

The ODA has been enormously successful. Before Congress enacted the ODA in 1983, the Food and Drug Administration, FDA, approved only 38 drugs in the United States specifically to treat orphan diseases. From the passage of the ODA in 1983 until May 2010, the FDA approved 353 orphan drugs and granted orphan designations to 2,116 compounds. As of 2010, 200 of the roughly 7,000 officially designated orphan diseases have become treatable.

Yet, despite the benefits of these policies, the incentives and access guarantees found in the ODA are not yet part of any free trade agreement negotiations.

The Bipartisan Congressional Trade Priorities and Accountability Act of 2015, or TPA, contain a number of negotiating objectives for the administration to follow. For example, the TPA law's negotiating objectives require that U.S. trade agreements provide a standard of intellectual property rights protection that is similar to that found in the United States, which includes providing incentives for biopharmaceutical innovation that are similar to those in the United States. The language in the TPA law is necessarily broad, and although it does not explicitly reference critical incentives for orphan drug development, I want to make it clear that these incentives, including the 7-year market exclusivity at the heart of the ODA, are consistent with the TPA law's requirement that U.S. trade agreements provide a standard of intellectual property protection that is similar to U.S. law.

This is especially important because vital incentives for orphan drug development are lacking in many markets outside the United States, hindering the development of treatments, diagnostics, and cures for rare diseases—particularly diseases endemic to those markets. A lack of incentives for orphan drug development in any one country can have a very real impact on the likelihood of investment into a research or cure for a given disease. Particularly in the case of ultra-rare diseases, those affecting fewer than 1 in 50,000 individuals, there may only be a handful of patients around the world who would benefit from a particular treatment or cure, and removing a number of them from the pool of potential patients may render investments in these therapies untenable and could drive up costs for rare disease patients in the United States.

Therefore, I want to make it clear that I believe it is appropriate for the administration to negotiate ODA incentives and access guarantees, including the 7-year market exclusivity period, in future U.S. trade agreements and that the intent of Congress is that TPA's negotiating objectives are consistent with that goal.

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, 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, March 9, 2016.

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. 15-81, concerning the Department of the Air Force's proposed Letter(s) of Offer and Acceptance to Indonesia for defense articles and services estimated to cost \$95 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. 15-81

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: Indonesia.
(ii) Total Estimated Value:

Table with 2 columns: Category and Value. Major Defense Equipment* \$ 80 million. Other 15 million. Total 95 million.

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

Major Defense Equipment (MDE): Thirty-six (36) AIM-120C-7 Advanced Medium-Range Air-to-Air Missiles (AMRAAMs), One (1) Missile Guidance Section.

Non-Major Defense Equipment (non-MDE): Control section support equipment, spare parts, services, integration activities, logistics, technical contractor engineering and technical support, loading adaptors, technical publications, familiarization training, test equipment, and other related elements.

(iv) Military Department: Air Force (X7-D-YAB).

(v) Prior Related Cases, if any: None.
(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 9, 2016

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

POLICY JUSTIFICATION

Indonesia-AIM-120C-7 Advanced Medium-Range Air-to-Air Missiles (AMRAAMs)

The Government of Indonesia has requested a possible sale of thirty-six (36) AIM-120C-7 AMRAAMs and one (1) Missile Guidance Section. Also included in this possible sale are: control section support equipment, spare parts, services, logistics, technical contractor engineering and technical support, loading adaptors, technical publications, familiarization training, test equipment, and other related elements. The total estimated value of MDE is \$80 million. The overall total estimated value is \$95 million.

This proposed sale contributes to the foreign policy and national security of the United States by helping to improve the security of a key partner that has been, and continues to be, an important force for political stability and economic progress in the Asia-Pacific region.

The proposed sale improves Indonesia's capability to deter regional threats and strengthen its homeland defense. Indonesia is able to absorb this additional equipment and support into its armed forces.

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

The prime contractor will be determined by competition. There are no known offset agreements proposed in connection with this potential sale.

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

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

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

Annex Item No. vii

(vii) Sensitivity of Technology

1. AIM-120C-7 Advanced Medium Range Air-to-Air (AMRAAM) is a radar-guided missile featuring digital technology and micro-miniature solid-state electronics. AMRAAM capabilities include look-down/shoot-down, multiple launches against multiple targets, resistance to electronic countermeasures, and interception of high flying, low flying, and maneuvering targets. The AMRAAM All Up Round is classified CONFIDENTIAL. Major components and subsystems are classified up to CONFIDENTIAL, and technology data and other documentation are classified up to SECRET.

2. If a technologically advanced adversary were to obtain knowledge of the specific hardware and software elements, the information could be used to develop countermeasures or equivalent systems that might reduce weapon system effectiveness or be used in the development of a system with similar or advanced capabilities.

3. This sale is necessary in furtherance of the U.S. foreign policy and national security objectives outlined in the Policy Justification. Moreover, the benefits to be derived from this sale, as outlined in the Policy Justification, outweigh the potential damage that could result if the sensitive technology were revealed to unauthorized persons.

4. All defense articles and services listed in this transmittal have been authorized for release and export to Indonesia.

REMEMBERING JUSTICE ANTONIN SCALIA

Mr. CASEY. Mr. President, today I wish to remember Justice Antonin