LRB093 16557 DRJ 42203 b

93RD GENERAL ASSEMBLY

State of Illinois

2003 and 2004

HB4624

Introduced 02/04/04, by Kathleen A. Ryg, Jack D. Franks

SYNOPSIS AS INTRODUCED:

New Act	
225 ILCS 85/4	from Ch. 111, par. 4124
225 ILCS 120/15	from Ch. 111, par. 8301-15
320 ILCS 50/10	
410 ILCS 620/16	from Ch. 56 1/2, par. 516
720 ILCS 570/102	from Ch. 56 1/2, par. 1102
740 ILCS 20/3	from Ch. 70, par. 903

Creates the Drug Repository Program Act. Requires the Department of Public Health to establish a drug repository program to accept and dispense prescription drugs donated for the purpose of being dispensed to Illinois residents who meet eligibility standards adopted by the Department. Provides for donations of drugs by drug manufacturers and health care facilities. Prohibits the acceptance of drugs with an expiration date less than 6 months from the date the drug is donated. Provides immunity from civil and criminal liability for persons who donate, accept, or dispense drugs in accordance with the program. Amends the Pharmacy Practice Act of 1987, the Wholesale Drug Distribution Licensing Act, the Senior Pharmaceutical Assistance Act, the Illinois Food, Drug and Cosmetic Act, the Illinois Controlled Substances Act, and the Cannabis and Controlled Substances Tort Claims Act to provide that persons engaged in donating or accepting, or packaging, repackaging, or labeling, prescription drugs to the extent permitted or required under the Drug Repository Program Act are exempt from provisions of those other Acts that might prohibit or otherwise regulate such activity.

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FISCAL NOTE ACT
MAY APPLY

A BILL FOR

AN ACT concerning health.

Be it enacted by the People of the State of Illinois, represented in the General Assembly:

Section 1. Short title. This Act may be cited as the Drug Repository Program Act.

Section 5. Definitions. In this Act:

"Department" means the Department of Public Health.

"Health care facility" means a hospital, nursing home, physician's office, or other location at which medical or health care services are provided.

"Health care professional" means any of the following who provide medical, dental, or other health-related diagnosis, care, or treatment:

(1) A physician licensed to practice medicine in all of its branches.

(2) A person licensed under the Podiatric Medical Practice Act of 1987.

(3) A registered nurse or licensed practical nurse licensed under the Nursing and Advanced Practice Nursing Act.

(4) A physician assistant licensed under the Physician Assistant Practice Act of 1987.

(5) A dentist or dental hygienist licensed under the Illinois Dental Practice Act.

(6) An optometrist licensed under the Illinois Optometric Practice Act of 1987.

(7) A pharmacist licensed under the Pharmacy Practice Act of 1987.

"Hospital" means a hospital licensed under the Hospital Licensing Act or subject to the University of Illinois Hospital Act.

"Nonprofit clinic" means any charitable organization not

organized and not operated for profit that provides health care services to indigent and uninsured persons. "Nonprofit clinic" does not include a hospital or a facility that is operated for profit.

"Nursing home" means a facility licensed under the Nursing Home Care Act.

"Pharmacy" has the meaning ascribed to that term in the Pharmacy Practice Act of 1987.

"Prescription drug" means any drug to which the following applies:

(1) Under the "Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, the drug is required to bear a label containing the legend, "Caution: Federal law prohibits dispensing without prescription" or "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian" or any similar restrictive statement, or the drug may be dispensed only upon a prescription.

(2) The drug may be dispensed only upon a prescription.

"Program" means the drug repository program established under this Act.

Section 10. Drug repository program. The Department shall establish a drug repository program to accept and dispense prescription drugs donated for the purpose of being dispensed to individuals who are residents of this State and meet eligibility standards established in rules adopted by the Department under Section 30. Only drugs in their original sealed and tamper-evident unit dose packaging may be accepted and dispensed. The packaging must be unopened, except that drugs packaged in single unit doses may be accepted and dispensed when the outside packaging is opened if the single unit dose packaging is undisturbed. Drugs donated by individuals bearing an expiration date that is less than 6 months from the date the drug is donated shall not be accepted

or dispensed. A drug shall not be accepted or dispensed if there is reason to believe that it is adulterated as described in the Illinois Food, Drug and Cosmetic Act. Subject to the limitation specified in this Act, unused drugs dispensed for purposes of the medical assistance program under Article V of the Illinois Public Aid Code may be accepted and dispensed under the drug repository program.

Section 15. Donations of prescription drugs.

(a) Any person, including a drug manufacturer or health care facility, may donate prescription drugs to the program. The drugs must be donated at a pharmacy, hospital, or nonprofit clinic that elects to participate in the program and meets criteria for participation in the program established in rules adopted by the Department under Section 30.

(b) Participation in the program by pharmacies, hospitals, and nonprofit clinics is voluntary. Nothing in this Act requires a pharmacy, hospital, or nonprofit clinic to participate in the program.

Section 20. Dispensing of donated drugs.

(a) A pharmacy, hospital, or nonprofit clinic eligible to participate in the program shall dispense drugs donated under this Act to individuals who are residents of this State and meet the eligibility standards established in rules adopted by the Department under Section 30 or to other government entities and nonprofit private entities to be dispensed to individuals who meet the eligibility standards. A drug may be dispensed only pursuant to a prescription issued by a licensed health care professional authorized to prescribe drugs.

(b) A pharmacy, hospital, or nonprofit clinic that accepts donated drugs shall comply with all applicable federal laws and laws of this State dealing with storage and distribution of dangerous drugs and shall inspect all drugs prior to dispensing them to determine that they are not adulterated as described in the Illinois Food, Drug and Cosmetic Act.

(c) The pharmacy, hospital, or nonprofit clinic may charge individuals receiving donated drugs a handling fee established in accordance with rules adopted by the Department under Section 30.

(d) Drugs donated to the repository may not be resold.

Section 25. Immunity.

(a) The following are immune from civil or criminal liability and from professional disciplinary action or other administrative liability in connection with their good faith conduct related to the donation, acceptance, or dispensing of drugs under the program:

(1) The Department of Public Health and its officers, employees, and agents.

(2) Any person, including a drug manufacturer, or government entity that donates drugs to the program.

(3) Any pharmacy, hospital, nonprofit clinic, or health care professional that accepts or dispenses drugs under the program.

(4) Any pharmacy, hospital, or nonprofit clinic that employs a health care professional who accepts or dispenses drugs under the program.

(b) A drug manufacturer is immune from civil or criminal liability for its good faith conduct related to the donation, acceptance, or dispensing of a drug manufactured by the drug manufacturer that is donated by any person under the program, including but not limited to liability for failure to transfer or communicate product or consumer information or the expiration date of the donated drug.

Section 30. Rules. The Department of Public Health shall adopt rules governing the program. The rules shall include, but need not be limited to, the following:

(1) Eligibility criteria for pharmacies, hospitals, and nonprofit clinics to receive and dispense donated drugs under the program.

(2) Standards and procedures for accepting, safely storing, and dispensing donated drugs.

(3) Standards and procedures for inspecting donated drugs to determine that the original unit dose packaging is sealed and tamper-evident and that the drugs are unadulterated, safe, and suitable for dispensing.

(4) Eligibility standards based on economic need for individuals to receive drugs.

(5) A means, such as an identification card, by which an individual who is eligible to receive donated drugs may demonstrate eligibility to the pharmacy, hospital, or nonprofit clinic dispensing the drugs.

(6) A form that an individual receiving a drug from the repository must sign before receiving the drug to confirm that the individual understands the immunity provisions of the program.

(7) A formula to determine the amount of a handling fee that pharmacies, hospitals, and nonprofit clinics may charge to drug recipients to cover restocking and dispensing costs.

(8) For drugs donated to the repository by individuals:

(A) A list of drugs, arranged either by category or by individual drug, that the repository will accept from individuals.

(B) A list of drugs, arranged either by category or by individual drug, that the repository will not accept from individuals. The list must include a statement as to why the drug is ineligible for donation.

(C) A form each donor must sign stating that the donor is the owner of the drugs and intends to voluntarily donate them to the repository.

(9) For drugs donated to the repository by health care facilities:

(A) A list of drugs, arranged either by category or by individual drug, that the repository will accept from health care facilities.

(B) A list of drugs, arranged either by category or by individual drug, that the repository will not accept from health care facilities. The list must include a statement as to why the drug is ineligible for donation.

(10) Any other standards and procedures the Department considers appropriate.

Section 90. The Pharmacy Practice Act of 1987 is amended by changing Section 4 as follows:

(225 ILCS 85/4) (from Ch. 111, par. 4124)

(Section scheduled to be repealed on January 1, 2008)

Sec. 4. Exemptions. Nothing contained in any Section of this Act shall apply to, or in any manner interfere with:

(a) the lawful practice of any physician licensed to practice medicine in all of its branches, dentist, podiatrist, veterinarian, or therapeutically or diagnostically certified optometrist within the limits of his or her license, or prevent him or her from supplying to his or her bona fide patients such drugs, medicines, or poisons as may seem to him appropriate;

(b) the sale of compressed gases;

(c) the sale of patent or proprietary medicines and household remedies when sold in original and unbroken packages only, if such patent or proprietary medicines and household remedies be properly and adequately labeled as to content and usage and generally considered and accepted as harmless and nonpoisonous when used according to the directions on the label, and also do not contain opium or coca leaves, or any compound, salt or derivative thereof, or any drug which, according to the latest editions of the following authoritative pharmaceutical treatises and standards, namely, The United States Pharmacopoeia/National Formulary (USP/NF), the United States Dispensatory, and the Accepted Dental Remedies of the Council of Dental Therapeutics of the American Dental Association or any or either of them, in use on the effective

date of this Act, or according to the existing provisions of the Federal Food, Drug, and Cosmetic Act and Regulations of the Department of Health and Human Services, Food and Drug Administration, promulgated thereunder now in effect, is designated, described or considered as a narcotic, hypnotic, habit forming, dangerous, or poisonous drug;

(d) the sale of poultry and livestock remedies in original and unbroken packages only, labeled for poultry and livestock medication;

(e) the sale of poisonous substances or mixture of poisonous substances, in unbroken packages, for nonmedicinal use in the arts or industries or for insecticide purposes; provided, they are properly and adequately labeled as to content and such nonmedicinal usage, in conformity with the provisions of all applicable federal, state and local laws and regulations promulgated thereunder now in effect relating thereto and governing the same, and those which are required under such applicable laws and regulations to be labeled with the word "Poison", are also labeled with the word "Poison" printed thereon in prominent type and the name of a readily obtainable antidote with directions for its administration;

(f) the delegation of limited prescriptive authority by a physician licensed to practice medicine in all its branches to a physician assistant under Section 7.5 of the Physician Assistant Practice Act of 1987. This delegated authority may but is not required to include prescription of Schedule III, IV, or V controlled substances, as defined in Article II of the Illinois Controlled Substances Act, in accordance with written guidelines under Section 7.5 of the Physician Assistant Practice Act of 1987; ~~and~~

(g) the ~~The~~ delegation of limited prescriptive authority by a physician licensed to practice medicine in all its branches to an advanced practice nurse in accordance with a written collaborative agreement under Sections 15-15 and 15-20 of the Nursing and Advanced Practice Nursing Act. This delegated authority may but is not required to include the prescription

of Schedule III, IV, or V controlled substances as defined in Article II of the Illinois Controlled Substances Act; and.

(h) the donation or acceptance, or the packaging, repackaging, or labeling, of prescription drugs to the extent permitted or required under the Drug Repository Program Act.

(Source: P.A. 90-116, eff. 7-14-97; 90-253, eff. 7-29-97; 90-655, eff. 7-30-98; 90-742, eff. 8-13-98.)

Section 91. The Wholesale Drug Distribution Licensing Act is amended by changing Section 15 as follows:

(225 ILCS 120/15) (from Ch. 111, par. 8301-15)

(Section scheduled to be repealed on January 1, 2013)

Sec. 15. Definitions. As used in this Act:

"Blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

"Blood component" means that part of blood separated by physical or mechanical means.

"Board" means the State Board of Pharmacy of the Department of Professional Regulation.

"Department" means the Department of Professional Regulation.

"Director" means the Director of Professional Regulation.

"Drug sample" means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.

"Manufacturer" means anyone who is engaged in the manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription drug. "Manufacturer" does not include anyone who is engaged in the packaging, repackaging, or labeling of prescription drugs only to the extent required under the Drug Repository Program Act.

"Person" means and includes a natural person, partnership, association or corporation.

"Pharmacy distributor" means any pharmacy licensed in this

State or hospital pharmacy that is engaged in the delivery or distribution of prescription drugs either to any other pharmacy licensed in this State or to any other person or entity including, but not limited to, a wholesale drug distributor engaged in the delivery or distribution of prescription drugs who is involved in the actual, constructive, or attempted transfer of a drug in this State to other than the ultimate consumer except as otherwise provided for by law.

"Prescription drug" means any human drug required by federal law or regulation to be dispensed only by a prescription, including finished dosage forms and active ingredients subject to subsection (b) of Section 503 of the Federal Food, Drug and Cosmetic Act.

"Wholesale distribution" or "wholesale distributions" means distribution of prescription drugs to persons other than a consumer or patient, but does not include any of the following:

(a) Intracompany sales, defined as any transaction or transfer between any division, subsidiary, parent, or affiliated or related company under the common ownership and control of a corporate entity.

(b) The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of a group organization.

(c) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in subsection (c)(3) of Section 501 of the U.S. Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law.

(d) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities that are under common control. For

purposes of this Act, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, contract, or otherwise.

(e) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons. For purposes of this Act, "emergency medical reasons" include transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage.

(f) The sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription.

(g) The distribution of drug samples by manufacturers' representatives or distributors' representatives.

(h) The sale, purchase, or trade of blood and blood components intended for transfusion.

(i) The donation of prescription drugs to the extent permitted under the Drug Repository Program Act.

"Wholesale drug distributor" means any person or entity engaged in wholesale distribution of prescription drugs, including, but not limited to, manufacturers; repackers; own label distributors; jobbers; private label distributors; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions, including, but not limited to, any pharmacy distributor as defined in this Section. A wholesale drug distributor shall not include any for hire carrier or person or entity hired solely to transport prescription drugs.

(Source: P.A. 87-594.)

Section 92. The Senior Pharmaceutical Assistance Act is amended by changing Section 10 as follows:

(320 ILCS 50/10)

Sec. 10. Definitions. In this Act:

"Manufacturer" includes:

(1) An entity that is engaged in (a) the production, preparation, propagation, compounding, conversion, or processing of prescription drug products (i) directly or indirectly by extraction from substances of natural origin, (ii) independently by means of chemical synthesis, or (iii) by combination of extraction and chemical synthesis; or (b) the packaging, repackaging, labeling or re-labeling, or distribution of prescription drug products.

(2) The entity holding legal title to or possession of the national drug code number for the covered prescription drug.

The term does not include a wholesale distributor of drugs, drugstore chain organization, or retail pharmacy licensed by the State. <u>The term also does not include anyone who is engaged in the packaging, repackaging, or labeling of prescription drugs only to the extent required under the Drug Repository Program Act.</u>

"Prescription drug" means a drug that may be dispensed only upon prescription by an authorized prescriber and that is approved for safety and effectiveness as a prescription drug under Section 505 or 507 of the Federal Food, Drug and Cosmetic Act.

"Senior citizen" or "senior" means a person 65 years of age or older.

(Source: P.A. 92-594, eff. 6-27-02.)

Section 93. The Illinois Food, Drug and Cosmetic Act is amended by changing Section 16 as follows:

(410 ILCS 620/16) (from Ch. 56 1/2, par. 516)

Sec. 16. (a) The Director is hereby authorized to promulgate regulations exempting from any labeling or

packaging requirement of this Act drugs and devices which are (i), in accordance with the practice of the trade, to be processed, labeled or repacked in substantial quantities at establishments other than those where originally processed or packaged on condition that such drugs and devices are not adulterated or misbranded under the provisions of this Act upon removal from such processing, labeling or repacking establishment or (ii) packaged, repackaged, or labeled to the extent required under the Drug Repository Program Act.

(b) Drugs and device labeling or packaging exemptions adopted under the Federal Act and supplements thereto or revisions thereof shall apply to drugs and devices in Illinois except insofar as modified or rejected by regulations promulgated by the Director.

(c) A drug intended for use by man which (A) is a habit-forming drug to which Section 15 (d) applies; or (B) because of its toxicity or other potentiality for harmful effect or the method of its use or the collateral measures necessary to its use is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or (C) is limited by an approved application under Section 505 of the Federal Act or Section 17 of this Act to use under the professional supervision of a practitioner licensed by law to administer such drug, shall be dispensed only in accordance with the provisions of the "Illinois Controlled Substances Act". The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in a drug being misbranded while held for sale.

(d) Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt from the requirements of Section 15, except subsections (a), (k) and (l) and clauses (2) and (3) of subsection (i), and the packaging requirements of subsections (g), (h) and (q), if the drug bears a label containing the proprietary name or names, or if there is none, the established name or names of the drugs, the dosage and

quantity, unless the prescribing practitioner, in the interest of the health of the patient, directs otherwise in writing, the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber and, if stated in the prescription, the name of the patient, and the directions for use and the cautionary statements, if any, contained in such prescription. This exemption shall not apply to any drug dispensed in the course of the conduct of business of dispensing drugs pursuant to diagnosis by mail, or to a drug dispensed in violation of subsection (a) of this Section.

(e) The Director may by regulation remove drugs subject to Section 15 (d) and Section 17 from the requirements of subsection (c) of this Section when such requirements are not necessary for the protection of the public health.

(f) A drug which is subject to subsection (c) of this Section shall be deemed to be misbranded if at any time before dispensing its label fails to bear the statement "Caution: Federal Law Prohibits Dispensing Without Prescription" or "Caution: State Law Prohibits Dispensing Without Prescription". A drug to which subsection (c) of this Section does not apply shall be deemed to be misbranded if at any time prior to dispensing its label bears the caution statement quoted in the preceding sentence.

(g) Nothing in this Section shall be construed to relieve any person from any requirement prescribed by or under authority of law with respect to controlled substances now included or which may hereafter be included within the classifications of controlled substances cannabis as defined in applicable Federal laws relating to controlled substances or cannabis or the Cannabis Control Act.

(Source: P.A. 84-1308.)

Section 94. The Illinois Controlled Substances Act is amended by changing Section 102 as follows:

(720 ILCS 570/102) (from Ch. 56 1/2, par. 1102)

Sec. 102. Definitions. As used in this Act, unless the context otherwise requires:

(a) "Addict" means any person who habitually uses any drug, chemical, substance or dangerous drug other than alcohol so as to endanger the public morals, health, safety or welfare or who is so far addicted to the use of a dangerous drug or controlled substance other than alcohol as to have lost the power of self control with reference to his addiction.

(b) "Administer" means the direct application of a controlled substance, whether by injection, inhalation, ingestion, or any other means, to the body of a patient, research subject, or animal (as defined by the Humane Euthanasia in Animal Shelters Act) by:

(1) a practitioner (or, in his presence, by his authorized agent),

(2) the patient or research subject at the lawful direction of the practitioner, or

(3) a euthanasia technician as defined by the Humane Euthanasia in Animal Shelters Act.

(c) "Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser. It does not include a common or contract carrier, public warehouseman or employee of the carrier or warehouseman.

(c-1) "Anabolic Steroids" means any drug or hormonal substance, chemically and pharmacologically related to testosterone (other than estrogens, progestins, and corticosteroids) that promotes muscle growth, and includes:

(i) boldenone,

(ii) chlorotestosterone,

(iii) chostebol,

(iv) dehydrochlormethyltestosterone,

(v) dihydrotestosterone,

(vi) drostanolone,

(vii) ethylestrenol,

(viii) fluoxymesterone,

(ix) formebulone,

(x) mesterolone,

(xi) methandienone,

(xii) methandranone,

(xiii) methandriol,

(xiv) methandrostenolone,

(xv) methenolone,

(xvi) methyltestosterone,

(xvii) mibolerone,

(xviii) nandrolone,

(xix) norethandrolone,

(xx) oxandrolone,

(xxi) oxymesterone,

(xxii) oxymetholone,

(xxiii) stanolone,

(xxiv) stanozolol,

(xxv) testolactone,

(xxvi) testosterone,

(xxvii) trenbolone, and

(xxviii) any salt, ester, or isomer of a drug or substance described or listed in this paragraph, if that salt, ester, or isomer promotes muscle growth.

Any person who is otherwise lawfully in possession of an anabolic steroid, or who otherwise lawfully manufactures, distributes, dispenses, delivers, or possesses with intent to deliver an anabolic steroid, which anabolic steroid is expressly intended for and lawfully allowed to be administered through implants to livestock or other nonhuman species, and which is approved by the Secretary of Health and Human Services for such administration, and which the person intends to administer or have administered through such implants, shall not be considered to be in unauthorized possession or to unlawfully manufacture, distribute, dispense, deliver, or possess with intent to deliver such anabolic steroid for purposes of this Act.

(d) "Administration" means the Drug Enforcement

Administration, United States Department of Justice, or its successor agency.

(e) "Control" means to add a drug or other substance, or immediate precursor, to a Schedule under Article II of this Act whether by transfer from another Schedule or otherwise.

(f) "Controlled Substance" means a drug, substance, or immediate precursor in the Schedules of Article II of this Act.

(g) "Counterfeit substance" means a controlled substance, which, or the container or labeling of which, without authorization bears the trademark, trade name, or other identifying mark, imprint, number or device, or any likeness thereof, of a manufacturer, distributor, or dispenser other than the person who in fact manufactured, distributed, or dispensed the substance.

(h) "Deliver" or "delivery" means the actual, constructive or attempted transfer of possession of a controlled substance, with or without consideration, whether or not there is an agency relationship. <u>The term does not include the donation of prescription drugs to the extent permitted under the Drug Repository Program Act.</u>

(i) "Department" means the Illinois Department of Human Services (as successor to the Department of Alcoholism and Substance Abuse) or its successor agency.

(j) "Department of State Police" means the Department of State Police of the State of Illinois or its successor agency.

(k) "Department of Corrections" means the Department of Corrections of the State of Illinois or its successor agency.

(l) "Department of Professional Regulation" means the Department of Professional Regulation of the State of Illinois or its successor agency.

(m) "Depressant" or "stimulant substance" means:

(1) a drug which contains any quantity of (i) barbituric acid or any of the salts of barbituric acid which has been designated as habit forming under section 502 (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352 (d)); or

(2) a drug which contains any quantity of (i) amphetamine or methamphetamine and any of their optical isomers; (ii) any salt of amphetamine or methamphetamine or any salt of an optical isomer of amphetamine; or (iii) any substance which the Department, after investigation, has found to be, and by rule designated as, habit forming because of its depressant or stimulant effect on the central nervous system; or

(3) lysergic acid diethylamide; or

(4) any drug which contains any quantity of a substance which the Department, after investigation, has found to have, and by rule designated as having, a potential for abuse because of its depressant or stimulant effect on the central nervous system or its hallucinogenic effect.

(n) (Blank).

(o) "Director" means the Director of the Department of State Police or the Department of Professional Regulation or his designated agents.

(p) "Dispense" means to deliver a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a prescriber, including the prescribing, administering, packaging, labeling, or compounding necessary to prepare the substance for that delivery.

(q) "Dispenser" means a practitioner who dispenses.

(r) "Distribute" means to deliver, other than by administering or dispensing, a controlled substance.

(s) "Distributor" means a person who distributes.

(t) "Drug" means (1) substances recognized as drugs in the official United States Pharmacopoeia, Official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; (2) substances intended for use in diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals; (3) substances (other than food) intended to affect the structure of any function of the body of man or animals and (4) substances intended for use as a component of any article specified in clause (1), (2), or

(3) of this subsection. It does not include devices or their components, parts, or accessories.

(t-5) "Euthanasia agency" means an entity certified by the Department of Professional Regulation for the purpose of animal euthanasia that holds an animal control facility license or animal shelter license under the Animal Welfare Act. A euthanasia agency is authorized to purchase, store, possess, and utilize Schedule II nonnarcotic and Schedule III nonnarcotic drugs for the sole purpose of animal euthanasia.

(t-10) "Euthanasia drugs" means Schedule II or Schedule III substances (nonnarcotic controlled substances) that are used by a euthanasia agency for the purpose of animal euthanasia.

(u) "Good faith" means the prescribing or dispensing of a controlled substance by a practitioner in the regular course of professional treatment to or for any person who is under his treatment for a pathology or condition other than that individual's physical or psychological dependence upon or addiction to a controlled substance, except as provided herein: and application of the term to a pharmacist shall mean the dispensing of a controlled substance pursuant to the prescriber's order which in the professional judgment of the pharmacist is lawful. The pharmacist shall be guided by accepted professional standards including, but not limited to the following, in making the judgment:

(1) lack of consistency of doctor-patient relationship,

(2) frequency of prescriptions for same drug by one prescriber for large numbers of patients,

(3) quantities beyond those normally prescribed,

(4) unusual dosages,

(5) unusual geographic distances between patient, pharmacist and prescriber,

(6) consistent prescribing of habit-forming drugs.

(u-1) "Home infusion services" means services provided by a pharmacy in compounding solutions for direct administration to a patient in a private residence, long-term care facility, or

hospice setting by means of parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion.

(v) "Immediate precursor" means a substance:

(1) which the Department has found to be and by rule designated as being a principal compound used, or produced primarily for use, in the manufacture of a controlled substance;

(2) which is an immediate chemical intermediary used or likely to be used in the manufacture of such controlled substance; and

(3) the control of which is necessary to prevent, curtail or limit the manufacture of such controlled substance.

(w) "Instructional activities" means the acts of teaching, educating or instructing by practitioners using controlled substances within educational facilities approved by the State Board of Education or its successor agency.

(x) "Local authorities" means a duly organized State, County or Municipal peace unit or police force.

(y) "Look-alike substance" means a substance, other than a controlled substance which (1) by overall dosage unit appearance, including shape, color, size, markings or lack thereof, taste, consistency, or any other identifying physical characteristic of the substance, would lead a reasonable person to believe that the substance is a controlled substance, or (2) is expressly or impliedly represented to be a controlled substance or is distributed under circumstances which would lead a reasonable person to believe that the substance is a controlled substance. For the purpose of determining whether the representations made or the circumstances of the distribution would lead a reasonable person to believe the substance to be a controlled substance under this clause (2) of subsection (y), the court or other authority may consider the following factors in addition to any other factor that may be relevant:

(a) statements made by the owner or person in control

of the substance concerning its nature, use or effect;

(b) statements made to the buyer or recipient that the substance may be resold for profit;

(c) whether the substance is packaged in a manner normally used for the illegal distribution of controlled substances;

(d) whether the distribution or attempted distribution included an exchange of or demand for money or other property as consideration, and whether the amount of the consideration was substantially greater than the reasonable retail market value of the substance.

Clause (1) of this subsection (y) shall not apply to a noncontrolled substance in its finished dosage form that was initially introduced into commerce prior to the initial introduction into commerce of a controlled substance in its finished dosage form which it may substantially resemble.

Nothing in this subsection (y) prohibits the dispensing or distributing of noncontrolled substances by persons authorized to dispense and distribute controlled substances under this Act, provided that such action would be deemed to be carried out in good faith under subsection (u) if the substances involved were controlled substances.

Nothing in this subsection (y) or in this Act prohibits the manufacture, preparation, propagation, compounding, processing, packaging, advertising or distribution of a drug or drugs by any person registered pursuant to Section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360).

(y-1) "Mail-order pharmacy" means a pharmacy that is located in a state of the United States, other than Illinois, that delivers, dispenses or distributes, through the United States Postal Service or other common carrier, to Illinois residents, any substance which requires a prescription.

(z) "Manufacture" means the production, preparation, propagation, compounding, conversion or processing of a controlled substance, either directly or indirectly, by extraction from substances of natural origin, or independently

by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling of its container, except that this term does not include:

(1) by an ultimate user, the preparation or compounding of a controlled substance for his own use; or

(2) by a practitioner, or his authorized agent under his supervision, the preparation, compounding, packaging, or labeling of a controlled substance:

(a) as an incident to his administering or dispensing of a controlled substance in the course of his professional practice; or

(b) as an incident to lawful research, teaching or chemical analysis and not for sale; or.

(3) the packaging, repackaging, or labeling of prescription drugs only to the extent required under the Drug Repository Program Act.

(z-1) "Methamphetamine manufacturing chemical" means any of the following chemicals or substances containing any of the following chemicals: benzyl methyl ketone, ephedrine, methyl benzyl ketone, phenylacetone, phenyl-2-propanone, pseudoephedrine, or red phosphorous or any of the salts, optical isomers, or salts of optical isomers of the above-listed chemicals.

(aa) "Narcotic drug" means any of the following, whether produced directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(1) opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate;

(2) any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in clause (1), but not including the isoquinoline alkaloids of opium;

(3) opium poppy and poppy straw;

(4) coca leaves and any salts, compound, isomer, salt of an isomer, derivative, or preparation of coca leaves including cocaine or ecgonine, and any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, but not including decocainized coca leaves or extractions of coca leaves which do not contain cocaine or ecgonine (for the purpose of this paragraph, the term "isomer" includes optical, positional and geometric isomers).

(bb) "Nurse" means a registered nurse licensed under the Nursing and Advanced Practice Nursing Act.

(cc) (Blank).

(dd) "Opiate" means any substance having an addiction forming or addiction sustaining liability similar to morphine or being capable of conversion into a drug having addiction forming or addiction sustaining liability.

(ee) "Opium poppy" means the plant of the species Papaver somniferum L., except its seeds.

(ff) "Parole and Pardon Board" means the Parole and Pardon Board of the State of Illinois or its successor agency.

(gg) "Person" means any individual, corporation, mail-order pharmacy, government or governmental subdivision or agency, business trust, estate, trust, partnership or association, or any other entity.

(hh) "Pharmacist" means any person who holds a certificate of registration as a registered pharmacist, a local registered pharmacist or a registered assistant pharmacist under the Pharmacy Practice Act of 1987.

(ii) "Pharmacy" means any store, ship or other place in which pharmacy is authorized to be practiced under the Pharmacy Practice Act of 1987.

(jj) "Poppy straw" means all parts, except the seeds, of the opium poppy, after mowing.

(kk) "Practitioner" means a physician licensed to practice medicine in all its branches, dentist, podiatrist,

veterinarian, scientific investigator, pharmacist, physician assistant, advanced practice nurse, licensed practical nurse, registered nurse, hospital, laboratory, or pharmacy, or other person licensed, registered, or otherwise lawfully permitted by the United States or this State to distribute, dispense, conduct research with respect to, administer or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

(ll) "Pre-printed prescription" means a written prescription upon which the designated drug has been indicated prior to the time of issuance.

(mm) "Prescriber" means a physician licensed to practice medicine in all its branches, dentist, podiatrist or veterinarian who issues a prescription, a physician assistant who issues a prescription for a Schedule III, IV, or V controlled substance in accordance with Section 303.05 and the written guidelines required under Section 7.5 of the Physician Assistant Practice Act of 1987, or an advanced practice nurse with prescriptive authority in accordance with Section 303.05 and a written collaborative agreement under Sections 15-15 and 15-20 of the Nursing and Advanced Practice Nursing Act.

(nn) "Prescription" means a lawful written, facsimile, or verbal order of a physician licensed to practice medicine in all its branches, dentist, podiatrist or veterinarian for any controlled substance, of a physician assistant for a Schedule III, IV, or V controlled substance in accordance with Section 303.05 and the written guidelines required under Section 7.5 of the Physician Assistant Practice Act of 1987, or of an advanced practice nurse who issues a prescription for a Schedule III, IV, or V controlled substance in accordance with Section 303.05 and a written collaborative agreement under Sections 15-15 and 15-20 of the Nursing and Advanced Practice Nursing Act.

(oo) "Production" or "produce" means manufacture, planting, cultivating, growing, or harvesting of a controlled substance.

(pp) "Registrant" means every person who is required to

register under Section 302 of this Act.

(qq) "Registry number" means the number assigned to each person authorized to handle controlled substances under the laws of the United States and of this State.

(rr) "State" includes the State of Illinois and any state, district, commonwealth, territory, insular possession thereof, and any area subject to the legal authority of the United States of America.

(ss) "Ultimate user" means a person who lawfully possesses a controlled substance for his own use or for the use of a member of his household or for administering to an animal owned by him or by a member of his household.

(Source: P.A. 92-449, eff. 1-1-02; 93-596, eff. 8-26-03; 93-626, eff. 12-23-03.)

Section 95. The Cannabis and Controlled Substances Tort Claims Act is amended by changing Section 3 as follows:

(740 ILCS 20/3) (from Ch. 70, par. 903)

Sec. 3. Definitions. As used in this Act, unless the context otherwise requires:

"Cannabis" includes marihuana, hashish, and other substances that are identified as including any parts of the plant Cannabis Sativa, whether growing or not, the seeds of that plant, the resin extracted from any part of that plant, and any compound, manufacture, salt, derivative, mixture, or preparation of that plant, its seeds, or resin, including tetrahydrocannabinol (THC) and all other cannabinol derivatives, including its naturally occurring or synthetically produced ingredients, whether produced directly or indirectly by extraction, independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis. "Cannabis" does not include the mature stalks of that plant, fiber produced from those stalks, oil or cake made from the seeds of that plant, any other compound, manufacture, salt, derivative, mixture, or preparation of mature stalks

(except the extracted resin), fiber, oil or cake, or the sterilized seeds of that plant that are incapable of germination.

"Controlled substance" means a drug, substance, or immediate precursor in the Schedules of Article II of the Illinois Controlled Substances Act.

"Counterfeit substance" means a controlled substance or the container or labeling of a controlled substance that, without authorization, bears the trademark, trade name, or other identifying mark, imprint, number, device, or any likeness thereof of a manufacturer, distributor, or dispenser other than the person who in fact manufactured, distributed, or dispensed the substance.

"Deliver" or "delivery" means the actual, constructive, or attempted transfer of possession of a controlled substance or cannabis, with or without consideration, whether or not there is an agency relationship. The term does not include the donation of prescription drugs to the extent permitted under the Drug Repository Program Act.

"Manufacture" means the production, preparation, propagation, compounding, conversion, or processing of a controlled substance, either directly or indirectly, by extraction from substances of natural origin, independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling of its container, except that the term does not include:

(1) by an ultimate user, the preparation or compounding of a controlled substance for his own use;

(2) by a practitioner or his authorized agent under his supervision, the preparation, compounding, packaging, or labeling of a controlled substance:~~;~~

(A) as an incident to his administering or dispensing of a controlled substance in the course of his professional practice; or

(B) as an incident to lawful research, teaching or

chemical analysis and not for sale; ~~or~~

(3) the preparation, compounding, packaging, or labeling of cannabis as an incident to lawful research, teaching, or chemical analysis and not for sale; or~~.~~

(4) the packaging, repackaging, or labeling of prescription drugs only to the extent required under the Drug Repository Program Act.

"Owner" means a person who has possession of or any interest whatsoever in the property involved.

"Person" means an individual, a corporation, a government, a governmental subdivision or agency, a business trust, an estate, a trust, a partnership or association, or any other entity.

"Production" means planting, cultivating, tending, or harvesting.

"Property" means real property, including things growing on, affixed to, and found in land, and tangible or intangible personal property, including rights, services, privileges, interests, claims, and securities.

(Source: P.A. 87-544.)