General Assembly **Substitute Bill No. 13**

February Session, 2022

* SB00013APP 042922 *

AN ACT REDUCING PRESCRIPTION DRUG PRICES.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. (NEW) (*Effective July 1, 2022*) There is established an account to be known as the "Covered Connecticut account" which shall be a separate, nonlapsing account within the General Fund. The account shall be administered by the Office of Health Strategy, established under section 19a-754a of the general statutes, and contain any moneys required by law to be deposited in the account. Moneys in the account shall be expended by the (1) Office of Health Strategy for the purpose of supporting the Covered Connecticut program established under section 19a-754c of the general statutes, and (2) Department of Social Services for the purpose of supporting the state medical assistance program administered by the department.

Sec. 2. (NEW) (*Effective July 1, 2022*) For the purposes of this section and sections 3 and 4 of this act:

(1) "Commissioner" means the Commissioner of Revenue Services;

(2) "Consumer price index" means the consumer price index, annual average, for all urban consumers: United States city average, all items, published by the United States Department of Labor, Bureau of Labor Statistics, or its successor, or, if the index is discontinued, an equivalent

index published by a federal authority, or, if no such index is published, a comparable index published by the United States Department of Labor, Bureau of Labor Statistics;

(3) "Covered Connecticut account" means the Covered Connecticut account established under section 1 of this act;

(4) "Identified prescription drug" means a prescription drug that is sold at a price that exceeds the sum calculated under subdivision (1) of subsection (a) of section 3 of this act for such drug;

(5) "Legend drug" has the same meaning as provided in section 20-571 of the general statutes;

(6) "Office of Health Strategy" means the Office of Health Strategy established under section 19a-754a of the general statutes;

(7) "Person" has the same meaning as provided in section 12-1 of the general statutes;

(8) "Pharmaceutical manufacturer" means a person that manufactures a prescription drug and sells, directly or through another person, the prescription drug for distribution in this state;

(9) "Prescription drug" means a legend drug approved by the federal Food and Drug Administration, or any successor agency, and prescribed by a health care provider to an individual in this state;

(10) "Reference price" means the wholesale acquisition cost of a drug (A) on January 1, 2022, or (B) on the date such drug is first commercially marketed in the United States if such drug is first commercially marketed in the United States after January 1, 2022; and

(11) "Wholesale acquisition cost" has the same meaning as provided in 42 USC 1395w-3a, as amended from time to time.

Sec. 3. (NEW) (*Effective July 1, 2022*) (a) (1) Notwithstanding any provision of the general statutes and except as provided in subdivision

(2) of this subsection, no pharmaceutical manufacturer shall, on or after January 1, 2023, sell a prescription drug with a wholesale acquisition cost equal to or greater than one hundred dollars in this state at a price that exceeds the sum of:

(A) The reference price for the prescription drug, adjusted for any increase or decrease in the consumer price index; and

(B) Two per cent of the reference price for the prescription drug for each twelve-month period that has elapsed since the date on which the reference price for such prescription drug was determined, compounded annually on the anniversary of such date.

(2) A pharmaceutical manufacturer may sell a prescription drug in this state at a price that exceeds the sum calculated for the prescription drug under subdivision (1) of this subsection if the federal Secretary of Health and Human Services determines, pursuant to 21 USC 356e, as amended from time to time, that such prescription drug is in shortage in the United States.

(b) (1) Except as provided in subdivision (2) of this subsection, any pharmaceutical manufacturer that violates the provisions of subsection (a) of this section shall be liable to this state for a civil penalty. Such civil penalty shall be imposed, calculated and collected on a calendar year basis, and the amount of such civil penalty for a calendar year shall be equal to eighty per cent of the difference between:

(A) The revenue that the pharmaceutical manufacturer earned from all sales of the identified prescription drug in this state during the calendar year; and

(B) The revenue that the pharmaceutical manufacturer would have earned from all sales of the identified prescription drug in this state during the calendar year if the pharmaceutical manufacturer had sold such identified prescription drug at a price that did not exceed the sum calculated under subdivision (1) of subsection (a) of this section for such identified prescription drug.

(2) No pharmaceutical manufacturer of an identified prescription drug shall be liable to this state for the civil penalty imposed under subdivision (1) of this subsection unless the pharmaceutical manufacturer made at least two hundred fifty thousand dollars in total annual sales in this state for the calendar year for which such civil penalty would otherwise be imposed.

(c) (1) (A) Not later than March 1, 2024, and annually thereafter, each pharmaceutical manufacturer that violated subsection (a) of this section during the preceding calendar year shall:

(i) Pay to the commissioner the civil penalty imposed under subsection (b) of this section for such calendar year; and

(ii) File with the commissioner a statement for such calendar year in a form and manner, and containing all information, prescribed by the commissioner.

(B) A pharmaceutical manufacturer that is required to file a statement and pay a civil penalty pursuant to subparagraph (A) of this subdivision shall electronically file such statement and make such payment by electronic funds transfer in the manner provided by chapter 228g of the general statutes, irrespective of whether the pharmaceutical manufacturer would have otherwise been required to electronically file such statement or make such payment by electronic funds transfer under chapter 228g of the general statutes.

(2) If no statement is filed pursuant to subdivision (1) of this subsection, the commissioner may make such statement at any time thereafter, according to the best obtainable information and the prescribed form.

(d) The commissioner may examine the records of any pharmaceutical manufacturer that is subject to the civil penalty imposed under subsection (b) of this section as the commissioner deems necessary. If the commissioner determines from such examination that the pharmaceutical manufacturer failed to pay the full amount of such

civil penalty, the commissioner shall bill such pharmaceutical manufacturer for the full amount of such civil penalty.

(e) (1) The commissioner may require each pharmaceutical manufacturer that is subject to a civil penalty imposed under this section to keep such records as the commissioner may prescribe, and produce books, papers, documents and other data, to provide or secure information pertinent to the enforcement and collection of such civil penalty.

(2) The commissioner, or any person authorized by the commissioner, may examine the books, papers, records and equipment of any person who is subject to the provisions of this section and may investigate the character of the business of such person to verify the accuracy of any statement made or, if no statement is made by such person, to ascertain and determine the amount required to be paid.

(f) Any pharmaceutical manufacturer that is subject to a civil penalty imposed under this section and aggrieved by any action of the commissioner under subdivision (2) of subsection (c) of this section or subsection (d) of this section may apply to the commissioner, in writing and not later than sixty days after the notice of such action is delivered or mailed to such pharmaceutical manufacturer, for a hearing, setting forth the reasons why such hearing should be granted and the amount by which the civil penalty should be reduced. The commissioner shall promptly consider each such application and may grant or deny the hearing requested. If the hearing request is denied, the commissioner shall immediately notify the pharmaceutical manufacturer. If the hearing request is granted, the commissioner shall notify the pharmaceutical manufacturer of the date, time and place for such hearing. After such hearing, the commissioner may make such order as appears just and lawful to the commissioner and shall furnish a copy of such order to the pharmaceutical manufacturer. The commissioner may, by notice in writing, order a hearing on the commissioner's own initiative and require a pharmaceutical manufacturer, or any other person who the commissioner believes to be in possession of relevant

information concerning such pharmaceutical manufacturer, to appear before the commissioner or the commissioner's authorized agent with any specified books of account, papers or other documents for examination under oath.

(g) Any pharmaceutical manufacturer that is aggrieved by any order, decision, determination or disallowance of the commissioner made under subsection (f) of this section may, not later than thirty days after service of notice of such order, decision, determination or disallowance, take an appeal therefrom to the superior court for the judicial district of New Britain, which appeal shall be accompanied by a citation to the commissioner to appear before said court. Such citation shall be signed by the same authority and such appeal shall be returnable at the same time and served and returned in the same manner as is required in case of a summons in a civil action. The authority issuing the citation shall take from the appellant a bond or recognizance to this state, with surety, to prosecute the appeal to effect and to comply with the orders and decrees of the court in the premises. Such appeals shall be preferred cases, to be heard, unless cause appears to the contrary, at the first session, by the court or by a committee appointed by the court. Said court may grant such relief as may be equitable and, if the civil penalty was paid prior to the granting of such relief, may order the Treasurer to pay the amount of such relief. If the appeal was taken without probable cause, the court may tax double or triple costs, as the case demands and, upon all such appeals that are denied, costs may be taxed against such pharmaceutical manufacturer at the discretion of the court but no costs shall be taxed against this state.

(h) The commissioner, and any agent of the commissioner duly authorized to conduct any inquiry, investigation or hearing pursuant to this section, shall have power to administer oaths and take testimony under oath relative to the matter of inquiry or investigation. At any hearing ordered by the commissioner, the commissioner, or the commissioner's agent authorized to conduct such hearing and having authority by law to issue such process, may subpoena witnesses and

require the production of books, papers and documents pertinent to such inquiry or investigation. No witness under any subpoena authorized to be issued under the provisions of this section shall be excused from testifying or from producing books, papers or documentary evidence on the ground that such testimony or the production of such books, papers or documentary evidence would tend to incriminate such witness, but such books, papers or documentary evidence so produced shall not be used in any criminal proceeding against such witness. If any person disobeys such process or, having appeared in obedience thereto, refuses to answer any pertinent question put to such person by the commissioner, or the commissioner's authorized agent, or to produce any books, papers or other documentary evidence pursuant thereto, the commissioner, or such agent, may apply to the superior court of the judicial district wherein the pharmaceutical manufacturer resides or wherein the business was conducted, or to any judge of such court if the same is not in session, setting forth such disobedience to process or refusal to answer, and such court or such judge shall cite such person to appear before such court or such judge to answer such question or to produce such books, papers or other documentary evidence and, upon such person's refusal so to do, shall commit such person to a community correctional center until such person testifies, but not for a period longer than sixty days. Notwithstanding the serving of the term of such commitment by any person, the commissioner may proceed in all respects with such inquiry and examination as if the witness had not previously been called upon to testify. Officers who serve subpoenas issued by the commissioner or under the commissioner's authority and witnesses attending hearings conducted by the commissioner pursuant to this section shall receive fees and compensation at the same rates as officers and witnesses in the courts of this state, to be paid on vouchers of the commissioner on order of the Comptroller from the proper appropriation for the administration of this section.

(i) The amount of any civil penalty unpaid under the provisions of this section may be collected under the provisions of section 12-35 of the

general statutes. The warrant provided under section 12-35 of the general statutes shall be signed by the commissioner or the commissioner's authorized agent. The amount of any such civil penalty shall be a lien on the real property of the pharmaceutical manufacturer from the last day of the month next preceding the due date of such civil penalty until such civil penalty is paid. The commissioner may record such lien in the records of any town in which the real property of such pharmaceutical manufacturer is situated, but no such lien shall be enforceable against a bona fide purchaser or qualified encumbrancer of such real property. When any civil penalty with respect to which a lien was recorded under the provisions of this subsection is satisfied, the commissioner shall, upon request of any interested party, issue a certificate discharging such lien, which certificate shall be recorded in the same office in which such lien was recorded. Any action for the foreclosure of such lien shall be brought by the Attorney General in the name of this state in the superior court for the judicial district in which the real property subject to such lien is situated, or, if such property is located in two or more judicial districts, in the superior court for any one such judicial district, and the court may limit the time for redemption or order the sale of such real property or make such other or further decree as it judges equitable. The provisions of section 12-39g of the general statutes shall apply to all civil penalties imposed under this section.

(j) (1) Any officer or employee of a pharmaceutical manufacturer who owes a duty to the pharmaceutical manufacturer to pay a civil penalty imposed under this section on behalf of such pharmaceutical manufacturer, file a statement with the commissioner pursuant to subsection (c) of this section on behalf of such pharmaceutical manufacturer, keep records or supply information to the commissioner on behalf of such pharmaceutical manufacturer pursuant to this section and wilfully fails, at the time required under this section, to pay such civil penalty, file such statement, keep such records or supply such information on behalf of such pharmaceutical manufacturer shall, in addition to any other penalty provided by law, be fined not more than one thousand dollars or imprisoned not more than one year, or both.

Notwithstanding the provisions of section 54-193 of the general statutes, no such officer or employee shall be prosecuted for a violation of the provisions of this subdivision committed on or after July 1, 2022, except within three years next after such violation is committed.

(2) Any officer or employee of a pharmaceutical manufacturer who owes a duty to the pharmaceutical manufacturer to deliver or disclose to the commissioner, or the commissioner's authorized agent, any list, statement, return, account statement or other document on behalf of such pharmaceutical manufacturer and wilfully delivers or discloses to the commissioner, or the commissioner's authorized agent, any such list, statement, return, account statement or other document that such officer or employee knows to be fraudulent or false in any material matter shall, in addition to any other penalty provided by law, be guilty of a class D felony.

(3) No officer or employee of a pharmaceutical manufacturer shall be charged with an offense under subdivisions (1) and (2) of this subsection in relation to the same civil penalty, but such officer or employee may be charged and prosecuted for both such offenses upon the same information.

(k) The proceeds from all civil penalties imposed under this section shall be deposited in the Covered Connecticut account. Each civil penalty imposed under this section shall be deemed to constitute a civil fine or penalty within the meaning of 42 USC 1396b(w), as amended from time to time. No portion of any civil penalty imposed under this section shall be waived under section 12-3a of the general statutes or any other applicable law. No tax credit shall be allowable against any civil penalty imposed under this section.

(l) Not later than July 1, 2024, and annually thereafter, the commissioner shall prepare a list containing the name of each pharmaceutical manufacturer that violated subsection (a) of this section during the preceding calendar year. The commissioner shall make each such list publicly available.

(m) The commissioner may adopt regulations, in accordance with the provisions of chapter 54 of the general statutes, to implement the provisions of this section.

Sec. 4. (NEW) (*Effective July 1, 2022*) (a) No pharmaceutical manufacturer of an identified prescription drug shall withdraw the identified prescription drug from sale in this state for the purpose of avoiding the civil penalty established in subsection (b) of section 3 of this act.

(b) Any pharmaceutical manufacturer that intends to withdraw an identified prescription drug from sale in this state shall, at least one hundred eighty days before such withdrawal, send advance written notice to the Office of Health Strategy disclosing such pharmaceutical manufacturer's intention.

(c) Any pharmaceutical manufacturer that violates the provisions of subsection (a) or (b) of this section shall be liable to this state for a civil penalty in the amount of five hundred thousand dollars.

Sec. 5. (NEW) (*Effective July 1, 2022*) For the purposes of this section and sections 6 to 10, inclusive, of this act unless the context otherwise requires:

(1) "Drug" means an article that is (A) recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States or official National Formulary, or any supplement thereto, (B) intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans, (C) not food and intended to affect the structure or any function of the human body, and (D) not a device and intended for use as a component of any other article specified in subparagraphs (A) to (C), inclusive, of this subdivision;

(2) "Drug Quality and Security Act" means the federal Drug Quality and Security Act, 21 USC 351, et seq., as amended from time to time;

(3) "Food, Drug and Cosmetic Act" means the Federal Food, Drug and

Cosmetic Act, 21 USC 301, et seq., as amended by the Drug Quality and Security Act, as both may be amended from time to time;

(4) "Importation program" means the Canadian legend drug importation program established by the Commissioner of Consumer Protection pursuant to section 6 of this act;

(5) "Institutional pharmacy" has the same meaning as provided in section 20-571 of the general statutes;

(6) "Laboratory testing" means a quantitative and qualitative analysis of a prescription drug consistent with the official United States Pharmacopoeia;

(7) "Legend drug" means a drug that (A) any applicable federal or state law provides shall only be (i) dispensed pursuant to a prescription, or (ii) used by a prescribing practitioner, or (B) applicable federal law requires to bear the following legend: "RX ONLY" IN ACCORDANCE WITH GUIDELINES ESTABLISHED IN THE FEDERAL FOOD, DRUG AND COSMETIC ACT;

(8) "Participating Canadian supplier" means a manufacturer or wholesale drug distributor that (A) is licensed or permitted under applicable Canadian law to manufacture or distribute prescription drugs, (B) exports legend drugs, in the manufacturer's original container, to a participating wholesaler for distribution in this state under the importation program, and (C) is properly registered, if such Canadian supplier is required to be registered, with the United States Food and Drug Administration, or any successor agency;

(9) "Participating wholesaler" means a qualified wholesaler that is designated by the Commissioner of Consumer Protection to participate in the importation program;

(10) "Pharmacy" has the same meaning as provided in section 20-571 of the general statutes;

(11) "Prescription" means a lawful oral, written or electronic order by a prescribing practitioner for a drug for a specific patient;

(12) "Qualified laboratory" means a laboratory that is (A) adequately equipped and staffed to properly perform qualitative and quantitative laboratory testing on legend drugs, and (B) accredited to International Organization for Standardization (ISO) 17025;

(13) "Qualified wholesaler" means a wholesaler, as defined in section 21a-70 of the general statutes, that has received a certificate of registration from the Commissioner of Consumer Protection pursuant to said section; and

(14) "Track-and-trace" means the product tracing process for the components of the pharmaceutical distribution supply chain, as described in Title II of the Drug Quality and Security Act.

Sec. 6. (NEW) (*Effective July 1, 2022*) (a) The Commissioner of Consumer Protection shall establish a program to be known as the "Canadian legend drug importation program". Under such importation program, the commissioner shall, notwithstanding any provision of the general statutes:

(1) Provide for the importation from Canada of safe and effective legend drugs that have the highest potential for cost savings for patients in this state;

(2) Develop and implement an application and approval process for qualified wholesalers to be designated as participating wholesalers; and

(3) Designate one or more participating wholesalers to distribute in this state legend drugs, imported from Canada, from a participating Canadian supplier and in the manufacturer's original container, to a licensed pharmacy or institutional pharmacy or a qualified laboratory.

(b) (1) Not later than July 1, 2023, the Commissioner of Consumer Protection shall submit a request to the federal Secretary of Health and

Human Services seeking approval for the importation program under 21 USC 384, as amended from time to time. Such request shall, at a minimum:

(A) Describe the commissioner's plans for operating the importation program;

(B) Demonstrate that the legend drugs to be imported and distributed in this state under the importation program shall:

(i) Meet all applicable federal and state standards for safety and effectiveness; and

(ii) Comply with all federal tracing procedures; and

(C) Disclose the costs of implementing the importation program.

(2) (A) If the federal Secretary of Health and Human Services approves the commissioner's request, the commissioner shall:

(i) Submit to (I) the Commissioner of Public Health a notice disclosing that the federal Secretary of Health and Human Services has approved such request, and (II) the joint standing committees of the General Assembly having cognizance of matters relating to appropriations, general law, human services and public health a notice disclosing that the federal Secretary of Health and Human Services has approved such request; and

(ii) Begin operating the importation program not later than one hundred eighty days after the date of such approval.

(B) Except as otherwise provided in this subsection, the Commissioner of Consumer Protection shall not operate the importation program unless the federal Secretary of Health and Human Services approves the commissioner's request.

Sec. 7. (NEW) (*Effective July 1, 2022*) (a) Each participating wholesaler may, subject to the provisions of this section and sections 6 and 9 of this

act, import into this state a legend drug from a participating Canadian supplier, and distribute such legend drug to a licensed pharmacy or institutional pharmacy, or a qualified laboratory in this state, under the importation program if:

(1) Such participating wholesaler:

(A) Is registered with the federal Secretary of Health and Human Services pursuant to Section 510(b) of the Food, Drug and Cosmetic Act, 21 USC 360(b), as amended from time to time; and

(B) Holds a valid labeler code that was issued to such participating wholesaler by the United States Food and Drug Administration, or any successor agency; and

(2) Such legend drug:

(A) May be imported into this state in accordance with applicable federal patent laws;

(B) Meets the United States Food and Drug Administration's, or any successor agency's, standards concerning drug safety, effectiveness, misbranding and adulteration; and

(C) Is not:

(i) A controlled substance, as defined in 21 USC 802, as amended from time to time;

(ii) A biological product, as defined in 42 USC 262, as amended from time to time;

(iii) An infused drug;

(iv) An intravenously, intradermally, intrathecally, intramuscularly or subcutaneously injected drug;

(v) A drug that is inhaled during surgery;

(vi) A drug that is a parenteral drug, the importation of which is determined by the federal Secretary of Health and Human Services to pose a threat to the public health; or

(vii) A drug that is a compound which is not commercially available.

(b) Each participating wholesaler shall:

(1) Comply with all applicable track-and-trace requirements, and make available to the Commissioner of Consumer Protection all track-and-trace records not later than forty-eight hours after the commissioner requests such records;

(2) Not import into, or distribute, dispense or sell, in this state any legend drugs under the importation program except in accordance with the provisions of this section and sections 6 and 9 of this act;

(3) Not distribute, dispense or sell outside of this state any legend drugs that are imported into this state under the importation program;

(4) Ensure the safety and quality of each legend drug that is imported and distributed in this state under the importation program;

(5) For each initial shipment of any legend drug that is imported into this state by such participating wholesaler, ensure that a qualified laboratory engaged by such participating wholesaler tests a statistically valid sample size for each batch of such legend drug in such shipment for authenticity and degradation in a manner that is consistent with the Food, Drug and Cosmetic Act;

(6) For each subsequent shipment of a legend drug that is imported into this state by such participating wholesaler, and sampled and tested pursuant to subdivision (5) of this subsection, ensure that a qualified laboratory engaged by such participating wholesaler tests a statistically valid sample of such legend drug in such shipment for authenticity and degradation in a manner that is consistent with the Food, Drug and Cosmetic Act, and quarantine such shipment until the results of such

test conducted pursuant to this subdivision indicate that such legend drug is consistent with its labeling;

(7) Certify to the Commissioner of Consumer Protection that each legend drug imported into this state under the importation program:

(A) Is approved for marketing in the United States and not adulterated or misbranded; and

(B) Meets all labeling requirements under 21 USC 352, as amended from time to time;

(8) Maintain laboratory records, including, but not limited to, complete data derived from all tests necessary to ensure that each legend drug imported into this state under the importation program satisfies the requirements of subdivisions (5) and (6) of this subsection;

(9) Maintain documentation demonstrating that the testing required by subdivisions (5) and (6) of this subsection was conducted at a qualified laboratory in accordance with the Food, Drug and Cosmetic Act and all other applicable federal and state laws and regulations concerning laboratory qualifications;

(10) Maintain the following information for each legend drug that such participating wholesaler imports and distributes in this state under the importation program, and submit such information to the Commissioner of Consumer Protection upon request by the commissioner:

(A) The name and quantity of the active ingredient of such legend drug;

(B) A description of the dosage form of such legend drug;

(C) The date on which such participating wholesaler received such legend drug;

(D) The quantity of such legend drug that such participating

wholesaler received;

(E) The point of origin and destination of such legend drug;

(F) The price paid by such participating wholesaler for such legend drug;

(G) A report for each legend drug that fails laboratory testing under subdivision (5) or (6) of this subsection; and

(H) Such additional information and documentation that the commissioner deems necessary to ensure the protection of the public health;

(11) Ensure that any legend drug that fails laboratory testing under subdivision (5) or (6) of this subsection is appropriately quarantined and destroyed; and

(12) Maintain all information and documentation that is submitted to the Commissioner of Consumer Protection pursuant to this subsection for a period of not less than three years.

Sec. 8. (NEW) (*Effective July 1, 2022*) Each participating Canadian supplier shall:

(1) Comply with all applicable track-and-trace requirements;

(2) Not distribute, dispense or sell outside of this state any legend drugs that are imported into this state under the importation program; and

(3) Maintain the following information and documentation and, upon request by the Commissioner of Consumer Protection, submit such information and documentation to the commissioner for each legend drug that such participating Canadian supplier exports into this state under the importation program:

(A) The original source of such legend drug, including, but not

limited to:

(i) The name of the manufacturer of such legend drug;

(ii) The date on which such legend drug was manufactured; and

(iii) The location where such legend drug was manufactured;

(B) The date on which such legend drug was shipped to a participating wholesaler;

(C) The quantity of such legend drug that was shipped to a participating wholesaler;

(D) The quantity of each lot of such legend drug that such participating Canadian supplier originally received and the source of such lot;

(E) The lot or control number and the batch number assigned to such legend drug by the manufacturer; and

(F) Such additional information and documentation that the commissioner deems necessary to ensure the protection of the public health.

Sec. 9. (NEW) (*Effective July 1, 2022*) (a) The Commissioner of Consumer Protection shall issue a written order:

(1) Suspending importation and distribution of a legend drug under the importation program if the commissioner discovers that such importation or distribution violates any provision of sections 6 to 8, inclusive, of this act or any other applicable state or federal law or regulation;

(2) Suspending all importation and distribution of legend drugs by a participating wholesaler under the importation program if the commissioner discovers that the participating wholesaler has violated any provision of section 6 or 7 of this act or any other applicable state or

federal law or regulation;

(3) Suspending all importation and distribution of legend drugs by a participating Canadian supplier under the importation program if the commissioner discovers that the participating Canadian supplier has violated any provision of section 6 or 8 of this act or any other applicable state or federal law or regulation;

(4) Requiring the quarantine, recall or seizure of any legend drug that was imported and distributed under the importation program if such legend drug has been identified as adulterated, within the meaning of section 21a-105 of the general statutes, or misbranded; or

(5) Requiring retesting, at the expense of the participating wholesaler and by a laboratory approved by the commissioner, of any legend drug distributed by the participating wholesaler if the commissioner deems such retesting necessary.

(b) The Commissioner of Consumer Protection shall send a notice to each participating Canadian supplier and participating wholesaler affected by an order issued pursuant to subsection (a) of this section notifying such participating Canadian supplier or participating wholesaler that:

(1) The commissioner has issued such order, and providing the legal and factual basis for such order; and

(2) Such participating Canadian supplier or participating wholesaler may request, in writing, a hearing before the commissioner, provided such request is received by the commissioner not later than thirty days after the date of such notice.

(c) If a participating Canadian supplier or participating wholesaler timely requests a hearing pursuant to subsection (b) of this section, the Commissioner of Consumer Protection shall, not later than thirty days after the receipt of the request, convene the hearing as a contested case in accordance with the provisions of chapter 54 of the general statutes.

Not later than sixty days after the receipt of such request, the commissioner shall issue a final decision vacating, modifying or affirming the commissioner's order. If the participating Canadian supplier or participating wholesaler is aggrieved by such final decision, such participating Canadian supplier or participating wholesaler may appeal such decision in accordance with the provisions of section 4-183 of the general statutes.

Sec. 10. (NEW) (*Effective July 1, 2022*) The Commissioner of Consumer Protection may, in consultation with the Commissioner of Public Health, adopt regulations in accordance with the provisions of chapter 54 of the general statutes to implement the provisions of sections 5 to 9, inclusive, of this act.

This act shall take effect as follows and shall amend the following sections:		
Section 1	*July 1, 2022*	New section
Sec. 2	*July 1, 2022*	New section
Sec. 3	*July 1, 2022*	New section
Sec. 4	*July 1, 2022*	New section
Sec. 5	*July 1, 2022*	New section
Sec. 6	*July 1, 2022*	New section
Sec. 7	*July 1, 2022*	New section
Sec. 8	*July 1, 2022*	New section
Sec. 9	*July 1, 2022*	New section
Sec. 10	*July 1, 2022*	New section

INS *Joint Favorable Subst.*

APP *Joint Favorable*