

DEBARMENT ENFORCEMENT OF BAD ACTOR  
 REGISTRANTS ACT OF 2020

NOVEMBER 16, 2020.—Committed to the Committee of the Whole House on the  
 State of the Union and ordered to be printed

Mr. PALLONE, from the Committee on Energy and Commerce,  
 submitted the following

R E P O R T

[To accompany H.R. 4806]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred  
 the bill (H.R. 4806) to amend the Controlled Substances Act to au-  
 thorize the debarment of certain registrants, and for other purpose,  
 having considered the same, reports favorably thereon with an  
 amendment and recommends that the bill as amended do pass.

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The amendment is as follows:

Strike all after the enacting clause and insert the following:

**SECTION 1. SHORT TITLE.**

This Act may be cited as the “Debarment Enforcement of Bad Actor Registrants Act of 2020” or the “DEBAR Act of 2020”.

**SEC. 2. DEBARMENT OF CERTAIN REGISTRANTS.**

Section 304 of the Controlled Substances Act (21 U.S.C. 824) is amended by adding at the end the following:

“(h) The Attorney General may issue an order to prohibit, conditionally or unconditionally, and permanently or for such period as the Attorney General may determine, any person from being registered under this title to manufacture, distribute, or dispense a controlled substance or a list I chemical, if the Attorney General finds that—

“(1) such person meets or has met any of the conditions for suspension or revocation of registration under subsection (a); and

“(2) such person has a history of prior suspensions or revocations of registration.”.

**I. PURPOSE AND SUMMARY**

H.R. 4806, the “Debarment Enforcement of Bad Actor Registrants Act of 2020”, or the “DEBAR Act of 2020”, introduced by Representative Robert E. Latta (R-OH) would amend the Controlled Substances Act (CSA) to allow the Attorney General to prohibit any registrant from manufacturing, distributing, or dispensing a controlled substance or a list I chemical if that registrant meets or has met any of the conditions for suspension or revocation of registration, or is a person with a history of prior suspension or revocations.

**II. BACKGROUND AND NEED FOR LEGISLATION**

Data from the Centers for Disease Control and Prevention (CDC) shows that since 1999, more than 450,000 Americans have lost their lives to an opioid overdose.<sup>1</sup> In 2018, nearly 47,000 deaths involved opioids, which is nearly six times the number of opioid-involved overdose deaths in 1999.<sup>2</sup> Part of the United States Government’s approach to combatting drug use is through the closed distribution system for controlled substances, including many opioids, set up by the CSA.<sup>3</sup>

The Drug Enforcement Administration (DEA) is charged with enforcing and implementing policies to protect the public health and safety of Americans through the CSA.<sup>4</sup> One lever DEA has at its disposal to manage diversion or non-compliance is the ability to revoke or surrender an individual’s CSA registration, which is needed to handle controlled substances. A recent DEA Inspector General (IG) report found, however, weaknesses in DEA’s registration process and instances where the agency did not fully utilize its regulatory authorities to address noncompliance.<sup>5</sup> Specifically, the DEA IG found cases where entities have been able to obtain a new license immediately after having one revoked.<sup>6</sup>

<sup>1</sup>Centers for Disease Control and Prevention, *Opioid Data Analysis and Resources* ([www.cdc.gov/drugoverdose/data/analysis.html](http://www.cdc.gov/drugoverdose/data/analysis.html)) (accessed October 20, 2020).

<sup>2</sup>*Id.*

<sup>3</sup>Public Law 91–513, as amended.

<sup>4</sup>Drug Enforcement Administration, *Mission* ([www.dea.gov/mission](http://www.dea.gov/mission)) (accessed October 20, 2020).

<sup>5</sup>U.S. Department of Justice Office of the Inspector General, *DOJ OIG Releases Report on the Drug Enforcement Administration’s Regulatory and Enforcement Efforts to Control the Diversion of Opioids* ([oig.justice.gov/news/doj-oig-releases-report-drug-enforcement-administrations-regulatory-and-enforcement-efforts](http://oig.justice.gov/news/doj-oig-releases-report-drug-enforcement-administrations-regulatory-and-enforcement-efforts)) (October 1, 2019).

<sup>6</sup>*Id.*

For example, the IG report outlined a case that included a doctor, who was engaged in serious misconduct and had his registration revoked, who moved to another State under the authority of a different DEA field division.<sup>7</sup> When the doctor reapplied for registration, it was granted.<sup>8</sup> Another example provided in the report includes a dentist who had voluntarily surrendered his medical license and DEA registration on two separate occasions.<sup>9</sup> This dentist also had been convicted of a felony, which is grounds for suspension or revocation of a registrant's registration under the CSA.<sup>10</sup> According to DEA, however, this dentist was still able to obtain another DEA registration.<sup>11</sup>

To combat this challenge, H.R. 4806 would grant DEA the authority to debar a registrant that meets the criteria for temporary or permanent suspension or revocation.

### III. COMMITTEE HEARINGS

For the purposes of section 103(i) of H. Res. 6 of the 116th Congress, the following hearing was used to develop or consider H.R. 4806 and 13 other bills:

The Subcommittee on Health held a legislative hearing on Tuesday, March 3, 2020, entitled, "Combatting an Epidemic: Legislation to Help Patients with Substance Use Disorders." The Subcommittee received testimony from the following witnesses:

#### *Panel I*

- ADM Brett P. Giroir, M.D., Assistant Secretary for Health and Senior Adviser to the Secretary on Opioid Policy, Department of Health and Human Services.
- Kimberly Brandt, Principal Deputy Administrator for Policy & Operations, Centers for Medicare & Medicaid Services.
- Thomas W. Prevoznik, Deputy Assistant Administrator, Diversion Control Division, Drug Enforcement Administration.

#### *Panel II*

- Michael P. Botticelli, Executive Director, Grayken Center for Addiction, Boston Medical Center.
- Smita Das, M.D., Ph.D., M.P.H., Addiction Psychiatrist, Dual Diagnosis Clinic, Clinical Assistant Professor, Psychiatry and Behavioral Sciences, Stanford University School of Medicine.
- Patty McCarthy, Chief Executive Officer, Faces & Voices of Recovery.
- Robert I.L. Morrison, Executive Director/Director of Legislative Affairs, National Association of State Alcohol and Drug Abuse Directors.
- Margaret B. Rizzo, Executive Director, JSAS HealthCare, Inc.
- Shawn A. Ryan, M.D., M.B.A., Chair, Legislative Advocacy Committee, American Society of Addiction Medicine.

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<sup>7</sup>*Id.*

<sup>8</sup>*Id.*

<sup>9</sup>*Id.*

<sup>10</sup>*Id.*

<sup>11</sup>*Id.*

#### IV. COMMITTEE CONSIDERATION

Representative Latta introduced H.R. 4806 on October 23, 2019, and the bill was referred to the Committee on Energy and Commerce. H.R. 4806 was then referred to the Subcommittee on Health on October 26, 2019. A legislative hearing was held on the bill on March 3, 2020.

On September 9, 2020, H.R. 4806 was discharged from further consideration by the Subcommittee on Health as it was called up for consideration by the full Committee on Energy and Commerce. The full Committee met in virtual open markup session on September 9, 2020, pursuant to notice, to consider H.R. 4806. During consideration of the bill, an amendment in the nature of a substitute offered by Mr. Latta was agreed to by a voice vote. Upon conclusion of consideration of the bill, the full Committee agreed to a motion on final passage by Mr. Pallone, Chairman of the committee, to order H.R. 4806 reported favorably to the House, amended, by a voice vote, a quorum being present.

#### V. COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list each record vote on the motion to report legislation and amendments thereto. The Committee advises that there were no record votes taken on H.R. 4806, including the motion for final passage of the bill.

#### VI. OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII and clause 2(b)(1) of rule X of the Rules of the House of Representatives, the oversight findings and recommendations of the Committee are reflected in the descriptive portion of the report.

#### VII. NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

Pursuant to 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee adopts as its own the estimate of new budget authority, entitlement authority, or tax expenditures or revenues contained in the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

The Committee has requested but not received from the Director of the Congressional Budget Office a statement as to whether this bill contains any new budget authority, spending authority, credit authority, or an increase or decrease in revenues or tax expenditures.

## VIII. CONGRESSIONAL BUDGET OFFICE ESTIMATE

<b>Controlled Substances Act Legislation</b>			
As ordered reported by the House Committee on the Judiciary on September 9, 2020			
By Fiscal Year, Millions of Dollars	2021	2021-2025	2021-2030
Direct Spending (Outlays)	*	*	*
Revenues	0	0	0
Increase or Decrease (-) in the Deficit	*	*	*
Spending Subject to Appropriation (Outlays)	0	0	not estimated
Statutory pay-as-you-go procedures apply?	Yes	<b>Mandate Effects</b>	
Increases on-budget deficits in any of the four consecutive 10-year periods beginning in 2031?	No	Contains intergovernmental mandate?	No
		Contains private-sector mandate?	Yes, Cannot Determine Costs
* = between zero and \$500,000.			

On September 9, 2020, the House Committee on the Judiciary ordered reported the following pieces of legislation that would make changes to the Drug Enforcement Administration's (DEA) Diversion Control Program:

- H.R. 3878, the Block, Report, and Suspend Suspicious Shipments Act of 2019, would require registrants who manufacture, distribute, or dispense controlled substances to take additional steps in reporting suspicious orders, including maintaining a record of due diligence, declining to fill the order, and notifying DEA.
- H.R. 4806, the DEBAR Act of 2019, would allow the Attorney General to issue an order prohibiting applicants from registering as a manufacturer, distributor, or dispenser of controlled substances if they meet certain criteria.
- H.R. 4812, the Ensuring Compliance Against Drug Diversion Act of 2019, would terminate authority to manufacture, distribute, or dispense controlled substances when a registrant dies, ceases legal existence, or discontinues business.

The Diversion Control Program is funded by registration fees, which are treated in the budget as reductions in direct spending; DEA is authorized to spend those fees without further appropriation. Each bill would either codify existing regulations or clarify procedures already in place. On that basis, and using information from the agency, CBO estimates that under the bill the increase in spending of those fees above current levels would not be significant.

H.R. 3878 would impose a private-sector mandate on manufacturers, distributors, and dispensers of controlled substances by expanding reporting requirements and prohibiting them from fulfilling unresolved suspicious orders. CBO is uncertain how DEA would implement the new requirements and cannot evaluate the potential costs for the mandated entities to comply. In 2019, DEA received reports of 370,000 suspicious orders; however, CBO cannot predict the number of orders that would be precluded by the bill or the value of such orders. CBO cannot estimate the potential

foregone revenue and therefore cannot determine whether the aggregate cost of the mandates would exceed the annual threshold established in UMRA for private-sector mandates (\$168 million in 2020, adjusted annually for inflation).

H.R. 4806 and H.R. 4812 do not contain private-sector mandates as defined in UMRA.

None of the bills contain intergovernmental mandates as defined in UMRA.

The CBO staff contacts for this estimate are Lindsay Wylie (for federal costs) and Lilia Ledezma (for mandates). The estimate was reviewed by H. Samuel Papenfuss, Deputy Director of Budget Analysis.

#### IX. FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

#### X. STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

Pursuant to clause 3(c)(4) of rule XIII, the general performance goal or objective of this legislation is to authorize DEA to debar certain registrants under the Controlled Substances Act if such registrant meets the conditions for suspension or revocation of registration, and has a history of prior suspensions or revocations.

#### XI. DUPLICATION OF FEDERAL PROGRAMS

Pursuant to clause 3(c)(5) of rule XIII, no provision of H.R. 4806 is known to be duplicative of another Federal program, including any program that was included in a report to Congress pursuant to section 21 of Public Law 111-139 or the most recent Catalog of Federal Domestic Assistance.

#### XII. COMMITTEE COST ESTIMATE

Pursuant to clause 3(d)(1) of rule XIII, the Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

#### XIII. EARMARKS, LIMITED TAX BENEFITS, AND LIMITED TARIFF BENEFITS

Pursuant to clause 9(e), 9(f), and 9(g) of rule XXI, the Committee finds that H.R. 4806 contains no earmarks, limited tax benefits, or limited tariff benefits.

#### XIV. ADVISORY COMMITTEE STATEMENT

No advisory committee within the meaning of section 5(b) of the Federal Advisory Committee Act was created by this legislation.

#### XV. APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or

accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

## XVI. SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

### *Section 1. Short title*

Section 1 designates that the short title may be cited as the “Debarment Enforcement of Bad Actor Registrants Act of 2020” or the “DEBAR Act of 2020”.

### *Sec. 2. Debarment of certain registrants*

Section 2 amends section 304 of the CSA by adding authority for the Attorney General to issue an order to prohibit, conditionally or unconditionally, a person from being registered to manufacture, distribute, or dispense a controlled substance or list I chemical if the Attorney General finds that a person has met any of the conditions for suspension or revocation and such person has a history of prior suspensions or revocations of registration. The Attorney General may issue this order permanently or for a period determined by the Attorney General.

## XVII. CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (new matter is printed in italics and existing law in which no change is proposed is shown in roman):

### **CONTROLLED SUBSTANCES ACT**

#### TITLE II—CONTROL AND ENFORCEMENT

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#### PART C—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES; PIPERIDINE REPORTING

\* \* \* \* \*

#### DENIAL, REVOCATION, OR SUSPENSION OF REGISTRATION

SEC. 304. (a) A registration pursuant to section 303 to manufacture, distribute, or dispense a controlled substance or a list I chemical may be suspended or revoked by the Attorney General upon a finding that the registrant—

- (1) has materially falsified any application filed pursuant to or required by this title or title III;
- (2) has been convicted of a felony under this title or title III or any other law of the United States, or of any State, relating to any substance defined in this title as a controlled substance or a list I chemical;
- (3) has had his State license or registration suspended, revoked, or denied by competent State authority and is no longer authorized by State law to engage in the manufacturing, distribution, or dispensing of controlled substances or list I chemi-

cals or has had the suspension, revocation, or denial of his registration recommended by competent State authority;

(4) has committed such acts as would render his registration under section 303 inconsistent with the public interest as determined under such section; or

(5) has been excluded (or directed to be excluded) from participation in a program pursuant to section 1128(a) of the Social Security Act.

A registration pursuant to section 303(g)(1) to dispense a narcotic drug for maintenance treatment or detoxification treatment may be suspended or revoked by the Attorney General upon a finding that the registrant has failed to comply with any standard referred to in section 303(g)(1).

(b) The Attorney General may limit revocation or suspension of a registration to the particular controlled substance or list I chemical with respect to which grounds for revocation or suspension exist.

(c)(1) Before taking action pursuant to this section, or pursuant to a denial of registration under section 303, the Attorney General shall serve upon the applicant or registrant an order to show cause why registration should not be denied, revoked, or suspended.

(2) An order to show cause under paragraph (1) shall—

(A) contain a statement of the basis for the denial, revocation, or suspension, including specific citations to any laws or regulations alleged to be violated by the applicant or registrant;

(B) direct the applicant or registrant to appear before the Attorney General at a time and place stated in the order, but not less than 30 days after the date of receipt of the order; and

(C) notify the applicant or registrant of the opportunity to submit a corrective action plan on or before the date of appearance.

(3) Upon review of any corrective action plan submitted by an applicant or registrant pursuant to paragraph (2), the Attorney General shall determine whether denial, revocation, or suspension proceedings should be discontinued, or deferred for the purposes of modification, amendment, or clarification to such plan.

(4) Proceedings to deny, revoke, or suspend shall be conducted pursuant to this section in accordance with subchapter II of chapter 5 of title 5, United States Code. Such proceedings shall be independent of, and not in lieu of, criminal prosecutions or other proceedings under this title or any other law of the United States.

(5) The requirements of this subsection shall not apply to the issuance of an immediate suspension order under subsection (d).

(d)(1) The Attorney General may, in his discretion, suspend any registration simultaneously with the institution of proceedings under this section, in cases where he finds that there is an imminent danger to the public health or safety. A failure to comply with a standard referred to in section 303(g)(1) may be treated under this subsection as grounds for immediate suspension of a registration granted under such section. A suspension under this subsection shall continue in effect until the conclusion of such proceedings, including judicial review thereof, unless sooner withdrawn by the Attorney General or dissolved by a court of competent jurisdiction.

(2) In this subsection, the phrase “imminent danger to the public health or safety” means that, due to the failure of the registrant to maintain effective controls against diversion or otherwise comply with the obligations of a registrant under this title or title III, there is a substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance will occur in the absence of an immediate suspension of the registration.

(e) The suspension or revocation of a registration under this section shall operate to suspend or revoke any quota applicable under section 306.

(f) In the event the Attorney General suspends or revokes a registration granted under section 303, all controlled substances or list I chemicals owned or possessed by the registrant pursuant to such registration at the time of suspension or the effective date of the revocation order, as the case may be, may, in the discretion of the Attorney General, be placed under seal. No disposition may be made of any controlled substances or list I chemicals under seal until the time for taking an appeal has elapsed or until all appeals have been concluded except that a court, upon application therefor, may at any time order the sale of perishable controlled substances or list I chemicals. Any such order shall require the deposit of the proceeds of the sale with the court. Upon a revocation order becoming final, all such controlled substances or list I chemicals (or proceeds of sale deposited in court) shall be forfeited to the United States; and the Attorney General shall dispose of such controlled substances or list I chemicals in accordance with section 511(e). All right, title, and interest in such controlled substances or list I chemicals shall vest in the United States upon a revocation order becoming final.

(g) The Attorney General may, in his discretion, seize or place under seal any controlled substances or list I chemicals owned or possessed by a registrant whose registration has expired or who has ceased to practice or do business in the manner contemplated by his registration. Such controlled substances or list I chemicals shall be held for the benefit of the registrant, or his successor in interest. The Attorney General shall notify a registrant, or his successor in interest, who has any controlled substances or list I chemicals seized or placed under seal of the procedures to be followed to secure the return of the controlled substance or list I chemical and the conditions under which it will be returned. The Attorney General may not dispose of any controlled substance or list I chemical seized or placed under seal under this subsection until the expiration of one hundred and eighty days from the date such substance or chemical was seized or placed under seal.

(h) *The Attorney General may issue an order to prohibit, conditionally or unconditionally, and permanently or for such period as the Attorney General may determine, any person from being registered under this title to manufacture, distribute, or dispense a controlled substance or a list I chemical, if the Attorney General finds that—*

*(1) such person meets or has met any of the conditions for suspension or revocation of registration under subsection (a); and*

*(2) such person has a history of prior suspensions or revocations of registration.*

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