I

117TH CONGRESS
2D SESSION

H. R. 6946

To amend the Controlled Substances Act with respect to fentanyl-related substances, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 7, 2022

Mr. PAPPAS (for himself, Mr. NEWHOUSE, and Mr. BUDD) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on 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

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A BILL

To amend the Controlled Substances Act with respect to fentanyl-related substances, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Save Americans from the Fentanyl Emergency Act of 2022'' or the ''SAFE Act of 2022''.

SEC. 2. CLASS SCHEDULING OF FENTANYL-RELATED SUBSTANCES.

Section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)) is amended by adding at the end of schedule I the following:

''(e)(1) Unless specifically exempted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of fentanyl-related substances, or which contains their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

''(2) In this subsection, except as provided in paragraph (3), the term 'fentanyl-related substance' means any substance that is structurally related to fentanyl by one or more of the following modifications:

''(A) By replacement of the phenyl portion of the phenethyl group by any monocycle, whether or not further substituted in or on the monocycle.

''(B) By substitution in or on the phenethyl group with alkyl, alkenyl, alkoxyl, hydroxyl, halo, haloalkyl, amino, or nitro groups.

''(C) By substitution in or on the piperidine ring with alkyl, alkenyl, alkoxyl, ester, ether, hydroxyl, halo, haloalkyl, amino, or nitro groups.

''(D) By replacement of the aniline ring with any aromatic monocycle whether or not further substituted in or on the aromatic monocycle.

''(E) By replacement of the N-propionyl group with another acyl group.

''(3) A substance that meets the criteria specified in paragraph (2) to be considered a fentanyl-related substance shall not be so considered as meeting such criteria if such substance—

''(A) is controlled by action of the Attorney General pursuant to section 201;

''(B) is expressly listed in this schedule or another schedule by a statutory provision other than this subsection; or

''(C) is removed from this schedule, or rescheduled to another schedule, pursuant to section 201(k).

''(4) The Attorney General shall publish in the Federal Register a list of individual substances that meet the definition of fentanyl-related substances in paragraph (2) within 60 days of determining such substances meet such definition. The absence of a substance on any such list does not negate the control status of such substance if the substance meets the criteria specified in paragraph (2) to be considered a fentanyl-related substance.

''(5) Notwithstanding any other provision of this title or title III, fentanyl-related substances shall not be subject to quantity-based mandatory minimum penalties pursuant to subparagraph (A)(vi) or (B)(vi) of section 401(b)(1) of this title or paragraph (1)(F) or (2)(F) of section 1010(b) of title III.''.

SEC. 3. PENALTY PROVISIONS WITH RESPECT TO FENTANYL-RELATED SUBSTANCES—DOMESTIC OFFENSES.

Section 401(b)(1) of the Controlled Substances Act (21 U.S.C. 841(b)(1)) is amended—

(1) in subparagraph (A), by striking clause (vi) and inserting the following:

''(vi)(I) 400 grams or more of a mixture or substance containing a detectable amount of fentanyl; or

''(II) 100 grams or more of a mixture or substance containing a detectable amount of any analogue of fentanyl that is controlled in schedule I or II or that is treated as a schedule I controlled substance pursuant to section 203(a), except for a fentanyl-related substance as defined in schedule I(e) of section 202(c);'';

(2) in subparagraph (B), by striking clause (vi) and inserting the following:

''(vi)(I) 40 grams or more of a mixture or substance containing a detectable amount of fentanyl; or

''(II) 10 grams or more of a mixture or substance containing a detectable amount of any analogue of fentanyl that is controlled in schedule I or II or that is treated as a schedule I controlled substance pursuant to section 203(a), except for a fentanyl-related substance as defined in schedule I(e) of section 202(c);''; and

(3) in subparagraph (C), by inserting '', including a fentanyl-related substance as defined in schedule I(e) of section 202(c),'' after ''a controlled substance in schedule I or II,''.

SEC. 4. PENALTY PROVISIONS WITH RESPECT TO FENTANYL-RELATED SUBSTANCES—IMPORT AND EXPORT OFFENSES.

Section 1010(b) of the Controlled Substances Import and Export Act (21 U.S.C. 960(b)) is amended—

(1) in paragraph (1), by striking subparagraph (F) and inserting the following:

''(F)(i) 400 grams or more of a mixture or substance containing a detectable amount of fentanyl; or

''(ii) 100 grams or more of a mixture or substance containing a detectable amount of any analogue of fentanyl that is controlled in schedule I or II or that is treated as a schedule I controlled substance pursuant to section 203(a) of the Controlled Substances Act, except for a fentanyl-related substance as defined in schedule I(e) of section 202(c) of the Controlled Substances Act;'';

(2) in paragraph (2), by striking subparagraph (F) and inserting the following:

''(F)(i) 40 grams or more of a mixture or substance containing a detectable amount of fentanyl; or

''(ii) 10 grams or more of a mixture or substance containing a detectable amount of any analogue of fentanyl that is controlled in schedule I or II or that is treated as a schedule I controlled substance pursuant to section 203(a) of the Controlled Substances Act, except for a fentanyl-related substance as defined in schedule I(e) of section 202(c) of the Controlled Substances Act;''; and

(3) in paragraph (3), by inserting ''including a fentanyl-related substance as defined in schedule I(e) of section 202(c) of the Controlled Substances

Act,'' after ''a controlled substance in schedule I or II,''.

SEC. 5. REMOVAL FROM SCHEDULE I OF FENTANYL-RELATED SUBSTANCES.

Section 201 of the Controlled Substances Act (21 U.S.C. 811) is amended by adding at the end the following new subsection:

''(k) REMOVAL FROM SCHEDULE I OF FENTANYL-RELATED SUBSTANCES.—

''(1) DETERMINATION RESULTING IN REMOVAL.—If the Secretary determines, taking into consideration factors as set forth in paragraph (3), that a fentanyl-related substance has a potential for abuse that is less than the drugs or other substances in schedule V—

''(A) the Secretary shall submit to the Attorney General a scientific and medical evaluation of that fentanyl-related substance supporting that determination;

''(B) the Secretary shall submit any such evaluation and determination in writing and include the bases therefor;

''(C) the scientific and medical determination of the Secretary contained in such evalua-

tion shall be binding on the Attorney General; and

''(D) not later than 90 days after receiving such evaluation and determination, the Attorney General shall issue an order removing such fentanyl-related substance from the schedules under section 202.

''(2) DETERMINATION RESULTING IN RESCHEDULING.—If the Secretary determines, taking into consideration factors as set forth in paragraph (3), that a fentanyl-related substance has a potential for abuse that is less than the drugs or other substances in schedules I and II—

''(A) the Secretary shall submit to the Attorney General a scientific and medical evaluation of that fentanyl-related substance supporting that determination;

''(B) the Secretary shall submit any such evaluation and determination in writing and include the bases therefor;

''(C) the scientific and medical determination of the Secretary contained in such evaluation shall be binding on the Attorney General; and

''(D) not later than 90 days after receiving such evaluation, the Attorney General shall issue an order removing such fentanyl-related substance from schedule I and controlling such substance under schedule III.

''(3) EVALUATION FACTORS.—

''(A) IN GENERAL.—In making a determination under paragraph (1) or (2), the Secretary—

''(i) shall consider—

''(I) the factor listed in paragraph (2) of subsection (c);

''(II) the factors listed in paragraphs (1), (3), and (6) of such subsection to the extent evidence exists with respect to such factors; and

''(III) any information submitted to the Secretary by the Attorney General for purposes of such determination; and

''(ii) may consider the factors listed in paragraphs (4), (5), and (7) of subsection (c) if the Secretary finds that evidence exists with respect to such factors.

"(B) CONSIDERATION OF SCIENTIFIC EVIDENCE OF PHARMACOLOGICAL EFFECT.—

"(i) IN GENERAL.—For the purposes of subparagraph (A)(i)(I), consideration by the Secretary of the results of an assessment consisting of the studies described in clause (ii) shall suffice to constitute consideration of the factor listed in paragraph (2) of subsection (c) if—

"(I) each such study is performed according to scientific methods and protocols commonly accepted in the scientific community; and

"(II) the Secretary determines that such assessment is adequate for such purposes.

"(ii) DESCRIBED STUDIES.—The studies described in this clause are any of the following:

"(I) A receptor binding study that can demonstrate whether the substance has affinity for the human mu opioid receptor.

"(II) An in vitro functional assay that can demonstrate whether the

substance has agonist activity at the human mu opioid receptor.

"(III) One or more in vivo animal behavioral studies that can demonstrate whether the substance has abuse-related drug effects consistent with mu opioid agonist activity, such as demonstrating similarity to the effects of morphine.

"(4) ADVANCE NOTICE REGARDING EVALUATION AND CONCLUSION.—The Secretary shall give the Attorney General at least 30 days notice before sending the Attorney General an evaluation and determination under paragraph (1) or (2) with respect to a fentanyl-related substance.

"(5) EXCEPTION FOR TREATY OBLIGATIONS.—If a fentanyl-related substance is a substance that the United States is obligated to control under international treaties, conventions, or protocols in effect on the date of enactment of the Save Americans from the Fentanyl Emergency Act of 2022, this subsection shall not require the Attorney General—

"(A) to remove such substance from control; or

''(B) to place such substance in a schedule less restrictive than that which the Attorney General determines is necessary to carry out such obligations.

''(6) IDENTIFICATION OF FENTANYL-RELATED SUBSTANCES.—If the Attorney General or any official of the Department of Justice determines that a substance is a fentanyl-related substance, the Attorney General shall—

''(A) within 30 days of such determination, notify the Secretary; and

''(B) include in such notification the identity of the substance, its structure, and the basis for the determination.

''(7) PETITIONS FOR REMOVING A FENTANYL-RELATED SUBSTANCE.—

''(A) IN GENERAL.—If a person petitions the Attorney General to remove a fentanyl-related substance from schedule I(e) or to reschedule such a substance to another schedule, the Attorney General shall consider such a petition in accordance with the procedures and standards set forth in—

''(i) subsections (a) and (b) of this section; and

"(ii) section 1308.43 of title 21, Code of Federal Regulations (or any successor regulations).

"(B) ATTORNEY GENERAL TO INFORM SECRETARY.—Within 30 days of receiving such a petition, the Attorney General shall forward a copy of the petition to the Secretary.

"(C) DETERMINATION PROCEDURE NOT PRECLUDED BY FILING OF PETITION.—The filing of a petition under this paragraph shall not preclude the Secretary from making a determination and sending an evaluation under paragraph (1) or (2).

"(8) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to preclude the Attorney General from transferring a substance listed in schedule I to another schedule, or removing such substance entirely from the schedules, pursuant to other provisions of this section and section 202.

"(9) SUBSEQUENT CONTROLLING OF REMOVED SUBSTANCE.—A substance removed from schedule I pursuant to this subsection may, at any time, be controlled pursuant to the other provisions of this section and section 202 without regard to the removal pursuant to this subsection.

''(10) EVALUATIONS OR STUDIES.—The Secretary may enter into contracts or other agreements to conduct or support evaluations or studies of fentanyl-related substances.

''(11) DEFINITION.—In this subsection, the term 'fentanyl-related substance' means a fentanyl-related substance as defined in schedule I(e) of section 202(c).''.

SEC. 6. PAST CASES INVOLVING REMOVED OR RESCHEDULED SUBSTANCES.

(a) DOMESTIC CASES.—Section 401(b) of the Controlled Substances Act (21 U.S.C. 841(b)) is amended by adding at the end the following:

''(8) PAST CONVICTIONS INVOLVING FENTANYL-RELATED SUBSTANCE.—

''(A) IN GENERAL.—In the case of a defendant whose offense of conviction under this title involved a fentanyl-related substance (as defined in schedule I(e) of section 202(c) as of the date the offense was committed) that has since been removed from designation as a fentanyl-related substance for purposes of this title and has been placed on any schedule other than schedule I or II or has been removed from the controlled substance schedules, the sentencing court may, on motion of the defendant, the

Bureau of Prisons, the attorney for the Government, or on its own motion, after considering the factors set forth in section 3553(a) of title 18, United States Code, vacate the previously imposed sentence, or impose a reduced sentence on any count of conviction as if the removal or placement was in effect at the time that the offense was committed. Nothing in this section may be construed to require a court to vacate or reduce any sentence.

''(B) DEFENDANT NOT REQUIRED TO BE PRESENT.—Notwithstanding rule 43 of the Federal Rules of Criminal Procedure, the defendant is not required to be present at any hearing on whether to vacate or reduce a sentence pursuant to this section.''.

(b) IMPORT AND EXPORT CASES.—Section 1010(b) of the Controlled Substances Import and Export Act (21 U.S.C. 960(b)) is amended by adding at the end the following:

''(8) In the case of a defendant whose offense of conviction under this title involved a fentanyl-related substance (as defined in schedule I(e) of section 202(c) of the Controlled Substances Act as of the date the offense was committed) that has since been removed from designation as a fentanyl-related substance for purposes of

this title and has been placed on any schedule other than schedule I or II or has been removed from the controlled substance schedules, the sentencing court may, on motion of the defendant, the Bureau of Prisons, the attorney for the Government, or on its own motion, after considering the factors set forth in section 3553(a) of title 18, United States Code, vacate the previously imposed sentence, or impose a reduced sentence on any count of conviction as if the removal or placement was in effect at the time that the offense was committed. Nothing in this section may be construed to require a court to vacate or reduce any sentence.''.

SEC. 7. REGISTRATION REQUIREMENTS RELATED TO RESEARCH.

(a) ALTERNATIVE REGISTRATION PROCESS FOR SCHEDULE I RESEARCH.—Section 303 of the Controlled Substances Act (21 U.S.C. 823) is amended by adding at the end the following new subsection:

''(l) SPECIAL PROVISIONS FOR THOSE CONDUCTING CERTAIN RESEARCH WITH SCHEDULE I CONTROLLED SUBSTANCES.—

''(1) IN GENERAL.—Notwithstanding subsection (f), a practitioner may conduct research that is described in paragraph (2) and that is with one or

more controlled substances in schedule I if one of the following conditions is satisfied:

"(A) RESEARCHER WITH A CURRENT SCHEDULE I OR II RESEARCH REGISTRATION.—If the practitioner is registered to conduct research with a controlled substance in schedule I or II, the practitioner may conduct research under this paragraph 30 days after the practitioner has sent a notice to the Attorney General containing the following information, with respect to each substance with which the research will be conducted:

"(i) The chemical name of the substance.

"(ii) The quantity of the substance to be used in such research.

"(iii) Demonstration that the research is described in paragraph (2), which demonstration can be satisfied—

"(I) in the case of research described in paragraph (2)(A), by supplying the number of the application submitted under section 505(i) of the Federal Food, Drug, and Cosmetic Act or section 351(a)(3) of the Public

Health Service Act and the sponsor of record on such application; or

"(II) in the case of research described in paragraph (2)(B), by identifying the sponsoring agency and supplying the number of the grant, contract, cooperative agreement, other transaction, or project.

"(iv) Demonstration that the researcher is authorized to conduct research with respect to the substance under the laws of the State in which the research will take place.

"(B) RESEARCHER WITHOUT A CURRENT SCHEDULE I OR II RESEARCH REGISTRATION.—If the practitioner is not currently registered to conduct research with a controlled substance in schedule I or II—

"(i) the practitioner may send a notice to the Attorney General containing the information listed in subparagraph (A), with respect to each substance with which the research will be conducted;

"(ii) the Attorney General shall treat such notice as a sufficient application for a research registration; and

"(iii) within 45 days after receiving such a notice that contains all information required by subparagraph (A), the Attorney General shall register the applicant, or serve an order to show cause upon the applicant in accordance with section 304(c).

"(C) VERIFICATION OF INFORMATION.—On request from the Attorney General, the Secretary of Health and Human Services or the Secretary of Veterans Affairs, as appropriate, shall verify information submitted by an applicant under subparagraph (A)(iii).

"(2) RESEARCH SUBJECT TO EXPEDITED PROCEDURE.—Research described in this paragraph is research that—

"(A) is the subject of an application under section 505(i) of the Federal Food, Drug, and Cosmetic Act or section 351(a)(3) of the Public Health Service Act for the investigation of a drug which is in effect in accordance with section 312.40 of title 21, Code of Federal Regulations; or

''(B) is conducted by the Department of Health and Human Services, the Department of Justice, or the Department of Veterans Affairs or is funded partly or entirely by a grant, contract, cooperative agreement, or other transaction from the Department of Health and Human Services, the Department of Justice, or the Department of Veterans Affairs.

''(3) ELECTRONIC SUBMISSIONS.—The Attorney General shall provide a means to allow practitioners to submit notifications under paragraph (1) electronically.

''(4) LIMITATION ON AMOUNTS.—A practitioner conducting research with a controlled substance in schedule I pursuant to this subsection shall be allowed to possess only the amounts of the controlled substance in schedule I identified in—

''(A) the notification to the Attorney General under paragraph (1); or

''(B) if the practitioner needs additional amounts for the research, a supplemental notification under this subsection that includes the practitioner's name, the additional quantity needed of the substance, and an attestation that the research to be conducted with the sub-

stance is consistent with the scope of the research that was the subject of the notification under paragraph (1).

''(5) IMPORTATION AND EXPORTATION REQUIREMENTS NOT AFFECTED.—Nothing in this section alters the requirements of part A of title III regarding the importation and exportation of controlled substances.''.

(b) SEPARATE REGISTRATIONS NOT REQUIRED FOR ADDITIONAL RESEARCHER IN SAME INSTITUTION.—Subsection (c) of section 302 of the Controlled Substances Act (21 U.S.C. 822) is amended by adding at the end the following:

''(4) An agent or employee of a research institution that is conducting research with a controlled substance if—

''(A) such agent or employee is acting within the scope of his or her professional practice;

''(B) another agent or employee of such institution is registered to conduct research with a controlled substance in the same schedule;

''(C) the researcher who is so registered—

''(i) informs the Attorney General of the name, position title, and employing in-

stitution of the agent or employee who is not separately registered;

''(ii) authorizes such agent or employee to perform research under the registered researcher's registration; and

''(iii) affirms that all acts taken by such agent or employee involving controlled substances shall be attributable to the registered researcher, as if the researcher had directly committed such acts, for purposes of any proceeding under section 304(a) to suspend or revoke the registration of the registered researcher; and

''(D) the Attorney General does not, within 30 days of receiving the information, authorization, and affirmation described in subparagraph (C), refuse, for a reason listed in section 304(a), to allow such agent or employee to possess such substance without a separate registration.''.

(c) SINGLE REGISTRATION FOR RELATED RESEARCH SITES.—Such section 302(e) of the Controlled Substances Act (21 U.S.C. 822(e)) is amended by adding at the end the following:

''(3)(A) Notwithstanding paragraph (1), a person registered to conduct research with a controlled substance under section 303(f) may conduct such research at multiple sites under a single registration if—

''(i) such research occurs exclusively at sites which are all within the same city or county and are all under the control of the same institution, organization, or agency; and

''(ii) the researcher notifies the Attorney General, prior to commencing such research, of all sites where—

''(I) the research will be conducted; or

''(II) the controlled substance will be stored or administered.

''(B) A site described by subparagraph (A) shall be included in such registration only if the researcher has notified the Attorney General of such site—

''(i) in the application for such registration; or

''(ii) before the research is conducted, or before the controlled substance is stored or administered, at such site.

''(C) The Attorney General may, in consultation with the Secretary of Health and Human Services, issue regulations addressing—

''(i) the manner in which controlled substances may be delivered to research sites described in subparagraph (A);

''(ii) the storage and security of controlled substances at such research sites;

''(iii) the maintenance of records for such research sites; and

''(iv) any other matters necessary to ensure effective controls against diversion at such research sites.''.

(d) NEW INSPECTION NOT REQUIRED IN CERTAIN SITUATIONS.—Subsection (f) of section 302 of the Controlled Substances Act (21 U.S.C. 822) is amended—

(1) by striking ''(f) The'' and inserting ''(f)(1) The''; and

(2) by adding at the end the following:

''(2)(A) A new inspection by the Attorney General of a registered location is not required if a person is registered under this title to conduct research with a controlled substance and applies for a registration, or for a modification of a registration, to conduct research with a second controlled substance that is—

''(i) in the same schedule as the first controlled substance; or

''(ii) is in a schedule with a higher numerical designation than the schedule of the first controlled substance.

''(B) Nothing in this paragraph shall prohibit the Attorney General from conducting any inspection if the Attorney General deems it necessary to ensure that the registrant maintains effective controls against diversion.''.

(e) CONTINUATION OF RESEARCH ON SUBSTANCES NEWLY ADDED TO SCHEDULE I.—Section 302 of the Controlled Substances Act (21 U.S.C. 822) is amended by adding at the end the following:

''(h) CONTINUATION OF RESEARCH ON SUBSTANCES NEWLY ADDED TO SCHEDULE I.—If a person is conducting research on a substance at the time the substance is added to schedule I, and such person is already registered under this title to conduct research with a controlled substance in schedule I, then—

''(1) the person shall, within 90 days of the scheduling in schedule I, submit a completed application for registration under this title or modification of an existing registration under this title, to conduct research on such substance, in accordance with regulations issued by the Attorney General;

''(2) the person may, notwithstanding subsections (a) and (b), continue to conduct the research on such substance until—

''(A) the person withdraws such application; or

''(B) the Attorney General serves on the person an order to show cause proposing the denial of the application pursuant to section 304(c);

''(3) if the Attorney General serves such an order to show cause and the person requests a hearing, such hearing shall be held on an expedited basis and not later than 45 days after the request is made, except that the hearing may be held at a later time if so requested by the person; and

''(4) if the person sends a copy of the application required by paragraph (1) to a manufacturer or distributor of such substance, receipt of such copy by such manufacturer or distributor shall constitute sufficient evidence that the person is authorized to receive such substance.''.

(f) TREATMENT OF CERTAIN MANUFACTURING ACTIVITIES AS COINCIDENT TO RESEARCH.—Section 302 of the Controlled Substances Act (21 U.S.C. 822), as amend-

ed by subsection (e), is further amended by adding at the end the following:

"(i) TREATMENT OF CERTAIN MANUFACTURING ACTIVITIES AS COINCIDENT TO RESEARCH.—

"(1) IN GENERAL.—Except as specified in paragraph (3), a person who is registered to perform research on a controlled substance may perform manufacturing activities with small quantities of that substance, including activities listed in paragraph (2), without being required to obtain a manufacturing registration, if such activities are performed for the purpose of the research and if the activities and the quantities of the substance involved in those activities are stated in—

"(A) a notification submitted to the Attorney General under section 303(l);

"(B) a protocol filed with an application for registration approval under section 303(f); or

"(C) a notification to the Attorney General that includes the registrant's name and an attestation that the research to be conducted with the small quantities of manufactured substance is consistent with the scope of the research that is the basis for the registration.

''(2) ACTIVITIES INCLUDED.—Activities permitted under paragraph (1) include—

''(A) processing the substance to create extracts, tinctures, oils, solutions, derivatives, or other forms of the substance consistent with the information provided as part of a notification submitted to the Attorney General under section 303(l) or a research protocol filed with the application for registration approval; and

''(B) dosage form development studies performed for the purpose of satisfying regulatory requirements of the Food and Drug Administration for submitting an investigational new drug application.

''(3) EXCEPTION REGARDING MARIHUANA.—The authority under paragraph (1) to manufacture substances does not include authority to grow marihuana.''.

(g) TRANSPARENCY REGARDING SPECIAL PROCEDURES.—Section 303 of such Act (21 U.S.C. 823), as amended by subsection (a), is further amended by adding at the end the following:

''(m) TRANSPARENCY REGARDING SPECIAL PROCEDURES.—

''(1) IN GENERAL.—If the Attorney General determines, with respect to a controlled substance, that an application by a practitioner to conduct research with such substance should be considered under a process, or subject to criteria, different from the process or criteria applicable to applications to conduct research with other controlled substances in the same schedule, the Attorney General shall make public, including by posting on the website of the Drug Enforcement Administration—

''(A) the identities of all substances for which such determinations have been made;

''(B) the process and criteria that will be applied to applications to conduct research with such substances; and

''(C) how such process and criteria differ from those applicable to applications to conduct research with other controlled substances in the same schedule.

''(2) TIMING OF POSTING.—The Attorney General shall make such information public upon making such determination, regardless of whether a practitioner has submitted such an application at that time.''.

SEC. 8. RULEMAKING.

(a) INTERIM FINAL RULES.—The Attorney General—

(1) not later than 1 year of the date of enactment of this Act, shall issue rules to implement this Act and the amendments made by this Act; and

(2) may issue such rules as interim final rules.

(b) PROCEDURE FOR FINAL RULE.—A rule issued by the Attorney General as an interim final rule under subsection (a) shall become immediately effective as an interim final rule without requiring the Attorney General to demonstrate good cause therefor. The interim final rule shall give interested persons the opportunity to comment and to request a hearing. After the conclusion of such proceedings, the Attorney General shall issue a final rule in accordance with section 553 of title 5, United States Code.

SEC. 9. GAO REPORT.

(a) IN GENERAL.—Not more than 4 years after the date of enactment of this Act, the Comptroller General of the United States shall submit to the Committees on Energy and Commerce and the Judiciary of the House of Representatives and the Committee on the Judiciary of the Senate a report analyzing the implementation and impact, to the extent information is available, of permanent class scheduling pursuant to schedule I(e) of section 202(c) of the Controlled Substances Act, as added by sec-

tion 2 of this Act, of fentanyl-related substances (as defined in such schedule I(e)), which report shall include—

(1) an analysis of the impact on research of fentanyl-related substances;

(2) an analysis of any actions taken to remove or reschedule in a different class any fentanyl-related substance;

(3) an analysis of the impact of permanent scheduling on the unlawful importation, manufacture, trafficking, and use of fentanyl-related substances, taking into consideration data collected concerning the proliferation of fentanyl-related substances since class scheduling was instituted;

(4) an analysis of sentences attributable to criminal charges involving fentanyl-related substances, comparing those sentences to sentences attributable to criminal charges involving fentanyl and individually scheduled fentanyl analogues; and

(5) an analysis of the efficacy of class scheduling generally, in terms of reducing the proliferation of new controlled substance analogues.

(b) CONSULTATIONS.—In developing the report required by subsection (a), the Comptroller General—

(1) shall consider the views of the Secretary of Health and Human Services, the Attorney General,

the Secretary of Homeland Security, the Secretary of State, the Director of the Office of National Drug Control Policy, the scientific and medical research community, the State and local law enforcement community, and the civil rights and criminal justice reform communities; and

(2) to the greatest extent possible, should base such report on reliable data and empirical information.

○