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Active Opioid Legislation in the House: In Brief

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Contents

Purpose of This Report.....	1
Bill Summaries.....	1

Contacts

Author Contact Information	7
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Purpose of This Report

The House is scheduled to vote on a dozen or more bills related to heroin and prescription opioid abuse during the week of May 9, leading some to dub this week “Opioid Week” in the House.¹ This report briefly summarizes opioid-related bills that are scheduled for consideration during “Opioid Week.” The brief summaries in this report may be useful illustrations of the range of approaches Members of Congress have proposed to address the problem of opioid addiction.

The full text of each bill as introduced is available on Congress.gov. Some bills have been reported or ordered to be reported with amendments. When a bill is reported (as amended), the new version is also available on Congress.gov. There is, however, a period between a committee’s ordering a bill to be reported and reporting the bill. This CRS report reflects the most up-to-date information about each bill that CRS has been able to obtain, including legislative text that may be available on the House website but not yet on Congress.gov.

For More Information

CRS Report R43749, *Drug Enforcement in the United States: History, Policy, and Trends*

CRS Report R43559, *Prescription Drug Abuse*

CRS Report R42593, *Prescription Drug Monitoring Programs*

CRS Report R44467, *Federal Support for Drug Courts: In Brief*

CRS In Focus IF10400, *Heroin Production in Mexico and U.S. Policy*

CRS In Focus IF10219, *Opioid Treatment Programs and Related Federal Regulations*

Not all bills scheduled for consideration during “Opioid Week” are related to opioids, and some may be related to opioids as well as substance abuse issues more broadly. This report focuses on bills that are specifically related to opioids, with the exception of the Infant Plan of Safe Care Improvement Act (H.R. 4843), which includes no specific reference to opioid abuse but has been discussed in that context.²

Not included is S. 524, the Comprehensive Addiction and Recovery Act of 2016 (which passed the Senate on March 10, 2016) because it is not scheduled for consideration in the House. During “Opioid Week,” the House may vote on an amendment (not currently publicly available) to S. 524 and a motion to go to conference on S. 524.³

Bill Summaries

Bills are summarized briefly in numeric order for the convenience of readers looking for a specific bill or bills. The bills included in this report are H.R. 3680, H.R. 3691, H.R. 4063, H.R. 4586, H.R. 4599, H.R. 4641, H.R. 4843, H.R. 4969, H.R. 4976, H.R. 4978, H.R. 4981, H.R. 4982, H.R. 4985, H.R. 5046, H.R. 5048, H.R. 5052, and S. 32.

¹ Mary Ellen McIntire, “Health Brief: Week in Review and What’s Ahead,” *Morning Consult*, May 1, 2016.

² House Committee on Education and the Workforce, “Kline Statement: Markup of H.R. 4843, the Improving Safe Care for the Prevention of Infant Abuse and Neglect Act,” press release, April 28, 2016, <http://edworkforce.house.gov/news/documentsingle.aspx?DocumentID=400648>.

³ See “Consideration of House Amendment to S. 524 – Comprehensive Addiction and Recovery Act of 2016” and “Motion to go to Conference on S. 524, and Possible Democrat Motion to Instruct Conferees” at <http://www.majorityleader.gov/floor/#weekly>.

H.R. 3680, the Co-Prescribing to Reduce Overdoses Act of 2016, as amended, passed the House by voice vote on May 11, 2016.⁴ It would authorize grants to encourage co-prescribing of naloxone (a drug to reverse the effects of opioid overdose) with prescription opioids and grants to support development of co-prescribing guidelines. It would specify eligible entities, application requirements, allowable uses of funds, program evaluations, and reporting requirements. It includes an offset that would reduce by \$5 million the authorization of appropriation for specified activities of the Centers for Disease Control and Prevention (CDC). The Congressional Budget Office estimates that implementing the bill as ordered to be reported would, on net, reduce costs by \$1 million over the 2017–2021 period.⁵

H.R. 3691, the Improving Treatment for Pregnant and Postpartum Women Act of 2016, as amended, passed the House by voice vote on May 11, 2016.⁶ It would reauthorize an existing grant program related to residential treatment of pregnant/postpartum women (authorizing appropriations through FY2020) and would authorize new grants to state substance abuse agencies for related pilot programs. For the pilot program grants, it would specify grant purposes, requirements for awarding grants, minimum services to be provided through the grants, maximum duration, evaluation and reporting requirements, and the maximum percentage of funds (for the larger grant program) to be used for the pilot program grants. The Congressional Budget Office estimates that implementing the bill as ordered to be reported would, on net, have a discretionary cost of \$65 million over the 2017–2021 period.⁷

H.R. 4063, the Promoting Responsible Opioid Management and Incorporating Scientific Expertise Act, as amended, passed the House by voice vote on May 10, 2016.⁸ The bill, as it appears in the Congressional Record, has six sections (including Section 1, Short Title).⁹ Section 2 would require the Secretary of Veterans Affairs (VA) to expand VA's Opioid Safety Initiative, implement education and training requirements for VA employees who prescribe opioids, establish protocols for the designation of a pain management team at each VA medical facility, ensure access to state prescription drug monitoring program (PDMP) data, maximize availability of naloxone, modify VA's Opioid Therapy Risk Report tool, and flag the health records of veterans at risk of opioid abuse. Section 3 would require the VA and Defense Secretaries to ensure that the Pain Management Working Group¹⁰ focus on specified issues, coordinate and consult with other entities as specified, and update the clinical practice guideline for management of opioid therapy for chronic pain. Section 4 would require a Government Accountability Office (GAO) report on VA's Opioid Safety Initiative, a quarterly progress report from VA about actions taken to address GAO's outstanding findings and recommendations, an annual report from VA on opioid prescription rates, and investigation by the Office of the Medical Inspector of the Veterans Health Administration when prescription rates are inconsistent with standards of appropriate and safe care. Section 5 would require VA to share information with state PDMPs. Section 6 would

⁴ *Congressional Record*, vol. 162, part 74 (May 11, 2016), pp. H2256–H2259.

⁵ U.S. Congressional Budget Office, H.R. 3680, *Co-Prescribing to Reduce Overdoses Act of 2015*, May 9, 2016, <https://www.cbo.gov/publication/51553>.

⁶ *Congressional Record*, vol. 162, part 74 (May 11, 2016), pp. H2263–H2266.

⁷ U.S. Congressional Budget Office, H.R. 3691, *Improving Treatment for Pregnant and Postpartum Women Act of 2015*, May 9, 2016, <https://www.cbo.gov/publication/51550>.

⁸ *Congressional Record*, vol. 162, part 73 (May 10, 2016), p. H2172. The title of the bill was amended so as to read: “A bill to improve the use by the Secretary of Veterans Affairs of opioids in treating veterans, and for other purposes.”

⁹ Both versions currently available on Congress.gov have multiple *titles* and are substantially different from the version in the Congressional Record.

¹⁰ 38 U.S.C. §320.

require the VA Secretary to limit the aggregate value of awards and bonuses. The Congressional Budget Office estimates that implementing the bill as ordered to be reported would cost \$138 million over the 2017–2021 period, subject to appropriation of the necessary amounts.¹¹

H.R. 4586, Lali’s Law, as amended, was considered under suspension of the rules on May 11, 2016; the yeas and nays were demanded, and the Speaker pro tempore announced that further proceedings would be postponed.¹² It would authorize grants to states (1) to develop standing orders (allowing naloxone to be dispensed to anyone meeting specified criteria); (2) to encourage pharmacies to dispense naloxone pursuant to standing orders; and (3) to implement guidelines for prescribing opioids, co-prescribing naloxone, and discussing naloxone with patients. It would specify requirements and preference in awarding grants; terms of grants (e.g., duration and amount); and application and reporting requirements. It would authorize appropriations through FY2019 and limit the percentage of funds that may be used for administrative costs. An amendment that was adopted during markup would change the authorization of appropriations (to \$5 million) and would include an offset that would reduce by \$5 million the authorization of appropriation for specified CDC activities. The Congressional Budget Office estimates that implementing the bill as ordered to be reported would, on net, not affect spending over the 2017–2021 period.¹³

H.R. 4599, the Reducing Unused Medications Act of 2016, as amended, passed the House by voice vote on May 11, 2016.¹⁴ It would amend the Controlled Substances Act (CSA, 21 U.S.C. §§801 et seq.) to allow partial fills of prescriptions for controlled substances on Schedule II¹⁵ of the CSA at the request of the prescriber or the patient (subject to limitations).

H.R. 4641 (no short title), as amended, passed the House by a vote of 412–4 on May 11, 2016.¹⁶ It would require the HHS Secretary to convene an interagency task force to review, modify, and update best practices for prescribing pain medication and managing chronic and acute pain. It would specify the membership, duties, limitations, and reporting requirements for the task force. The Congressional Budget Office estimates that implementing the bill as ordered to be reported would cost \$2 million over the 2016–2021 period, assuming appropriation of the estimated amounts.¹⁷

H.R. 4843, the Infant Plan of Safe Care Improvement Act, as amended, passed the House by a vote of 421–0 on May 11, 2016.¹⁸ It aims to strengthen state processes and compliance related to the development of a safe plan of care for newborns affected by illegal substance abuse, withdrawal symptoms, or a Fetal Alcohol Spectrum Disorder.¹⁹ The bill would amend the Child

¹¹ U.S. Congressional Budget Office, *H.R. 4063, Promoting Responsible Opioid Management and Incorporating Scientific Expertise Act*, May 4, 2016, <https://www.cbo.gov/publication/51531>.

¹² *Congressional Record*, vol. 162, part 74 (May 11, 2016), pp. H2270–H2273.

¹³ U.S. Congressional Budget Office, *H.R. 4586, Lali’s Law*, May 9, 2016, <https://www.cbo.gov/publication/51554>.

¹⁴ *Congressional Record*, vol. 162, part 74 (May 11, 2016), pp. H2273–H2275.

¹⁵ The CSA categorizes controlled substances into five schedules. Substances on Schedule I (e.g., heroin) have high risk of abuse and no accepted medical use. Those on Schedule II (e.g., hydrocodone) have high risk of abuse and an accepted medical use; they are the most tightly controlled of the prescription controlled substances.

¹⁶ *Congressional Record*, vol. 162, part 74 (May 11, 2016), pp. H2234–2247, 2253.

¹⁷ U.S. Congressional Budget Office, *H.R. 4641, a bill to provide for the establishment of an inter-agency task force to review, modify, and update best practices for pain management and prescribing pain medication, and for other purposes*, May 3, 2016, <https://www.cbo.gov/publication/51519>.

¹⁸ *Congressional Record*, vol. 162, part 74 (May 11, 2016), pp. H2248–2253.

¹⁹ H.R. 4843 may be considered under suspension of the rules; see <http://docs.house.gov/billsthisweek/20160509/HR4843.pdf>.

Abuse Prevention and Treatment Act (CAPTA)²⁰ to clarify that such plans are to address the infant's safety and well-being, including by addressing the substance abuse treatment needs of the infant, and his/her parent(s) or caregiver(s). Among other things, the bill would additionally require the Secretary of Health and Human Services (HHS) to conduct specific monitoring of state compliance with this requirement and to maintain and disseminate (via the national clearinghouse on child abuse and neglect) information about best practices in developing such plans of safe care. The Congressional Budget Office estimates that implementing the bill as ordered to be reported would cost less than \$500,000 annually, subject to the availability of funds.²¹

H.R. 4969, the John Thomas Decker Act, as amended, passed the House by voice vote on May 11, 2016.²² It would require the CDC to develop and disseminate informational materials and resources about youth sports injuries that might be treated with prescription opioids (potentially leading to addiction), including information about non-opioid treatment options, the dangers of opioid use and misuse, and how to seek addiction treatment. The Congressional Budget Office estimates that implementing the bill as ordered to be reported would cost \$2 million over the 2017–2021 period, subject to the availability of funds.²³

H.R. 4976, the Opioid Review Modernization Act, passed the House by voice vote on May 11, 2016.²⁴ It would (1) require referring new drug applications for opioids without abuse-deterrent properties to a Food and Drug Administration (FDA) advisory committee (with exceptions); (2) require the HHS Secretary to seek recommendations from FDA's Pediatric Advisory Committee before approving labeling (or labeling changes) for opioids intended for pediatric use; (3) require the HHS Secretary, acting through the FDA Commissioner, to develop recommendations for prescriber education as part of FDA's evaluation of the Risk Evaluation and Mitigation Strategy for extended-release and long-acting opioids; and (4) require the FDA Commissioner to publish a final version of draft guidance entitled "General Principles for Evaluating the Abuse Deterrence of Generic Solid Oral Opioid Drug Products," within two years of the end of the public comment period.²⁵ The Congressional Budget Office estimates that implementing the bill as ordered to be reported would "not have a significant budgetary effect because FDA is implementing similar requirements through their action plan on opioids."²⁶

H.R. 4978, the Nurturing and Supporting Healthy Babies Act, as amended, passed the House by voice vote on May 11, 2016.²⁷ It would require a GAO report on Neonatal Abstinence Syndrome. As amended in committee, it would also (1) exclude abuse-deterrent formulations of drugs from the definition of a "line extension" under Medicaid;²⁸ (2) limit disclosure of the means used in

²⁰ 42 U.S.C. §§5101 et seq.

²¹ U.S. Congressional Budget Office, H.R. 4843, *Infant Plan of Safe Care Improvement Act*, May 6, 2016, <https://www.cbo.gov/publication/51537>.

²² *Congressional Record*, vol. 162, part 74 (May 11, 2016), pp. H2268–H2270.

²³ U.S. Congressional Budget Office, H.R. 4969, *John Thomas Decker Act of 2016*, May 9, 2016, <https://www.cbo.gov/publication/51552>.

²⁴ *Congressional Record*, vol. 162, part 74 (May 11, 2016), pp. H2276–H2280.

²⁵ See <https://www.federalregister.gov/articles/2016/03/25/2016-06766/general-principles-for-evaluating-the-abuse-deterrence-of-generic-solid-oral-opioid-drugs-products>.

²⁶ U.S. Congressional Budget Office, H.R. 4976, *Opioid Review Modernization Act of 2016*, May 9, 2016, <https://www.cbo.gov/publication/51555>.

²⁷ *Congressional Record*, vol. 162, part 74 (May 11, 2016), pp. H2259–H2263.

²⁸ Whether a drug is considered a "line extension" affects the amount of the rebate drug manufacturers must offer under the Medicaid program. See Centers for Medicare & Medicaid Services, *Medicaid Drug Rebate Program*, (continued...)

development as well as the algorithms used to identify fraud in Medicare, Medicaid, and the Children’s Health Insurance Program; and (3) make \$5 million available to the Medicaid Improvement Fund for FY2021 and thereafter. The Congressional Budget Office estimates that implementing the bill as ordered to be reported would not, on net, change direct spending over the 2017–2026 period and would have a discretionary cost of less than \$500,000 (subject to the availability of funds).²⁹

H.R. 4981, the Opioid Use Disorder Treatment Expansion and Modernization Act, as amended, passed the House by voice vote on May 11, 2016.³⁰ It would (1) expand the qualifying practitioners to treat opioid addiction with buprenorphine to include nurse practitioners or physician assistants; (2) raise the maximum number of patients a qualifying practitioner can treat from 100 to 250; (3) allow the HHS Secretary to recommend revoking or suspending Drug Enforcement Administration registration for practitioners who fail to comply; and (4) require reports to Congress on treatment services (the contents of which would be revised by an amendment).

H.R. 4982, the Examining Opioid Treatment Infrastructure Act of 2016, as amended, passed the House by voice vote on May 11, 2016.³¹ It would require a GAO report on treatment capacity, availability, and need. As amended, it would also require the GAO report to assess barriers to real-time reporting of drug overdoses and treatment availability for American Indians and Alaska Natives. The Congressional Budget Office estimates that implementing the bill as ordered to be reported would cost less than \$500,000 over the 2017–2021 period, subject to the availability of funds.³²

H.R. 4985, the Kingpin Designation Improvement Act of 2016, passed the House by voice vote on May 10, 2016.³³ It would amend the Foreign Narcotics Kingpin Designation Act³⁴ to protect classified information from disclosure in the case of any judicial review in federal court of a determination made pursuant to such classified information. Specifically, it would authorize such classified information to be submitted to a reviewing court *ex parte* and *in camera*.³⁵ The Congressional Budget Office estimates that implementing the bill as ordered to be reported “would have no significant effect on the federal budget because it would have a negligible effect on the workload of the U.S. courts.”³⁶

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<https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Medicaid-Drug-Rebate-Program.html>.

²⁹ U.S. Congressional Budget Office, H.R. 4978, *Nurturing and Supporting Healthy Babies Act*, May 9, 2016, <https://www.cbo.gov/publication/51551>.

³⁰ *Congressional Record*, vol. 162, part 74 (May 11, 2016), pp. H2276–H2280.

³¹ *Congressional Record*, vol. 162, part 74 (May 11, 2016), pp. H2275–H2276.

³² U.S. Congressional Budget Office, H.R. 4982, *Examining Opioid Treatment Infrastructure Act of 2016*, May 9, 2016, <https://www.cbo.gov/publication/51549>.

³³ *Congressional Record*, vol. 162, part 73 (May 10, 2016), pp. H2173–H2175.

³⁴ 21 U.S.C. §1903.

³⁵ Black’s Law Dictionary (10th ed. 2014) defines *ex parte* as “Done or made at the instance and for the benefit of one party only, and without notice to, or argument by, anyone having an adverse interest; of, relating to, or involving court action taken or received by one party without notice to the other, usu. for temporary or emergency relief <an *ex parte* hearing> <an *ex parte* injunction>.” It defines *in camera* as “1. In the judge’s private chambers. 2. In the courtroom with all spectators excluded. 3. (Of a judicial action) taken when court is not in session.—Also termed (in reference to the opinion of one judge) in chambers.”

³⁶ U.S. Congressional Budget Office, H.R. 4985, *Kingpin Designation Improvement Act of 2016*, May 6, 2016, (continued...)

H.R. 5046, the Comprehensive Opioid Abuse Reduction Act of 2016, was reported by the House Judiciary Committee on May 10, 2016.³⁷ It would amend the Omnibus Crime Control and Safe Streets Act of 1968 (P.L. 90-351) to authorize the Attorney General to make grants to assist State and local governments in addressing the national epidemic of opioid abuse, and for other purposes. Grant funds would go toward the following: treatment alternatives to incarceration (including specialized courts such as drug courts); training and resources for first responders' use of an opioid overdose reversal drug (e.g., naloxone); investigative activities related to unlawful distribution of opioids; medication-assisted treatment programs used or operated by a criminal justice agency; (for states only) prescription drug monitoring programs; programs to prevent and address opioid abuse by juveniles; and integrated and comprehensive opioid response programs. H.R. 5046 would authorize \$20 million in emergency federal law enforcement assistance funds for each fiscal year ending *after* FY2021. It would eliminate the current authorization³⁸ of appropriations of \$20 million annually for the Department of Justice (DOJ) to make grants to state and local governments for law enforcement emergencies. The Congressional Budget Office estimates that implementing the bill as ordered to be reported would have a net discretionary cost of \$248 million from 2017–2021 and \$167 million after 2021.³⁹

H.R. 5048, the Good Samaritan Assessment Act of 2016, passed the House by voice vote on May 10, 2016.⁴⁰ It would require a GAO study on state Good Samaritan laws that pertain to treatment of opioid overdoses. Specifically, the study would report to Congress on (1) the extent to which the Director of National Drug Control Policy has reviewed Good Samaritan laws including findings regarding effects of these laws, (2) efforts by the Director to encourage enactment of these laws, and (3) a compilation of these laws in effect in the states, territories, and the District of Columbia.⁴¹ The Congressional Budget Office estimates that implementing the bill as ordered to be reported “would have no significant effect on the federal budget because the information needed to complete the report is readily available and would not take significant time or resources to compile.”⁴²

H.R. 5052, the Opioid Program Evaluation Act, as amended, passed the House by a vote of 410–1 on May 10, 2016.⁴³ It would evaluate how effective federal grant programs have been in

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<https://www.cbo.gov/publication/51564>.

³⁷ U.S. Congress, House Committee on the Judiciary, H.R. 5046, to amend the Omnibus Crime Control and Safe Streets Act of 1968 to authorize the Attorney General to make grants to assist State and local governments in addressing the national epidemic of opioid abuse, and for other purposes, 114th Cong., 2nd sess., May 3, 2016, H.Rept. 114-539. The House passed H.Res. 720, providing for the consideration of H.R. 5046, on May 11, 2016. See *Congressional Record*, vol. 162, part 74 (May 11, 2016), pp. H2227–H2234.

³⁸ 42 U.S.C. §10513(a).

³⁹ U.S. Congressional Budget Office, H.R. 5046, *Comprehensive Opioid Abuse Reduction Act of 2016*, May 4, 2016, <https://www.cbo.gov/publication/51530>.

⁴⁰ *Congressional Record*, vol. 162, part 73 (May 10, 2016), pp. H2179–2181.

⁴¹ According to the National Conference of State Legislatures, 35 states and the District of Columbia have enacted “some form of a Good Samaritan or 911 drug immunity law.” Good Samaritan laws generally provide immunity from supervision violations or low-level drug offenses when an individual that observes or experiences an overdose calls for emergency assistance or otherwise seeks medical assistance. See National Conference of State Legislatures, *Drug Overdose Immunity and Good Samaritan Laws*, April 12, 2016, <http://www.ncsl.org/research/civil-and-criminal-justice/drug-overdose-immunity-good-samaritan-laws.aspx>.

⁴² U.S. Congressional Budget Office, H.R. 5048, *Good Samaritan Assessment Act of 2016*, May 4, 2016, <https://www.cbo.gov/publication/51560>.

⁴³ *Congressional Record*, vol. 162, part 73 (May 10, 2016), pp. H2181–2184.

addressing problems relating to opioid abuse—the bill appears to be referring to a DOJ grant program (the Comprehensive Opioid Abuse Grant Program) that would be enacted were H.R. 5046 to be enacted. It also refers to any program at HHS that provides grants for the primary purpose of providing assistance to address opioid abuse. The Congressional Budget Office estimates that implementing the bill as ordered to be reported would cost about \$4 million over the 2016–2021, assuming enactment of separate legislation establishing the grant program.⁴⁴

S. 32, the Transnational Drug Trafficking Act of 2015, passed the Senate by unanimous consent on October 7, 2015 and passed the House by voice vote on May 10, 2016.⁴⁵ It would lower the knowledge threshold for extraterritorial drug trafficking violations⁴⁶ so that individuals who have “reasonable cause to believe” (in addition to intending or knowing) that illegal drugs will be trafficked into the United States could be prosecuted. It would also put in place penalties against foreign producers of listed precursor chemicals, intending or knowing that the chemicals would be used to make illegal drugs and intending, knowing, or having reasonable cause to believe that they would be unlawfully imported into the United States. The bill also would make a technical fix to clarify that the trafficking of counterfeit drugs is a federal felony offense if the seller knows that the drugs are counterfeit. The Congressional Budget Office estimates that implementing the bill as reported by the Senate Judiciary Committee would have no significant cost to the federal government.⁴⁷

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⁴⁴ U.S. Congressional Budget Office, H.R. 5052, *Opioid Program Evaluation Act*, May 5, 2016, <https://www.cbo.gov/publication/51533>.

⁴⁵ *Congressional Record*, vol. 162, part 73 (May 10, 2016), pp. H2175–2179. The provisions of S. 32 were also added as Title VIII to S. 524, the Comprehensive Addiction and Recovery Act of 2016, which passed the Senate on March 10, 2016 by Yea-Nay Vote, 94-1. The House companion bill to S. 32 is H.R. 3380, also entitled the Transnational Drug Trafficking Act of 2015, and which was ordered to be reported by the House Judiciary Committee on April 20, 2016. During markup, an amendment was offered to limit the applicability of the reduced knowledge threshold to prosecutions of leaders or organizers of illegal drug trafficking, out of concern that the law would be used too often against low-level offenders and contribute to more individuals receiving mandatory minimum sentences. The amendment was reportedly rejected 16-6 in Committee. See Andrew Siddons, “Panel Advances Drug-Trafficking Measures,” CQ Roll Call, April 20, 2016.

⁴⁶ 21 U.S.C. §959.

⁴⁷ U.S. Congressional Budget Office, S. 32, Transnational Drug Trafficking Act of 2015, September 28, 2015, <https://www.cbo.gov/publication/50848>.