

see him go, but I know we can expect many more years of outstanding leadership from him. In fact, he and his wife have just been accepted to the Peace Corps, where they look forward to training physicians in Africa. I wish them both the very best in this exciting work, and I once again thank Dr. Chen for his incredible contributions to our State and beyond.

#### ARMS SALES NOTIFICATION

Mr. CORKER. Mr. President, section 36(b) of the Arms Export Control Act requires that Congress receive prior notification of certain proposed arms sales as defined by that statute. Upon such notification, the Congress has 30 calendar days during which the sale may be reviewed. The provision stipulates that, in the Senate, the notification of proposed sales shall be sent to the chairman of the Senate Foreign Relations Committee.

In keeping with the committee's intention to see that relevant information is available to the full Senate, I ask unanimous consent to have printed in the RECORD the notifications which have been received. If the cover letter references a classified annex, then such annex is available to all Senators in the office of the Foreign Relations Committee, room SD-423.

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

DEFENSE SECURITY  
COOPERATION AGENCY,  
Arlington, VA.

Hon. BOB CORKER,  
Chairman, Committee on Foreign Relations,  
U.S. Senate, Washington, DC.

DEAR MR. CHAIRMAN: Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 17-02, concerning the Air Force's proposed Letter(s) of Offer and Acceptance to the Government of the United Kingdom for defense articles and services estimated to cost \$150 million. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

J.W. RIXEY,  
Vice Admiral, USN, Director.

Enclosures.

TRANSMITTAL NO. 17-02

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) Prospective Purchaser: United Kingdom.

(ii) Total Estimated Value:

Major Defense Equipment\* \$135.0 million.  
Other \$ 15.0 million.

Total \$150.0 million.

(iii) Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:

Major Defense Equipment (MDE):

One thousand (1,000) AGM-114-R1/R2 Hellfire II Semi-Active Laser (SAL) Missiles.  
Non-MDE:

Logistics support services and other related program support.

(iv) Military Department: Air Force (YAI).

(v) Prior Related Cases, if any: UK-D-YAC—\$22M—May 2008; UK-D-YAF—\$21M—Mar 2011; UK-D-YAY—\$134M—Aug 2013.

(vi) Sales Commission. Fee. etc., Paid. Offered, or Agreed to be Paid: None.

(vii) Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold: See Attached Annex.

(viii) Date Report Delivered to Congress: March 16, 2017.

\*As defined in Section 47(6) of the Arms Export Control Act.

#### POLICY JUSTIFICATION

##### United Kingdom—Hellfire Missiles

The Government of the United Kingdom (UK) requested a possible sale of 1,000 AGM-114-R1/R2 Hellfire II Semi-Active Laser (SAL) Missiles with logistics support services and other related program support. The estimated cost is \$150 million.

This proposed sale directly contributes to the foreign policy and national security policies of the United States by enhancing the close air support capability of the UK in support of NATO and other coalition operations. Commonality between close air support capabilities greatly increases interoperability between our two countries' military and peacekeeping forces and allows for greater burden sharing.

The proposed sale improves the UK's capability to meet current and future threats by providing close air support to counter enemy attacks on coalition ground forces in the U.S. Central Command area of responsibility (AOR) and other areas, as needed. The UK already has Hellfire missiles in its inventory and will have no difficulty absorbing these additional missiles.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

There is no principal contractor for this sale as the missiles are coming from U.S. stock.

Implementation of this proposed sale will not require the assignment of any additional U.S. Government or contractor representatives to the UK.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

#### 2017 FOOD AND DRUG ADMINISTRATION USER FEE REAUTHORIZATION

Mr. ALEXANDER. Mr. President, I ask unanimous consent to have printed in the RECORD a copy of my remarks at the Senate Committee on Health, Education, Labor, and Pensions earlier today.

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

##### 2017 FOOD AND DRUG ADMINISTRATION USER FEE REAUTHORIZATION

The Senate Committee on Health, Education, Labor and Pensions will please come to order. We're holding a hearing today on "FDA User Fee Agreements: Improving Medical Product Regulation and Innovation for Patients Part 1."

Now, Senator Murray and I will each have an opening statement, then we will introduce our panel of witnesses. After our witness testimony, senators will have 5 minutes of questions. The subject of today is the Food and Drug Administration's medical device and drug user fees. It seems like a long time ago, but it really wasn't that long ago, that Congress passed the 21st Century Cures Act. 94 Senators voted for it, President Obama and Vice President Biden were strongly in support of it. So were Speaker Ryan and Mitch McConnell, who called it

"the most important piece of legislation in the last Congress."

It came through this committee and I thank the members of the committee, especially for resolving our differences of opinions and making it possible to reach a consensus. That bill was about the moving medical products, drugs and devices more rapidly, in a safe way, through the investment and the regulatory process into the hands of patients and doctors offices.

Today, we are talking about really implementing that great goal, one that shows so much promise for virtually every American. We're here to talk about how we continue the fund the Food and Drug Administration, the agency responsible for making sure the promising research supported by 21st Century Cures actually reaches patients.

We will hear from witnesses from the agency itself to tell us how the user fee agreements will improve the agency's abilities to regulate medical products and promote innovation. We will hear from patients, device manufacturers, and brand and generic drug manufacturers in a second hearing, which is tentatively scheduled for April 4.

I want to thank the witnesses for taking the time to testify today. We respect the great amount of expertise and service that you've given for our country. I want to thank you also for moving so quickly to implement the 21st Century Cures Act. I noticed specifically that the provision involving regenerative medicine was published with about a month after President Obama signed the law.

The first medical product user fee agreement was enacted in 1992. FDA worked with the drug manufacturers to hammer out an agreement that the agency would collect user fees from drug manufacturers in exchange for more timely, predictable reviews. The agreement was a success—it decreased review times and increased patient access to medicines.

Before September 30 of this year, 4 different user fee agreements need to be reauthorized: The Prescription drug user fee is the first one. Now it's common around here to call it PDUFA, I'm not going to do it. I just can't stand PDUFA, and MDUFA and GDUFA and the other UFA. So I'm going to call them if you don't mind, the prescription drug user fee, which accounted for over 70 percent of the brand drug review budget in FY2015.

The second one is the Medical device user fee, which accounted for 35 percent of the medical device review budget in 2015.

The Generic drug user fee accounted for 70 percent of the generic drug review budget. Biosimilar user fee accounted for 7 percent of the biosimilar review budget.

##### CONSEQUENCES OF FAILING TO REAUTHORIZE

So a lot of the money for the FDA comes from these agreements with manufacturers of prescription drugs and devices.

The authority for FDA to collect user fees for medical product review will expire on September 30 of this year—six months from now.

Now this is probably the most important part of what I have to say this morning. If we do not move quickly to reauthorize these agreements, the FDA will be forced to begin sending layoff notices to more than 5,000 employees to notify them that they may lose their jobs in 60 days—that's what they have to do by law.

A delay in reauthorizing these agreements would delay the reviews of drugs and devices submitted after April 1, only a few days away.

For example, if we do not pass these reauthorizations into law before the current agreements expire, an FDA reviewer who

gets started reviewing a cancer drug submitted to the agency in April would be laid off on October 1, before the reviewer is able to finish his or her work. The sooner we reauthorize the agreements, the better—to give patients, reviewers, and companies certainty.

In addition to harming patients and families that rely on medical innovation, a delay in reauthorizing the user fees would threaten biomedical industry jobs and America's global leadership in biomedical innovation.

#### PROCESS FOR REAUTHORIZATION

I am hopeful that this committee, and this Congress, can work in a bipartisan manner to reauthorize the user fees before the August recess.

Congress must pass legislation reauthorizing and updating the fees to support the recommendations contained in what are called "commitment letters" sent to Congress in January.

Now these commitment letters are part of the agreements between FDA and industry—they establish the agency's commitments, such as timelines for application review or to put out guidances in exchange for the fees Congress authorizes. The letters were transmitted to Congress in January of this year.

So today's hearing is not the first time members of Congress or the public is hearing about the recommendations for reauthorization.

In Congress, while we were working on the 21st Century Cures and after it was signed into law, the HELP Committee had 15 bipartisan briefings, some of which were in conjunction with the Energy and Commerce Committee in the House of Representatives as well, so we could hear from FDA and industry about the reauthorization. The first of those briefings was back in late 2015.

Outside of Congress, the FDA posted meeting minutes after every negotiation, and held public meetings to hear feedback.

So the content of the commitment letters, and the changes to the fee authorizations, should not be new, or a surprise, for any member of this committee.

After the April 4th hearing, I hope to move to mark-up the legislation in committee as soon as possible.

This is the first time that the user fees have sunset in the first year of a new administration, so we are starting hearings a little later this year than we did in 2012.

In order to get this done on time, any additional policies that Senators may want to attach need to be broadly bipartisan, related to human medical products, and non-controversial in order to avoid slowing the package down.

#### HOW REAUTHORIZATION BUILDS ON 21ST CENTURY CURES

There are many improvements in the commitment letters and fee structure in these reauthorizations to be excited about.

The prescription drug and medical device reauthorizations include many provisions that build on the work of 21st Century Cures, such as: involving patients in drug and medical device development, dedicated staff to assist in the development and review of rare disease drugs, improved timelines, increased guidance for drug and device combination products, and modernizing the clinical trial process.

There are important structural reforms. Each agreement contains reporting measures built both by FDA and by independent third parties, so we can see how the changes are working. FDA is going to work to implement full time reporting by 2022, so Congress, patients, and medical product manufacturers will have a better picture about how resources are being used at FDA and understand what is needed to do what we ask.

The biosimilar and generic drug user fee agreement includes additional staff and resources to approve more biosimilars and more generic drugs, which provide more competition and lower drug costs.

These are just a few of the highlights of the reauthorization and commitment letters. It is a good agreement for patients, and I look forward to working with Senator Murray and all the members of the Committee to get it done expeditiously.

#### TRIBUTE TO NINA M. SERAFINO

Mr. CARDIN. Mr. President, I would like to take this opportunity to extend my appreciation to a dedicated public servant at the Congressional Research Service, CRS, of the Library of Congress, Ms. Nina M. Serafino. Ms. Serafino recently retired after more than 35 years of service to Congress. This length of public service is not only a credit to Ms. Serafino, but also a demonstration of the dedication that she and many other CRS employees bring to support our work here in Congress.

During Ms. Serafino's 35 years with CRS, she provided Congress with many types of assistance to help inform national policymaking on a variety of war and peace issues. From 1981, when she joined CRS, through the 1980s, she was deeply involved in bipartisan efforts to evaluate U.S. policy in Central America. Her work focused on providing a common understanding of the problems and possibilities in the region in order to shape U.S. options and alternatives. Particularly noteworthy was her original research on aspects of the Central American conflicts where there was a little or no information available from other sources. Responding to a congressional request, she conducted field research and delved into the Library of Congress's historical materials to provide a unique report on the many parties of the civic opposition to the Sandinista government in Nicaragua. Similarly, her field research on the Latin American "Contadora" effort significantly informed congressional deliberations regarding the peace process to end the conflicts in Nicaragua and El Salvador.

With the advent of U.S. military involvement in peacekeeping operations in the Balkans and elsewhere beginning in the 1990s, Ms. Serafino contributed to congressional efforts to comprehend the plethora of institutional and budgetary considerations relevant to our government's ability to bring its full toolbox to bear in those operations. Providing information and analysis through reports, briefings, and several comprehensive conferences and workshops for Members and staff, Ms. Serafino assisted Congress in understanding the possibilities, constraints, and options for legislating and overseeing military and civilian tools and the development of interagency resources and mechanisms.

As Congress sought to comprehend and deal with the post-9/11 world, Ms. Serafino supplemented targeted CRS

work on Afghanistan and Iraq with conferences and reports that brought an historical perspective to congressional deliberations. The conferences and reports provided insights on a wide variety of international experiences in dealing with terrorism and contained historical information and pertinent analysis on previous U.S. interventions and occupations.

Over the past decade, Ms. Serafino also developed a number of products on security assistance and cooperation. Most recently, as the U.S. Government has expanded U.S. military efforts to build partner capacity among foreign security forces worldwide, Ms. Serafino contributed an historical perspective on U.S. security assistance and cooperation development in the post-World War II period to inform our deliberations on an evolving legislative framework for such assistance. Her written work on post-9/11 topics has enlightened both Congress and the broader foreign policy and defense communities.

Throughout Ms. Serafino's career, she won the respect and admiration of her colleagues for her geniality and expertise on Latin America and international security affairs. She won a Distinguished Service Award and several Merit Service and Special Achievement awards. Her steadfast dedication to serve Congress and her commitment to the highest standards of research made a lasting contribution to congressional policy discourse. I have said many times that the Federal workforce is a critical national asset. Ms. Serafino and the other talented and dedicated public servants at CRS are yet another example. While we will miss her contributions, I know my colleagues will want to join me in sending our best wishes to Ms. Serafino for a happy retirement.

#### ADDITIONAL STATEMENTS

##### TRIBUTE TO STEVE HAMMOND

● Mr. CARDIN. Mr. President, today I wish to recognize the three decades of distinguished service journalist Steve Hammond has provided to the citizens of Maryland's Eastern Shore and the viewers of WBOC-TV 16 in Salisbury, MD, "Delmarva's News Leader."

Steve Hammond is a Maryland native, raised in Towson's Rodgers Forge neighborhood. He learned many of life's lessons on the football and lacrosse fields before graduating from the University of Delaware with a degree in mass communications. Since his mother, sister, and brother have all been involved in television production, it is no surprise, perhaps, that Steve gravitated toward the business of broadcasting and interned for several stations. He discovered he felt most at home in the newsroom and was drawn particularly to the variety of daily reporting. In 1985, after working without pay for 2 weeks to illustrate his potential value, Steve was hired by WHYY, a