II

118TH CONGRESS
2D SESSION

S. 5243

To amend the Federal Food, Drug, and Cosmetic Act to provide for the regulation of cannabis and cannabinoid products, and for other purposes.

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 25, 2024

Mr. WYDEN introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide for the regulation of cannabis and cannabinoid products, 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; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Cannabinoid Safety and Regulation Act''.

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

TITLE I—FOOD AND DRUG ADMINISTRATION REGULATION OF CANNABINOID PRODUCTS

SEC. 101. FDA REGULATION OF CANNABINOID PRODUCTS.

(a) IN GENERAL.—The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) is amended by adding at the end the following:

"CHAPTER XI—CANNABINOID PRODUCTS

"SEC. 1101. CENTER FOR CANNABINOID PRODUCTS.

''Not later than 120 days after the date of enactment of the Cannabinoid Safety and Regulation Act, the Secretary shall establish within the Food and Drug Administration the Center for Cannabinoid Products, which shall report to the Commissioner in the same manner as the other agency centers within the Food and Drug Administration. The Center shall be responsible for the implementation of this chapter and related matters assigned by the Commissioner.

"SEC. 1102. ADULTERATED CANNABINOID PRODUCTS.

''A cannabinoid product shall be deemed to be adulterated if—

''(1) it consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise contaminated by any added poisonous or added deleterious substance that may render the product injurious to health;

''(2) it has been manufactured, prepared, processed, packed, or held in insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health;

''(3) it bears or contains any poisonous or deleterious substance that may render it injurious to health;

''(4) its container is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents injurious to health;

''(5) it bears or contains an unsafe color additive that is unsafe within the meaning of section 721(a);

''(6) the methods used in, or the facilities or controls used for, its manufacture, preparing, processing, packing, or storage are not in conformity with applicable requirements under section 1105(c);

''(7) it has been manufactured, prepared, processed, packed, or held in any factory, warehouse, or establishment and the owner, operator, or agent of such factory, warehouse, or establishment delays, denies, or limits an inspection, or refuses to permit entry or inspection; or

''(8) it bears or contains, or has been manufactured, prepared, or processed from, artificially or synthetically derived cannabinoids of any kind.

''SEC. 1103. MISBRANDED CANNABINOID PRODUCTS.

''A cannabinoid product shall be deemed to be misbranded—

''(1) if its labeling, advertising, or promotion is false or misleading in any particular, except that no cannabinoid product shall be deemed to be misbranded solely because its labeling, advertising, or promotion uses the term 'cannabis';

''(2) if it is a finished product, unless it bears a label containing—

''(A) a prominent statement on the front of the product packaging, and on any internal product insert or packaging, that the product contains cannabinoids;

''(B) the name, place of business, and contact information (including, as applicable,

phone number, email address, and physical address) of its manufacturer, packer, or distributor;

"(C) an accurate statement of the quantity of its contents in terms of weight, measure, or numerical count;

"(D) a statement of its form as specified in regulations promulgated pursuant to section 1105(a);

"(E) if it is intended for animal consumption or human consumption and is packaged and labeled in such a way as to suggest more than one serving, dose, or the equivalent, information on how such product may be divisible into, or measured into, a portion equivalent to one serving, dose, or the equivalent;

"(F) if it is intended for animal consumption or human consumption and is packaged and labeled in such a way as to suggest more than one serving, dose, or the equivalent, a statement of the amount of total tetrahydrocannabinol, in milligrams, in one serving, dose, or the equivalent;

"(G)(i) a statement of the content and amount, in milligrams, of any other

cannabinoids in the product, other than naturally occurring cannabinoids present at trace amounts; and

"(ii) if it is packaged and labeled in such a way as to suggest more than one serving, dose, or the equivalent, a statement of the amount of such other cannabinoids in one serving, dose, or the equivalent;

"(H) adequate directions for use and how to report adverse events, if deemed necessary for the protection of the public health in regulations promulgated pursuant to section 1105(a);

"(I) if it is intended for human consumption, a statement disclosing the presence or the possibility of the presence of any major food allergen or other food allergen which the Secretary may, by order, require to be disclosed;

"(J) if it is intended for human use, a statement disclosing any known risks to special populations, including children, individuals who are pregnant or breastfeeding, and individuals taking drugs known to interact with the product, including the following statement: 'Keep out of reach of children and pets. This product should not be consumed by women who are

pregnant or nursing. Consult your health care provider if you have any other medical conditions or are taking any medication(s). This product may be purchased only by persons 21 and older.';

''(K) a statement disclosing risks posed by consuming or using the specific cannabinoid contained or purported to be contained in the product, including the risk of drug test failure;

''(L) unless it is a dietary supplement that bears the statement required by section 403(r)(6)(C), a statement disclosing that the Food and Drug Administration has not determined the product to be safe or effective for treating any condition, including the following statement: 'This product has not been evaluated for safety or efficacy by the Food and Drug Administration.';

''(M) if it is intended for use in animals, a prominently placed, conspicuous—

''(i) warning that the product should not be used by humans; and

''(ii) statement that the product is intended for use in animals, including a specification of the intended species;

''(N) the applicable universal symbol described in section 1105(d);

''(O) beginning not later than 90 days after issuance of an order or finalization of a rule under section 1105(f)(1), as applicable, information on the safety test results for such product, or information on where to obtain such safety test results; and

''(P) such other information as the Secretary determines, in regulations promulgated pursuant to section 1105(a), to be necessary for the protection of the public health;

''(3) if it is a dietary supplement or a food and its label or labeling bears a statement describing the role of a cannabis constituent or cannabinoid intended to affect the structure or any function of the body of humans or other animals, unless there is substantiation that such statement is truthful and not misleading;

''(4) if any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render

it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

''(5) if it purports to be, or is represented as, a cannabinoid product that is subject to a cannabinoid product standard established under section 1106 unless such cannabinoid product is in all respects in conformity with such standard;

''(6) if its sale, distribution, or label or labeling is not in conformity with applicable requirements under subsections (a) and (b) of section 1105;

''(7) if it was manufactured, prepared, propagated, compounded, processed, packaged, packed, imported, labeled, or held in an establishment not duly registered under section 1104, if it was not included in a list required by section 1104, or if it was manufactured, prepared, propagated, compounded, processed, packaged, packed, imported, labeled, or held by or in an establishment for which the registration was suspended under section 1104 and such registration has not been reinstated;

''(8) if it takes such a form as to imitate or replicate a product that is marketed to or is commonly associated with children or minors, imitates a commercially available candy, snack, or beverage

packaging or labeling, or is in the shape of real or imagined animals, people, vehicles, or characters, including anthropomorphic non-human animals, vehicles, foods, plants, or other characters, and including cartoon characters;

''(9) it is a gummy product, unless it is in the shape of a cube, rectangle, sphere, or other geometric shape; or

''(10) if it purports to be, or is represented as, an eye drop, nasal spray, or injectable.

''SEC. 1104. REGISTRATION.

''(a) REGISTRATION BY COVERED ENTITIES.—

''(1) INITIAL REGISTRATION.—

''(A) EXISTING FACILITIES.—Each covered entity that, on the date of enactment of the Cannabinoid Safety and Regulation Act, owns or operates a facility that carries out a covered activity shall register each such facility with the Secretary not later than 90 days after such date of enactment, in accordance with subsection (b).

''(B) NEW FACILITIES.—Each covered entity that owns or operates a facility that first carries out, after the date of enactment of the Cannabinoid Safety and Regulation Act, a cov-

ered activity shall register with the Secretary not later than 30 days after the date on which a covered entity first engages in such covered activity or 30 days after the deadline for registration under subparagraph (A), whichever is later, in accordance with subsection (b).

''(2) RENEWAL OF REGISTRATION.—Each covered entity required to register a facility under this section shall renew such registration with the Secretary on or before December 31 of each even-numbered year.

''(b) CONTENT OF REGISTRATION.—

''(1) IN GENERAL.—For each facility at which a covered entity carries out a covered activity, such covered entity shall submit to the Secretary, through the website established under paragraph (2)(A), a registration that includes—

''(A) information necessary to notify the Secretary of the name (including trade name), address, and telephone number of such facility;

''(B)(i) in the case of a domestic facility, the email address and telephone number for the contact person of such facility; or

''(ii) in the case of a foreign facility, the email address and telephone number for the United States agent for such facility;

''(C) the general activities conducted at such facility, including the 1 or more categories of cannabinoid products manufactured, prepared, propagated, compounded, processed, packaged, packed, imported, labeled, or held at such facility;

''(D) the facility registration number for such facility, if any, previously assigned by the Secretary;

''(E) all brand names under which cannabinoid products manufactured, prepared, propagated, compounded, processed, packaged, packed, imported, labeled, or held in such facility are sold, on the condition that the Secretary shall keep such information confidential;

''(F) an assurance that the Secretary will be permitted to inspect such facility at the times and in the manner permitted by this Act, including section 704; and

''(G) any other information the Secretary may require.

''(2) PROCEDURE.—

"(A) WEBSITE.—

"(i) IN GENERAL.—Not later than the applicable date described in clause (ii), the Secretary shall establish a website for submission of registration under this subsection.

"(ii) APPLICABLE DATE DESCRIBED.—The applicable date described in this clause is—

"(I) 180 days after the date of enactment of the Cannabinoid Safety and Regulation Act; or

"(II) if December 31 is less than 180 days after such date of enactment, 240 days after such date of enactment.

"(B) NOTIFICATION OF RECEIPT; REGISTRATION NUMBERS.—Not later than 30 days after the date on which the Secretary receives a completed registration submitted under this subsection, the Secretary shall—

"(i) notify the applicable covered entity of the receipt of such registration; and

"(ii) assign such covered entity a registration number.

''(C) OWNERS, OPERATORS, AND AGENTS IN CHARGE.—A registration under this subsection shall—

''(i) in the case of a domestic facility, be submitted by the owner or operator of such facility; and

''(ii) in the case of a foreign facility, be submitted by the owner or operator of such facility.

''(c) UNIFORM PRODUCT IDENTIFICATION SYSTEM.—The Secretary may—

''(1) by regulation prescribe a uniform system for the identification of cannabinoid products; and

''(2) require persons who are required to list such cannabinoid products under subsection (f)—

''(A) to list such cannabinoid products in accordance with such system; and

''(B) to include the identification number for such cannabinoid products on the labels for such cannabinoid products.

''(d) REGISTRATION INFORMATION.—The Secretary shall compile and maintain an up-to-date list of facilities that are registered under this section.

''(e) FEE FOR REGISTRATION.—

''(1) IN GENERAL.—The Secretary may charge a fee for registration under this section, which shall be due upon submission of such registration.

''(2) ELECTRONIC PAYMENT.—Payment of the fee under paragraph (1) may be made electronically pursuant to an online method of payment provided by the Secretary.

''(3) AMOUNT OF FEE; INFLATION ADJUSTMENTS.—

''(A) IN GENERAL.—If the Secretary charges a fee under paragraph (1), the Secretary shall establish the amount of the fee as follows:

''(i) For fiscal year 2024, an amount not to exceed $500.

''(ii) For fiscal year 2025 and each fiscal year thereafter, an amount equal to the product obtained by multiplying—

''(I) the dollar amount of the fee established under clause (i); and

''(II) the percentage (if any) by which the Consumer Price Index for All Urban Consumers, as published by the Bureau of Labor Statistics of the

Department of Labor, increased during the most recent 12-month period.

"(B) EFFECT.—Nothing in this paragraph prevents the Secretary from decreasing the amount of the registration fee under paragraph (1).

"(4) REGISTRATION REFUSED OR WITHDRAWN.—The Secretary shall refund 75 percent of the fee paid under paragraph (1) for any registration that is denied, refused, or withdrawn.

"(f) REGISTRATION INFORMATION.—

"(1) PRODUCT LIST.—

"(A) IN GENERAL.—Each covered entity that registers with the Secretary under this section shall, at the time of such registration, file with the Secretary—

"(i) a list of all cannabinoid products which are being manufactured, prepared, propagated, compounded, processed, packaged, packed, imported, labeled, or held by such covered entity for commercial distribution and which have not been included in any list of cannabinoid products filed by such covered entity with the Secretary

under this paragraph or paragraph (2) before such time of registration; and

''(ii) such other information as the Secretary may require, by regulation, to carry out the purposes of the Cannabinoid Safety and Regulation Act, including the amendments made by such Act.

''(B) FORM AND MANNER OF LIST.—The list under subparagraph (A)(i) shall include—

''(i) the facility registration number of each facility where the cannabinoid product is manufactured, prepared, propagated, compounded, processed, packaged, packed, imported, labeled, or held;

''(ii) the name and contact number of the responsible person and the name for the cannabinoid product, as such name appears on the label;

''(iii) the name and contact number of the person submitting the listing; and

''(iv) an electronic copy of the label, and an electronic copy of the package insert, if any.

''(2) REPORT OF ANY CHANGE IN PRODUCT LIST.—Each covered entity that registers with the

Secretary under this section shall report to the Secretary as follows:

"(A) Prior to the introduction into commercial distribution of a cannabinoid product that has not been included in any list previously filed by the registrant, a list containing such cannabinoid product.

"(B) A notice of discontinuance of the manufacturing, preparing, propagating, compounding, processing, packaging, packing, importing, labeling, or holding for commercial distribution of a cannabinoid product included in a list filed under subparagraph (A) or paragraph (1), and the date of such discontinuance.

"(C) A notice of resumption of the manufacturing, preparing, propagating, compounding, processing, packaging, packing, importing, labeling, or holding for commercial distribution of the cannabinoid product with respect to which a notice of discontinuance was reported under subparagraph (B).

"(D) A list of each cannabinoid product included in a notice filed under subparagraph (C) prior to the resumption of the introduction into

commercial distribution of such cannabinoid product.

''(g) SUSPENSIONS.—

''(1) SUSPENSION OF REGISTRATION OF A FACILITY.—The Secretary may suspend the registration of a facility if the Secretary—

''(A) determines that a cannabinoid product manufactured, prepared, propagated, compounded, processed, packaged, packed, imported, labeled, or held by such registered facility and distributed in the United States has a reasonable probability of causing a serious adverse effect in humans or other animals; and

''(B) has a reasonable belief that other cannabinoid products manufactured, prepared, propagated, compounded, processed, packaged, packed, imported, labeled, or held by such registered facility may be similarly affected because of a failure that cannot be isolated to a product or products, or is sufficiently pervasive to raise concerns about other products manufactured, prepared, propagated, compounded, processed, packaged, packed, imported, labeled, or held in such registered facility.

''(2) NOTICE OF SUSPENSION.—Before suspending the registration of a facility under this subsection, the Secretary shall provide—

''(A) notice to the applicable covered entity of the intent to suspend the facility registration, which shall specify the basis of the determination by the Secretary that the facility registration should be suspended; and

''(B) an opportunity, within 5 business days of the notice provided under subparagraph (A), for such covered entity to provide a corrective action plan to demonstrate how such covered entity plans to correct the violations found by the Secretary.

''(3) HEARING.—

''(A) IN GENERAL.—The Secretary shall provide a covered entity the facility registration of which is suspended under this subsection with an opportunity for an informal hearing, to be held as soon as practicable, but in any case not later than 5 business days after such registration is suspended, or such other time period as is agreed upon by the Secretary and the covered entity, on the actions required for reinstatement of registration and why the registra-

tion that is subject to the suspension should be reinstated.

''(B) POST-HEARING REINSTATEMENT.—If a covered entity requests a hearing under subparagraph (A), and the Secretary determines, based on evidence presented at such hearing, that adequate grounds do not exist to continue the suspension of such registration, the Secretary shall reinstate such registration.

''(C) POST-HEARING CORRECTIVE ACTION PLAN.—

''(i) IN GENERAL.—If a covered entity requests a hearing under subparagraph (A), and the Secretary determines, based on evidence presented at such hearing, that the suspension of registration remains necessary, the Secretary shall require the applicable covered entity to submit to the Secretary a corrective action plan described in paragraph (2)(B), if not already submitted.

''(ii) REVIEW.—The Secretary shall review, and approve or deny, a plan submitted under paragraph (2)(B) or clause (i), as applicable, not later than 14 busi-

ness days after such submission or such other time period as is determined by the Secretary, in consultation with the applicable covered entity.

''(D) VACATING OF ORDER; REINSTATEMENT.—Upon a determination by the Secretary that adequate grounds do not exist to continue the suspension of a registration of a facility under this subsection, the Secretary shall promptly vacate such suspension and reinstate such registration.

''(4) EFFECT OF SUSPENSION.—If the registration of a facility is suspended under this subsection, no person shall carry out a covered activity at such facility.

''(h) DISCLOSURE.—

''(1) IN GENERAL.—The list described in subsection (d), any information submitted by a covered entity pursuant to this section, and any information derived from such list or information, shall be exempt from disclosure under section 552 of title 5, United States Code, to the extent that such list or information discloses the identity or location of a registered facility, unless such information was previously lawfully disclosed to the public.

''(2) APPLICABILITY.—For purposes of paragraph (1), this section shall be considered a statute described in section 552(b)(3)(B) of title 5, United States Code.

''(i) REGULATIONS.—The Secretary may promulgate such regulations as may be necessary to carry out this section.

''(j) DEFINITIONS.—In this section:

''(1) COVERED ACTIVITY.—The term 'covered activity' means—

''(A) in the case of a domestic facility, the manufacturing, preparing, propagating, compounding, processing, packaging, packing, importing, labeling, or holding of a cannabinoid product for commercial distribution in the United States; or

''(B) in the case of a foreign facility, the manufacturing, preparing, propagating, compounding, processing, packaging, packing, labeling, or holding of a cannabinoid product that is imported or offered for import into the United States.

''(2) COVERED ENTITY.—The term 'covered entity' means any person who owns or operates a do-

mestic facility or foreign facility that is engaged in a covered activity.

''(3) DOMESTIC FACILITY.—The term 'domestic facility' means a facility located in any State.

''(4) FOREIGN FACILITY.—The term 'foreign facility' means a facility that manufactures, prepares, propagates, compounds, processes, packages, packs, labels, or holds a cannabinoid product that is imported or offered for import into the United States.

''SEC. 1105. GENERAL PROVISIONS FOR CONTROL OF CANNABINOID PRODUCTS.

''(a) RESTRICTIONS ON SALE AND DISTRIBUTION.—

''(1) REMOTE SALES.—Not later than 2 years after the date of enactment of the Cannabinoid Safety and Regulation Act, the Secretary shall propose, and not later than 3 years after such date of enactment, the Secretary shall finalize, regulations regarding the promotion, sale, and distribution of cannabinoid products intended for human consumption and that contain detectable levels of any tetrahydrocannabinol that occur through means other than a direct, face-to-face exchange between a retailer and a consumer, in order to prevent the sale and distribution of cannabinoid products to individuals who have not attained the age of 21, including

requirements for age verification. Such regulations shall require age to be verified at the time of purchase or prior to shipment, either through use of a reliable online age verification service or by obtaining and examining a copy of a valid, non-expired government-issued identification, including identification issued by an Indian Tribe (as defined in section 1110).

''(2) PREVENTING USE OF CANNABINOID PRODUCTS IN MINORS.—The Secretary shall, by regulation, impose such restrictions on sales of cannabinoid products as the Secretary determines necessary and appropriate to prevent the consumption or application of cannabinoid products intended for human consumption by individuals under 21 years of age. Such regulations shall prohibit sales of cannabinoid products, whether directly or indirectly, to individuals under 21 years of age, and any other action that has the primary purpose of initiating or increasing the use of cannabinoid products in such individuals.

''(3) GOOD FAITH CONSULTATION WITH INDIAN TRIBES.—In issuing regulations under paragraphs (1) and (2), the Secretary shall conduct good faith,

meaningful, and timely consultations with Indian Tribes (as defined in section 1110).

''(b) LABELING STATEMENTS.—The label and labeling of a cannabinoid product shall bear such appropriate statements of the restrictions required by a regulation under subsection (a) as the Secretary may in such regulation prescribe.

''(c) STANDARDIZED INFORMATION PANEL FOR INGESTIBLE CANNABINOID PRODUCTS.—The Secretary may prescribe by order a standardized format or label for labeling information required under this chapter for cannabinoid products intended for human consumption.

''(d) UNIVERSAL SYMBOL.—

''(1) IN GENERAL.—The universal symbol referred to in section 1103(2)(N) is, as applicable—

''(A) the most recent international symbol established by ASTM International indicating that a product contains intoxicating cannabinoids; or

''(B) the most recent international symbol established by ASTM International indicating that a product contains nonintoxicating cannabinoids.

''(2) STATE AUTHORITY.—

''(A) IN GENERAL.—The State in which a cannabinoid product is offered for sale may determine which of the universal symbols described in subparagraphs (A) and (B) of paragraph (1) shall be required to be included on the label for such cannabinoid product for purposes of section 1103(2)(N).

''(B) STATE LABELS.—Before the date on which an international symbol described in paragraph (1)(B) is established, the State in which a cannabinoid product is offered for sale may establish, for purposes of section 1103(2)(N), a symbol that indicates that a product contains either intoxicating cannabinoids or nonintoxicating cannabinoids.

''(e) TAMPER-EVIDENT AND CHILD SAFETY PACKAGING.—

''(1) IN GENERAL.—The Secretary may establish by order requirements for tamper-evident and child safety packaging for cannabinoid products intended for human consumption and that contain more than 1 serving and are packaged in a container that exceeds 4 ounces.

''(2) EFFECT.—Nothing in this subsection shall authorize the Secretary to prescribe by order or rule-

making specific packaging designs, product content, package quantity, or, with the exception of authority granted in section 1103, labeling and packaging.

''(f) GOOD MANUFACTURING PRACTICE REQUIREMENTS.—

''(1) IN GENERAL.—Not later than 9 months after the date of enactment of the Cannabinoid Safety and Regulation Act, the Secretary shall promulgate regulations to require that the methods used in, and the facilities and controls used for, the manufacture, preparing, processing, packing, and holding of a cannabinoid product conform to current good manufacturing practice, including testing of cannabinoid products.

''(2) CERTIFICATION.—The Secretary may require each covered entity with a registered facility under section 1104 to certify with respect to such registered facility compliance with the good manufacturing practice regulations described in paragraph (1).

''(g) GOOD TESTING PRACTICE REQUIREMENTS.—

''(1) IN GENERAL.—Not later than 18 months after the date of enactment of the Cannabinoid Safety and Regulation Act, the Secretary shall promulgate regulations or issue an order to require a

cannabinoid product to be tested for safety in a laboratory certified, accredited, licensed, or otherwise formally recognized for the testing of cannabinoid products in the State in which the cannabinoid product is produced. Such regulations may include requirements for laboratory accreditation standards, such as ISO 17025 of the International Organization for Standardization (or a successor standard).

''(2) REQUIREMENTS FOR ENTITIES CONDUCTING TESTING.—The regulations or order under paragraph (1) shall require that an entity conducting a test of a cannabinoid product described in such paragraph—

''(A) be registered and accredited for the testing of cannabinoid products or cannabis products in the applicable State; or

''(B) be registered and in good standing with the Drug Enforcement Agency as a Hemp Analytical Testing Laboratory.

''(3) REQUIREMENTS FOR TESTING.—The regulations or order under paragraph (1) shall require that a test of a cannabinoid product described in such paragraph—

''(A) shall be completed using—

''(i) statistically valid sampling of the cannabinoid product; and

''(ii) analytical testing methodologies that are—

''(I) based on published, peer-reviewed methods validated for cannabis testing by an independent third party; or

''(II) verified by the testing entity for compliance with the Official Methods of Analysis of AOAC International, 22nd edition (or any successor edition);

''(B) shall include—

''(i) testing for—

''(I) pesticides and other chemical residues or residual solvents, regardless of whether a tolerance for such pesticides or other chemical residues or residual solvents has been established;

''(II) synthetic inputs used to produce semi-synthetic cannabinoid products, including hydrochloric acid and sulphuric acid;

''(III) heavy metals, including arsenic, cadmium, lead, and copper, regardless of whether a tolerance for such heavy metals has been established; and

''(IV) foreign matter, including mildew, organic materials foreign to the product, and inorganic materials; and

''(ii) a potency analysis, which may not be adulterated or manipulated by any means, including by the addition of trichromes or other matter incidentally removed while manipulating the product for testing, including measurements of—

''(I) the total tetrahydrocannabinol content of the finished product;

''(II) the total cannabinoid content of the finished product;

''(III) the concentration of tetrahydrocannabinol; and

''(IV) the concentration of cannabinoids;

"(C) shall be conducted subject to quality assurance protocols to ensure the validity and reliability of test results;

"(D) shall use analytical method selection, validation, and verification that ensure that the testing method used is appropriate for the product type and method of consumption by the end user, including post-decarboxylation, if applicable;

"(E) shall ensure that analytical tests are sufficiently sensitive for the purposes of the detectability requirements of required testing; and

"(F) shall use testing protocols that include an effective disposal procedure for noncompliant samples that do not meet the requirements of this section.

"(4) PRODUCT SAFETY THRESHOLDS.—The regulations or order under paragraph (1) shall establish thresholds for cannabinoid product safety with respect to residual solvent levels, heavy metals, foreign matter, mycotoxin levels, and byproducts of semi-synthetic manufacturing processes.

"(h) FOODS CONTAINING CANNABINOIDS.—

"(1) IN GENERAL.—A food may also be a cannabinoid product, or contain a cannabinoid prod-

uct, if it otherwise complies with all applicable requirements for food under chapter IV and all applicable requirements for cannabinoid products under this chapter.

''(2) EFFECT.—A food that is also a cannabinoid product, or that contains a cannabinoid product, shall not be deemed—

''(A) adulterated under section 402(a)(2)(C)(i) solely on account of constituents made or derived from cannabinoids; or

''(B) a food to which has been added a drug approved under section 505 or a drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public for purposes of section 301(ll) solely on account of constituents made or derived from cannabis.

''(i) DIETARY SUPPLEMENTS CONTAINING CANNABINOIDS.—

''(1) IN GENERAL.—A dietary supplement may also be a cannabinoid product, or contain a cannabinoid product, if it otherwise complies with all applicable requirements for dietary supplements and food under chapter IV and all applicable requirements for cannabinoid products under this chapter.

''(2) EFFECT.—A dietary supplement that is also a cannabinoid product, or that contains a cannabinoid product, shall not be—

''(A) deemed adulterated under section 402(f) solely on account of constituents made or derived from cannabinoids; or

''(B) excluded from the definition of dietary supplement under section 201(ff)(3) solely on account of constituents made or derived from cannabis.

''(j) MANUFACTURING, PROCESSING, AND PRODUCTION OF CANNABINOIDS AND SEMI-SYNTHETIC CANNABINOIDS.—

''(1) IN GENERAL.—The Secretary may promulgate regulations regarding the manufacturing, processing, or production of artificially or synthetically derived cannabinoids and semi-synthetic cannabinoids in order to protect the public health.

''(2) SAFETY; REMOVAL OF DANGEROUS CANNABINOIDS.—If promulgated, the regulations under paragraph (1)—

''(A) shall determine the safety of artificially or synthetically derived cannabinoids and semi-synthetic cannabinoids across various methods of administration; and

''(B) may establish a process for the removal from the market of—

''(i) dangerous artificially or synthetically derived cannabinoids or semi-synthetic cannabinoids; or

''(ii) artificially or synthetically derived cannabinoids or semi-synthetic cannabinoids that cause a serious adverse effect (as defined in section 201(tt)(5)).

''SEC. 1106. CANNABINOID PRODUCT STANDARDS.

''(a) IN GENERAL.—Not later than 1 year after the date of enactment of the Cannabinoid Safety and Regulation Act, the Secretary shall, by regulation, adopt cannabinoid product standards that are appropriate for protection of the public health and that distinguish different cannabinoid product types.

''(b) CONTENT OF STANDARDS.—A cannabinoid product standard established under this section shall include provisions—

''(1) on the ingredients of the cannabinoid product, including, where appropriate—

''(A) cannabinoid yields of the product, which may consider or address, as appropriate, different types of cannabinoids and the interaction between the constituents of the product;

''(B) provisions respecting the construction, components, ingredients, additives, constituents, including smoke constituents, and properties of the cannabinoid product, which may consider, as appropriate, the interaction between constituents and components of the cannabinoid product; and

''(C) provisions for the reduction or elimination of harmful constituents or components of the product, including smoke constituents;

''(2) for the testing of the cannabinoid product, including requiring that the testing of the cannabinoid product be done by a person licensed, certified, or otherwise authorized to perform such testing in the State where such testing occurs;

''(3) requiring that the results of testing the cannabinoid product show that the cannabinoid product is in conformity with applicable standards, including with respect to the level of heavy metals, chemical byproducts, or pesticide residues;

''(4) for the measurement of the characteristics of the cannabinoid product, where appropriate, including total product weight, size, color, appearance, and other distinguishing features;

''(5) requiring that the sale and distribution of the cannabinoid product be restricted but only to the extent that the sale and distribution of a cannabinoid product may be restricted under a regulation under this Act;

''(6) where appropriate, requiring the use and prescribing the form and content of labeling for the proper use of the cannabinoid product and any potential serious adverse effects of the product; and

''(7) requiring cannabinoid products containing foreign-grown hemp or cannabinoids to meet the same standards applicable to cannabinoid products containing domestically grown cannabis.

''(c) PERIODIC REEVALUATION OF STANDARDS.—The Secretary shall provide for periodic evaluation of cannabinoid product standards established under this section to determine whether such standards should be changed to reflect new medical, scientific, or other technological data.

''SEC. 1107. RECALL AUTHORITY.

''(a) IN GENERAL.—If the Secretary finds that there is a reasonable probability that a cannabinoid product would cause a serious adverse effect, the Secretary shall issue an order requiring the appropriate person (including the manufacturers, importers, distributors, or retailers of

the cannabinoid product) to immediately cease distribution of such cannabinoid product. The order shall provide the person subject to the order with an opportunity to appear and introduce testimony, to be held not later than 20 days after the date of the issuance of the order, on the actions required by the order and on whether the order should be amended to require a recall of such cannabinoid product. If, after providing an opportunity to appear and introduce testimony, the Secretary determines that inadequate grounds exist to support the actions required by the order, the Secretary shall vacate the order.

''(b) AMENDMENT OF ORDER TO REQUIRE RECALL.—

''(1) IN GENERAL.—If, after providing an opportunity to appear and introduce testimony under subsection (a), the Secretary determines that the order should be amended to include a recall of the cannabinoid product with respect to which the order was issued, the Secretary shall, except as provided in paragraph (2), amend the order to require a recall. The Secretary shall specify a timetable in which the cannabinoid product recall will occur and shall require periodic reports to the Secretary describing the progress of the recall.

''(2) NOTICE.—An amended order under paragraph (1)—

''(A) shall not include recall of a cannabinoid product from individuals; and

''(B) shall provide for notice to persons subject to the risks associated with the use of such cannabinoid product.

''(3) USE OF RETAILERS.—In providing the notice required by paragraph (2)(B), the Secretary may use the assistance of retailers and other persons who distributed such cannabinoid product. If a significant number of such persons cannot be identified, the Secretary shall notify such persons pursuant to section 705(b).

"SEC. 1108. RECORDS AND REPORTS ON CANNABINOID PRODUCTS.

''(a) IN GENERAL.—Each person who is a cannabinoid product manufacturer or importer of a cannabinoid product shall establish and maintain such records, make such reports, and provide such information, as the Secretary may by regulation reasonably require to assure that such cannabinoid product is not adulterated or misbranded and to otherwise protect public health.

''(b) REPORTS OF REMOVALS AND CORRECTIONS.—

''(1) REQUIREMENT.—

"(A) IN GENERAL.—Except as provided in paragraph (2), the Secretary shall by regulation require a cannabinoid product manufacturer or importer of a cannabinoid product to report promptly to the Secretary any corrective action taken or removal from the market of a cannabinoid product undertaken by such manufacturer or importer if the removal or correction was undertaken—

"(i) to reduce a risk to health posed by the cannabinoid product; or

"(ii) to remedy a violation of this chapter caused by the cannabinoid product which may present a risk to health.

"(B) RECORDS.—A cannabinoid product manufacturer or importer of a cannabinoid product who undertakes a corrective action or removal from the market of a cannabinoid product that is not required to be reported under this subsection shall keep a record of such correction or removal.

"(2) EXCEPTION.—No report of the corrective action or removal of a cannabinoid product may be required under paragraph (1)(A) if a report of the

corrective action or removal is required and has been submitted under subsection (a).

"SEC. 1109. PROHIBITION ON FLAVORED ELECTRONIC CANNABINOID PRODUCT DELIVERY SYSTEM.

"(a) IN GENERAL.—Except as provided in subsection (b), any electronic cannabinoid product delivery system shall not contain an added artificial or natural flavor, including mint, mango, strawberry, grape, peach, orange, berry or mixed berry, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, watermelon, lemon, lime or lemon-lime, coffee, any combination thereof, or any other flavor that the Secretary may determine by order.

"(b) APPLICATION TO TERPENES.—An electronic cannabinoid product delivery system may contain added or naturally occurring terpenes, including naturally occurring non-cannabis terpenes, on the conditions that—

"(1) if the cannabinoid product delivered by the electronic cannabinoid product delivery system contains added terpenes but not naturally occurring terpenes, not greater than 5 percent of the total weight of such cannabinoid product shall be added terpenes;

"(2) if the cannabinoid product delivered by the electronic cannabinoid product delivery system con-

tains naturally occurring terpenes but not added terpenes, not greater than 6 percent of the total weight of such cannabinoid product shall be naturally occurring terpenes; and

''(3) if the cannabinoid product delivered by the electronic cannabinoid product delivery system contains both added terpenes and naturally occurring terpenes, not greater than 6 percent of the total weight of the cannabinoid product shall be such naturally occurring terpenes and added terpenes.

''(c) DEFINITION.—In this section, the term 'electronic cannabinoid product delivery system' means an electronic device that delivers a cannabinoid product via an aerosolized or vaporized solution to the user inhaling from the device, and any component, liquid, part, or accessory of such a device, whether or not sold separately.

''SEC. 1110. EFFECT.

''(a) PRESERVATION OF FEDERAL, STATE, TRIBAL, AND LOCAL AUTHORITY.—

''(1) EFFECT.—

''(A) IN GENERAL.—Except as provided in subparagraph (B), nothing in this chapter, or rules promulgated under this chapter, shall be construed to limit the authority of a Federal agency (including the Armed Forces), a State

or political subdivision of a State, or the government of an Indian Tribe to enact, adopt, promulgate, and enforce any law, rule, regulation, or other measure with respect to cannabinoid products that is in addition to, or more stringent than, requirements established under this chapter, including a law, rule, regulation, or other measure relating to or prohibiting the manufacture, sale, distribution, possession, exposure to, access to, advertising and promotion of, or use of cannabinoid products by individuals of any age, information reporting to the State or Indian Tribe, or measures relating to fire safety or environmental standards for cannabinoid products. No provision of this chapter shall limit or otherwise affect any State, Tribal, or local taxation of cannabinoid products.

''(B) RESTRICTION.—No State or political subdivision of a State may enact, adopt, promulgate, and enforce any law, rule, regulation, or other measure for the labeling of cannabinoid products that is not identical to the requirements for the packaging or labeling of a

cannabinoid product required by section 1103 (including regulations).

''(C) TRANSPORTATION OF CANNABINOID PRODUCTS.—No State or Indian Tribe may prohibit the transportation or shipment of cannabinoid products produced in accordance with this chapter (including regulations) through the State or land under the jurisdiction of the Indian Tribe.

''(2) RULE OF CONSTRUCTION REGARDING PRODUCT LIABILITY.—No provision of this chapter relating to a cannabinoid product shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State or Indian Tribe.

''(3) DEFINITION OF INDIAN TRIBE.—In this subsection, the term 'Indian Tribe' means the governing body of any individually identified and federally recognized Indian or Alaska Native tribe, band, nation, pueblo, village, community, affiliated Tribal group, or component reservation included on the list published most recently as of the date of enactment of the Cannabinoid Safety and Regulation Act pursuant to section 104(a) of the Federally Recognized Indian Tribe List Act of 1994.

''(b) AUTHORITY OF USDA.—Nothing in this chapter affects the jurisdiction of the Secretary of Agriculture over the planting, cultivation, growing, and harvesting of hemp (as defined in section 297A of the Agricultural Marketing Act of 1946).''.

SEC. 102. AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.

(a) DEFINITIONS.—Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended—

(1) in paragraph (g)(1)(C), by striking ''(other than food)'' and inserting ''(other than food or cannabinoid products)'';

(2) in paragraph (ff)(1), by striking ''(other than tobacco)'' and inserting ''(other than a tobacco product or a cannabinoid product)'';

(3) in paragraph (rr)(4), by inserting ''cannabinoid product,'' after ''medical device''; and

(4) by adding at the end the following:

''(tt)(1)(A) The term 'cannabis' means—

''(i) all parts of the plant Cannabis sativa L., whether growing or not;

''(ii) the seeds of such plant;

''(iii) the resin extracted from any part of such plant; and

''(iv) every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin, or other constituent element derived from such plant.

''(B) The term 'cannabis' does not include—

''(i) any cannabis plant actively under cultivation that is being cultivated in accordance with the requirements of subtitle G of the Agricultural Marketing Act of 1946;

''(ii) a cannabinoid product; or

''(iii) the mature stalks of the plant Cannabis sativa L., fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, cake, or the sterilized seed of such plant that is incapable of germination.

''(2) The term 'cannabinoid' means any of the following:

''(A) Any chemical in any plant of the genus Cannabis that is unique in nature to such plant, including any of the following chemicals:

''(i) Tetrahydrocannabinol.

''(ii) Cannabinol.

''(iii) Cannabidiol.

‘‘(iv) Cannabigerol.

‘‘(v) Cannabichromene.

‘‘(vi) Tetrahydrocannabivarin.

‘‘(vii) Cannabivarin.

‘‘(viii) Cannabidivarin.

‘‘(ix) Cannabielsion.

‘‘(x) Cannabicyclol.

‘‘(xi) Cannabitriol.

‘‘(xii) Cannabicitran.

‘‘(B) Any isomer of a chemical described in clause (A), and any acids, acetates, salts, esters, ethers, and derivatives thereof.

‘‘(C) Any chemical, regardless of origin or method of production, that is equivalent in chemical structure to a chemical referred to in clause (A), or has both a similar terpenophenolic chemical structure and pharmacological effect to a chemical referred to in clause (A).

‘‘(D) Any chemical derived from a plant of the genus Cannabis that is a CB–1 or CB–2 receptor agonist or partial agonist.

‘‘(E) Any chemical that the Secretary has, by order, deemed to be a cannabinoid.

''(3)(A) The term 'cannabinoid product' means any article or product, including its components or parts, that—

''(i) contains or purports to contain any quantity of 1 or more cannabinoids that are derived from hemp (as defined in section 297A of the Agricultural Marketing Act of 1946); and

''(ii) is intended for use in, through any route of administration, or to be applied to, the body of humans or other animals.

''(B) The term 'cannabinoid product' does not include—

''(i) a drug that is subject to the requirements of chapter V or section 351 of the Public Health Service Act;

''(ii) a device that is subject to the requirements of chapter V;

''(iii) any cannabis plant actively under cultivation that is being cultivated in accordance with the requirements of subtitle G of the Agricultural Marketing Act of 1946; or

''(iv) a virus, serum, toxin, or analogous product subject to the requirements of the eighth paragraph of the matter under the heading 'BUREAU OF

ANIMAL INDUSTRY' in the Act of March 4, 1913 (commonly known as the 'Virus-Serum-Toxin Act').

''(4) With respect to cannabis or a cannabinoid product, the term 'manufacture' does not include the planting, cultivation, growing, or harvesting of cannabis.

''(5) With respect to a cannabinoid product, the term 'serious adverse effect' means that use of the product—

''(A) results in—

''(i) death;

''(ii) a life-threatening adverse experience;

''(iii) inpatient hospitalization or prolongation of existing hospitalization;

''(iv) a persistent or significant disability or incapacity;

''(v) a congenital anomaly or birth defect; or

''(vi) other serious medical event; or

''(B) requires, based on reasonable medical judgment, a medical or surgical intervention to prevent an outcome described in clause (A).

''(uu) The term 'intended for human consumption', with respect to a cannabinoid product, means a cannabinoid product intended for ingestion or inhalation by a human.

''(vv) The term 'tetrahydrocannabinol' means—

''(1) the chemical substance found in the Cannabis sativa L. plant, including the delta–6a, delta–7, delta–8, delta–9, delta–10a, and delta–10 forms, whether naturally occurring in the Cannabis sativa L. plant or synthetically or semi-synthetically derived;

''(2) all isomers of tetrahydrocannabinol, and any acids, acetates, metabolites (including 11-hydroxy-THC, 3-hydroxy-THC, and 7-hydroxy-THC and their isomers), salts, esters, ethers, and derivatives thereof, including its precursor form, tetrahydrocannabinolic acid;

''(3) tetrahydrocannabivarins, including delta-8 tetrahydrocannabivarin, and exo-tetrahydrocannabinol;

''(4) hydrogenated forms of tetrahydrocannabinol including hexahydrocannabinol, hexahydrocannabiphorol, and hexahydrocannabihexol;

''(5) analogues of tetrahydrocannabinols with an alkyl chain of four or more carbon atoms, including tetrahydrocannabiphorols, tetrahydrocannabiocytls, tetrahydrocannabihexols, or tetrahydrocannabutols; and

''(6) any combination of the chemical substances described in subparagraphs (1) through (5) whether naturally or artificially derived or synthetically or semi-synthetically produced.

''(ww)(1) The term 'artificially or synthetically derived cannabinoid' means a cannabinoid or a cannabinoid-like compound that is produced using chemical synthesis, chemical modification, or chemical conversion, including by using in-vitro biosynthesis or other bioconversion.

''(2) The term 'artificially or synthetically derived cannabinoid' does not include—

''(A) a cannabinoid or a cannabinoid-like compound produced through the decarboxylation of naturally occurring cannabinoids from their acidic forms;

''(B) a cannabinoid product or input that undergoes the removal of solvents, catalysts, or other unwanted materials from the cannabinoid product or input; or

''(C) a semi-synthetic cannabinoid.

''(3)(A) For purposes of subparagraph (2)(C), the term 'semi-synthetic cannabinoid' means a substance that is created by a single chemical reaction that converts one cannabinoid extracted from a cannabis plant directly into

a different cannabinoid that is found in more than trace amounts in a cannabis plant.

''(B) For purposes of subparagraph (2)(C), the term 'semi-synthetic cannabinoid' includes a cannabinoid that is produced by the conversion of cannabidiol, including cannabinol and delta–8 tetrahydrocannabinol.

''(C) For purposes of subparagraph (2)(C), the term 'semi-synthetic cannabinoid' does not include a cannabinoid that is produced through the decarboxylation of naturally occurring acidic forms of cannabinoids into the corresponding neutral cannabinoid through the use of heat or light, without the use of chemical reagents or catalysts, and that results in no other chemical change.''.

(b) PROHIBITED ACTS.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended—

(1) by inserting ''cannabinoid product,'' after ''tobacco product,'' each place it appears in paragraphs (g) and (h);

(2) in paragraph (j), by striking ''or 920(b)'' and inserting ''920(b), or 1104'';

(3) in paragraph (p)—

(A) by striking ''510 or 905'' and inserting ''510, 905, or 1104'';

(B) by striking ''or 905(j)'' and inserting ''905(j), or 1104(g)''; and

(C) by striking ''or 905(i)(3)'' and inserting '', 905(i)(3), or 1104(g)(2)'';

(4) in paragraph (q)(2) by inserting '', cannabinoid product,'' after ''device'';

(5) in paragraph (r), by inserting ''cannabinoid product,'' after ''device,'' each place it appears; and

(6) by adding at the end the following:

''(jjj)(1) The sale or distribution of a cannabinoid product intended for human consumption and that contains detectable levels of any tetrahydrocannabinol to any person younger than 21 years of age.

''(2) The sale or distribution of an article that is a cannabinoid product and that contains alcohol, tobacco, nicotine, or another substance with effects that could interact with cannabinoids or enhance or alter the effects of cannabinoids, as determined by the Secretary through rulemaking.

''(3) The failure of a manufacturer or distributor to notify the Attorney General of its knowledge of cannabinoid products used in illicit trade.

''(kkk)(1) The introduction or delivery for introduction into commerce of any cannabinoid product that is adulterated or misbranded.

''(2) The introduction or delivery for introduction into interstate commerce of an article intended for ingestion in tablet, capsule, powder, softgel, gelcap, liquid, or other form, which is not represented as a conventional food and not represented for use as a sole item of a meal or of the diet if it—

''(A) contains any synthetic ingredient with a molecular structure that does not occur in nature; and

''(B) does not meet the definition of a dietary supplement in section 201(ff), except that this subsection does not apply to any article introduced or delivered for introduction into interstate commerce in compliance with chapter V, VI, or IX or with section 351 of the Public Health Service Act.

''(3) The adulteration or misbranding of any cannabinoid product in commerce.

''(4) The receipt in commerce of any cannabinoid product that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

''(5) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to a cannabinoid product, if such act is done while such article is held for sale (whether or not the first sale) after ship-

ment in commerce and results in such article being adulterated or misbranded.

''(lll)(1) The sale or distribution of a cannabinoid product intended for human consumption that contains multiple servings, unless the contents of such cannabinoid product are readily divisible into portions equivalent to one serving.

''(2) The sale or distribution of a cannabinoid product intended for human consumption that is in liquid form, unless such cannabinoid product—

''(A) contains not more than one serving; or

''(B) if the serving size is less than 1 fluid ounce, includes a convenient device for measuring servings, such as a dropper or measuring cup, unless it is a food.''.

(c) PENALTIES.—Section 303(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(f)) is amended—

(1) in paragraph (5)—

(A) in subparagraph (A)—

(i) in the first sentence, by striking ''or (9)'' and inserting ''(9), or (11)''; and

(ii) by inserting ''or no-cannabinoid-product-sale order'' after ''no-tobacco-sale order'' each place it appears;

(B) in subparagraph (B)—

(i) by inserting ''or no-cannabinoid-product-sale order'' after ''no-tobacco-sale order'' each place it appears; and

(ii) in the second sentence, by inserting ''or cannabinoid products, as applicable,'' after ''tobacco products'';

(C) in subparagraph (C), in the first sentence, by striking ''or (9)'' and inserting ''(9), or (11)''; and

(D) in subparagraph (D) by inserting ''or no-cannabinoid-product-sale order'' after ''no-tobacco-sale order'';

(2) in paragraph (6), by inserting ''or no-cannabinoid- product-sale order'' after ''no-tobacco-sale order'' each place it appears; and

(3) by adding at the end the following:

''(10) CIVIL MONETARY PENALTIES FOR VIOLATION OF CANNABINOID PRODUCT REQUIREMENTS.—

''(A) IN GENERAL.—Any person who violates a requirement of this Act that relates to cannabinoid products shall be liable to the United States for a civil penalty in an amount not to exceed $15,000 for each such violation, and not to exceed $15,000,000 for all such violations adjudicated in a single proceeding.

''(B) ENHANCED CIVIL PENALTIES.—Any person who knowingly violates a requirement of this Act that relates to cannabinoid products shall be subject to a civil monetary penalty of—

''(i) not to exceed $250,000 per violation, and not to exceed $10,000,000 for all such violations adjudicated in a single proceeding; or

''(ii) in the case of a violation that continues after the Secretary provides written notice of the violation to such person, $250,000 for the first 30-day period (or any portion thereof) that the person continues to be in violation, and such amount shall double for every 30-day period thereafter that the violation continues, not to exceed $10,000,000 for any 30-day period, and not to exceed $20,000,000 for all such violations adjudicated in a single proceeding.

''(11) REPEATED VIOLATIONS RELATING TO CANNABINOID PRODUCTS.—

''(A) IN GENERAL.—If the Secretary finds that a person has committed repeated violations of a requirement of this Act that relates to

cannabinoid products at a particular retail or online outlet, or association of retail or online outlets, then the Secretary may impose a no-cannabinoid-product-sale order on that person prohibiting the sale of cannabinoid products in that outlet. A no-cannabinoid-product-sale order may be imposed with a civil penalty under paragraph (1).

''(B) HEARING.—Prior to the entry of a no-cannabinoid-product-sale order under this paragraph, a person shall be entitled to a hearing pursuant to the procedures established through regulations of the Food and Drug Administration for assessing civil money penalties, including, at a retailer's request, a hearing by telephone, or at the nearest regional or field office of the Food and Drug Administration, or at a Federal, State, or county facility within 100 miles from the location of the retail outlet, if such a facility is available.''.

(d) SEIZURE AUTHORITIES.—Section 304 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 334) is amended—

(1) in subsection (a)—

(A) in paragraph (1), by inserting ''cannabinoid product,'' after ''drug,''; and

(B) in paragraph (2)—

(i) by striking ''and (H) Any punch'' and inserting ''(H) Any punch''; and

(ii) by inserting before the period at the end the following: '', and (I) Any adulterated or misbranded cannabinoid product'';

(2) in subsection (d)(1), by inserting ''cannabinoid product,'' after ''tobacco product,''; and

(3) in subsection (g), by striking ''or tobacco product'' each place it appears in paragraphs (1) and (2)(A) and inserting '', tobacco product, or cannabinoid product''.

(e) FACTORY INSPECTION.—Section 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374) is amended—

(1) in subsection (a)—

(A) by inserting ''cannabinoid products,'' after ''tobacco products,'' each place it appears;

(B) by striking ''or tobacco products'' each place it appears and inserting ''tobacco products, or cannabinoid products''; and

(C) by striking ''and tobacco products'' and inserting ''tobacco products, and cannabinoid products''; and

(2) in subsection (b)(1), by inserting ''cannabinoid product,'' after ''tobacco product,''.

(f) PUBLICITY.—Section 705(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 375(b)) is amended by inserting ''cannabinoid products,'' after ''tobacco products,''.

(g) PRESUMPTION.—Section 709 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379a) is amended by inserting ''cannabinoid product,'' after ''tobacco product,''.

(h) IMPORTS AND EXPORTS.—Section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381) is amended—

(1) in subsection (a)—

(A) by inserting ''cannabinoid products,'' after ''tobacco products,'';

(B) by striking ''or tobacco products'' each place it appears and inserting '', tobacco products, or cannabinoid products''; and

(C) by striking ''or section 905(h)'' and inserting '', 905(h), or 1104''; and

(2) in subsection (e), by striking ''tobacco product or'' and inserting ''tobacco product, cannabinoid product, or''.

SEC. 103. REGULATION OF CANNABINOID BEVERAGES CONTAINING TETRAHYDROCANNABINOL.

Not later than 60 days after the date of enactment of this Act, the Secretary of Agriculture, the Commissioner of Food and Drugs, the Attorney General, and the Director of the Alcohol and Tobacco Tax and Trade Bureau, acting jointly, shall publish a report that includes recommendations for a Federal regulatory framework for cannabinoid beverages that contain tetrahydrocannabinol (as defined in paragraph (vv) of section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)) that—

(1) is modeled on the Federal regulatory framework for alcohol; and

(2) delineates responsibilities among the Department of Agriculture, the Food and Drug Administration, the Department of Justice, and the Alcohol and Tobacco Tax and Trade Bureau, for labeling, taxation, manufacturing, and adulteration standards of cannabinoid beverages that contain tetrahydrocannabinol.

TITLE II—PUBLIC HEALTH

SEC. 201. PUBLIC HEALTH SURVEILLANCE AND DATA COLLECTION.

(a) IN GENERAL.—Section 392A of the Public Health Service Act (42 U.S.C. 280b–1) is amended—

(1) in the section heading, by inserting ''**AND ADVERSE HEALTH EFFECTS OF CANNABIS USE**'' after ''**SUBSTANCES**'';

(2) in subsection (a)—

(A) in paragraph (2)—

(i) in subparagraph (C) by inserting ''and adverse health effects of cannabis use'' before the period; and

(ii) in subparagraph (D) by inserting '', cannabis, and polysubstance use'' before the period; and

(B) in paragraph (4), by inserting ''and collect data to better understand the use and health effects of cannabis, stimulants, and polysubstances, and'' after ''conduct studies and evaluations'';

(3) in subsection (e), by striking ''$496,000,000 for each of fiscal years 2019 through 2023'' and inserting ''$596,000,000 for each of fiscal years 2024 through 2028''; and

(4) by adding at the end the following:

''(f) ADDITIONAL FUNDING.—In addition to amounts otherwise available, there is appropriated, out of any funds in the Treasury not otherwise appropriated, $100,000,000 for each of fiscal years 2024 through 2028 to carry out this section.''.

SEC. 202. AWARDS TO PREVENT UNDERAGE CANNABIS USE.

Part D of title V of the Public Health Service Act (42 U.S.C. 290dd et seq.) is amended by adding at the end the following:

''SEC. 553. AWARDS TO PREVENT UNDERAGE CANNABIS USE.

''(a) IN GENERAL.—The Secretary, acting through the Assistant Secretary, shall award grants, contracts, and cooperative agreements to eligible entities to prevent and reduce underage use of cannabis.

''(b) ELIGIBLE ENTITIES.—To receive an award under this section, an entity shall be a State, a political subdivision of a State, an Indian Tribe or Tribal organization, an urban Indian organization, a nonprofit community-based organization, or any other nonprofit entity the Secretary determines appropriate.

''(c) USE OF FUNDS.—An eligible entity receiving an award under this subsection shall use funds from such award to—

''(1) establish, enhance, and support culturally- and linguistically-appropriate programs, including community-based, school-based, and higher-education based programs, and programs that target youth within the juvenile justice and child welfare systems, that offer screening, prevention, early intervention, diagnosis, treatment, referral, and recovery support services related to underage cannabis use;

''(2) design, test, evaluate, and disseminate evidence-based and evidence-informed strategies to maximize the effectiveness of community-wide approaches to preventing and reducing underage cannabis use;

''(3) educate children, adolescents, youth, parents, health care providers, and communities about the dangers of underage cannabis use, including impaired driving due to cannabis use;

''(4) collect data on underage cannabis use to identify and address needs, service gaps, and trends;

''(5) strengthen collaboration among communities, the Federal Government, and State, local, and Tribal governments to prevent underage cannabis use;

''(6) address community norms regarding underage cannabis use, reduce opportunities for under-

age cannabis use, and reduce the prevalence of negative consequences associated with underage cannabis use; and

''(7) support other evidence-based and evidence-informed practices to reduce underage cannabis use, as determined by the Secretary.

''(d) SUPPLEMENT NOT SUPPLANT.—Funds awarded under this section shall supplement, and not supplant, existing State, Federal, local, and Tribal funds to prevent and reduce underage cannabis use.

''(e) PRIORITY CONSIDERATION.—In making awards under this section, the Secretary shall give priority to eligible entities that serve medically underserved communities, communities with high rates of underage cannabis use, and communities that have historically experienced disproportionate arrest and conviction rates related to the sale, possession, use, manufacture, or cultivation of cannabis (but not counting convictions involving distribution of cannabis to a minor).

''(f) FUNDING.—In addition to amounts otherwise available, there is appropriated, out of any funds in the Treasury not otherwise appropriated, $25,000,000 for each of fiscal years 2024 through 2028 to carry out this section.

''(g) DEFINITIONS.—In this section:

''(1) CANNABIS.—The term 'cannabis' means cannabis or a cannabinoid product (as such terms are defined in section 201(tt) of the Federal Food, Drug, and Cosmetic Act).

''(2) INDIAN TRIBE.—the term 'Indian Tribe' means the governing body of any individually identified and federally recognized Indian or Alaska Native tribe, band, nation, pueblo, village, community, affiliated Tribal group, or component reservation included on the list published most recently as of the date of enactment of the Cannabinoid Safety and Regulation Act pursuant to section 104(a) of the Federally Recognized Indian Tribe List Act of 1994.

''(3) TRIBAL ORGANIZATION.—The term 'Tribal organization' means the governing body of an Indian Tribe.

''(4) URBAN INDIAN ORGANIZATION.—The term 'urban Indian organization' has the meaning given such term in section 4 of the Indian Health Care Improvement Act.''.

TITLE III—CANNABIS-IMPAIRED DRIVING PREVENTION

SEC. 301. DEFINITIONS.

In this title:

(1) ADMINISTRATOR.—The term ''Administrator'' means the Administrator of the National Highway Traffic Safety Administration.

(2) CANNABIS.—The term ''cannabis'' means—

(A) cannabis (as defined in paragraph (tt) of section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)); and

(B) a cannabinoid product (as so defined).

(3) SECRETARY.—The term ''Secretary'' means the Secretary of Transportation.

(4) THC.—The term ''THC'' means tetrahydrocannabinol (as defined in paragraph (vv) of section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)).

SEC. 302. CANNABIS-IMPAIRED DRIVING RESEARCH.

(a) CANNABIS-IMPAIRED DRIVING DATA.—

(1) IN GENERAL.—The Secretary shall collect and, as appropriate, share with the Secretary of Health and Human Services, data relating to cannabis-impaired driving, or a combination of cannabis and another substance, including through the collection of crash data specific to crashes involving drivers with—

(A) THC in their system; or

(B) a combination of THC and another substance in their system.

(2) NATIONAL ROADSIDE SURVEY.—

(A) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Administrator shall initiate a National Roadside Survey to collect data on drivers with THC in their system.

(B) REPORT.—Not later than 3 years after the date of enactment of this Act, the Secretary shall submit to the Committees on Commerce, Science, and Transportation, Environment and Public Works, and Health, Education, Labor, and Pensions of the Senate and the Committee on Transportation and Infrastructure of the House of Representatives a report summarizing the data acquired, and conclusions drawn, from the National Roadside Survey required under subparagraph (A).

(b) RESEARCH ON RISKS OF CANNABIS-IMPAIRED DRIVING.—

(1) STUDY REQUIRED.—

(A) IN GENERAL.—Not later than 3 years after the date of enactment of this Act, the Sec-

retary shall carry out a study to evaluate and quantify the risks of cannabis-impaired driving.

(B) REQUIREMENTS.—The study required under subparagraph (A) shall analyze—

(i) whether there is an increased likelihood of crashing a motor vehicle after recent cannabis use;

(ii) the effect of cannabis on driving behavior;

(iii) whether there is a correlation between THC level (as tested in oral fluids or through any other test designated by the Secretary in consultation with the Secretary of Health and Human Services) and level of impairment;

(iv) whether the current Standard Field Sobriety Test developed by the National Highway Traffic Safety Administration accurately identifies cannabis impairment and impairment due to cannabis and other substance use;

(v) whether driving behavior changes depending on frequency of cannabis use;

(vi) whether there are any measurable increased risks associated with using cannabis together with another substance;

(vii) whether there is a measurable effect of cannabis use by drivers on pedestrian safety; and

(viii) any other data necessary to improve safe driving outcomes, as determined by the Secretary.

(2) REPORT.—Not later than 3 years after the date of enactment of this Act, and annually thereafter until the date on which the study required under paragraph (1) is complete, the Secretary shall submit to the Committees on Commerce, Science, and Transportation, Environment and Public Works, and Health, Education, Labor, and Pensions of the Senate and the Committee on Transportation and Infrastructure of the House of Representatives a report summarizing the data acquired, and conclusions drawn, from the study required under paragraph (1).

SEC. 303. DOT CANNABIS-IMPAIRED DRIVING PREVENTION PROGRAMS.

(a) IN GENERAL.—The Secretary shall research and implement data-driven strategies to educate the public

about the dangers of cannabis-impaired driving, which shall include the following:

(1) CANNABIS-IMPAIRED DRIVING USE PREVENTION BEST PRACTICES.—

(A) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary shall develop and issue best practices for States and communities to prevent cannabis-impaired driving, including impaired driving involving the use of cannabis and another substance and practices targeting drivers under the age of 21, in consultation with the Director of the Centers for Disease Control and Prevention, the Secretary of Health and Human Services, and the heads of other Federal agencies as appropriate.

(B) UPDATES.—Not less frequently than biannually, the Secretary shall update and reissue the best practices required under subparagraph (A) as new research and data becomes available.

(2) CANNABIS-IMPAIRED DRIVING USE PREVENTION CAMPAIGNS.—Not later than 2 years after the date of enactment of this Act, the Secretary shall es-

tablish and carry out national campaigns to prevent cannabis-impaired driving, including—

(A) cannabis-impaired driving involving the use of cannabis and another substance; and

(B) cannabis-impaired driving among drivers under the age of 21.

(b) CAMPAIGN EVALUATION.—Not less frequently than once every 3 years, the Secretary shall evaluate the effectiveness of the campaigns required under subsection (a)(2) and the activities carried out by States using a grant awarded under section 409 of title 23, United States Code, by using a variety of factors, including—

(1) collecting data, including behavioral data, and comparing that data from before and after the campaigns;

(2)(A) engaging with stakeholders that were involved in the campaigns; and

(B) analyzing feedback from those stakeholders on what the stakeholders saw as strengths and weaknesses of the campaigns;

(3) determining whether the campaigns accomplished the objectives the Secretary set out to accomplish through analysis of data relating to the campaigns; and

(4) any other factors the Secretary determines appropriate included in the document of the National Highway Traffic Safety Administration entitled ''The Art of Appropriate Evaluation: A Guide for Highway Safety Program Managers'' and dated December 2008 (or a successor document).

(c) REPORT.—Not later than 6 months after the date on which the Secretary completes an evaluation conducted under subsection (b), the Secretary shall submit to the Committees on Commerce, Science, and Transportation, Environment and Public Works, and Health, Education, Labor, and Pensions of the Senate and the Committee on Transportation and Infrastructure of the House of Representatives a report that—

(1) summarizes the data collected and provides the analysis of the data from an evaluation conducted under subsection (b);

(2) includes recommendations for future impaired driving campaigns; and

(3) includes any determinations that a national campaign or an activity carried out by a State using a grant awarded under section 409 of title 23, United States Code, is ineffective at preventing cannabis-impaired driving.

SEC. 304. STATE CANNABIS-IMPAIRED DRIVING PREVENTION GRANT PROGRAM.

(a) IN GENERAL.—Chapter 4 of title 23, United States Code, is amended by inserting after section 408 the following:

"§ 409. State cannabis-impaired driving prevention grant program

''(a) DEFINITIONS.—In this section:

''(1) CANNABIS.—The term 'cannabis' has the meaning given the term in paragraph (tt) of section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

''(2) GRANT PROGRAM.—The term 'grant program' means the grant program established under subsection (b).

''(3) THC.—The term 'THC' means tetrahydrocannabinol (as defined in paragraph (vv) of section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)).

''(b) ESTABLISHMENT.—Not later than 1 year after the date of enactment of the Cannabinoid Safety and Regulation Act, the Secretary, acting through the Administrator of the National Highway Traffic Safety Administration, shall establish a program to provide grants to States, in accordance with subsection (c), to implement programs to prevent impaired driving due to cannabis use.

''(c) ELIGIBILITY.—The Secretary may provide a grant under this section to any State that—

''(1) describes how the State will use the grant funds in accordance with a highway safety program under section 402, including how the State will implement the best practices developed by the Secretary under section 303(a)(1) of the Cannabinoid Safety and Regulation Act; and

''(2) agrees to provide data and information, as determined by the Secretary, to assist with the evaluation of the effectiveness of the eligible activities described in subsection (d).

''(d) USE OF FUNDS.—A State may use a grant awarded under this section for the following activities:

''(1) Enforcement activities, including—

''(A) to train public safety personnel to detect impaired driving due to the use of cannabis or a combination of cannabis and another substance;

''(B) to increase the capacity of impaired driving toxicology testing laboratories in the State to support impaired driving investigations, including to purchase equipment, hire staff, provide training, and improve procedures, including to improve toxicology testing stand-

ards to be consistent with the standards contained in the document of the National Safety Council entitled 'Recommendations for Toxicological Investigation of Drug-Impaired Driving and Motor Vehicle Fatalities–2021 Update' (or a successor document);

''(C) to train for and implement impaired driving assessment programs or other tools designed to increase the probability of identifying the recidivism risk of an individual convicted of driving under the influence of cannabis, or a combination of cannabis and another substance, and to determine the most effective mental health or substance abuse treatment or sanction that will reduce that risk;

''(D) to develop and implement high-visibility enforcement efforts relating to cannabis-impaired driving; and

''(E) for court support of high-visibility enforcement efforts, to train and educate criminal justice professionals (including law enforcement personnel, prosecutors, judges, and probation officers) to assist those professionals in—

''(i) handling cannabis-impaired driving cases;

"(ii) hiring traffic safety resource prosecutors;

"(iii) hiring judicial outreach liaisons; and

"(iv) establishing driving while intoxicated courts.

"(2) Data collection activities, including—

"(A) to collect data relating to the use of cannabis, drugs, or multiple substances by drivers, including the prevalence of the use of those substances among drivers arrested for impaired driving; and

"(B) to increase drug testing and reporting for all fatal crashes and serious injuries to better understand the scope of cannabis-impaired driving, or a combination of cannabis and another substance.

"(3) Education activities, including—

"(A) to develop and carry out educational campaigns to better educate the public about the harms associated with cannabis-impaired driving, including impaired driving associated with the use of cannabis and another substance; and

''(B) to participate in national campaigns organized by the Secretary under section 303(a)(2) of the Cannabinoid Safety and Regulation Act.

''(e) PROHIBITION.—The Secretary may prohibit the use of grant funds for an activity described in subsection (d) if the Secretary determines that the activity is ineffective at preventing cannabis-impaired driving after conducting an evaluation required under section 303(b) of the Cannabinoid Safety and Regulation Act.

''(f) GRANT AMOUNTS.—

''(1) IN GENERAL.—The allocation of grant funds to a State under this section for a fiscal year shall be in proportion to the apportionment of funds a State receives under section 402(c)(2).

''(2) REQUIREMENT.—Not less than 10 percent of the funds allocated to a State under this section shall be used to carry out activities described in subsection (d)(1)(B).

''(g) FEDERAL SHARE.—

''(1) IN GENERAL.—For the first 3 fiscal years after the date on which the grant program is established under subsection (b), and each fiscal year thereafter for a State that meets the condition described in paragraph (2)(B) during that fiscal year,

the Federal share of the costs of activities carried out with a grant awarded under the grant program shall be 80 percent in any fiscal year in which the State is awarded a grant.

''(2) DECREASED FEDERAL SHARE.—

''(A) IN GENERAL.—For any State that does not meet the condition described in subparagraph (B), the Federal share of the costs of activities carried out with a grant awarded under the grant program shall be—

''(i) 70 percent in the fourth fiscal year after the date on which the grant program is established under subsection (b);

''(ii) 60 percent in the fifth fiscal year after that date; and

''(iii) 50 percent in the sixth fiscal year after that date and each fiscal year thereafter.

''(B) CONDITION.—The condition referred to in paragraph (1) and subparagraph (A) is that the State shall implement an open container law relating to cannabis products.

''(h) FUNDING.—In addition to amounts otherwise available, there is appropriated, out of any money in the Treasury not otherwise appropriated, $40,000,000 for

each of fiscal years 2024 through 2028 to carry out this section.''.

(b) CLERICAL AMENDMENT.—The analysis for chapter 4 of title 23, United States Code, is amended by inserting after the item relating to section 408 the following:

''409. State cannabis-impaired driving prevention grant program.''.

SEC. 305. NATIONAL CANNABIS IMPAIRMENT STANDARD.

(a) IN GENERAL.—Not later than 3 years after the date of enactment of this Act, and once every 2 years thereafter, the Secretary shall make a determination as to whether or not it is feasible to establish a national standard for determining impairment for cannabis-impaired driving.

(b) RULEMAKING REQUIRED.—If the Secretary determines that establishing a national standard relating to cannabis-impaired driving under subsection (a) is feasible, the Secretary shall, not later than 1 year after that determination, promulgate regulations establishing a model cannabis impairment standard for States.

SEC. 306. FUNDING.

In addition to amounts otherwise available, there is appropriated, out of any money in the Treasury not otherwise appropriated, $30,000,000 for each of fiscal years 2024 through 2029 to carry out sections 302 and 303.

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