clinical trial in Florida, where doctors took cells out of the bone marrow in his hip, spun them in a centrifuge, and then injected those into his eye.

Three days later, he began to see.

His eyesight eventually improved enough to get his driver's license back, and he became an effective advocate for more support for regenerative medicine, which we included in the 21st Century Cures Act.

So, with his improved vision, he began writing letters and visiting me to advocate for more support for regenerative medicine, which we did in the 21st Century Cures Act.

Two years ago, Doug gave me the cane he had used while he was blind. He said: "I don't need it anymore."

In Cures, we included a pathway to bring new regenerative medicine treatments, similar to the treatment Doug received, to patients more quickly.

Dr. Gottlieb has worked to implement that new pathway to help develop safe treatments to ensure more patients are able to take advantage of this cutting-edge, personalized medical technology.

Additionally, Dr. Gottlieb has helped the agency develop and advance guidances for gene therapies that will help new innovative companies developing these promising therapies, some of which may be for specific diseases and conditions that provide roadmaps for biotechnology companies who are leading the way in precision medicine.

During this exciting time in biomedical research, we are fortunate that Dr. Gottlieb was willing to serve.

The FDA and the biomedical community is in better shape today to advance medical innovation and develop the treatments and cures of the future because of his leadership.

CELEBRATING ROMANI AMERICAN HERITAGE

Mr. CARDIN. Madam President, today I rise to celebrate International Roma Day, which occurred yesterday, April 8, 2019. Last week, Senator WICKER, the Helsinki Commission's Senate cochairman, and I introduced a resolution that celebrates Romani American heritage.

As a member of the U.S. Helsinki Commission and the Organization for Security and Cooperation in Europe (OSCE) Parliamentary Assembly Special Representative on Anti-Semitism, Racism & Intolerance, I have long worked to improve the situation of Roma throughout the OSCE region.

The resolution we introduced on April 4 does four things.

First, it recognizes and celebrates Romani American heritage. Roma have

come to the United States with every wave of European migration since the colonial period. In the United States, there may be as many as 1 million Americans with some Romani ancestry, whether distant or more recent. Romani people have made distinct and important contributions in many fields, including agriculture, art, crafts, literature, medicine, military service, music, sports, and science.

Second, it supports International Roma Day and the Department of State's robust engagement in activities to honor that occasion. On April 8, 1971, the First World Romani Congress met in London, bringing together Roma from across Europe and the United States with the goal of promoting transnational cooperation among Roma, combating social marginalization, and building a positive future for Roma everywhere. April 8 is now celebrated as International Roma Day around the world. U.S. Ambassadors and our Embassies across Europe are frequently asked to participate in April 8 celebrations across the region. I commend the important work they are doing as they demonstrate U.S. commitment to inclusive societies not only on April 8 but throughout the entire year.

Third, this resolution commemorates the 75th anniversary of the destruction of the so-called Gypsy Family Camp at Auschwitz. Experts estimate that 200,000 to 500,000 Romani people were killed in death camps and elsewhere throughout Europe. On August 2 to 3, 1944, Nazis murdered between 4,200 and 4,300 Romani men, women, and children in gas chambers when the Nazis decided to liquidate this camp. A number of governments have taken important steps in recent years to commemorate the genocide of Roma, to remember the victims, and educate future generations. Germany took an important step when it opened a memorial in Berlin for Sinti and Roma victims of national socialism. I also commend the Czech Government for its decision to remove the pig farm at the site of the Lety concentration camp and address remaining issues regarding the proper memorialization of that sensitive site.

Finally, this resolution commends the U.S. Holocaust Memorial Museum for its critically important role in promoting remembrance of the Holocaust and educating audiences about the genocide of Roma. The U.S. Holocaust Memorial Museum is the preeminent Federal institution dedicated to serving as a living memorial to the Holocaust. I am honored to serve as a member of the U.S. Holocaust Memorial Museum Council and I welcome the initiatives of the museum to ensure that Romani victims are remembered and support related scholarship.

I am pleased that Senator WICKER has joined me in introducing this resolution and urge other colleagues to join us in celebrating Romani-American heritage.

TRIBUTE TO LIEUTENANT
COMMANDER STEVEN DAVIES

Mrs. HYDE-SMITH. Madam President, I am pleased to commend LCDR Steven Davies for his dedication to duty and service as a U.S. Coast Guard congressional fellow on my staff. Steve was recently selected to serve as executive officer of USCGC *Thetis* and will soon depart to fulfill that important responsibility.

A native of Lebanon, PA, Steve was commissioned after his graduation from the U.S. Coast Guard Academy, where he earned a bachelor of science degree in management, served as vice president of his class, and captained the men's soccer team. He is in the process of earning a master's degree.

Steve has served in a broad range of assignments during his Coast Guard career. He has served overseas in Kuwait and deployed with Patrol Forces Southwest Asia in support of Operations Iraqi and Enduring Freedom, conducted national security missions on five ships in the Arabian Gulf. In addition to deployments overseas, he has served in vital roles in support of U.S. security interests. As commanding officer of USCGC *Sailfish*, he led search and rescue operations and various law enforcement missions in the Port of New York and New Jersey. As Commanding Officer of USCGC *Kathleen Moore*, Steve led a 26-person crew that interdicted \$18 million of cocaine and nearly 700 undocumented migrants attempting to reach the United States.

Most recently, Steve served as the congressional fellow on my staff and, prior to that, for the Honorable Senator Thad Cochran of Mississippi. Steve's operational experience in the Gulf of Mexico, Southwest Asia, and the Arabian Gulf, in addition to his technical expertise in counterdrug and migrant interdictions, search and rescue operations, and law enforcement missions, have been pivotal in helping to shape Department of Homeland Security and U.S. Coast Guard appropriations for fiscal years 2018 and 2019.

As a congressional fellow, he has served the State of Mississippi, the Coast Guard, and our Nation admirably. My staff and I have enjoyed the benefit of Steve's counsel and have truly enjoyed working with him. Steve's leadership has brought great credit to the Coast Guard, and I appreciate and commend his commitment to continue to serve our nation.

It is a pleasure to recognize and thank LCDR Steve Davies for his service to this country. My staff and I extend our gratitude to Steve and wish him "Fair winds and following seas" as he continues his journey in the U.S. Coast Guard.

NATIONAL NUCLEAR SECURITY
ADMINISTRATION FISCAL YEAR
2020 BUDGET REQUEST

Mr. ALEXANDER. Mr. President, I ask unanimous consent that a copy of

my opening statement at the Subcommittee on Energy and Water Development's budget hearing for the National Nuclear Security Administration's fiscal year 2020 budget request be printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

NATIONAL NUCLEAR SECURITY ADMINISTRATION FISCAL YEAR 2020 BUDGET REQUEST

Mr. ALEXANDER. The Subcommittee on Energy and Water Development will please come to order.

Today's hearing will review the administration's fiscal year 2020 budget request for the National Nuclear Security Administration.

This is the second of the Subcommittee's four budget hearings this year.

We heard from Secretary Perry last week, and we'll have two more hearings in the coming weeks to review the Nuclear Regulatory Commission and the Army Corps of Engineers and the Bureau of Reclamation budget requests.

Senator Feinstein and I will each have an opening statement.

I will then recognize each Senator for up to five minutes for an opening statement, alternating between the majority and minority, in the order in which they arrived.

We will then turn to Administrator Lisa Gordon-Hagerty to present testimony on behalf of the National Nuclear Security Administration and then give Admiral Frank Caldwell an opportunity to give a brief statement.

At the conclusion of the witnesses' testimony, I will then recognize Senators for five minutes of questions each, alternating between the majority and minority in the order in which they arrived.

First, I would like to thank our witnesses for being here today, and also Senator Feinstein, with whom I have the pleasure to work with again this year to draft the Energy and Water Appropriations bill.

Our witnesses today include: Ms. Lisa Gordon-Hagerty, the Administrator of the National Nuclear Security Administration (NNSA); Dr. Charles Verdon, Deputy Administrator for Defense Programs; Dr. Brent Park, Deputy Administrator for Defense Nuclear Nonproliferation (Dr. Park is a former Associate Laboratory Director for Oak Ridge National Laboratory); and Admiral Frank Caldwell, Deputy Administrator for Naval Reactors.

Our subcommittee has a good record of being the first of the appropriations bills to be considered by the Committee and by the Senate each year. For each of the past four years, Senator Feinstein and I have been able to have our bill signed into law.

Last year, we worked together in a bipartisan way on the fiscal year 2019 Energy and Water Development Appropriations bill that was signed into law before the start of the fiscal year—the first time that happened since 2000.

In last year's appropriations bill we provided \$15.2 billion for the National Nuclear Security Administration, including \$1.9 billion for the six life extension programs, which fix or replace components in weapons systems to make sure they're safe and reliable.

We also funded the Uranium Processing Facility at the Y-12 National Security Complex at \$703 million, which will continue to keep this project on time and on budget, with a completion year of 2025 at a cost no greater than \$6.5 billion.

I look forward to working with Senator Feinstein on another strong bill this year.

We're here today to review the administration's fiscal year 2020 budget request for the National Nuclear Security Administration (NNSA), the semi-autonomous agency within the Department of Energy that is responsible for a vital mission—maintaining our nuclear weapons stockpile, reducing the global dangers posed by weapons of mass destruction, and providing the Navy with safe and effective nuclear power.

The president's fiscal year 2020 budget request for the NNSA is \$16.5 billion, an increase of \$1.3 billion (or 8 percent) over last year (the fiscal year 2019 enacted level).

Today, I'd like to focus my remarks and questions on three main areas:

1. Effectively maintaining our nuclear weapons stockpile;
2. Keeping critical projects on time and on budget; and
3. Supporting our nuclear Navy.

When the Senate agreed to ratify the New Start Treaty in December 2010, we also agreed to support funding to modernize and maintain our nuclear weapons stockpile, plus the facilities to do the work. A vital part of NNSA's mission is completion of the five ongoing life extension programs, which fix or replace components in weapons systems to make sure they're safe and reliable. The budget request includes \$2.1 billion to continue the life extension programs. I want to make sure we are spending taxpayer dollars effectively.

Completing all of the work that needs to be done for these weapons systems will result in a higher workload than the weapons program has had in any time since the height of the Cold War, and it will require a large number of highly-trained experts at the production sites, like Y-12 in Oak Ridge Tennessee, the weapons laboratories, and the federal employees that work for NNSA. I'd like to hear more today about whether NNSA has enough qualified people to do this work. I would also like to discuss today whether NNSA will be able to keep the life extension programs on time and on budget.

The NNSA is responsible for some of the largest construction projects in the federal government. Senator Feinstein and I have worked hard to keep costs from skyrocketing. We want to make sure hard-earned taxpayer dollars are spent wisely and that these projects are on time and on budget.

First we focused on our oversight on the Uranium Processing Facility in Tennessee. We held routine meetings with the Department's leadership to discuss the project—particularly how the Department implemented the recommendations of a Red Team review, completed in 2014, to get the project on track.

After completing more than 90% of the design for the nuclear facilities, NNSA began construction of the Uranium Processing Facility last year. I'd like to hear more about the progress on construction from the witnesses today.

Senator Feinstein and I also worked with the Department on ways to get excess plutonium out of South Carolina more quickly and for less cost. Last year, Secretary Perry canceled the MOX project in favor of the Dilute and Disposal alternative, which the Department of Energy estimated will save taxpayers more than \$20 billion. I'd like to hear more today on the progress NNSA is making at removing the plutonium from South Carolina.

Lastly, the NNSA is restarting our ability to make plutonium pits for the stockpile. The budget request includes \$712 million for plutonium sustainment, which is 97% more than the current funding level. This difficult, but important work, will be done in New Mexico and South Carolina. The NNSA has