

115TH CONGRESS
2D SESSION

H. R. 5531

To provide for a comprehensive, multifaceted approach to preventing and treating opioid addiction.

IN THE HOUSE OF REPRESENTATIVES

APRIL 17, 2018

Mr. BUCHANAN (for himself and Mrs. MURPHY of Florida) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Ways and Means, the Budget, Veterans' Affairs, Oversight and Government Reform, and the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To provide for a comprehensive, multifaceted approach to preventing and treating opioid addiction.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Opioid Emergency Response Act”.

6 (b) TABLE OF CONTENTS.—The table of contents for
7 this Act is as follows:

- Sec. 1. Short title; table of contents.
- Sec. 2. Alternatives to opioids prescribing.

Sec. 3. Opioids and STOP Pain Initiative.

Sec. 4. Veteran over-medication prevention.

Sec. 5. Amendment relating to the account for the State response to the opioid abuse crisis.

Sec. 6. Mental health access improvement.

Sec. 7. Synthetics Trafficking and Overdose Prevention.

Sec. 8. Stop the Importation and Trafficking of Synthetic Analogues.

1 SEC. 2. ALTERNATIVES TO OPIOIDS PRESCRIBING.

2 (a) ESTABLISHMENT.—Beginning not later than one
3 year after the date of the enactment of this Act, the Sec-
4 retary of Health and Human Services (in this Act referred
5 to as the “Secretary”) shall carry out a 5-year demonstra-
6 tion project under which payment shall be made under the
7 hospital outpatient prospective payment system under part
8 B of title XVIII of the Social Security Act (42 U.S.C.
9 1395j et seq.) to participating hospitals for items and
10 services furnished as alternatives to opioid medications to
11 individuals enrolled under such part to treat conditions
12 designated under subsection (c)(1) for purposes of evalu-
13 ating the benefits of using, instead of opioid medications,
14 such alternatives to treat in emergency departments such
15 symptoms and conditions.

16 (b) EMERGENCY DEPARTMENTS.—

17 (1) SELECTION.—The Secretary shall select
18 from hospitals with emergency departments volun-
19 tarily submitting applications under paragraph (4),
20 not fewer than 30 hospitals with emergency depart-
21 ments, and not more than 50 hospitals with emer-

1 gency departments, for participation in the dem-
2 onstration project.

3 (2) DIVERSITY.—In selecting hospitals with
4 emergency departments, the Secretary shall ensure
5 such hospitals and emergency departments are di-
6 verse in geography and size.

7 (3) VOLUNTARY PARTICIPATION.—Participation
8 in the demonstration project under this section shall
9 be on a voluntary basis.

10 (4) APPLICATIONS.—

11 (A) IN GENERAL.—To participate in the
12 demonstration project, a hospital with an emer-
13 gency department shall submit to the Secretary
14 an application at such time, in such manner,
15 and containing such information (in addition to
16 the written commitment described in subpara-
17 graph (B)) as specified by the Secretary. The
18 Secretary shall take such measures as is nec-
19 essary to make available such application form
20 to potential participants no later than 180 days
21 after the date of the enactment of this Act.

22 (B) INFORMATION REQUIRED.—Each ap-
23 plication submitted by a hospital under sub-
24 paragraph (A) shall include a binding written
25 commitment to participate in the demonstration

1 project for the duration of the project signed by
2 the Chief Executive Officer of the hospital, the
3 physician medical director of the emergency de-
4 partment of the hospital, the nursing director of
5 the emergency department of the hospital, and
6 the pharmacy director of the emergency depart-
7 ment of the hospital.

8 (c) ELEMENTS OF DEMONSTRATION PROJECT.—

9 Under the demonstration project, the following shall
10 apply:

11 (1) The Secretary shall designate no fewer than
12 five conditions or sets of symptoms that will be mon-
13 itored during the demonstration project.

14 (2) The performance during each year of the
15 demonstration project, with respect to such condi-
16 tions designated under paragraph (1), of all emer-
17 gency departments of hospitals participating in the
18 demonstration project will be measured against the
19 performance of such emergency departments during
20 a base year, which shall represent the most recent
21 set of full year data available before the first date
22 of the demonstration project.

23 (3) The Secretary shall provide hospitals par-
24 ticipating in the demonstration project with a de-
25 scription of clearly defined treatments that are con-

1 sidered alternatives to opioids to be applied for pur-
2 poses of subsection (a).

3 (d) INCENTIVE PAYMENT.—Under the demonstration
4 project, the Secretary shall create a payment structure
5 under which hospitals participating in the demonstration
6 project that increase the use of alternatives to opioids and
7 decrease the use of opioids may receive a shared savings
8 bonus in addition to what would otherwise be made for
9 items and services furnished under subsection (a). The
10 amount of such shared savings shall be based on the dif-
11 ference between readmission rates for individuals treated
12 with an alternative to opioids at the emergency depart-
13 ment of the participating hospital and the average rate
14 of readmissions for individuals treated with opioids and
15 discharged from a representative group of emergency de-
16 partments of hospitals not participating in the demonstra-
17 tion project in the same region as the participating hos-
18 pital over a period of five years.

19 (e) CLARIFICATION.—Nothing under this section
20 shall prevent a health care provider from prescribing an
21 opioid if an opioid is a medically necessary treatment.

22 (f) REPORTS TO CONGRESS.—

23 (1) INITIAL REPORT.—Not later than 180 days
24 after the date of the enactment of this Act, the Sec-

1 retary shall submit to Congress a report that in-
2 cludes—

3 (A) the application form described in sub-
4 section (b)(4)(A) that is to be made available to
5 potential participants; and

6 (B) a progress report with respect to des-
7 ignating the conditions under subsection (c)(1)
8 and establishing the description of clearly de-
9 fined treatments described in subsection (c)(3).

10 (2) PERIODIC DEMONSTRATION REPORTS.—Be-
11 ginning after the first year of the demonstration
12 project and annually thereafter for each year of the
13 demonstration project and not later than one year
14 after the completion of the demonstration, the Sec-
15 retary shall submit to Congress a report that in-
16 cludes the following data for each hospital partici-
17 pating under the demonstration project:

18 (A) With respect to each condition or set
19 of symptom designated under subsection (c)(1),
20 the number of individuals treated.

21 (B) With respect to each such condition,
22 the number of individuals treated only with an
23 alternative to opioids.

24 (C) With respect to each such condition,
25 the number of individuals treated first with an

1 alternative to opioids, followed by an opioid in
2 the same visit.

3 (D) With respect to each such condition,
4 the number of individuals treated only with an
5 opioid.

6 (E) With respect to each individual de-
7 scribed in subparagraph (A) treated for such a
8 condition or set of symptoms, whether or not
9 the individual involved returned to the emer-
10 gency department of the hospital or an emer-
11 gency department of a different hospital for the
12 same condition or symptoms.

13 (F) The difference in cost between treating
14 an individual with an alternative to opioid
15 versus an opioid.

16 (G) Any additional information the Sec-
17 retary determines necessary.

18 **SEC. 3. OPIOIDS AND STOP PAIN INITIATIVE.**

19 (a) ESTABLISHMENT.—There is established an
20 Opioids and STOP Pain Initiative, to be administered by
21 the Director of the National Institutes of Health, in co-
22 ordination with other agencies, as appropriate, which shall
23 include efforts to support research on the following:

24 (1) Section 108 of the Comprehensive Addiction
25 and Recovery Act of 2016 (42 U.S.C. 284q–1),

1 known as the STOP Pain Act, which directs the Na-
2 tional Institutes of Health to intensify and coordi-
3 nate fundamental, translational, and clinical re-
4 search with respect to—

5 (A) the understanding of pain;

6 (B) the discovery and development of
7 therapies for chronic pain; and

8 (C) the development of alternatives to
9 opioids for effective pain treatments.

10 (2) Developing improved options and evidence
11 for medication-assisted treatment.

12 (3) Developing improved options and evidence
13 for opioid overdose reversal treatments.

14 (4) The Federal Pain Research Strategy, in-
15 cluding research that focuses on—

16 (A) novel drugs, non-addictive, and non-
17 pharmacological treatments for pain;

18 (B) screening tools and outcome measure
19 for assessments across the continuum of pain;

20 (C) national registries, datasets, and re-
21 search networks;

22 (D) effective models of care delivery for
23 pain management; and

24 (E) precision medicine methodology to pre-
25 vent and treat pain.

1 (5) The components of the Department of
2 Health and Human Services five-point strategy to
3 address the opioid crisis that states: “Providing sup-
4 port for cutting edge research on pain and addic-
5 tion”.

6 (6) The pain therapy screening program estab-
7 lished under subsection (c).

8 (7) Other elements that the Secretary of Health
9 and Human Services may designate, in consultation
10 with the Director of the National Institutes of
11 Health.

12 (b) FUNDING FOR THE OPIOIDS AND STOP PAIN
13 INITIATIVE.—

14 (1) IN GENERAL.—There is authorized to be
15 appropriated, and there is appropriated,
16 \$500,000,000, to be used during the 5-fiscal-year
17 period beginning in the fiscal year in which such
18 funds are appropriated, to the National Institutes of
19 Health Innovation Account to be used to administer
20 the Opioids and STOP Pain Initiative established
21 under subsection (a).

22 (2) EMERGENCY SPENDING.—

23 (A) IN GENERAL.—Amounts appropriated
24 under paragraph (1) are designated as an emer-
25 gency requirement pursuant to section 4(g) of

1 the Statutory Pay-As-You-Go Act of 2010 (2
2 U.S.C. 933(g)).

3 (B) DESIGNATION IN THE SENATE.—In
4 the Senate, amounts appropriated under sub-
5 section (a) are designated as an emergency re-
6 quirement pursuant to section 403(a) of S.
7 Con. Res. 13 (111th Congress), the concurrent
8 resolution on the budget for fiscal year 2010.

9 (c) PAIN THERAPY SCREENING PROGRAM.—

10 (1) IN GENERAL.—The Secretary of Health and
11 Human Services (referred to in this section as the
12 “Secretary”) shall carry out through the National
13 Institutes of Health a program to be known as the
14 “Pain Therapy Screening Program” that focuses on
15 the development of pain therapeutics.

16 (2) GRANTS.—The Secretary shall award
17 grants under the program under paragraph (1) to
18 eligible public and private nonprofit entities to sup-
19 port the development of new pre-clinical models for
20 pain disorders, and the application of these models
21 in drug, device, or other therapy screening.

22 (3) MODEL.—The program under this section
23 shall be modeled after the Epilepsy Therapy Screen-
24 ing Program carried out by the National Institute of
25 Neurological Disorders and Stroke.

1 (4) FEES.—The Secretary of Health and
2 Human Services may assess reasonable fees on pri-
3 vate pharmaceutical or medical device industry enti-
4 ties that utilize the program under this section to
5 screen proprietary molecular compounds and devices.
6 Such fees shall be paid to the Foundation for the
7 National Institutes of Health and transferred to the
8 NIH Innovation Account to be used for the Opioids
9 and STOP Pain Initiative established under sub-
10 section (a).

11 (5) FUNDING.—The Director of the National
12 Institutes of Health shall determine the amount, and
13 allocate, funds from the amount appropriated under
14 subsection (b), to carry out this section.

15 (d) FUNDING PROVISIONS.—

16 (1) SUPPLEMENT NOT SUPPLANT.—Amounts
17 appropriated in this section (including the amend-
18 ments made by this section) shall be used to supple-
19 ment, not supplant, current funding for pain and
20 opioid research at the National Institutes of Health.

21 (2) ACCEPTANCE OF DONATIONS.—Notwith-
22 standing section 1342 of title 31, United States
23 Code, the Secretary of Health and Human Services
24 may accept donations (including from the pharma-
25 ceutical and medical device industries) to be used to

1 assist in carrying out programs and activities under
2 this section (and the amendments made by this sec-
3 tion). Such donations shall be paid to the Founda-
4 tion for the National Institutes of Health and trans-
5 ferred to the NIH Innovation Account to be used for
6 the Opioids and STOP Pain Initiative established
7 under subsection (a).

8 (3) INCLUSION OF CONTRIBUTION AMOUNTS IN
9 BASIC RESEARCH FOR PURPOSES OF RESEARCH
10 CREDIT.—

11 (A) IN GENERAL.—Paragraph (6) of sec-
12 tion 41(e) of the Internal Revenue Code of
13 1986 is amended by adding at the end the fol-
14 lowing new subparagraph:

15 “(E) OPIOIDS AND STOP PAIN INITIA-
16 TIVE.—The National Institutes of Health, if the
17 payment is made in support of the Opioids and
18 STOP Pain Initiative, as established by the
19 Opioids and STOP Pain Initiative Act.”.

20 (B) EFFECTIVE DATE.—The amendments
21 made by this subsection shall apply to taxable
22 years beginning after the date of the enactment
23 of this Act.

24 (e) AUTHORITY.—Notwithstanding any other provi-
25 sion of the law, the Director of the National Institutes

1 of Health may use funds available under subsection (b)
2 to enter into transactions (other than contracts, coopera-
3 tive agreements, or grants) to carry out research identified
4 pursuant to the Opioids and STOP Pain Initiative estab-
5 lished under subsection (a).

6 (f) REPORTS.—

7 (1) ANNUAL REPORTS.—Not later than October
8 1 of each of fiscal years 2019 through 2026, the Di-
9 rector of the National Institutes of Health shall sub-
10 mit to the Committee on Health, Education, Labor,
11 and Pensions and the Committee on Appropriations
12 of the Senate and the Committee on Energy and
13 Commerce and the Committee on Appropriations of
14 the House of Representatives, a report that in-
15 cludes—

16 (A) the amount obligated or expended in
17 the fiscal year prior to the fiscal year in which
18 the report is being submitted for each program
19 or activity described in this section (or an
20 amendment made by this section);

21 (B) a description of all such programs or
22 activities carried out using funds provided
23 under this section (or amendments); and

24 (C) a description of how such programs or
25 activities are advancing public health, including

1 the impact on treating pain and addressing
2 opioid misuse in the United States.

3 (2) ADDITIONAL REPORTS.—At the request of
4 the Committee on Health, Education, Labor, and
5 Pensions or the Committee on Appropriations of the
6 Senate, or the Committee on Energy and Commerce
7 or the Committee on Appropriations of the House of
8 Representatives, the Director of the National Insti-
9 tutes of Health shall provide to the relevant com-
10 mittee an update in the form of testimony and addi-
11 tional reports concerning the allocation of funding
12 under this section (or the amendments made by this
13 section) or the description of the programs and ac-
14 tivities carried out with such funding.

15 **SEC. 4. VETERAN OVER-MEDICATION PREVENTION.**

16 (a) REVIEW REQUIRED.—

17 (1) IN GENERAL.—Not later than 90 days after
18 the date of the enactment of this Act, the Secretary
19 of Veterans Affairs shall seek to enter into an agree-
20 ment with the National Academies of Sciences, En-
21 gineering, and Medicine under which the National
22 Academies shall conduct a review of the deaths of all
23 covered veterans who died by suicide during the five-
24 year period ending on the date of the enactment of
25 this Act, regardless of whether information relating

1 to such deaths has been reported by the Centers for
2 Disease Control and Prevention.

3 (2) ELEMENTS.—The review required by para-
4 graph (1) shall include the following:

5 (A) The total number of covered veterans
6 who died by suicide during the five-year period
7 ending on the date of the enactment of this Act.

8 (B) The total number of covered veterans
9 who died by a violent death during such five-
10 year period.

11 (C) The total number of covered veterans
12 who died by an accidental death during such
13 five-year period.

14 (D) A description of each covered veteran
15 described in subparagraphs (A) through (C), in-
16 cluding age, gender, race, and ethnicity.

17 (E) A comprehensive list of prescribed
18 medications and legal or illegal substances as
19 annotated on toxicology reports of covered vet-
20 erans described in subparagraphs (A) through
21 (C), specifically listing any medications that
22 carried a black box warning, were prescribed for
23 off-label use, were psychotropic, or carried
24 warnings that included suicidal ideation.

1 (F) A summary of medical diagnoses by
2 physicians of the Department of Veterans Af-
3 fairs or physicians providing services to covered
4 veterans through programs of the Department
5 that led to the prescribing of medications re-
6 ferred to in subparagraph (E) in cases of post-
7 traumatic stress disorder, traumatic brain in-
8 jury, military sexual trauma, and other anxiety
9 and depressive disorders.

10 (G) The number of instances in which a
11 covered veteran described in subparagraph (A),
12 (B), or (C) was concurrently on multiple medi-
13 cations prescribed by physicians of the Depart-
14 ment or physicians providing services to vet-
15 erans through programs of the Department to
16 treat post-traumatic stress disorder, traumatic
17 brain injury, military sexual trauma, other anx-
18 iety and depressive disorders, or instances of
19 comorbidity.

20 (H) The number of covered veterans de-
21 scribed in subparagraphs (A) through (C) who
22 were not taking any medication prescribed by a
23 physician of the Department or a physician pro-
24 viding services to veterans through a program
25 of the Department.

1 (I) With respect to the treatment of post-
2 traumatic stress disorder, traumatic brain in-
3 jury, military sexual trauma, or other anxiety
4 and depressive disorders, the percentage of cov-
5 ered veterans described in subparagraphs (A)
6 through (C) who received a non-medication
7 first-line treatment compared to the percentage
8 of such veterans who received medication only.

9 (J) With respect to the treatment of cov-
10 ered veterans described in subparagraphs (A)
11 through (C) for post-traumatic stress disorder,
12 traumatic brain injury, military sexual trauma,
13 or other anxiety and depressive disorders, the
14 number of instances in which a non-medication
15 first-line treatment (such as cognitive behav-
16 ioral therapy) was attempted and determined to
17 be ineffective for such a veteran, which subse-
18 quently led to the prescribing of a medication
19 referred to in subparagraph (E).

20 (K) A description and example of how the
21 Department determines and continually updates
22 the clinical practice guidelines governing the
23 prescribing of medications.

24 (L) An analysis of the use by the Depart-
25 ment, including protocols or practices at med-

1 ical facilities of the Department, of systemati-
2 cally measuring pain scores during clinical en-
3 counters under the Pain as the 5th Vital Sign
4 Toolkit of the Department and an evaluation of
5 the relationship between the use of such meas-
6 urements and the number of veterans concu-
7 rently on multiple medications prescribed by
8 physicians of the Department.

9 (M) A description of the efforts of the De-
10 partment to maintain appropriate staffing levels
11 for mental health professionals, such as mental
12 health counselors, marriage and family thera-
13 pists, and other appropriate counselors, includ-
14 ing—

15 (i) a description of any impediments
16 to carry out the education, training, and
17 hiring of mental health counselors and
18 marriage and family therapists under sec-
19 tion 7302(a) of title 38, United States
20 Code, and strategies for addressing those
21 impediments;

22 (ii) a description of the objectives,
23 goals, and timing of the Department with
24 respect to increasing the representation of
25 such counselors and therapists in the be-

1 havioral health workforce of the Depart-
2 ment, including—

3 (I) a review of eligibility criteria
4 for such counselors and therapists and
5 a comparison of such criteria to that
6 of other behavioral health professions
7 in the Department; and

8 (II) an assessment of the partici-
9 pation of such counselors and thera-
10 pists in the mental health profes-
11 sionals trainee program of the De-
12 partment and any impediments to
13 such participation;

14 (iii) an assessment of the development
15 by the Department of hiring guidelines for
16 mental health counselors, marriage and
17 family therapists, and other appropriate
18 counselors;

19 (iv) a description of how the Depart-
20 ment—

21 (I) identifies gaps in the supply
22 of mental health professionals; and

23 (II) determines successful staff-
24 ing ratios for mental health profes-
25 sionals of the Department;

1 (v) a description of actions taken by
2 the Secretary, in consultation with the Di-
3 rector of the Office of Personnel Manage-
4 ment, to create an occupational series for
5 mental health counselors and marriage and
6 family therapists of the Department and a
7 timeline for the creation of such an occu-
8 pational series; and

9 (vi) a description of actions taken by
10 the Secretary to ensure that the national,
11 regional, and local professional standards
12 boards for mental health counselors and
13 marriage and family therapists are com-
14 prised of only mental health counselors and
15 marriage and family therapists and that
16 the liaison from the Department to such
17 boards is a mental health counselor or
18 marriage and family therapist.

19 (N) The percentage of covered veterans de-
20 scribed in subparagraphs (A) through (C) with
21 combat experience or trauma related to combat
22 experience (including military sexual trauma,
23 traumatic brain injury, and post-traumatic
24 stress).

1 (O) An identification of the medical facili-
2 ties of the Department with markedly high pre-
3 scription rates and suicide rates for veterans re-
4 ceiving treatment at those facilities.

5 (P) An analysis, by State, of programs of
6 the Department that collaborate with State
7 Medicaid agencies and the Centers for Medicare
8 and Medicaid Services, including the following:

9 (i) An analysis of the sharing of pre-
10 scription and behavioral health data for
11 veterans.

12 (ii) An analysis of whether Depart-
13 ment staff check with State prescription
14 drug monitoring programs before pre-
15 scribing medications to veterans.

16 (iii) A description of the procedures of
17 the Department for coordinating with pre-
18 scribers outside of the Department to en-
19 sure that veterans are not overprescribed.

20 (iv) A description of actions that the
21 Department takes when a veteran is deter-
22 mined to be overprescribed.

23 (Q) An analysis of the collaboration of
24 medical centers of the Department with medical

1 examiners' offices or local jurisdictions to deter-
2 mine veteran mortality and cause of death.

3 (R) An identification and determination of
4 a best practice model to collect and share vet-
5 eran death certificate data between the Depart-
6 ment of Veterans Affairs, the Department of
7 Defense, States, and tribal entities.

8 (S) A description of how data relating to
9 death certificates of veterans is collected, deter-
10 mined, and reported by the Department of Vet-
11 erans Affairs.

12 (T) An assessment of any patterns appar-
13 ent to the National Academies of Sciences, En-
14 gineering, and Medicine based on the review
15 conducted under paragraph (1).

16 (U) Such recommendations for further ac-
17 tion that would improve the safety and well-
18 being of veterans as the National Academies of
19 Sciences, Engineering, and Medicine determine
20 appropriate.

21 (3) COMPILATION OF DATA.—

22 (A) FORM OF COMPILATION.—The Sec-
23 retary of Veterans Affairs shall ensure that
24 data compiled under paragraph (2) is compiled
25 in a manner that allows it to be analyzed across

1 all data fields for purposes of informing and
2 updating clinical practice guidelines of the De-
3 partment of Veterans Affairs.

4 (B) COMPILATION OF DATA REGARDING
5 COVERED VETERANS.—In compiling data under
6 paragraph (2) regarding covered veterans de-
7 scribed in subparagraphs (A) through (C) of
8 such paragraph, data regarding veterans de-
9 scribed in each such subparagraph shall be
10 compiled separately and disaggregated by year.

11 (4) COMPLETION OF REVIEW AND REPORT.—
12 The agreement entered into under paragraph (1)
13 shall require that the National Academies of
14 Sciences, Engineering, and Medicine complete the
15 review under such paragraph and submit to the Sec-
16 retary of Veterans Affairs a report containing the
17 results of the review not later than 180 days after
18 entering into the agreement.

19 (b) REPORT.—Not later than 30 days after the com-
20 pletion by the National Academies of Sciences, Engineer-
21 ing, and Medicine of the review required under subsection
22 (a), the Secretary of Veterans Affairs shall—

23 (1) submit to the Committee on Veterans' Af-
24 fairs of the Senate and the Committee on Veterans'

1 Affairs of the House of Representatives a report on
2 the results of the review; and

3 (2) make such report publicly available.

4 (c) DEFINITIONS.—In this section:

5 (1) The term “black box warning” means a
6 warning displayed on the label of a prescription drug
7 that is designed to call attention to the serious or
8 life-threatening risk of the prescription drug.

9 (2) The term “covered veteran” means a vet-
10 eran who received hospital care or medical services
11 furnished by the Department of Veterans Affairs
12 during the five-year period preceding the death of
13 the veteran.

14 (3) The term “first-line treatment” means a po-
15 tential intervention that has been evaluated and as-
16 signed a high score within clinical practice guide-
17 lines.

18 (4) The term “State” means each of the States,
19 territories, and possessions of the United States, the
20 District of Columbia, and the Commonwealth of
21 Puerto Rico.

1 **SEC. 5. AMENDMENT RELATING TO THE ACCOUNT FOR THE**
2 **STATE RESPONSE TO THE OPIOID ABUSE CRI-**
3 **SIS.**

4 Section 1003 of the 21st Century Cures Act (Public
5 Law 114–255; 42 U.S.C. 290ee–3 note) is amended in
6 subsection (b)(3), by adding at the end the following new
7 subparagraph:

8 “(C) APPROPRIATIONS AFTER FISCAL
9 YEAR 2018.—There is authorized to be appro-
10 priated, and there is appropriated, out of any
11 monies in the Treasury not otherwise appro-
12 priated, to the Account For the State Response
13 to the Opioid Abuse Crisis \$500,000,000 for
14 each of fiscal years 2019 through 2023.”.

15 **SEC. 6. MENTAL HEALTH ACCESS IMPROVEMENT.**

16 (a) COVERAGE OF SERVICES.—

17 (1) IN GENERAL.—Section 1861(s)(2) of the
18 Social Security Act (42 U.S.C. 1395x(s)(2)) is
19 amended—

20 (A) in subparagraph (FF), by striking
21 “and” after the semicolon at the end;

22 (B) in subparagraph (GG), by inserting
23 “and” after the semicolon at the end; and

24 (C) by adding at the end the following new
25 subparagraph:

1 “(HH) marriage and family therapist services
 2 (as defined in subsection (jjj)(1)) and mental health
 3 counselor services (as defined in subsection
 4 (jjj)(3));”.

5 (2) DEFINITIONS.—Section 1861 of the Social
 6 Security Act (42 U.S.C. 1395x) is amended by add-
 7 ing at the end the following new subsection:

8 “Marriage and Family Therapist Services; Marriage and
 9 Family Therapist; Mental Health Counselor Serv-
 10 ices; Mental Health Counselor

11 “(jjj)(1) The term ‘marriage and family therapist
 12 services’ means services performed by a marriage and
 13 family therapist (as defined in paragraph (2)) for the diag-
 14 nosis and treatment of mental illnesses, which the mar-
 15 riage and family therapist is legally authorized to perform
 16 under State law (or the State regulatory mechanism pro-
 17 vided by State law) of the State in which such services
 18 are performed, as would otherwise be covered if furnished
 19 by a physician or as an incident to a physician’s profes-
 20 sional service, but only if no facility or other provider
 21 charges or is paid any amounts with respect to the fur-
 22 nishing of such services.

23 “(2) The term ‘marriage and family therapist’ means
 24 an individual who—

1 “(A) possesses a master’s or doctoral degree
2 which qualifies for licensure or certification as a
3 marriage and family therapist pursuant to State
4 law;

5 “(B) after obtaining such degree has performed
6 at least 2 years of clinical supervised experience in
7 marriage and family therapy; and

8 “(C) in the case of an individual performing
9 services in a State that provides for licensure or cer-
10 tification of marriage and family therapists, is li-
11 censed or certified as a marriage and family thera-
12 pist in such State.

13 “(3) The term ‘mental health counselor services’
14 means services performed by a mental health counselor (as
15 defined in paragraph (4)) for the diagnosis and treatment
16 of mental illnesses which the mental health counselor is
17 legally authorized to perform under State law (or the
18 State regulatory mechanism provided by the State law) of
19 the State in which such services are performed, as would
20 otherwise be covered if furnished by a physician or as inci-
21 dent to a physician’s professional service, but only if no
22 facility or other provider charges or is paid any amounts
23 with respect to the furnishing of such services.

24 “(4) The term ‘mental health counselor’ means an
25 individual who—

1 “(A) possesses a master’s or doctor’s degree in
2 mental health counseling or a related field;

3 “(B) after obtaining such a degree has per-
4 formed at least 2 years of supervised mental health
5 counselor practice; and

6 “(C) in the case of an individual performing
7 services in a State that provides for licensure or cer-
8 tification of mental health counselors or professional
9 counselors, is licensed or certified as a mental health
10 counselor or professional counselor in such State.”.

11 (3) PROVISION FOR PAYMENT UNDER PART
12 B.—Section 1832(a)(2)(B) of the Social Security
13 Act (42 U.S.C. 1395k(a)(2)(B)) is amended by add-
14 ing at the end the following new clause:

15 “(v) marriage and family therapist
16 services (as defined in section 1861(jjj)(1))
17 and mental health counselor services (as
18 defined in section 1861(jjj)(3));”.

19 (4) AMOUNT OF PAYMENT.—Section 1833(a)(1)
20 of the Social Security Act (42 U.S.C. 1395l(a)(1))
21 is amended—

22 (A) by striking “and (BB)” and inserting
23 “(BB)”; and

24 (B) by inserting before the semicolon at
25 the end the following: “, and (CC) with respect

to marriage and family therapist services and mental health counselor services under section 1861(s)(2)(HH), the amounts paid shall be 80 percent of the lesser of the actual charge for the services or 75 percent of the amount determined for payment of a psychologist under subparagraph (L)”.

(5) EXCLUSION OF MARRIAGE AND FAMILY THERAPIST SERVICES AND MENTAL HEALTH COUNSELOR SERVICES FROM SKILLED NURSING FACILITY PROSPECTIVE PAYMENT SYSTEM.—Section 1888(e)(2)(A)(ii) of the Social Security Act (42 U.S.C. 1395yy(e)(2)(A)(ii)) is amended by inserting “marriage and family therapist services (as defined in section 1861(jjj)(1)), mental health counselor services (as defined in section 1861(jjj)(3)),” after “qualified psychologist services,”.

(6) INCLUSION OF MARRIAGE AND FAMILY THERAPISTS AND MENTAL HEALTH COUNSELORS AS PRACTITIONERS FOR ASSIGNMENT OF CLAIMS.—Section 1842(b)(18)(C) of the Social Security Act (42 U.S.C. 1395u(b)(18)(C)) is amended by adding at the end the following new clauses:

“(vii) A marriage and family therapist (as defined in section 1861(jjj)(2)).

1 “(viii) A mental health counselor (as defined in
2 section 1861(jjj)(4)).”.

3 (b) COVERAGE OF CERTAIN MENTAL HEALTH SERV-
4 ICES PROVIDED IN CERTAIN SETTINGS.—

5 (1) RURAL HEALTH CLINICS AND FEDERALLY
6 QUALIFIED HEALTH CENTERS.—Section
7 1861(aa)(1)(B) of the Social Security Act (42
8 U.S.C. 1395x(aa)(1)(B)) is amended by striking “or
9 by a clinical social worker (as defined in subsection
10 (hh)(1))” and inserting “, by a clinical social worker
11 (as defined in subsection (hh)(1)), by a marriage
12 and family therapist (as defined in subsection
13 (jjj)(2)), or by a mental health counselor (as defined
14 in subsection (jjj)(4))”.

15 (2) HOSPICE PROGRAMS.—Section
16 1861(dd)(2)(B)(i)(III) of the Social Security Act (42
17 U.S.C. 1395x(dd)(2)(B)(i)(III)) is amended by in-
18 serting “, marriage and family therapist, or mental
19 health counselor” after “social worker”.

20 (c) AUTHORIZATION OF MARRIAGE AND FAMILY
21 THERAPISTS AND MENTAL HEALTH COUNSELORS TO
22 DEVELOP DISCHARGE PLANS FOR POST-HOSPITAL SERV-
23 ICES.—Section 1861(ee)(2)(G) of the Social Security Act
24 (42 U.S.C. 1395x(ee)(2)(G)) is amended by inserting “,
25 including a marriage and family therapist and a mental

1 health counselor who meets qualification standards estab-
 2 lished by the Secretary” before the period at the end.

3 (d) EFFECTIVE DATE.—The amendments made by
 4 this section shall apply with respect to services furnished
 5 on or after January 1, 2019.

6 **SEC. 7. SYNTHETICS TRAFFICKING AND OVERDOSE PRE-**
 7 **VENTION.**

8 (a) FORMAL ENTRY REQUIREMENTS—POSTAL
 9 SERVICE AS CONSIGNEE.—Subparagraph (B) of section
 10 484(a)(2) of the Tariff Act of 1930 (19 U.S.C.
 11 1484(a)(2)(B)) is amended to read as follows:

12 “(B)(i) When an entry of merchandise is made
 13 under this section, the required documentation or in-
 14 formation shall be filed or electronically trans-
 15 mitted—

16 “(I) by the owner or purchaser of the mer-
 17 chandise; or

18 “(II) when appropriately designated by the
 19 owner, purchaser, or consignee of the merchan-
 20 dise, by a person holding a valid license under
 21 section 641.

22 “(ii) The Postmaster General shall be deemed
 23 the consignee for merchandise, as defined by section
 24 498(c), imported through the mail, and the Post-
 25 master General shall, at the Postmaster General’s

1 sole expense, designate a person holding a valid li-
2 cense under section 641 to file the required docu-
3 mentation or information or ensure that the owner
4 or purchaser of the merchandise or a person holding
5 a valid license under section 641 that is designated
6 by the owner or purchaser files the required docu-
7 mentation or information.

8 “(iii) When a consignee declares on entry that
9 he or she is the owner or purchaser of merchandise,
10 U.S. Customs and Border Protection may, without
11 liability, accept the declaration.

12 “(iv) For the purposes of this Act, the importer
13 of record must be one of the parties who is eligible
14 to file the documentation or information required by
15 this section.”.

16 (b) INFORMAL ENTRIES.—Section 498 of the Tariff
17 Act of 1930 (19 U.S.C. 1498) is amended by adding at
18 the end the following:

19 “(c) APPLICATION TO POSTAL SHIPMENTS.—

20 “(1) DEFINITIONS.—In this subsection:

21 “(A) DOCUMENT.—The term ‘document’
22 means a piece of written, drawn, printed, or
23 digital information, excluding objects of mer-
24 chandise, that—

1 “(i) is conveyed in an envelope that is
2 less than or equal to 165 millimeters in
3 width, 245 millimeters in length, and 5
4 millimeters in depth; and

5 “(ii) weighs 100 grams or less when
6 conveyed.

7 “(B) MERCHANDISE.—The term ‘merchan-
8 dise’ has the same meaning as that term is de-
9 fined in section 401 but does not include a doc-
10 ument.

11 “(2) REQUIREMENT.—Notwithstanding any
12 other provision of law, for merchandise meeting the
13 requirements of subsection (a), the Postmaster Gen-
14 eral shall comply with the entry requirements of sec-
15 tion 484.

16 “(3) REGULATIONS.—Any regulation issued
17 pursuant to this subsection shall apply identical
18 entry procedures for merchandise imported through
19 the mail as are applied for merchandise imported via
20 a private carrier.”.

21 (c) DE MINIMIS SHIPMENTS.—Section 321 of the
22 Tariff Act of 1930 (19 U.S.C. 1321) is amended by add-
23 ing at the end the following:

24 “(c)(1) For imported articles that qualify for the ad-
25 ministrative exemption under subsection (a)(2) and that

1 arrive at international mail facilities in the United States,
2 the Postmaster General shall be deemed the consignee for
3 such articles that are considered merchandise, as the term
4 is defined in section 498(c).

5 “(2) In addition to the parties that are authorized
6 to comply with the entry requirements of sections 498 and
7 484, the Postmaster General, as a consignee, may, using
8 reasonable care, enter such merchandise that qualifies for
9 the administrative exemption under subsection (a)(2).”.

10 (d) CUSTOMS FEES.—

11 (1) IN GENERAL.—Paragraph (6) of section
12 13031(a) of the Consolidated Omnibus Budget Rec-
13 onciliation Act of 1985 (19 U.S.C. 58c(a)(6)) is
14 amended to read as follows:

15 “(6)(A) For the arrival of shipments of mer-
16 chandise (as the term is defined in section 498(c) of
17 the Trade Act of 1930) or any other item that is
18 valued at \$2,000 or less (or such higher amount as
19 the Secretary of the Treasury may set by regulation
20 pursuant to section 498 of the Tariff Act of 1930
21 (19 U.S.C. 1498) and subject to adjustment under
22 subsection (l)) arriving at an international mail facil-
23 ity:

1 “(i) \$1 per individual airway bill or bill of
2 lading (subject to adjustment under subsection
3 (l)); or

4 “(ii) if such merchandise is formally en-
5 tered, the fee provided for in paragraph (9), if
6 applicable.

7 “(B) Notwithstanding section 451 of the Tariff
8 Act of 1930 (19 U.S.C. 1451), the payment required
9 by subparagraph (A) shall be the only payment re-
10 quired for reimbursement of U.S. Customs and Bor-
11 der Protection in connection with the processing of
12 an individual airway bill or bill of lading in accord-
13 ance with such subparagraph and for providing serv-
14 ices at international mail facilities, except that U.S.
15 Customs and Border Protection may require such
16 facilities to cover expenses of the agency for ade-
17 quate office space, equipment, furnishings, supplies,
18 and security.

19 “(C) The payment required by subparagraphs
20 (A) and (B) shall be paid on a quarterly basis by the
21 Postmaster General in accordance with regulations
22 prescribed by the Secretary of the Treasury. The
23 payments shall be allocated as follows:

24 “(i) 50 percent of the amount of payments
25 received in this paragraph shall, in accordance

1 with section 524 of the Tariff Act of 1930 (19
2 U.S.C. 1524), be deposited in the Customs
3 User Fee Account and shall be used to directly
4 reimburse each appropriation for the amount
5 paid out of that appropriation for the costs in-
6 curred in providing services to international
7 mail facilities. Amounts deposited in accordance
8 with the preceding sentence shall be available
9 until expended for the provision of customs
10 services to international mail facilities.

11 “(ii) Notwithstanding section 524 of the
12 Tariff Act of 1930 (19 U.S.C. 1524), 50 per-
13 cent of the amount of payments received under
14 this paragraph shall be paid to the Secretary of
15 the Treasury, which is in lieu of the payment
16 of fees under paragraph (10).”.

17 (2) TECHNICAL AMENDMENTS.—Paragraph
18 (10) of section 13031(a) of the Consolidated Omni-
19 bus Budget Reconciliation Act of 1985 (19 U.S.C.
20 58c(a)(10)) is amended—

21 (A) by striking “or” in subparagraph (B);

22 (B) by striking the period at the end of
23 subparagraph (C)(iii) and inserting a comma
24 and “or”;

1 (C) by inserting after subparagraph
2 (C)(iii) the following:

3 “(D) an international mail facility.”; and

4 (D) in the undesignated material at the
5 end by striking the period and inserting “or re-
6 ferred to in subparagraph (D) see paragraph
7 (6).”.

8 (e) MANDATORY ADVANCED ELECTRONIC INFORMA-
9 TION FOR POSTAL SHIPMENTS.—Subparagraph (K) of
10 section 343(a)(3) of the Trade Act of 2002 (Public Law
11 107–210; 19 U.S.C. 2071 note) is amended to read as
12 follows:

13 “(K) The Secretary shall require the Post-
14 master General to transmit or to ensure the
15 transmission of the information required in
16 paragraphs (1) and (2) to U.S. Customs and
17 Border Protection for all shipments by the
18 United States Postal Service which includes
19 shipments that the United States Postal Service
20 receives from foreign postal operators (ship-
21 ments from foreign postal operators may be
22 transported by private carriers). All regulations
23 issued pursuant to this provision are required
24 to impose the same information requirements

1 on the United States Postal Service and private
2 carriers.”.

3 (f) MANIFEST PENALTIES APPLIED TO THE UNITED
4 STATES POSTAL SERVICE.—

5 (1) PENALTIES FOR VIOLATIONS OF THE AR-
6 RIVAL, REPORTING, ENTRY, AND CLEARANCE RE-
7 QUIREMENTS.—Section 436 of the Tariff Act of
8 1930 (19 U.S.C. 1436) is amended by adding at the
9 end the following new subsection:

10 “(e) CIVIL PENALTIES ARISING FROM VIOLATIONS
11 FOR POSTAL SHIPMENTS.—With respect to civil penalties
12 provided for in subsections (b) and (d), the Postmaster
13 General shall be liable for the penalty if the violation was
14 caused by a foreign postal operator or the United States
15 Postal Service.”.

16 (2) PENALTIES FOR FALSITY OR LACK OF
17 MANIFEST.—Section 584 of the Tariff Act of 1930
18 (19 U.S.C. 1584) is amended by adding at the end
19 the following new subsection:

20 “(c) PERSON DIRECTLY OR INDIRECTLY RESPON-
21 SIBLE SHALL INCLUDE THE POSTMASTER GENERAL.—
22 For purposes of subsection (a), the Postmaster General
23 may be the person directly or indirectly responsible for a
24 discrepancy if the discrepancy is the result of—

1 “(1) an omission by a foreign postal operator or
2 the United States Postal Service; or

3 “(2) false information regarding the shipment
4 that was provided to the carrier by a foreign postal
5 operator or the United States Postal Service.”.

6 (g) LIMITATION ON INTERNATIONAL POSTAL AR-
7 RANGEMENTS.—

8 (1) EXISTING AGREEMENTS.—

9 (A) IN GENERAL.—In the event that any
10 provision in this section is found to be in viola-
11 tion of obligations of the United States under
12 the Universal Postal Union, the Secretary of
13 State shall negotiate to amend the relevant pro-
14 visions of the agreement so that the United
15 States is no longer in violation of the agree-
16 ment.

17 (B) CONSTRUCTION.—Nothing in this sub-
18 section may be construed to require or permit
19 any delay in the implementation of this section.

20 (2) FUTURE AGREEMENTS.—The Secretary of
21 State may not conclude any international postal ar-
22 rangement pursuant to the authority set out in sec-
23 tion 407 of title 39, United States Code, that is in-
24 consistent with this section or any amendment made
25 by this section.

1 (h) APPLICATION OF OTHER CUSTOMS LAWS.—

2 (1) IN GENERAL.—U.S. Customs and Border
3 Protection shall ensure that all merchandise, as that
4 term is defined in subsection (c) of section 498 of
5 the Tariff Act of 1930 (19 U.S.C. 1498), imported
6 to the United States through the mail shall be sub-
7 ject to the same import procedures, legal restric-
8 tions, and certifications as merchandise imported by
9 private carriers.

10 (2) REGULATIONS.—The Secretary of the
11 Treasury shall issue regulations pursuant to this
12 section to ensure that merchandise imported through
13 the mail is in accordance with Federal law.

14 (i) COST RECOUPMENT.—The Postmaster General
15 shall ensure that all costs associated with complying with
16 this section, as well as all penalties assessed against the
17 Postmaster General, are charged directly to foreign ship-
18 pers, foreign postal operators, or United States ultimate
19 consignees.

20 (j) EFFECTIVE DATE; REGULATIONS.—

21 (1) EFFECTIVE DATE.—This section shall be-
22 come effective upon the date of the enactment of
23 this Act.

24 (2) REGULATIONS.—Not later than 1 year after
25 the date of the enactment of this Act, the Secretary

1 shall prescribe all regulations required under this
2 section.

3 **SEC. 8. STOP THE IMPORTATION AND TRAFFICKING OF**
4 **SYNTHETIC ANALOGUES.**

5 (a) ESTABLISHMENT OF SCHEDULE A.—Section 202
6 of the Controlled Substances Act (21 U.S.C. 812) is
7 amended—

8 (1) in subsection (a), by striking “five schedules
9 of controlled substances, to be known as schedules I,
10 II, III, IV, and V” and inserting “six schedules of
11 controlled substances, to be known as schedules I,
12 II, III, IV, V, and A”;

13 (2) in subsection (b), by adding at the end the
14 following:

15 “(6) SCHEDULE A.—

16 “(A) IN GENERAL.—The drug or substance—

17 “(i) has—

18 “(I) a chemical structure that is sub-
19 stantially similar to the chemical structure
20 of a controlled substance in schedule I, II,
21 III, IV, or V; and

22 “(II) an actual or predicted stimulant,
23 depressant, or hallucinogenic effect on the
24 central nervous system that is substantially
25 similar to or greater than the stimulant,

depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I, II, III, IV, or V; and “(ii) is not—

“(I) listed or otherwise included in any other schedule in this section or by regulation of the Attorney General; and

“(II) with respect to a particular person, subject to an exemption that is in effect for investigational use, for that person, under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) to the extent conduct with respect to such substance is pursuant to such exemption.

“(B) PREDICTED STIMULANT, DEPRESSANT, OR HALLUCINOGENIC EFFECT.—For purpose of this paragraph, a predicted stimulant, depressant, or hallucinogenic effect on the central nervous system may be based on—

“(i) the chemical structure, structure activity relationships, binding receptor assays, or other relevant scientific information about the substance;

“(ii)(I) the current or relative potential for abuse of the substance; and

1 “(II) the clandestine importation, manu-
 2 facture, or distribution, or diversion from legiti-
 3 mate channels, of the substance; or

4 “(iii) the capacity of the substance to
 5 cause a state of dependence, including physical
 6 or psychological dependence that is similar to or
 7 greater than that of a controlled substance in
 8 schedule I, II, III, IV, or V.”; and

9 (3) in subsection (c)—

10 (A) in the matter preceding schedule I, by
 11 striking “IV, and V” and inserting “IV, V, and
 12 A”; and

13 (B) by adding at the end the following:

14 “SCHEDULE A

15 “(a) Unless specifically excepted or unless listed in
 16 another schedule, any of the following substances, as
 17 scheduled in accordance with section 201(k)(5):

18 “(1) 4-fluoroisobutyl fentanyl.

19 “(2) Valeryl fentanyl.

20 “(3) 4-methoxybutyl fentanyl.

21 “(4) 4-methylphenethyl acetyl fentanyl.

22 “(5) 3-furanyl fentanyl.

23 “(6) Ortho-fluorofentanyl.

24 “(7) Tetrahydrofuran fentanyl.

25 “(8) Ocfentanil.

26 “(9) 4-fluorobutyl fentanyl.

1 “(10) Methoxyacetyl fentanyl.

2 “(11) Meta-fluorofentanyl.

3 “(12) Isobutyryl fentanyl.

4 “(13) Acryl fentanyl.”.

5 (b) TEMPORARY AND PERMANENT SCHEDULING OF
6 SCHEDULE A SUBSTANCES.—Section 201 of the Con-
7 trolled Substances Act (21 U.S.C. 811) is amended by
8 adding at the end the following:

9 “(k) TEMPORARY AND PERMANENT SCHEDULING OF
10 SCHEDULE A SUBSTANCES.—

11 “(1) The Attorney General may issue a tem-
12 porary order adding a drug or substance to schedule
13 A if the Attorney General finds that—

14 “(A) the drug or other substance satisfies
15 the criteria for being considered a schedule A
16 substance; and

17 “(B) adding such drug or substance to
18 schedule A will assist in preventing abuse or
19 misuse of the drug or other substance.

20 “(2) A temporary scheduling order issued under
21 paragraph (1) shall not take effect until 30 days
22 after the date of the publication by the Attorney
23 General of a notice in the Federal Register of the in-
24 tention to issue such order and the grounds upon
25 which such order is to be issued. The temporary

1 scheduling order shall expire not later than 5 years
2 after the date it becomes effective, except that the
3 Attorney General may, during the pendency of pro-
4 ceedings under paragraph (5), extend the temporary
5 scheduling order for up to 180 days.

6 “(3) A temporary scheduling order issued under
7 paragraph (1) shall be vacated upon the issuance of
8 a permanent order issued under paragraph (5) with
9 regard to the same substance, or upon the subse-
10 quent issuance of any scheduling order under this
11 section.

12 “(4) A temporary scheduling order issued under
13 paragraph (1) shall not be subject to judicial review.

14 “(5) The Attorney General may, by rule, issue
15 a permanent order adding a drug or other substance
16 to schedule A if such drug or substance satisfies the
17 criteria for being considered a schedule A substance.
18 Such rulemaking may be commenced simultaneously
19 with the issuance of the temporary scheduling order
20 issued under paragraph (1) with regard to the same
21 substance.

22 “(6) Before initiating proceedings under para-
23 graph (1) or (5), the Attorney General shall trans-
24 mit notice of an order proposed to be issued to the
25 Secretary of Health and Human Services. In issuing

1 an order under paragraph (1) or (5), the Attorney
2 General shall take into consideration any comments
3 submitted by the Secretary of Health and Human
4 Services in response to a notice transmitted pursu-
5 ant to this paragraph.

6 “(7) On the date of the publication of a notice
7 in the Federal Register pursuant to paragraph (2),
8 the Attorney General shall transmit the same notice
9 to Congress. The temporary scheduling order shall
10 take effect according to paragraph (2), except that
11 the temporary scheduling order may be disapproved
12 by Act of Congress within 180 days from the date
13 of publication of the notice in the Federal Reg-
14 ister.”.

15 (c) PENALTIES.—

16 (1) CONTROLLED SUBSTANCES ACT.—The Con-
17 trolled Substances Act (21 U.S.C. 801 et seq.) is
18 amended—

19 (A) in section 401(b)(1) (21 U.S.C.
20 841(b)(1)), by adding at the end the following:

21 “(F)(i) In the case of any controlled substance in
22 schedule A, such person shall be sentenced to a term of
23 imprisonment of not more than 10 years and if death or
24 serious bodily injury results from the use of such sub-
25 stance shall be sentenced to a term of imprisonment of

1 not more than 15 years, a fine not to exceed the greater
2 of that authorized in accordance with the provisions of
3 title 18, United States Code, or \$500,000 if the defendant
4 is an individual or \$2,500,000 if the defendant is other
5 than an individual, or both.

6 “(ii) If any person commits such a violation after a
7 prior conviction for a felony drug offense has become final,
8 such person shall be sentenced to a term of imprisonment
9 of not more than 20 years and if death or serious bodily
10 injury results from the use of such substance shall be sen-
11 tenced to a term of imprisonment of not more than 30
12 years, a fine not to exceed the greater of twice that author-
13 ized in accordance with the provisions of title 18, United
14 States Code, or \$1,000,000 if the defendant is an indi-
15 vidual or \$5,000,000 if the defendant is other than an in-
16 dividual, or both.

17 “(iii) Any sentence imposing a term of imprisonment
18 under this subparagraph shall, in the absence of such a
19 prior conviction, impose a term of supervised release of
20 not less than 2 years in addition to such term of imprison-
21 ment and shall, if there was such a prior conviction, im-
22 pose a term of supervised release of not less than 4 years
23 in addition to such term of imprisonment.”;

24 (B) in section 403(a) (21 U.S.C.
25 843(a))—

1 (i) in paragraph (8), by striking “or”
2 at the end;

3 (ii) in paragraph (9), by striking the
4 period at the end and inserting “; or”; and

5 (iii) by inserting after paragraph (9)
6 the following:

7 “(10) to export a substance in violation of the
8 controlled substance laws of the country to which
9 the substance is exported.”; and

10 (C) in section 404 (21 U.S.C. 844), by in-
11 serting after subsection (a) the following:

12 “(b) A person shall not be subject to a criminal or
13 civil penalty under this title or under any other Federal
14 law solely for possession of a schedule A controlled sub-
15 stance.”.

16 (2) CONTROLLED SUBSTANCES IMPORT AND
17 EXPORT ACT.—Section 1010(b) of the Controlled
18 Substances Import and Export Act (21 U.S.C.
19 960(b)) is amended by adding at the end the fol-
20 lowing:

21 “(8) In the case of a violation under subsection (a)
22 involving a controlled substance in schedule A, the person
23 committing such violation shall be sentenced to a term of
24 imprisonment of not more than 20 years and if death or
25 serious bodily injury results from the use of such sub-

1 stance shall be sentenced to a term of imprisonment of
2 not more than life, a fine not to exceed the greater of that
3 authorized in accordance with the provisions of title 18,
4 United States Code, or \$1,000,000 if the defendant is an
5 individual or \$5,000,000 if the defendant is other than
6 an individual, or both. If any person commits such a viola-
7 tion after a prior conviction for a felony drug offense has
8 become final, such person shall be sentenced to a term
9 of imprisonment of not more than 30 years and if death
10 or serious bodily injury results from the use of such sub-
11 stance shall be sentenced to not more than life imprison-
12 ment, a fine not to exceed the greater of twice that author-
13 ized in accordance with the provisions of title 18, United
14 States Code, or \$2,000,000 if the defendant is an indi-
15 vidual or \$10,000,000 if the defendant is other than an
16 individual, or both. Notwithstanding section 3583 of title
17 18, United States Code, any sentence imposing a term of
18 imprisonment under this paragraph shall, in the absence
19 of such a prior conviction, impose a term of supervised
20 release of not less than 3 years in addition to such term
21 of imprisonment and shall, if there was such a prior con-
22 viction, impose a term of supervised release of not less
23 than 6 years in addition to such term of imprisonment.
24 Notwithstanding the prior sentence, and notwithstanding
25 any other provision of law, the court shall not place on

1 probation or suspend the sentence of any person sentenced
2 under the provisions of this paragraph which provide for
3 a mandatory term of imprisonment if death or serious
4 bodily injury results.”.

5 (d) FALSE LABELING OF SCHEDULE A CONTROLLED
6 SUBSTANCES.—

7 (1) IN GENERAL.—Section 305 of the Con-
8 trolled Substances Act (21 U.S.C. 825) is amended
9 by adding at the end the following:

10 “(f) FALSE LABELING OF SCHEDULE A CON-
11 TROLLED SUBSTANCES.—

12 “(1) It shall be unlawful to import, export,
13 manufacture, distribute, dispense, or possess with
14 intent to manufacture, distribute, or dispense, a
15 schedule A substance or product containing a sched-
16 ule A substance, unless the substance or product
17 bears a label clearly identifying a schedule A sub-
18 stance or product containing a schedule A substance
19 by the nomenclature used by the International
20 Union of Pure and Applied Chemistry (IUPAC).

21 “(2)(A) A product described in subparagraph
22 (B) is exempt from the International Union of Pure
23 and Applied Chemistry nomenclature requirement of
24 this subsection if such product is labeled in the man-

1 ner required under the Federal Food, Drug, and
2 Cosmetic Act.

3 “(B) A product is described in this subpara-
4 graph if the product—

5 “(i) is the subject of an approved applica-
6 tion as described in section 505(b) or (j) of the
7 Federal Food, Drug, and Cosmetic Act; or

8 “(ii) is exempt from the provisions of sec-
9 tion 505 of such Act relating to new drugs be-
10 cause—

11 “(I) it is intended solely for investiga-
12 tional use as described in section 505(i) of
13 such Act; and

14 “(II) such product is being used ex-
15 clusively for purposes of a clinical trial
16 that is the subject of an effective investiga-
17 tional new drug application.”.

18 (2) PENALTIES.—Section 402 of the Controlled
19 Substances Act (21 U.S.C. 842) is amended—

20 (A) in subsection (a)(16), by inserting “or
21 subsection (f)” after “subsection (e)”; and

22 (B) in subsection (c)(1)(D), by inserting
23 “or a schedule A substance” after “anabolic
24 steroid”.

1 (e) REGISTRATION REQUIREMENTS FOR HANDLERS
2 OF SCHEDULE A SUBSTANCES.—

3 (1) CONTROLLED SUBSTANCES ACT.—Section
4 303 of the Controlled Substances Act (21 U.S.C.
5 823) is amended by adding at the end the following:

6 “(k)(1) The Attorney General shall register an appli-
7 cant to manufacture schedule A substances if—

8 “(A) the applicant demonstrates that the sched-
9 ule A substances will be used for research, analyt-
10 ical, or industrial purposes approved by the Attorney
11 General; and

12 “(B) the Attorney General determines that such
13 registration is consistent with the public interest and
14 with the United States obligations under inter-
15 national treaties, conventions, or protocols in effect
16 on the date of enactment of this subsection.

17 “(2) In determining the public interest under para-
18 graph (1)(B), the Attorney General shall consider—

19 “(A) maintenance of effective controls against
20 diversion of particular controlled substances and any
21 controlled substance in schedule A compounded
22 therefrom into other than legitimate medical, sci-
23 entific, research, or industrial channels, by limiting
24 the importation and bulk manufacture of such con-
25 trolled substances to a number of establishments

1 which can produce an adequate and uninterrupted
2 supply of these substances under adequately com-
3 petitive conditions for legitimate medical, scientific,
4 research, and industrial purposes;

5 “(B) compliance with applicable State and local
6 law;

7 “(C) promotion of technical advances in the art
8 of manufacturing substances described in subpara-
9 graph (A) and the development of new substances;

10 “(D) prior conviction record of applicant under
11 Federal and State laws relating to the manufacture,
12 distribution, or dispensing of substances described in
13 paragraph (A);

14 “(E) past experience in the manufacture of con-
15 trolled substances, and the existence in the establish-
16 ment of effective control against diversion; and

17 “(F) such other factors as may be relevant to
18 and consistent with the public health and safety.

19 “(3) If an applicant is registered to manufacture con-
20 trolled substances in schedule I or II under subsection (a),
21 the applicant shall not be required to apply for a separate
22 registration under this subsection.

23 “(1)(1) The Attorney General shall register an appli-
24 cant to distribute schedule A substances—

1 “(A) if the applicant demonstrates that the
2 schedule A substances will be used for research, ana-
3 lytical, or industrial purposes approved by the Attor-
4 ney General; and

5 “(B) unless the Attorney General determines
6 that the issuance of such registration is inconsistent
7 with the public interest.

8 “(2) In determining the public interest under para-
9 graph (1)(B), the Attorney General shall consider—

10 “(A) maintenance of effective control against
11 diversion of particular controlled substances into
12 other than legitimate medical, scientific, and indus-
13 trial channels;

14 “(B) compliance with applicable State and local
15 law;

16 “(C) prior conviction record of applicant under
17 Federal or State laws relating to the manufacture,
18 distribution, or dispensing of substances described in
19 subparagraph (A);

20 “(D) past experience in the distribution of con-
21 trolled substances; and

22 “(E) such other factors as may be relevant to
23 and consistent with the public health and safety.

24 “(3) If an applicant is registered to distribute a con-
25 trolled substance in schedule I or II under subsection (b),

1 the applicant shall not be required to apply for a separate
2 registration under this subsection.

3 “(m)(1) Not later than 90 days after the date on
4 which a substance is placed in schedule A, any practitioner
5 who was engaged in research on the substance before the
6 placement of the substance in schedule A and any manu-
7 facturer or distributor who was handling the substance be-
8 fore the placement of the substance in schedule A shall
9 register with the Attorney General.

10 “(2)(A) Not later than 60 days after the date on
11 which the Attorney General receives an application for
12 registration to conduct research on a schedule A sub-
13 stance, the Attorney General shall—

14 “(i) grant, or initiate proceedings under section
15 304(c) to deny, the application; or

16 “(ii) request supplemental information from the
17 applicant.

18 “(B) Not later than 30 days after the date on which
19 the Attorney General receives supplemental information
20 requested under subparagraph (A)(ii) in connection with
21 an application described in subparagraph (A), the Attor-
22 ney General shall grant or deny the application.

23 “(n)(1) The Attorney General shall register a sci-
24 entific investigator or a qualified research institution to
25 conduct research with controlled substances in schedule A

1 in accordance with this subsection. In evaluating applica-
2 tions for such registration, the Attorney General shall
3 apply the criteria set forth in subsection (f) of this section
4 that apply to practitioners seeking a registration to con-
5 duct research with a schedule I controlled substance, ex-
6 cept that the applicant shall not be required to submit a
7 research protocol.

8 “(2) If the applicant is not currently registered under
9 subsection (f) to conduct research with a schedule I con-
10 trolled substance, the Attorney General shall refer the ap-
11 plication to the Secretary, who shall determine whether
12 the applicant will be engaged in bona fide research and
13 is qualified to conduct such research.

14 “(3) If the applicant is currently registered under
15 subsection (f) to conduct research with a schedule I con-
16 trolled substance, the applicant will be considered qualified
17 to conduct research with controlled substances in schedule
18 A and the Attorney General shall modify the applicant’s
19 registration to include schedule A controlled substances in
20 accordance with this paragraph. The applicant shall notify
21 the Attorney General of his intent to conduct research
22 with a controlled substance in schedule A. Upon receiving
23 such notification, the Attorney General shall modify the
24 practitioner’s existing registration to authorize research
25 with schedule A controlled substances, unless the Attorney

1 General determines that the registration modification
2 would be inconsistent with the public interest based on the
3 criteria of subsection (f).

4 “(4) Registrations issued under this subsection to a
5 qualified research institution will apply to all agents and
6 employees of that institution acting within the scope of
7 their professional practice.

8 “(5) At least thirty days prior to conducting any re-
9 search with a controlled substance in schedule A, the reg-
10 istrant shall provide the Attorney General with written no-
11 tification of the following:

12 “(A) The name of and drug code for each sub-
13 stance.

14 “(B) The name of each individual with access
15 to each substance.

16 “(C) The amount of each substance.

17 “(D) Other similar information the Attorney
18 General may require.

19 “(6) The quantity of a schedule A controlled sub-
20 stance possessed by a person registered under this sub-
21 section shall be appropriate for the research being con-
22 ducted, subject to the additional limitations set forth in
23 this paragraph. To reduce the risk of diversion, the Attor-
24 ney General may establish limitations on the quantity of
25 schedule A controlled substances that may be manufac-

1 tured or possessed for purposes of research under this sub-
2 section and shall publish such limitations on the website
3 of the Drug Enforcement Administration. A person reg-
4 istered under this subsection may, based on legitimate re-
5 search needs, apply to the Attorney General to manufac-
6 ture or possess an amount greater than that so specified
7 by the Attorney General. The Attorney General shall
8 specify the manner in which such applications shall be
9 submitted. The Attorney General shall act on an applica-
10 tion filed under this subparagraph within 30 days of re-
11 ceipt of such application. If the Attorney General fails to
12 act within 30 days, the registrant shall be allowed to man-
13 ufacture and possess up to the amount requested. The At-
14 torney General shall have the authority to reverse the in-
15 crease for cause.

16 “(7) The Attorney General shall by regulation specify
17 the manner in which applications for registration under
18 this subsection shall be submitted.

19 “(8) Registrants authorized under this subsection
20 may manufacture and possess schedule A controlled sub-
21 stances up to the approved amounts only for use in their
22 own research setting or institution. Manufacturing for use
23 in any other setting or institution shall require a manufac-
24 turer’s registration under section 303(a).”.

1 (2) CONTROLLED SUBSTANCES IMPORT AND
2 EXPORT ACT.—Section 1008 of the Controlled Sub-
3 stances Import and Export Act (21 U.S.C. 958) is
4 amended by adding at the end the following:

5 “(j)(1) The Attorney General shall register an appli-
6 cant to import or export a schedule A substance if—

7 “(A) the applicant demonstrates that the sched-
8 ule A substances will be used for research, analyt-
9 ical, or industrial purposes approved by the Attorney
10 General; and

11 “(B) the Attorney General determines that such
12 registration is consistent with the public interest and
13 with the United States obligations under inter-
14 national treaties, conventions, or protocols in effect
15 on the date of enactment of this subsection.

16 “(2) In determining the public interest under para-
17 graph (1)(B), the Attorney General shall consider the fac-
18 tors described in subparagraphs (A) through (F) of sec-
19 tion 303(k)(2).

20 “(3) If an applicant is registered to import or export
21 a controlled substance in schedule I or II under subsection
22 (a), the applicant shall not be required to apply for a sepa-
23 rate registration under this subsection.”.

24 (f) ADDITIONAL CONFORMING AMENDMENTS.—

1 (1) CONTROLLED SUBSTANCES ACT.—The Con-
2 trolled Substances Act (21 U.S.C. 801 et seq.) is
3 amended—

4 (A) in section 303(c) (21 U.S.C. 823(c))—

5 (i) by striking “subsections (a) and
6 (b)” and inserting “subsection (a), (b), (k),
7 or (l)”;

8 (ii) by striking “schedule I or II” and
9 inserting “schedule I, II, or A”;

10 (B) in section 306 (21 U.S.C. 826)—

11 (i) in subsection (a), in the first sen-
12 tence, by striking “schedules I and II” and
13 inserting “schedules I, II, and A”;

14 (ii) in subsection (b), in the second
15 sentence, by striking “schedule I or II”
16 and inserting “schedule I, II, or A”;

17 (iii) in subsection (c), in the first sen-
18 tence, by striking “schedules I and II” and
19 inserting “schedules I, II, and A”;

20 (iv) in subsection (d), in the first sen-
21 tence, by striking “schedule I or II” and
22 inserting “schedule I, II, or A”;

23 (v) in subsection (e), in the first sen-
24 tence, by striking “schedule I or II” and
25 inserting “schedule I, II, or A”; and

1 (vi) in subsection (f), in the first sen-
 2 tence, by striking “schedules I and II” and
 3 inserting “schedules I, II, and A”;

4 (C) in section 308(a) (21 U.S.C. 828(a)),
 5 by striking “schedule I or II” and inserting
 6 “schedule I, II, or A”;

7 (D) in section 402(b) (21 U.S.C. 842(b)),
 8 in the matter preceding paragraph (1), by strik-
 9 ing “schedule I or II” and inserting “schedule
 10 I, II, or A”;

11 (E) in section 403(a)(1) (21 U.S.C.
 12 843(a)(1)), by striking “schedule I or II” and
 13 inserting “schedule I, II, or A”; and

14 (F) in section 511(f) (21 U.S.C. 881(f)),
 15 by striking “schedule I or II” each place it ap-
 16 pears and inserting “schedule I, II, or A”.

17 (2) CONTROLLED SUBSTANCES IMPORT EXPORT
 18 ACT.—The Controlled Substances Import and Ex-
 19 port Act (21 U.S.C. 951 et seq.) is amended—

20 (A) in section 1002(a) (21 U.S.C.
 21 952(a))—

22 (i) in the matter preceding paragraph
 23 (1), by striking “schedule I or II” and in-
 24 serting “schedule I, II, or A”; and

1 (ii) in paragraph (2), by striking
 2 “schedule I or II” and inserting “schedule
 3 I, II, or A”;

4 (B) in section 1003 (21 U.S.C. 953)—

5 (i) in subsection (c), in the matter
 6 preceding paragraph (1), by striking
 7 “schedule I or II” and inserting “schedule
 8 I, II, or A”; and

9 (ii) in subsection (d), by striking
 10 “schedule I or II” and inserting “schedule
 11 I, II, or A”;

12 (C) in section 1004(1) (21 U.S.C. 954(1)),
 13 by striking “schedule I” and inserting “sched-
 14 ule I or A”;

15 (D) in section 1005 (21 U.S.C. 955), by
 16 striking “schedule I or II” and inserting
 17 “schedule I, II, or A”; and

18 (E) in section 1009(a) (21 U.S.C. 959(a)),
 19 by striking “schedule I or II” and inserting
 20 “schedule I, II, or A”.

21 (g) CONTROLLED SUBSTANCE ANALOGUES.—Section
 22 102 of the Controlled Substances Act (21 U.S.C. 802) is
 23 amended—

24 (1) in paragraph (6), by striking “or V” and in-
 25 serting “V, or A”;

1 (2) in paragraph (14)—

2 (A) by striking “schedule I(c) and” and in-
3 serting “schedule I(c), schedule A, and”; and

4 (B) by striking “schedule I(c),” and insert-
5 ing “schedule I(c) and schedule A,”; and

6 (3) in paragraph (32)(A), by striking “(32)(A)”
7 and all that follows through clause (iii) and inserting
8 the following:

9 “(32)(A) Except as provided in subparagraph (C),
10 the term ‘controlled substance analogue’ means a sub-
11 stance whose chemical structure is substantially similar to
12 the chemical structure of a controlled substance in sched-
13 ule I or II—

14 “(i) which has a stimulant, depressant, or hal-
15 lucinogenic effect on the central nervous system that
16 is substantially similar to or greater than the stimu-
17 lant, depressant, or hallucinogenic effect on the cen-
18 tral nervous system of a controlled substance in
19 schedule I or II; or

20 “(ii) with respect to a particular person, which
21 such person represents or intends to have a stimu-
22 lant, depressant, or hallucinogenic effect on the cen-
23 tral nervous system that is substantially similar to
24 or greater than the stimulant, depressant, or hallu-

1 cinogenic effect on the central nervous system of a
2 controlled substance in schedule I or II.”.

3 (h) AMENDMENT TO THE SENTENCING GUIDE-
4 LINES.—Section 2D1.1 of the Federal Sentencing Guide-
5 lines is amended, in Application Note 6 (Analogues and
6 Controlled Substances Not Referenced in this Guideline)
7 of the Commentary, by striking “In determining the most
8 closely related controlled substance, the court shall, to the
9 extent practicable, consider the following:” and inserting
10 the following: “In determining the most closely related
11 controlled substance and the applicable guideline or drug
12 equivalence, the court shall—

13 “(A) if Attorney General has provided
14 guidance on the appropriate sentencing equiva-
15 lency or ratio to a controlled substance that is
16 referenced in the guidelines through publication
17 in the Federal Register (whether such guidance
18 is included in or separate from any notice of
19 proposed temporary or permanent scheduling of
20 such substance under section 201 of the Con-
21 trolled Substances Act (21 U.S.C. 811)), apply
22 any such sentencing equivalency or ratio; and

23 “(B) in the absence of guidance with re-
24 spect to a substance or group of substances as
25 described in paragraph (A), use equivalencies

1 for the following structural classes of sub-
 2 stances as if they were included on the Drug
 3 Equivalency Tables:

“Drug Class	Marihuana Equivalency of 1 gm of subject substance
Synthetic Opioids	1 gm = 10 kg
Synthetic Cannabinoids	1 gm = 167 gm
Synthetic Cathinones	1 gm = 380 gm
Tryptamine	1 gm = 80 gm
Phenethylamines	1 gm = 2.5 kg
Piperazines	1 gm = 2 kg
Benzofurans	1 gm = 500 gm
Arylcyclohexylamines (PCP-like substances)	1 gm = 1 kg
Methylphenidate analogs	1 gm = 100 gm
Benzodiazepines	1 ‘unit’ (as defined in Note (F) to the Drug Quantity Table in 2D1.1) = 0.0625 gm

4 In the case of a substance for which paragraphs (A)
 5 and (B) above are not applicable, the court shall de-
 6 termine an equivalency or ratio by considering the
 7 following factors, to the extent practicable:”.

8 (i) RULES OF CONSTRUCTION.—Nothing in this sec-
 9 tion, or the amendments made by this section, may be con-
 10 strued to limit—

11 (1) the prosecution of offenses involving con-
 12 trolled substance analogues under the Controlled
 13 Substances Act (21 U.S.C. 801 et seq.); or

14 (2) the authority of the Attorney General to
 15 temporarily or permanently schedule, reschedule, or
 16 decontrol controlled substances under provisions of
 17 section 201 of the Controlled Substances Act (21

1 U.S.C. 811) that are in effect on the day before the
2 date of enactment of this Act.

3 (j) STUDY BY COMPTROLLER GENERAL.—Not later
4 than 2 years after the date of enactment of this Act, the
5 Comptroller General of the United States shall complete
6 a study and submit a report to the Committees on the
7 Judiciary of the House of Representatives and of the Sen-
8 ate regarding the costs associated with the amendments
9 made by subsection (c), including—

10 (1) the annual amounts expended by Federal
11 agencies in carrying out the amendments;

12 (2) the costs associated with arrests, trials, con-
13 victions, imprisonment, or imposition of other sanc-
14 tions in accordance with the amendments; and

15 (3) the impact (including the fiscal impact) of
16 the amendments on existing correctional facilities
17 and the likelihood that those amendments will create
18 a need for additional capacity for housing prisoners.

○