

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