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H.R. 2430 – FDA Reauthorization Act of 2017 (Walden, R-OR)

CONTACT: Amanda Lincoln, 202-226-2076

FLOOR SCHEDULE:

Expected to be considered July 12 under suspension of the rules, which requires a 2/3 majority for passage.

TOPLINE SUMMARY:

H.R. 2430 would reauthorize the Food and Drug Administration (FDA)'s four drug and device-related user fee programs, generally increasing and restructuring the industry-paid user fees in exchange for a more predictable and timely review process. In addition, the bill would reauthorize certain other FDA programs, and includes new policies related to pediatric drug and device development, the medical device inspection process, and access to generic therapies.

COST:

No Congressional Budget Office (CBO) estimate is available at this time.

Rule 28(a)(1) of the Rules of the Republican Conference prohibit measures from being scheduled for consideration under suspension of the rules without an accompanying cost estimate. Rule 28(b) provides that the cost estimate requirement may be waived by a majority of the Elected Leadership.

CBO estimated that if a similar Senate bill were enacted, net discretionary spending would increase by approximately $740 million between 2017 and 2022, assuming appropriation actions consistent with the bill, and also increase direct spending by $13 million and decrease revenues by $2 million during the same time period, so pay-as-you-go procedures would apply. Altogether, CBO projected budget deficits would increase by $15 million during the five-year period.

CONSERVATIVE CONCERNS:

- **Expand the Size and Scope of the Federal Government?** The bill would generally expand FDA's regulatory authority.
- **Encroach into State or Local Authority?** The bill would pre-empt state and local laws related to the distribution of hearing aids intended for mild or moderate hearing impairment, but would also deregulate the industry.
- **Delegate Any Legislative Authority to the Executive Branch?** No.
- **Contain Earmarks/Limited Tax Benefits/Limited Tariff Benefits?** No.

BACKGROUND:

In general, manufacturers of biomedical products must obtain FDA approval or clearance in order to demonstrate that their product is safe and effective for its intended use before it can be

marketed in the United States. Widespread delays in the approval process for prescription drugs served as the impetus for Congress to pass the Prescription Drug User Fee Act (PDUFA) in 1992, which authorized FDA to collect user fees from brand manufacturers in order to fund (and ideally expedite) the review process for new prescription drugs. Two principles included in PDUFA were particularly important to securing its passage, and have been consistently incorporated into all of FDA's user fee authorities: the user fees (1) do not guarantee product approval and (2) must supplement – not supplant – annual discretionary appropriations. PDUFA is seen by many as a success and has been repeatedly reauthorized. Moreover, similar arrangements were subsequently established for medical devices in 2002 and for generic drugs and biosimilars in 2012.

The four human drug and device-related user fee programs -- Prescription Drug User Fee Act (PDUFA), Medical Device User Fee Act (MDUFA), Generic Drug User Fee Act (GDUFA), and Biosimilar User Fee Act (BsUFA) – will sunset on September 30. Current law, however, provides for a reauthorization process which is currently ongoing. In accordance with statutory deadlines, FDA submitted recommendations for each user fee agreement to Congress by January 15, 2017. These recommendations cover the next five fiscal years (FY18-22), and take the form of: (1) a "commitment letter" outlining the performance goals and targets that FDA will commit to in exchange for the user fees and (2) proposed authorizing language. FDA negotiates the terms of each commitment letter with industry representatives, and the commitment letters are entered into the Congressional Record and referenced in the various user fee acts as containing the only priorities that the user fees may be used to support.

DETAILED SUMMARY AND ANALYSIS

H.R. 2430 would reauthorize the FDA's authority to collect each of the four user fees for five years, through October 1, 2022, and maintain existing annual performance and financial reporting requirements, which would sunset on January 31, 2023. The bill would also maintain the existing reauthorization process for each user fee program, updating the date by which FDA must provide recommendations to Congress to January 15, 2022. The effective date of the amendments to each user fee program would be October 1, 2017 or the date of enactment, whichever is later. FDA will continue to review any submissions made prior to October 1, 2017 and assess related fees based on the terms of the user fee agreements established in 2012.

Title I: Prescription Drug User Fee Amendments (PDUFA) of 2017

Title I would reauthorize FDA's authority to collect user fees to support the review process for brand prescription drugs and specify that the user fees could only be used to support the activities outlined in the PDUFA VI commitment letter. The bill would increase the base fee amount to $878.6 million in FY18, compared to $718.7 million in FY17, and would restructure the fees so that 20 percent of target revenue comes from product application fees and 80 percent from program fees for approved products. Under current law, application fees, product fees, and establishment fees each make up one-third of target revenue, which can result in an unpredictable revenue stream. In addition, the bill would fund 230 additional full time employees to support the terms of the PDUFA VI commitment letter. Funding to support these employees would be phased in according to the following schedule:

FY18	FY19	FY20	FY21	FY22
$20.1 million	$21.3 million	$17 million	$5.4 million	$2.8 million

H.R. 2430 would also replace the current law workload adjustment, which independent evaluations have found to be suboptimal, with a new capacity planning adjuster to better align the user fees with workload.

FDA would be required to contract with an independent consulting or accounting firm to develop the new capacity planning methodology, which would be phased in after a review of comments posted during a public comment period.

Title II: Medical Device User Fee Amendments of 2017

Title II would reauthorize FDA's ability to collect user fees to support the review process for medical devices and stipulate that the user fees may only be used to support the priorities outlined in the MDUFA IV commitment letter. The bill would increase the target base fee amount each year according to the following schedule:

FY18	FY19	FY20	FY21	FY22
$183 million	$190.7 million	$200 million	$211.7 million	$213.7 million

The bill would also update the inflation adjuster, permit the secretary to increase fees to meet the base target if necessary, and provide FDA with new authority to collect fees for de novo classification requests, which are becoming more common. H.R. 2430 would also reauthorize a program providing for third-party review of medical devices and require the secretary to conduct a public guidance development process to identify which devices are eligible for third party review. In addition, the bill would establish a new pilot program, known as the Accreditation Scheme for Conformity Assessment (ASCA), which would authorize the secretary to audit and certify laboratories that conduct device conformance testing through 2022. Finally, although FDA currently receives application submissions in both paper and electronic form, the bill would require all submissions to be made electronically by October 1, 2021, and allow the secretary flexibility to extend this deadline to April 1, 2023.

Title III: Generic Drug User Fee Amendments of 2017

Title III would reauthorize the FDA's ability to collect user fees to support the review process for generic drugs and stipulate that the user fees may only be used to support the priorities outlined in the GDUFA II commitment letter. GDUFA II would substantially increase the base fee amount from $299 million in FY17 to $493.6 million in FY18. This increase is designed to better align the user fees with workload: stakeholders expected that FDA would receive about 750 generic drug applications each fiscal year when GDUFA I was negotiated in 2012, but the agency reports receiving closer to 1,000 applications each year. The bill would also update the fee structure to improve revenue predictability and increase flexibility for small manufacturers. One-third of the total revenue would be derived from application fees, one-fifth from generic drug facility fees, seven percent from active pharmaceutical ingredient facility fees, and 35 percent from a new generic drug applicant program fee. The program fee would be determined according to the number of FDA-approved applications each sponsor has, with manufacturers with 20 or more approved applications paying the full fee, manufacturers with between six and 19 approved applications paying 40 percent of the full fee, and manufacturers with five or fewer approved applications paying 10 percent of the full fee.

Title IV: Biosimilar User Fee Amendments of 2017

Title IV would reauthorize the FDA's ability to support the review process for biosimilars and specify that the user fees may only be used to support the priorities outlined in the BSUFA II commitment letter. Under current law, BSUFA user fees are tied to PDUFA rates, but H.R. 2430 would create a new independent fee structure based on the BSUFA program costs, increasing the base fee to $45 million in FY18, compared to $20 million in FY17. The Secretary would have authority to adjust the base fee by a maximum of $9 million if necessary to reflect updated workload and cost estimates for FY18. The new fee structure includes the

following types of fees: (1) an Initial Biosimilar Development Fee assessed in the first year after a sponsor begins clinical trials for a new biosimilar; (2) an Annual Biosimilar Development Fee assessed in subsequent years while a sponsor develops a new biosimilar; (3) a Biosimilar Program Fee (BPF) for sponsors of approved biosimilars; and, (4) an Application Fee for new biosimilar applications. The bill would allow the Secretary to modify the amount and/or percentage of target revenue generated from each fee type annually, but the Secretary would be required to publish supporting rationale in the Federal Register.

Title V

This title contains numerous provisions related to pediatric drug and device development. Specifically, the bill would:

- Grant FDA new authority to require manufacturers to conduct a pediatric study for adult cancer drugs sharing a common molecular target with a pediatric cancer and require the Secretary, within one year of enactment, to publish a list of molecular targets and cancers for which the requirement will be automatically waived. Current law provisions allow the secretary to extrapolate pediatric effectiveness from adequate and well-controlled studies in adults would also be applied to molecularly-targeted drugs. Conservatives will be pleased that this section includes strong protections for confidential commercial information.
- Reauthorize FDA's authority to issue grants to Pediatric Device Consortia working to develop pediatric devices through 2022 and allow the funds to be used to provide regulatory consultation to device sponsors in support of pediatric device applications, where appropriate.
- Reauthorize funding for the National Institutes of Health (NIH) to conduct pediatric trials not conducted by drug sponsors, and require the NIH to post study data, and FDA to link to that data when opening a docket for comments on proposed pediatric labeling changes. Conservatives will be pleased that this section includes strong protections for confidential commercial information and the privacy rights of human research participants.
- Reauthorize rules regarding device development for rare pediatric conditions.
- Allow flexibility for review of devices subject to the humanitarian device exemption to be conducted by either Institutional Review Boards or other committees.
- Require the secretary to convene a public meeting and report on pediatric device development, approval or clearance, and labeling.
- Update the content required to be included in FDA's annual report to Congress on pediatric devices.
- Require FDA to meet with device sponsors upon request regarding pediatric study plans no later than the end-of-Phase I meeting or within 30 calendar days of receipt of the request, an earlier deadline than under current law.
- Require FDA to act on pediatric study requests and proposed amendments to a written request within 120 calendar days of receipt.
- Require FDA to provide responses to the internal review committee that reviews written requests for pediatric studies.
- Require that the internal review committee implement a plan to achieve earlier submission of pediatric studies.
- Ensure that FDA's Office of Pediatric Therapeutics maintains a position for a neonatologist.
- Require FDA to issue guidance on drug development for neonates.
- Require Pediatric Research and Equity Act (PREA) non-compliance letters to be shared with the Pediatric Advisory Committee.
- Update the information required of the FDA's annual pediatric report to include information regarding the duration of PREA studies and details of the written request process.
- Require FDA to report to Congress regarding the lack of information in orphan pediatric drug labeling.

Title VI

In general, this title reauthorizes and modifies numerous existing FDA programs through 2022. The bill would:

- Reauthorize a program providing the secretary authority to grant exclusivity for drugs containing single enantiomers, the Critical Path public-private partnerships, and orphan drug grants.
- Clarify that prescription drugs that are not intended for sale in the United States cannot be diverted there unless legally imported to address a drug shortage.
- Expand the definition of patient experience data to include the physical and psychosocial impacts of a disease or condition, or participation in clinical trials for a therapy to treat such a disease.
- Expand the Secretary's authority to require sponsors to conduct a Risk Evaluation Mitigation Strategy (REMS) to allow the secretary to require manufacturers to communicate with health care providers regarding product formulation.
- Clarify that a manufacturer must demonstrate, when seeking exclusivity, that a drug candidate is clinically superior to a previously approved orphan drug.
- Clarify when pediatric labeling must be included and when it can be left out to improve generic access.
- Require FDA and NIH to convene a public meeting on clinical trial inclusion and exclusion criteria and issue a report on clinical trial participation, barriers to enrollment, and potential solutions.
- Require GAO to report to Congress on FDA's Expanded Access program.
- Require FDA to issue one or more guidances on broadening clinical trial eligibility and improving treatment access for those who cannot participate in clinical trials.
- Require FDA to issue new or revise existing guidance or regulations to streamline the review of individual patient expanded access protocols.
- Close a loophole in current law to ensure that priority review vouchers for neglected tropical diseases are awarded only in instances where the manufacturer has conducted one or more new clinical investigations that are essential to application approval.

This section also includes a Sense of Congress that Congress and the Administration should take legislative and administrative action to lower the cost of prescription drugs for consumers and taxpayers, while striving to increase competition and promote timely access to generics, as well as balancing the needs to promote affordability and innovation.

Title VII

This title contains numerous provisions related to the medical device inspection process. Specifically, it would:

- Establish a new model for risk-based schedule for devices to improve FDA's ability to examine higher risk facilities.
- Establish new standards to improve the predictability of scheduled device facility inspections (i.e., not for cause inspections).
- Reauthorize FDA's ability to use accredited organizations to conduct inspections.
- Clarify the process for obtaining a foreign export certificate for medical devices, and would establish a new pathway for manufacturers to present information to FDA and correct any ongoing problems when denied a certificate.
- Allow FDA to recognize foreign auditors to improve international alignment of inspection standards and improve FDA's access to audit data.
- Allow FDA to approve a medical imaging device with use of a contrast agent, so long as the contrast agent does not pose any additional safety risk and is used in the same concentration, with the same

rate and route of administration, in the same patient population, and with the same type of imaging technology.

- Clarify how FDA can implement the 21st Century Cures provision requiring FDA to classify device accessories based on their intended use rather than the class of their parent device.
- Create a new voluntary pilot project for device manufacturers to meet reporting or post-market safety requirements using active surveillance.
- Establish a new category of over-the-counter hearing and subjects those devices to FDA regulation. Some conservatives may have concerns that this bill pre-empts state and local laws regarding the distribution of hearing aids, however, the bill would also deregulate the hearing aid industry.
- Finally, the title requires the Secretary to report to Congress and make publicly available a report on the quality and safety of devices with respect to servicing.

Title VIII

This title contains numerous provisions aimed at improving access to generic drugs. Specifically, it would:

- Require FDA to act on a generic drug application within eight months in instances where the generic drug candidate is on the drug shortage list or there are no more than three approved drugs and no blocking patents affecting the candidate's ability to come to market. In order to receive the eight month review timeline, generic drug manufacturers would be required to provide FDA information regarding their manufacturing facilities 60 days before submitting the application.
- Create a new competitive therapy designation and allow the Secretary to expedite the review process for generic drug candidates which obtain this designation, including through additional meetings.
- Require FDA to issue guidance to specify the process and criteria through which the Secretary will make the competitive therapy designation and what actions the Secretary may take to expedite the review process. Generic drug candidates would be eligible for the designation if the Secretary determines that there is "inadequate generic competition," which the statute defines as a scenario in which there is no more than one approved drug other than the reference listed drug and one other generic drug.
- Require the Secretary to determine whether drug candidates meet for the competitive therapy designation within 60 calendar days after the manufacturer's request.
- Require the drug sponsor must report to the Secretary within one year of approval of a competitive generic therapy regarding whether the drug has been marketed in interstate commerce.
- Establish a new 180-day exclusivity period to encourage manufacturers to develop alternative generics in markets where only one generic drug exists.
- Require FDA to post a list of drugs with limited competition on the FDA website, and update it at least once every six months.
- Require FDA to develop a process for expediting re-inspections in scenarios where facility issues are the only reason or delay in review of a generic drug application
- Improve transparency about the number of pending generic drug applications and inspection process.
- Require the Secretary to provide generic drug manufacturers with periodic status review updates for pending applications.
- Require GAO to report on the rate of first cycle approvals between 2012 and 2017, including explanations of why the rates were less than 20 percent (if they were) and what FDA could do to improve the first cycle generic rate.

Title IX

This title includes additional sundry provisions, including technical corrections to the 21st Century Cures Act. It would improve transparency of facility inspections and require FDA to publish information regarding the inspection process. It requires FDA to report on new metrics in the annual user fee report in

order to increase transparency about where the Agency is meeting its user fee goals. It would require FDA to analyze its performance and propose a corrective action plan if user fee goals are missed, would require FDA Center Directors to testify before Congress at least annually, and would limit the user of user fees for maintenance, renovation, and repair of facilities, acquisitions, fixtures, and furniture beginning October 1, 2023.

COMMITTEE ACTION:

This bill was introduced by Representative Walden (R-OR) on May 16, 2017 and referred to the House Committee on Energy and Commerce. The Energy and Commerce Health Subcommittee reported the bill by voice vote on May 18 and the full Energy and Commerce Committee reported the bill by a vote of 54-0 on June 7.

ADMINISTRATION POSITION:

No Statement of Administration Policy is available at this time.

CONSTITUTIONAL AUTHORITY:

According to the sponsor: Congress has the power to enact this legislation pursuant to the following: Article I, Section 8, Clause 3 of the United States Constitution.

NOTE: *RSC Legislative Bulletins are for informational purposes only and should not be taken as statements of support or opposition from the Republican Study Committee.*

H.R. 2664 – Enhancing Detection of Human Trafficking Act (Walberg, R-MI)

CONTACT: Amanda Lincoln, 202-226-2076

FLOOR SCHEDULE:

Expected to be considered the week of July 10 under suspension of the rules, which requires a 2/3 majority for passage.

TOPLINE SUMMARY:

H.R. 2664 would require certain Department of Labor (DOL) personnel to be trained in how to effectively detect and assist law enforcement in preventing human trafficking.

COST:

No Congressional Budget Office (CBO) estimate is available at this time.

Rule 28(a)(1) of the Rules of the Republican Conference prohibit measures from being scheduled for consideration under suspension of the rules without an accompanying cost estimate. Rule 28(b) provides that the cost estimate requirement may be waived by a majority of the Elected Leadership.

CONSERVATIVE CONCERNS:

- **Expand the Size and Scope of the Federal Government?** No.
- **Encroach into State or Local Authority?** No.
- **Delegate Any Legislative Authority to the Executive Branch?** The bill provides the DOL Secretary with substantial authority to define the scope and size of a new training program for the DOL workforce.
- **Contain Earmarks/Limited Tax Benefits/Limited Tariff Benefits?** No.

DETAILED SUMMARY AND ANALYSIS:

H.R. 2664 would require the Secretary of Labor to establish and implement a program that trains, and periodically retrains, certain personnel at the Department of Labor in effectively detecting and assisting law enforcement in preventing human trafficking. The training could be conducted in person or online, and must include: (1) methods for identifying suspected victims of human trafficking and perpetrators; (2) content that is appropriate for the location or environment where the relevant DOL personnel work; (3) other topics that the secretary deems appropriate related to current trends and best practices for DOL personnel in their work environment; (4) a clear course of action for referring potential human trafficking cases to the Department of Justice or other authorities; and, (5) post-training evaluation. Some conservatives may be concerned that this legislation gives substantial discretion to the secretary to determine the size and scope of the program. The bill would also require the Secretary of Labor to report to Congress on the training, including on its overall effectiveness, within one year of enactment.

COMMITTEE ACTION:

This bill was introduced by Representative Walberg (R-MI) on May 25, 2017 and referred to the House Committee on Education and Workforce. No further action has occurred.

ADMINISTRATION POSITION:

No Statement of Administration Policy is available at this time.

CONSTITUTIONAL AUTHORITY:

According to the sponsor: Congress has the power to enact this legislation pursuant to the following: Article I, Section 8, Clause 3.

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H.R. 2480 – Empowering Law Enforcement to Fight Sex Trafficking Demand Act (Rep. Hartzler, R-MO)

CONTACT: Jennifer Weinhart, 202-226-0706

FLOOR SCHEDULE:

Expected to be considered on July 12, 2017, under a suspension of the rules, which requires 2/3 majority for passage.

TOPLINE SUMMARY:

H.R. 2480 would add an additional allowable use to those enumerated under the Byrne JAG statue, to permit states and local jurisdictions to receive grant funding for programs to fight human trafficking, including those seeking to reduce the demand for commercial sex.

COST:

The Congressional Budget Office (CBO) estimate is not yet available.

Rule 28(a)(1) of the Rules of the Republican Conference prohibit measures from being scheduled for consideration under suspension of the rules without an accompanying cost estimate. Rule 28(b) provides that the cost estimate requirement may be waived by a majority of the Elected Leadership.

CONSERVATIVE CONCERNS:

- **Expand the Size and Scope of the Federal Government?** The bill would expand the permissible uses of federal grant funding.
- **Encroach into State or Local Authority?** No.
- **Delegate Any Legislative Authority to the Executive Branch?** No.
- **Contain Earmarks/Limited Tax Benefits/Limited Tariff Benefits?** No.

DETAILED SUMMARY AND ANALYSIS:

Generally, the Byrne JAG program provides funds for law enforcement in state and local jurisdictions for a variety issues, including protecting their communities, preventing crime, and undertaking crime victim initiatives. This legislation would add anti-human trafficking efforts to the list of allowable uses under the Byrne JAG program, so that state and local officials can fight commercial demand and is intended to help protect individuals vulnerable to being trafficked. Because demand reduction programs are generally carried out at a local level, this legislation would provide communities with additional, federally supported tools to fight trafficking.

COMMITTEE ACTION:

H.R. 2480 was introduced on May 17, 2017 and was referred the House Committee on the Judiciary. It was reported by voice vote on June 28, 2017.

ADMINISTRATION POSITION:

A Statement of Administration Policy is not yet available.

CONSTITUTIONAL AUTHORITY:

According to the sponsor, Congress has the power to enact this legislation pursuant to the following: Clauses 1 and 3 of Article I, Section 8 of the United States Constitution.

NOTE: *RSC Legislative Bulletins are for informational purposes only and should not be taken as statements of support or opposition from the Republican Study Committee.*

H.R. 2200 – Frederick Douglass Trafficking Victims Prevention and Protection Reauthorization Act of 2017, as amended (Smith, R-NJ)

CONTACT: Brittan Specht, 202-226-9143

FLOOR SCHEDULE:

Expected to be considered July 12 under suspension of the rules, which requires a 2/3 majority for passage.

TOPLINE SUMMARY:

H.R. 2200 would reauthorize the Trafficking Victims Protection Act and International Megan's Law to Prevent Child Exploitation and Other Sexual Crimes Through Advanced Notification of Traveling Sex Offenders through 2021 and would expand programs to combat human trafficking.

COST:

The Congressional Budget Office (CBO) estimates that, as reported by committee, implementing the bill would cost almost $450 million over the 2018-2022 period, assuming appropriation of the authorized and necessary amounts. The remaining amounts would spend in years after 2022. CBO and the staff of the Joint Committee on Taxation (JCT) estimate that enacting H.R. 2200 would decrease revenues by $13 million over the 2018-2027 period but would have insignificant effects on direct spending. Pay-as-you-go procedures apply because enacting the legislation would affect direct spending and revenues.

CONSERVATIVE CONCERNS:

- **Expand the Size and Scope of the Federal Government?** The bill would expand the permissible uses of some grants.
- **Encroach into State or Local Authority?** No.
- **Delegate Any Legislative Authority to the Executive Branch?** The bill would, overall, reduce the discretion available to officials in making determinations about foreign nation's actions to combat trafficking.
- **Contain Earmarks/Limited Tax Benefits/Limited Tariff Benefits?** No.

DETAILED SUMMARY AND ANALYSIS:

Reauthorizations

H.R. 2200 would reauthorize a suite of anti-human trafficking programs at current funding levels, including programs under the jurisdiction of the Departments of Justice, Homeland Security, Health and Human Services, and Labor.

Specifically, the bill would authorize:

- $33 million for each year FY2018-2021 for Department of State programs to monitor and prevent trafficking and $15 million for each year FY2018-2021 for foreign assistance programs to combat trafficking
- For the Department of Health and Human Services for each year FY2018-2021: $14.5 to provide assistance to victims of trafficking; $8 million for grants for similar purposes; and $2 million for residential treatment facilities for juvenile victims of trafficking
- For the Department of Labor: $5 million for each year FY2018-2021 to provide assistance to victims of trafficking who are citizens or legal permanent residents.

Federal Grants

The bill would authorize the Secretary of Health and Human Services to award additional grants from within the existing authorization for local school districts and non-profits to educate staff and students about how to recognize and respond to labor and sex trafficking.

The bill would require the designation of an employees at U.S. diplomatic posts abroad to receive reports from individuals who were victims of severe forms of trafficking while in the United States. This information would be required to be transmitted to the Departments of Justice, Labor, and Homeland Security.

The bill would amend the Trafficking Victims Protection Act of 2000 to more specifically detail what type of care and housing programs may be funded by Department of Justice Grants Specifically, the bill would require that such funds should be used to provide long-term housing options and trauma-based care for individuals who are between the ages of 12-24, and who are homeless, in foster care or transitioning out of foster care, or involved in the criminal justice system.

Government Contracting and Procurement

The bill would require air carriers that enter into contracts with the federal government to submit an annual report on the number of employees of the carrier who are trained in the detection and reporting of potential human trafficking.

The bill would also create a preference program for booking of lodging for official government travel for facilities that implement anti-human trafficking measures. Such measures include: maintaining a zero tolerance policy for sex trafficking of minors; trains employees annually on identifying potential cases of such trafficking and exploitation; and keeps records of reports of such instances. The Administrator of the General Services Administration would be directed to maintain a list of preferred lodging and to issue regulations to implement the preference.

The bill would require the Departments of State, Justice, and Homeland Security, as well as the U.S. Agency for International Development and the Office of Management and Budget to issue a report to congress annually detailing what official in the agency's legal or procurement department responsible for implementing anti-human trafficking requirements for government contracting. The report would also be required to include statistical information on the number of human trafficking reports the agency received or identified, and any remedial action or referral for prosecution that resulted therefrom.

Tax Treatment of Civil Awards

The bill would exempt from taxable income any amount awarded as civil damages to victims of trafficking.

Diplomatic Visas

The bill would limit the Secretary of State's existing discretion to suspend the issuance of diplomatic visas to a foreign mission if officials are involved in trafficking. Specifically, the bill would require such suspension to be for at least on year, as opposed to a period determined by the secretary. Further, the bill would require such suspension for a broader set of actions of embassy officials or their families, including

in the event that officials refuse voluntary interviews regarding trafficking or abuse or refuse to waive immunity in a tracking prosecution brought by the U.S. government against an accredited individual.

Foreign Nations
The Trafficking in Victims Protection Act allows the president to restrict non-humanitarian aid to nations that do not make reasonable efforts to combat human trafficking. Such determination is made by the Department of State based on independently collected information and through requests for information to foreign governments. In general, H.R. 2200 would reduce the discretion of the Secretary of State in making such determinations, and increase the thresholds for nations to be in compliance, resulting in stricter enforcement of aid limitations.

The bill would eliminate a benefit-of-the-doubt exemption for nations that submit only partial data. Rather than allowing the secretary to assume that the partially-submitting nation is making a good faith effort, he would be required to presume that the nation is not doing so. Further, the bill would require that nations that are designated as on the Tier 2 Watch List (on notice for being downgraded to Tier 3, where aid restrictions apply) take action to implement the recommendations of the most recent State Department Trafficking in Persons report in order to avoid being downgraded to Tier 3.

Finally, the bill modifies the existing prohibition on U.S. military cooperation with nations that use child soldiers to include those nations that recruit or use children in police or other security forces.

COMMITTEE ACTION:
This bill was introduced by Representative Smith (R-NJ) on April 27, 2017 and referred to the House Committee on Foreign Affairs, which ordered the bill reported, as amended, by voice vote on May 3. No further action has occurred.

ADMINISTRATION POSITION:
No Statement of Administration Policy is available at this time.

CONSTITUTIONAL AUTHORITY:
According to the sponsor: "Congress has the power to enact this legislation pursuant to the following: Article I, Section 8, Clauses 3 and 18. Article 4, Section 3."