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HOUSE BILL NO. 96

Offered January 10, 1996

A BILL to amend and reenact § 54.1-3401 of the Code of Virginia, relating to the Drug Control Act.

Patron—Morgan

Referred to Committee on Health, Welfare and Institutions

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-3401 of the Code of Virginia is amended and reenacted as follows:

§ 54.1-3401. Definitions.

As used in this chapter, unless the context requires a different meaning:

"Administer" means the direct application of a controlled substance, whether by injection, inhalation, ingestion or any other means, to the body of a patient or research subject by (i) a practitioner or by his authorized agent and under his direction, or (ii) the patient or research subject at the direction and in the presence of the practitioner.

"Advertisement" means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of drugs or devices.

"Anabolic steroid" means any drug or hormonal substance, chemically and pharmacologically related to testosterone, other than estrogens, progestins, and corticosteroids, that promotes muscle growth.

"Animal" means any nonhuman animate being endowed with the power of voluntary action.

"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.

"Board" means the Board of Pharmacy.

"Compound" means the taking of two or more ingredients and fabricating them into a single preparation, usually referred to as a dosage form.

"Controlled substance" means a drug, substance or immediate precursor in Schedules I through VI of this chapter. The term shall not include distilled spirits, wine, malt beverages, or tobacco as those terms are defined or used in Title 3.1 or Title 4.1.

"Cosmetic" means all articles intended to be rubbed, poured, sprinkled or sprayed on, introduced into or otherwise applied to the human body for cleansing, beautifying, promoting attractiveness or altering the appearance, and articles intended for use as a component of any such articles except soap.

"DEA" means the Drug Enforcement Administration, United States Department of Justice, or its successor agency.

"Deliver" or "delivery" means the actual, constructive, or attempted transfer of any item regulated by this chapter, whether or not there exists an agency relationship.

"Device" means instruments, apparatus, and contrivances, including their components, parts and accessories, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals or to affect the structure or any function of the body of man or animals.

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

"Dispenser" means a practitioner who dispenses.

"Distribute" means to deliver other than by administering or dispensing a controlled substance.

"Distributor" means a person who distributes.

"Drug" means (i) articles or substances recognized in the official United States Pharmacopoeia National Formulary or official Homeopathic Pharmacopoeia of the United States, or any supplement to any of them; (ii) articles or substances intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or animals; (iii) articles or substances, other than food, intended to affect the structure or any function of the body of man or animals; or (iv) articles or substances intended for use as a component of any article specified in clause (i), (ii) or (iii). "Drug" does not include devices or their components, parts or accessories.

"Hashish oil" means any oily extract containing one or more cannabinoids, but shall not include any such extract with a tetrahydrocannabinol content of less than twelve percent by weight.

"Immediate precursor" means a substance which the Board of Pharmacy has found to be and by regulation designates as being the principal compound commonly used or produced primarily for use, and which is an immediate chemical intermediary used or likely to be used in the manufacture of a

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

"Label" means a display of written, printed or graphic matter upon the immediate container of any article. A requirement made by or under authority of this chapter that any word, statement or other information appear on the label shall not be considered to be complied with unless such word, statement or other information also appears on the outside container or wrapper, if any, of the retail package of such article, or is easily legible through the outside container or wrapper.

"Labeling" means all labels and other written, printed or graphic matter on an article or any of its containers or wrappers, or accompanying such article.

"Manufacture" means the production, preparation, propagation, compounding, conversion or processing of any item regulated by this chapter, 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 or relabeling of its container. This term does not include the preparing, compounding, packaging or labeling of a controlled substance by a practitioner as an incident to his administering or dispensing of a controlled substance or marijuana in the course of his professional practice, or by a practitioner, or by his authorized agent under his supervision, for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale.

"Manufacturer" means every person who manufactures.

"Marijuana" means any part of a plant of the genus Cannabis whether growing or not, its seeds or resin; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds, or its resin. ~~Marijuana shall not include~~ *Unless mixed or intermingled with marijuana as defined herein, the following substances shall not constitute marijuana: (i)* any oily extract containing one or more cannabinoids unless such extract contains less than twelve percent of tetrahydrocannabinol by weight~~, or~~ *; (ii)* the mature stalks of such plant~~,~~*; (iii)* fiber produced from such stalk~~,~~*; (iv)* oil or cake made from the seeds of such plant~~,~~*; (v)* any other compound, manufacture, salt, derivative, mixture or preparation of such mature stalks, fiber, oil, or cake~~,~~*;* or *(vi)* the sterilized seed of such plant which is incapable of germination.

"Medical equipment supplier" means any person, as defined in § 1-13.19, engaged in the delivery to the ultimate consumer, pursuant to the lawful order of a practitioner, of hypodermic syringes and needles, medicinal oxygen, Schedule VI controlled devices, and those Schedule VI controlled substances with no medicinal properties which are used for the operation and cleaning of medical equipment.

"Narcotic drug" means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis: (i) opium, opiates, and any salt, compound, derivative, or preparation of opium or opiates; (ii) any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in clause (i), but not including the isoquinoline alkaloids of opium; (iii) opium poppy and poppy straw; (iv) coca leaves and any salt, compound, derivative, or preparation of coca leaves, 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 extraction of coca leaves which do not contain cocaine or ecgonine.

"New drug" means: (i) any drug, except a new animal drug or an animal feed bearing or containing a new animal drug, the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to the enactment of this chapter it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or (ii) any drug, except a new animal drug or an animal feed bearing or containing a new animal drug, the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

"Official compendium" means the official United States Pharmacopoeia National Formulary, official Homeopathic Pharmacopoeia of the United States, or any supplement to any of them.

"Official written order" means an order written on a form provided for that purpose by the United States Drug Enforcement Administration, under any laws of the United States making provision therefor, if such order forms are authorized and required by federal law, and if no such order form is provided then on an official form provided for that purpose by the Board of Pharmacy.

"Opiate" means any substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability. It does not include, unless specifically designated as controlled under

Article 4 (§ 54.1-3437 et seq.) of this chapter, the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts (dextromethorphan). It does include its racemic and levorotatory forms.

"Opium poppy" means the plant of the species Papaver somniferum L., except the seeds thereof.

"Original package" means the unbroken container or wrapping in which any drug or medicine is enclosed together with label and labeling, put up by or for the manufacturer, wholesaler, or distributor for use in the delivery or display of such article.

"Person" means both the plural and singular, as the case demands, and includes individual, partnership, corporation, association, governmental agency, trust, or other institution or entity.

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

"Practitioner" means a physician, dentist, licensed nurse practitioner pursuant to § 54.1-2957.01, licensed physician's assistant pursuant to § 54.1-2952.1, veterinarian, scientific investigator, or other person licensed, registered or otherwise permitted to distribute, dispense, prescribe and administer, or conduct research with respect to, a controlled substance in the course of professional practice or research in this Commonwealth.

"Prescription" means an order for drugs or medical supplies, written or signed or transmitted by word of mouth, telephone, telegraph or other means of communication to a pharmacist by a duly licensed physician, dentist, veterinarian or other practitioner, authorized by law to prescribe and administer such drugs or medical supplies.

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

"Production" or "produce" includes the manufacture, planting, cultivation, growing or harvesting of a controlled substance or marijuana.

"Proprietary medicine" means a completely compounded nonprescription drug in its unbroken, original package which does not contain any controlled substance or marijuana as defined in this chapter and is not in itself poisonous, and which is sold, offered, promoted or advertised directly to the general public by or under the authority of the manufacturer or primary distributor, under a trademark, trade name or other trade symbol privately owned, and the labeling of which conforms to the requirements of this chapter and applicable federal law. However, this definition shall not include a drug which is only advertised or promoted professionally to licensed practitioners, a narcotic or drug containing a narcotic, a drug which may be dispensed only upon prescription or the label of which bears substantially the statement "Warning - may be habit-forming," or a drug intended for injection.

"Sale" includes barter, exchange, or gift, or offer therefor, and each such transaction made by any person, whether as individual, proprietor, agent, servant or employee.

"Warehouser" means any person, other than a wholesale distributor, engaged in the business of selling or otherwise distributing prescription drugs or devices to any person who is not the ultimate user or consumer. No person shall be subject to any state or local tax by reason of this definition.

"Wholesale distribution" means distribution of prescription drugs to persons other than consumers or patients, subject to the exceptions set forth in § 54.1-3401.1.

"Wholesale distributor" means any person engaged in wholesale distribution of prescription drugs including, but not limited to, manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses conducting wholesale distributions, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies conducting wholesale distributions. No person shall be subject to any state or local tax as a wholesale merchant by reason of this definition.

The words "drugs" and "devices" as used in Chapter 33 (§ 54.1-3300 et seq.) of this title and in this chapter shall not include surgical or dental instruments, physical therapy equipment, X-ray apparatus or glasses or lenses for the eyes.

The terms "pharmacist," "pharmacy" and "practice of pharmacy" as used in this chapter shall be defined as provided in Chapter 33 of this title unless the context requires a different meaning.

2. That the provisions of this act may result in a net increase in periods of imprisonment in state correctional facilities. Pursuant to § 30-19.1:4, the estimated amount of the necessary appropriation is $0.