# REPORT OF THE PHARMACY AND DRUG LAWS STUDY COMMITTEE TO THE GOVERNOR



HD20

COMMONWEALTH OF VIRGINIA Department of Purchases and Supply Richmond 1970

## MEMBERS OF THE COMMITTEE

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## To: HONORABLE MILLS E. GODWIN, JR.

Governor of Virginia

#### Dear Governor:

It is an honor to transmit herewith the Report of your Committee directed to study and make recommendations with respect to the pharmacy and drug laws of the Commonwealth.

The Committee met regularly for the past 13 months. All meetings have been open. The first several sessions were widely advertised and a number of persons and representatives from various organizations appeared and offered suggestions. Additionally, staff and individual committeemen gave an unusual amount of time in study, travel and research.

The Committee sought information from sister states, professional societies and the federal government. Laws, regulations and proposals were researched.

The greatest problem area appeared to be drug abuse, the illicit use of drugs —with marijuana leading the list and causing the most concern.

Areas of specific interest that received considerable attention were:

Reorganization of the several sections of the Pharmacy and Drug Act into one chapter for logical sequence and understanding;

Educational requirements for pharmacists, including college, practical experience and continuing education;

Licensing of pharmacists including examinations and reciprocity with other states;

Drug diversion—the breakdown in normal channels of distribution whereby a useful drug finds its way into non-professional hands and illegal use;

Comprehensive studies of present penalties for drug violations, including a comparison of our present laws with those of sister states, and those in effect and under consideration by the federal government.

The result of these studies suggests our greatest problem to be in the area of drug abuse especially with respect to marijuana. This market is fed by illicit drugs and legal drugs that have been diverted.

Your Committee therefore set about to improve and update the Pharmacy and Drug Act as it concerns the practice of Pharmacy and the distribution of legitimate drugs, with particular attention given to the problem of illicit drug traffic.

Our recommendations are included in the proposed legislation submitted here-

Some of the more significant proposals are:

1. Continuing education requirement for pharmacists. To fulfill his obligation as a professional the pharmacist must continue his education throughout his years of practice or he will fail to meet his obligations to the public in the ever changing drug armamentarium. Encouragement by professional societies has failed to persuade a satisfactory percentage of practicing pharmacists to avail themselves of these educational opportunities. We therefore recommend a requirement in this area to be enforced by the Board.

2. Licensing physicians to practice pharmacy. Under current law any licensed physician is authorized to obtain a permit to practice pharmacy if he practices in a town of less than 1,000 population. The original intent of this provision was to provide for exceptional situations where no pharmaceutical service was available. However, in recent years and particularly since Medicaid, increasing numbers

of physicians are securing these permits in areas where pharmaceutical service is reasonably available. Abuses in this area are evident in the administration of the government sponsored medical care programs. We propose that the Board be authorized to determine when the public interest requires that a physician be authorized to practice pharmacy.

3. Drug Classification. The several special laws covering narcotics, dangerous drugs, abuse drugs and others have been brought under one heading and divided into schedules. Each schedule is defined according to appropriate scientific criteria. Such classifications tend to conform with those established by the federal government. These classifications characterize the potential for abuse and afford a rational guideline for the various penalty provisions.

Under the proposed law, scheduled drugs can be dispensed only by pharmacists or licensed practitioners. Not included in the scheduled drugs are a host of over-the-counter drugs which are subject to abuse and contain ingredients with potential harmful effects. In this State there is presently no adequate restriction on the sale of these drugs. It is the unanimous view of this committee that the present availability of these drugs presents a grave threat to the public health; and the Committee is also of the opinion that where these drugs are available, a pharmacist should be present to consult with the consumer to prevent misuse and abuse.

It is apparent to the Committee that any proposed restriction on the sale of these drugs will arouse opposition from diverse economic interests which might overshadow the numerous significant proposals here offered for consideration. For this reason, no regulation of these drugs is contained in these proposals; but, we have attached a suggested amendment to the legislation proposed by this Report which will effect this regulation.

It is the hope of the Committee that the General Assembly will give serious consideration to this problem.

4. *Penalties.* Conflicting opinions were expressed as to the degree of penalty in the area of drug abuse—particularly for the first offender. We believe the penalties suggested are appropriate and wish to call your attention to the provisions for "Conditional Discharge for Possession as First Offense". This provision would permit a court latitude in certain cases where usual penalties appear too severe, and where rehabilitation appears probable, for the first offender.

In general, our proposed changes in penalties for violation of this chapter have three effects: (1) to provide greater discretion for judges in assessing punishment, (2) to reduce somewhat the penalty for simple possession of certain drugs, and (3) to deal with greater severity with those violators who traffic in illegal drugs.

5. *Licenses.* Fees for pharmacies, wholesalers and manufacturers have been increased. Better controls for licensure are recommended that will result in more effective prevention of drug diversion from legitimate to illicit markets. The responsibility of the licensed pharmacist-in-charge is clearly defined.

6. Mail order prescriptions and advertising. Mail order prescriptions disregard the physician-patient-pharmacist relationship, and are prohibited in the proposed legislation.

The Board of Pharmacy, having administered the pharmacy and drug laws since 1886 and having discharged its duties with distinction, is the logical agency to continue effective application of any new laws in this area. We believe that our Board and the M.C.V. School of Pharmacy are instrumental factors in making the profession of pharmacy, as practiced in Virginia, among the most respected in the country. Working with the State Police and federal agencies when necessary, the Board of Pharmacy has and continues to be highly effective. Division of responsibilities in drug control could bring about a less efficient system. We believe that the Board should be strengthened where desirable but should be continued as the agency with prime responsibility for drug control. The Committee wishes to acknowledge and express its appreciation for the services of staff counsel, David T. Walker; State Board of Pharmacy Secretary, J. B. Carson; M.C.V. School of Pharmacy Dean, Warren E. Weaver; all of whom made invaluable contributions to the work of the Committee. The legal division of the American Pharmaceutical Association is also cited for its research and information as to similar legislation among other states and Congressional activities, past and present.

We hope the proposed legislation included herewith will be favorably received by the Legislature.

We, the Committee, are pleased to have had the honor to serve the Commonwealth in this capacity.

Respectfully submitted,

J. CURTIS NOTTINGHAM, *Chairman* LLOYD C. BIRD WILLIAM R. COGAR CHARLES F. KINGERY WALLACE S. KLEIN, JR. IVAN E. ROOP, JR. R. MACLIN SMITH W. ROY SMITH WALLACE B. THACKER C. EUGENE WHITE

## APPENDIX

# LEGISLATIVE PROPOSALS

- I. Basic Drug Control Act
- II. Recommended amendment to add provision on sales of over-the-counter drugs.

A BILL to amend the Code of Virginia by adding a new chapter numbered 15.1 in Title 54 consisting of sections 54-524.1 through 54-524.109, enacting The Drug Control Act, relating to the Virginia State Board of Pharmacy, appointments, number and term of members, regulations, examinations, licensing of pharmacists and physicians, distribution of drugs, classification of drugs, misbranding and adulteration of drugs, prohibited acts and penalties therefore; to repeal Chapter 15 in Title 54 consisting of sections 54-399 through 54-524, as amended, of the Code of Virginia, relating to pharmacists and drugs and matters referred to above.

Be it enacted by the General Assembly of Virginia:

1. That the Code of Virginia be amended by adding a new chapter numbered 15.1 in Title 54 consisting of sections 54-524.1 through 54-524.109, as follows:

### CHAPTER 15.1

## The Drug Control Act

## ARTICLE 1.

### General Provisions

§ 54-524.1. This Chapter may be cited as "The Drug Control Act."

§ 54-524.2. (a) Finding.—The practice of pharmacy in the State of Virginia is declared a professional practice affecting the public health, safety and welfare and is subject to regulation and control in the public interest.

(b) Definitions—As used in this chapter, unless the context otherwise indi-

(1) "Administer" means the giving of a dose of a drug to a patient for his immediate need, either by a practitioner or by his authorized agent under the direction of the practitioner.

(2) "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, devices or cosmetics.

(3) "Animal" means any animate being, which is not human, endowed with the power of voluntary action.

(4) "Board" means the State Board of Pharmacy.

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

(6) "Controlled drug" means a drug, or substance in Schedules I through V of article 6 of this Act. 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 of the Code of Virginia.

(7) "Cosmetic" means all (a) articles intended to be rubbed, poured, sprinkled or sprayed on, introduced into or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness or altering the appearance, and (b) articles intended for use as a component of any such articles; except that such term shall not include soap.

(8) "Deliver" or "delivery" means the actual, constructive, or attempted transfer of a controlled drug, whether or not there exists an agency relationship.

(9) "Device" means instruments, apparatus, and contrivances, including their components, parts and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals.

(10) "Dispense" means the issuing of one or more doses of a drug or a device in a suitable container, appropriately labeled, for subsequent administration to or use by a patient.

(11) "Distribute" means to deliver a controlled drug. "Distributor" means a person who delivers a controlled drug.

(12) "Drug" means (a) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; (b) articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals; (c) articles, other than food, intended to affect the structure or any function of the body of man or other animals; and (d) articles intended for use as a component of any article specified in clause (a), (b) or (c); but does not include devices.

(13) "Label" means a display of written, printed or graphic matter upon the immediate container of any article; and 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 there be, of the retail package of such article, or is easily legible through the outside container or wrapper.

(14) "Labeling" means all labels and other written, printed or graphic matter (a) upon an article or any of its containers or wrappers, or (b) accompanying such article.

(15) "Manufacturer" means every person who produces, derives, prepares, processes, compounds or packages drugs, devices, or cosmetics, or repackages or otherwise changes the container or the labeling for purposes of sale or other disposition to any person who is not the ultimate user or consumer.

(16) "Marijuana" means all parts of the plant Cannabis sativa L., whether growing or not; the seeds thereof, the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin; but shall not include the mature stalks of such plant, fiber produced from such stalk, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination.

(17) "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:

(a) opium, coca leaves, and opiates;

(b) a compound, manufacture, salt, derivative, or preparation of opium, coca leaves, or opiates;

(c) a substance (and any compound, manufacture, salt, derivative, or preparation thereof) which is chemically identical with any of the substances referred to in clauses (a) and (b), except that the words "narcotic drug" as used in this chapter shall not include decocainized coca leaves or extracts of coca leaves, which extracts do not contain cocaine or ecgonine.

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

(19) "Official written order" means an order written on a form provided for that purpose by the United States Bureau of Narcotics and Dangerous Drugs, 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 State Board of Pharmacy.

(20) "Opiate" means any controlled drug 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.

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

(22) "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.

(23) "Person" shall be construed to import both the plural and singular, as the case demands, and includes individual, partnership, corporation, association, governmental agency, trust, or other institution or entity.

(24) "Pharmacist" means a natural person who holds a valid license issued by the Board to practice pharmacy under the laws of this State.

(25) "Pharmacy" shall mean every place or establishment, except manufacturers and distributors or as hereinafter provided, in which prescriptions or drugs are prepared, compounded, dispensed, repackaged or relabeled.

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

(27) "Practitioner" means a physician, dentist, veterinarian, or other person licensed in this State to prescribe or administer drugs or devices which are subject to this chapter.

(28) "Prescription" shall mean and include 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 or to a patient by a duly licensed physician, dentist, veterinarian or other practitioner, licensed by law to prescribe and administer such drugs or medical supplies.

(29) "Production" or "produce" includes the manufacture, planting, cultivation, growing, or harvesting of a controlled drug.

(30) "Proprietary medicine" means a completely compounded non-prescription drug in its unbroken, original package which does not contain any controlled drug 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 thereof, 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; provided that this definition shall not include (a) a drug which is only advertised or promoted professionally to licensed practitioners, (b) a narcotic or drug containing a narcotic, (c) a drug which may be dispensed only upon prescription or the label of which bears substantially the statement "Warning—may be habit-forming," or (d) a drug intended for injection.

(31) "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.

(32) "Wholesaler" or "distributor" means every person, except a manufacturer, engaged in the business of distributing, supplying, selling or otherwise disposing of drugs or medicines to any person who is not the ultimate user or consumer; provided that no person shall be subject to any State or local tax as a wholesale merchant by reason of this definition.

§ 54-524.3. Disposition of fines and fees.—All fines and fees collected under this chapter shall be paid into the State treasury.

§ 54-524.4. Chapter not applicable to economic poisons.—Nothing in this chapter shall be construed to apply to economic poisons used for the control of insects, animals pests, weeds, fungus diseases or other substances sold for use in agricultural, horticultural or related arts and sciences (provided such substances which are poisons within the meaning of this chapter are sold in original unbroken packages bearing a label having plainly printed upon it the name of the contents and the word POISON and an effective antidote) nor to any person, persons, cor-

porations or associations engaged in the business of selling, making, compounding or manufacturing industrial chemicals for distribution or sale at wholesale or for making, compounding or manufacturing other products therefrom.

#### ARTICLE 2.

#### Board of Pharmacy

§ 54-524.5. Board continued.—The State Board of Pharmacy, in this chapter sometimes called the Board, is continued.

§ 54-524.6. Appointment and Qualifications of members; terms and vacancies.—The Board shall consist of five members, each of whom shall be a registered pharmacist and a graduate of an approved school or college of pharmacy, to be appointed by the Governor, each for a term of five years from June thirtieth of the year of appointment. Their terms shall continue to be so arranged that the term of one of them expires each year; and all vacancies occurring on the Board shall be filled by the Governor.

§ 54-524.7. Nominations by Virginia Pharmaceutical Association.—Each appointment on the Board may be made from a list of at least five names for each vacancy sent to the Governor by the Virginia Pharmaceutical Association. Nominations are to be made to the Governor by June first of each year. The Governor shall notify the Association promptly of any vacancy other than by expiration and like nominations may be made for the filling of the vacancy. In no case shall the Governor be bound to make any appointment from among the nominees of the Association.

§ 54-524.8. Oath of office.—Every person appointed a member of the Board shall, before entering upon the duties of his office, take the oath of office before some officer authorized to administer an oath, and file the certificate of the oath with the secretary-treasurer of the Board.

§ 54-524.9. Limitation on number of terms.—No person shall be eligible to serve for or during more than two successive terms, and incumbency during the term in force on June twenty-fourth, nineteen hundred and forty-four constitutes the first of the two successive terms with respect to eligibility for appointment.

§ 54-524.10. Removal of members.—The Governor may remove any member of the Board for misconduct, incapacity or neglect of duty and he shall be the sole judge of the sufficiency of the cause for removal. He shall report every such removal at once to the General Assembly if it is in session, and, if not, at the beginning of the next session.

§ 54-524.11. Officers and terms of office.—There shall be a president of the Board, who shall be selected by the Board from its own members; a secretarytreasurer who shall be someone other than a member of the Board, qualified under the Personnel Act, selected by the lawful board at time of selection to serve as their executive officer. The president shall hold office for a period of one year from his election and qualification, or until his successor is elected and qualified. The tenure of office of the secretary-treasurer shall be the same as that for State classified personnel under the State Personnel Act.

§ 54-524.12. Bond of secretary-treasurer.—The secretary-treasurer of the Board shall give bond for the faithful performance of the duties of his office in such penalty and with such security as may be approved by the Board.

§ 54-524.13. Meetings of Board; quorum.—The Board shall hold its annual meetings on the fourth Monday in April of each year, in the city of Richmond, Virginia, and such other meetings at such times and places, and upon such notice as the Board may determine and as its business may require. Three members of the Board shall constitute a quorum for the transaction of business.

§ 54-524.14. Expenses of Board.—The expenses incurred by the Board in the discharge of the duties imposed upon it shall be paid out of the treasury of the Commonwealth.

§ 54-524.15. Compensation.—The salary of the secretary-treasurer shall be fixed by the Board subject to provisions of Chapter 10 (Section 2.1-110 et seq.) of Title 2.1. Each member of the Board shall be paid the sum of twenty-five dollars for every day he is actually engaged in its service, and shall be reimbursed for such actual and legitimate expenses as he may incur in going to and from the place of meeting and remaining thereat during the sessions of the Board.

§ 54-524.16. Powers and duties of Board generally.—The Board shall regulate the practice of pharmacy and the manufacturing, dispensing, selling, distributing, processing, compounding, or other disposal of drugs, cosmetics and devices, control the character and standard of all drugs, cosmetics and devices within the State, investigate all complaints as to the quality and strength of all drugs, cosmetics and devices and take such action as may be necessary to prevent the manufacturing, dispensing, selling, distributing, processing, compounding and other disposal of such drugs, cosmetics and devices as do not conform to the requirement of law.

The Board may engage and pay for such professional and other services as it may deem necessary in investigating violations of the law, and the enforcement of its provisions. The Board may transact all business relating to the practice of pharmacy.

§ 54-524.17. Bylaws, rules and regulations.—The Board may, subject to the provisions of Chapter 1.1 (§ 9-6.1 et seq.) of Title 9 of the Code, make such rules and regulations, not inconsistent with the laws of the State, as may be necessary for the lawful exercise of its powers.

§ 54-524.18. The Board may collect and examine specimens of drugs, devices and cosmetics manufactured, stored or dispensed in this State.

§ 54-524.19. The members of the Board and their duly authorized agents shall have the power to inspect in a lawful manner the drugs, cosmetics and devices which are manufactured, stored or dispensed in the State, and for this purpose shall have the right to enter and inspect during business hours any pharmacy, or any other place in the State of Virginia where drugs, cosmetics or devices are manufactured, stored or dispensed. The Board shall report any evidence of violation of the previsions of this chapter by practitioners of medicine, homeopthy, osteopathy, chiropractic, naturopathy, chiropody (podiatry) or physical therapy, to the Board of Medical Examiners for action by it.

§ 54-524.20. Annual report.—The Board shall render annually to the Governor a report of its proceedings, including receipts and disbursements, during the preceding year.

# ARTICLE 3.

#### Licenses and Permits

§ 54-524.21. Qualifications of pharmacist.—In order to be licensed and registered as a pharmacist within the meaning of this chapter, an applicant shall present to the Board satisfactory evidence that he is at least twenty-one years of age; of good moral character; that he is a graduate in pharmacy of a school of pharmacy approved by the State Board of Pharmacy; that he is a citizen of the United States of America, and that he has had a suitable period of experience acceptable to the Board. The period of practical experience required under this section shall not exceed twelve months.

§ 54-524.22. The Board of Pharmacy shall not grant a license or permit to any applicant if satisfied that the safety of the public health will be endangered by

reasons of the habits or character of the applicant. If any person shall have obtained a license or permit by misrepresentation or fraud, or shall become unfit or incompetent by reason of negligence, habits, unprofessional conduct, or other cause, or if any licensee shall violate any of the provisions of law relating to pharmacy or the regulations established by the Board, the Board may revoke or suspend such license or permit upon sufficient evidence of such violation, after giving such licensee reasonable notice and an opportunity to be heard in accordance with Chapter 1.1 (§ 9-6.1 et seq.) of Title 9 of the Code, which may be in addition to any other punishment imposed by law for such violation.

§ 54-524.23. Every person desiring to be licensed by examination as a pharmacist shall file with the secretary-treasurer of the Board an application, duly verified under oath, setting forth the name and age of the applicant, the place or places at which, and the time spent in, the study of the science and art of pharmacy.

Every applicant for original licensure by examination as a pharmacist shall pay to the secretary-treasurer of the Board the sum of fifty dollars.

§ 54-524.24. The applicant for licensure by examination as a pharmacist shall appear at the time and place designated by the Board and submit to an examination as to his qualifications for such licensure. The Board shall conduct examinations of applicants for licensure when so determined by the Board, and not less frequently than once in six months.

§ 54-524.25. The Board may issue a license to be known as that of "pharmacist." If the applicant has complied with all the requirements of this article, the Board shall enroll his name upon the register of pharmacists and issue him such license.

§ 54-524.26. The Board of Pharmacy may issue temporary or probationary licenses to practice pharmacy in this State for a period of not less than one year, without examination, to such persons as have been legally licensed as pharmacists in other states, the District of Columbia and territories of the United States; provided that the applicant for such license shall present satisfactory evidence of the qualifications equal to those required of applicants for licensure by examination in this State and that he was licensed by examination by the Board of Pharmacy in such other state, District or territory, and that the standard of competence required in such other state, District or territory, is not lower than that required in this State; provided, further, that the Board may issue a regular license at the end of one year of practice to those applicants whose qualifications are in accordance with the regulations established by the Board.

The fee for issuance of such a license shall be one hundred dollars, which shall be forwarded by applicants with their applications to the secretary-treasurer of the Board.

§ 54-524.27. The Board shall also require and provide for the annual renewal of every pharmacist's license in this State, and charge and receive the sum of ten dollars for each such renewal. The Board shall not renew a certificate or licensure until the applicant gives evidence of his qualifications for relicensure. Such qualifications may be established by written or oral examination, or participation in at least twenty-five hours of continuing education programs in pharmaceutical sciences, including but not limited to graduate studies, seminars, lectures, conferences, workshops or such other forms of continuing education as may be approved by the Board.

§ 54-524.28. Whenever the Board shall revoke the license of any pharmacist, it shall notify the licensed person of such action, and he shall immediately deliver his license to the Board, or its representative.

§ 54-524.29. Recognition and recording of licenses.—The Board of Pharmacy shall recognize all licenses issued by former boards of this State and make and keep a record of all licenses issued by it. Such records shall be open to inspection by any citizen of this State.

§ 54-524.30.—Every person licensed to practice as a pharmacist must at all times display his license conspicuously in the place in which he regularly practices under such license.

 $\S$  54-524.31. (a) No person shall conduct a pharmacy without first obtaining a permit from the Board.

(b) The application for such permit shall be made on a form provided by the Board and signed by a pharmacist who will be in full and actual charge of the pharmacy and who will be fully engaged in the practice of pharmacy at the location designated on the application.

(c) The application shall show the corporate name and/or trade name and shall list any pharmacist in addition to the pharmacist-in-charge practicing at the location indicated on the application.

(d) If the owner is other than the pharmacist making the application, the type of ownership shall be indicated and shall list any partner or partners, and, if a corporation, then the corporate officers and directors.

(e) The permit shall be issued only to the pharmacist who signs the application as the pharmacist-in-charge and as such assumes the full responsibilities for the legal operation of the pharmacy. Provided, however, that nothing contained herein shall be construed to negate any responsibility of any pharmacist or other person.

(f) Upon termination of practice by the pharmacist-in-charge, or upon any change in partnership composition, or upon the acquisition of the existing corporation by another person, the permit previously issued shall be surrendered to the Board by the pharmacist-in-charge and an application for a new permit may be made in accordance with the requirements of this chapter.

(g) The pharmacist to whom such permit is issued shall provide safeguards against diversion of all controlled drugs.

(h) An application for a pharmacy permit shall be accompanied by a fee of twenty-five dollars. All permits shall expire on December thirty-first of each year.

(i) Every pharmacy must be equipped so that prescriptions can be properly filled. The Board of Pharmacy shall prescribe the minimum of such professional and technical equipment, which a pharmacy shall at all times possess, and such list shall include the latest revisions of the United States Pharmacopoeia and the National Formulary. No permit shall be issued or continued for the conduct of a pharmacy until or unless the provisions of this chapter, and regulations promulgated by the Board have been complied with.

§ 54-524.32. Appeal from revocation of permit.—Any person who may feel himself aggrieved at the revocation of his permit may appeal from the action of the Board as provided by Chapter 1.1 (§ 9-6.1 et seq.) of Title 9 of the Code of Virginia.

§ 54-524.33. In addition to the remedy provided in Section 54-432.1 or any other remedies at law, the Board may apply to a court of equity of the proper venue for an injunction to restrain any person, partnership, corporation, or other type of firm, from the practice of pharmacy in violation of any regulation of the Board or any law regulating the practice of pharmacy. The Board shall not be compelled to allege or prove that an adequate remedy at law does not exist.

§ 54-524.34. For good cause shown the Board may grant a license to any physician regularly licensed under the laws of Virginia which license shall authorize such physician to dispense drugs to persons to whom a pharmaceutical service is not reasonably available; such license may be renewed annually in which event

the Board shall charge the sum of twenty-five dollars for the issuance of each such license or renewal thereof.

§ 54-524.35. When pharmacist considered guilty of unprofessional conduct. —Any pharmacist shall be considered guilty of unprofessional conduct who (1) is found guilty of any crime involving grave moral turpitude, or is guilty of fraud or deceit in obtaining a certificate of registration; or (2) is an habitual drunkard or habitually addicted to the use of Schedule I, Schedule II, Schedule III or Schedule V drugs; or (3) issues, publishes, broadcasts by radio, or otherwise, or distributes or uses in any way whatsoever advertising matter in which statements are made about his professional service which have a tendency to deceive or defraud the public, contrary to the public health and welfare; or (4) publishes, advertises or promotes, directly or indirectly, in any manner whatsoever, any amount, price, fee, premium, discount, rebate or credit terms for professional services or for drugs containing narcotics or for any drugs which may be dispensed only by prescription.

§ 54-524.36. It shall be lawful to manufacture, make, produce, pack, package, repackage, relabel or prepare any drug not controlled by Schedule I, dentifrice, cosmetic or device after first obtaining the appropriate permit from the Board. Such permits shall be subject to such regulations, with respect to sanitation, equipment, and safeguards against diversion as the Board may from time to time adopt for the protection of the public health and safety. This provision shall not apply to manufacturers or packers of medicated feeds who manufacture or package no other drugs and no cosmetics.

§ 54-524.37. No drugs, dentifrices, cosmetics or devices shall be manufactured, made, produced, packed, packaged, repackaged, relabeled or prepared within this State, except under the personal and immediate supervision of a pharmacist or such other person as may be approved by the State Board of Pharmacy after an investigation and a determination by the Board that they are qualified by scientific or technical training to perform such duties or supervision as may be necessary to protect the public health and safety, except that this provision shall not apply to manufacturers or packers of medicated feeds who manufacture or pack no other drugs and no cosmetics. Medicated feeds are hereby defined as products obtained by mixing a commercial feed and a drug.

§ 54-524.38. Display of permit.—Permits issued under the provisions of this article shall be exposed in a conspicuous place in the factory or place for which issued.

§ 54-524.39. Such permits shall not be transferable and shall be renewed annually as provided in § 54-524.40 through 54-524.43.

§ 54-524.40. Every person desiring to manufacture any drug, cosmetic, dentifrice, or device controlled by this Chapter shall apply to the Board for a Class A manufacturing permit on a form prescribed by the Board. The application shall be accompanied by the required fee of fifty dollars which shall also be paid as the fee for renewal of such permit. Separate applications shall be made and separate permits issued for each specific place of manufacturing.

§ 54-524.41. No person shall be granted a Class A permit as a manufacturer unless he is of good moral character and properly equipped as to land, buildings, equipment and safeguards against diversion to carry out the functions of a manufacturer with due regard to the protection of the public safety.

§ 54-524.42. Every person desiring to manufacture any drug not controlled by Article VI of this Chapter, cosmetics, dentifrices or devices shall apply to the Board for a Class B manufacturing permit on a form prescribed by the Board. The application shall be accompanied by the required fee of thirty-five dollars which shall also be paid as the fee for renewal of such permit. Separate applications shall be made and separate permits issued for each separate place of manufacturing. § 54-524.43. No person shall be granted a Class B permit as a manufacturer unless he is of good moral character and properly equipped as to land, buildings and equipment to carry out the functions of a manufacturer with due regard to the protection of the public safety.

§ 54-524.44. Every person desiring to act as a wholesaler or distributor as defined in paragraph (32) of § 54-524.2 in this State shall (1) apply to the Board for a permit so to do; (2) renew such permit, if granted, each year and (3) remit a fee of thirty-five dollars payable January first of each year with application for such permit, such permit fee to be prorated quarterly in equal amounts.

§ 54-524.45. No person shall be granted a permit as a wholesaler or distributor unless he is of good moral character and properly equipped as to land, building and equipment to carry out the functions of a wholesaler or distributor with due regard to the protection of the public. The Board may adopt such regulations as may be necessary to prevent diversion and to protect the public in the storage, handling, and distribution by wholesalers or distributors of drugs subject to the requirements of this chapter.

Application for such permit shall not be required of manufacturers of drugs and medicines and cosmetics who are subject to § 54-524.36. Nor shall it be required of wholesalers or distributors of medicated feeds, insecticides, fungicides and rodenticides properly registered as provided by law.

§ 54-524.46. The Board may revoke a permit issued to a manufacturer, wholesaler or distributor for failure to comply with its regulations promulgated pursuant to the provisions of § 54-524.36 or § 54-524.44, or for failure to comply with any provision of this chapter; such revocation to be in accordance with Chapter 1.1 (§ 9-6.1 et seq.) of Title 9 of the Code.

§ 54-524.47. Nothing in this article shall be construed to apply to the proprietor of a pharmacy if the products manufactured or purchased are dispensed within the premises and not sold for distribution and resale outside the premises.

## ARTICLE 4.

## Pharmacies and Retailing Drugs Generally

§ 54-524.48. Except as prescribed in this chapter it shall be unlawful for any person to practice as a pharmacist, or to engage in, carry on, or be employed in the dispensing, or compounding of drugs within this State; the possession by any person in any place of a miscellaneous stock of drugs, shall be prima facie evidence that such person is practicing pharmacy.

§ 54-524.49. Certain advertising and signs unlawful.—It shall be unlawful for any place of business which is not a pharmacy as defined in this chapter to advertise or to have upon it or in it as a sign the words, "pharmacy," "pharmacist," "apothecary," "drugstore," "druggist," "drugs," "medicine store," "drug sundries," "prescriptions filled" or any like words indicating that drugs are compounded or sold or prescriptions filled therein. Each day during which, or a part of which, such advertisement appears or such sign is allowed to remain upon or in such place of business shall constitute a separate offense under this section.

§ 54-524.50. No person shall, in the course of his normal activities and pursuant to solicitation, receive, dispense, or deliver a prescription by mail or participate in any other plan, arrangement, or practice which eliminates or impairs a bona fide physician-pharmacist-patient relationship. The physician-pharmacistpatient relationship is that situation which permits either the physician, pharmacist, or patient to inquire readily and easily, in customary manner, concerning factors relating to the prescription and which permits the physician and pharmacist to render such other professional services as required for protection of the health and welfare of the patient. § 54-524.51. Every pharmacy shall be under the personal supervision of a pharmacist in the pharmacy.

§ 54-524.52. Temporary permit in absence of pharmacist.—The Board of Pharmacy may, in its discretion, issue permits to such pharmacies as may be temporarily not under the supervision of a pharmacist to remain open for business for a period not to exceed ten days, but such pharmacy may not during such period sell nor compound or dispense physicians' prescriptions. Pharmacies desiring such permit must make application to the Board, setting forth the circumstances upon which their applications are based.

§ 54-524.53. Physicians, Dentists, and Veterinarians supplying medicine for patients.—This chapter shall not be construed to interfere with any legally qualified practitioner of medicine, dentistry, osteopathy, chiropody (podiatry), or veterinary medicine, who is not the proprietor of a pharmacy for the dispensing or retailing of drugs, or who is not in the employ of such a proprietor, in the compounding of his own prescriptions or the purchase and possession of such drugs and medicines as he may require, or to prevent him from administering or supplying to his patients such medicines as he may deem proper, or from making a charge for such medicines as are not sold to his patients for his own convenience or for the purpose of supplementing his income.

§ 54-524.54. Nothing in this article shall be construed to prevent the operation of mechanical devices used in hospitals for the dispensing of drugs for which the Board has prescribed standards of operation.

### ARTICLE 5.

#### Distribution of Drugs Generally

§ 54-524.55. Acts prohibited.—It shall be unlawful for any person to manufacture or produce any drug, or possess, have under his control, sell, prescribe, administer, dispense, compound or otherwise dispose of, any controlled drug except as authorized in this chapter.

§ 54-524.56. (a) Upon the effective date of this act, or within six months thereafter, each person manufacturing, compounding, processing, selling, dispensing or otherwise disposing of drugs in Schedules I, II, III, or Schedule V shall make a complete and accurate record of all stocks of such drugs on hand. Thereafter, complete and accurate records of all such drugs shall be maintained for three years. Each two-year period after the effective date of this Act, at the time of his regular fiscal inventory, each person manufacturing, producing, compounding, processing, selling, distributing, dispensing or otherwise disposing of such drugs shall prepare a complete and accurate inventory of each such drug in his possession.

(b) The record of such drugs received shall in every case show the date of receipt, the name and address of the person from whom received and the kind and quantity of drugs received; the kind and quantity of drugs produced or removed from process of manufacture, and the date of such production or removal from process of manufacture; and the record shall in every case show the proportion of morphine, cocaine, or ecgonine contained in or producible from crude opium or coca leaves received or produced. The record of all drugs sold, administered, dispensed, or otherwise disposed of, shall show the date of selling, administering, or dispensing, the name and address of the person to whom or for whose use, or the owner and species of animal for which the drugs were sold, administered or dispensed, and the kind and quantity of drugs; and any person selling, administering, dispensing or otherwise disposing of such drugs shall make such record at the time of each transaction. Every such record shall be kept for a period of three years from the date of the transaction recorded. The keeping of a record required by or under the federal laws, containing substantially the same in-

formation as is specified above, shall constitute compliance with this section, except that every such record shall contain a detailed list of drugs lost, destroyed or stolen, if any, the kind and quantity of such drugs, and the date of the discovery of such loss, destruction or theft.

(c) The form of records shall be prescribed by the Board.

§ 54-524.57. Every person required to prepare or obtain, and keep, records, and any carrier maintaining records with respect to any shipment containing any drug, and every person in charge, or having custody, of such records, shall, upon request of an agent designated by the Board, permit such agent at reasonable times to have access to and copy such records. For the purposes of verification of such records and of enforcement of this chapter agents designated by the Board are authorized, upon presenting appropriate credentials to the owner, operator, or agent in charge, to enter, at reasonable times, any factory, warehouse, establishment, or vehicle in which any drug is held, manufactured, compounded, processed, sold, delivered, or otherwise disposed of and to inspect, within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle, and all pertinent equipment, finished and unfinished material, containers and labeling therein, and all things therein (including records, files, papers, processes, controls, and facilities) bearing on violation of this chapter; and to inventory any stock of any such drug therein and obtain samples of any such drug. If a sample is thus obtained, the agent making the inspection shall, upon completion of the inspection and before leaving the premises, give to the owner, operator, or agent in charge a receipt describing the sample obtained. No inspection authorized shall extend to financial data, sales data other than shipment data, pricing data, personnel data or research data.

§ 54-524.58. No agent of the Board having knowledge by virtue of his office of any prescriptions, papers, records, or stocks of drugs shall divulge such knowledge, except in connection with a prosecution or proceeding in court or before a licensing or registration board or officer, to which prosecution or proceeding the person to whom such prescriptions, papers or records relate is a party.

§ 54-524.58:1. It shall be lawful for a person to manufacture, and for a practitioner to administer, Schedule I drugs provided:

(a) The manufacturer and practitioner are expressly authorized to engage in such activities by the Attorney General of the United States, or pursuant to the Federal Food, Drug and Cosmetic Act; and

(b) the manufacturer holds a permit issued pursuant to § 54-524.40; and

(c) that any Schedule I drug so manufactured must be sold or furnished on an official written order to a practitioner or other authorized person; and

(d) the manufacturer and practitioner comply with all other requirements of this chapter.

§ 54-524.59. To whom sales by manufacturers and wholesalers may be made.—(1) A duly licensed manufacturer or wholesaler may sell Schedule II drugs to any of the following persons, but only on official written orders:

(a) To a manufacturer, wholesaler, or pharmacist;

(b) To a practitioner;

(c) To a person in charge of a hospital, but only for use by or in that hospital;

(d) To a person in charge of a laboratory, but only for use in that laboratory for scientific and medical purposes.

(2) A duly licensed manufacturer or wholesaler may sell Schedule II drugs to any of the following persons:

(a) On a special written order accompanied by a certificate of exemption, as required by the federal laws, to a person in the employ of the United States govern-

ment or of any state, territorial district, county, municipal, or insular government, purchasing, receiving or possessing drugs by reason of his official duties;

(b) To a master of a ship or a person in charge of any aircraft upon which no physician is regularly employed, for the actual medical needs of persons on board such ship or aircraft, when not in port. Provided, however, that such drugs shall be sold to the master of such ship or person in charge of such aircraft only in pursuance of a special order form approved by a commissioned medical officer or acting assistant surgeon of the United States Public Health Service;

(c) To a person in a foreign country if the provisions of the federal laws are complied with.

(3) A duly licensed manufacturer or wholesaler may sell drugs classified in Schedule III, Schedule IV, and Schedule V to all the persons listed in this section without an official written order.

§ 54-524.60. An official written order for any Schedule II drug shall be signed by the purchasing registrant or by his duly authorized agent. The original shall be presented to the person who supplies the drug or drugs named therein. In event of the acceptance of such order by such person, each party to the transaction shall preserve his copy of such order, for a period of three years, in such way as to be readily accessible for inspection by any public officer or employee engaged in the enforcement of this article. It shall be deemed a compliance with this section if the parties to the transaction have complied with the federal laws, respecting the requirements governing the use of order forms.

§ 54-524.61. The owner of any stock Schedule II drugs obtained in compliance with this Act, upon discontinuance of dealing in such drugs, may dispose of such stock only on an official written order in the manner described in this section and as follows:

(1) A pharmacy or practitioner may dispose of such stock to a manufacturer or wholesaler holding a valid license to deal in such drugs, or to another pharmacy or practitioner.

(2) A manufacturer or wholesaler may dispose of such stock only to a manufacturer or wholesaler holding a valid license to deal in such drugs.

§ 54-524.62. A pharmacist, only upon an official written order, may sell to a physician, dentist, or veterinarian, in quantities not exceeding one ounce at any one time, aqueous or oleaginous solutions compounded by the pharmacist, of which the content of narcotic drugs does not exceed a proportion greater than twenty per centum of the complete solution, to be used for medical purposes.

§ 54-524.63. Possession lawful.—Possession of or control of drugs obtained as authorized by the four preceding sections shall be lawful if in the regular course of business, occupation, profession, employment or duty of the possessor.

§ 54-524.64. Use restricted.—A person in charge of a hospital or of a laboratory, or in the employ of this State or of any political subdivision thereof, and a master or other proper officer of a ship or aircraft, who obtains drugs under the provisions of the preceding sections or otherwise, shall not administer, nor dispense, nor otherwise use such drugs, within this State, except within the scope of his employment or official duty not in conflict with, and subject to the provisions of this Chapter.

§ 54-524.65. Professional use by physicians and dentists.—A practitioner, acting in good faith and in the course of his professional practice only, may prescribe, on a written prescription or on oral prescription as authorized by § 54-524.67 and administer drugs, or he may cause the same to be administered by a nurse or intern under his direction and supervision. Such a prescription shall be dated and signed by the person prescribing on the day when issued, and shall bear the full name and address of the patient for whom the drug is prescribed, and the full name, address, and registry number under the federal laws of the person prescribing, provided he is required by those laws to be so registered.

§ 54-524.66. Professional use by Veterinarians.—A veterinarian, acting in good faith and in the course of his professional practice only, and not for use by a human being, may prescribe, on a written prescription or on oral prescription as authorized by § 54-524.67, and administer drugs, and he may cause them to be administered by an assistant or orderly under his direction and supervision. Such a prescription shall be dated and signed by the person prescribing on the day when issued, and shall bear the full name and address of the owner of the animal, and the species of the animal, for which the drug is prescribed and the full name, address and registry number, under the federal laws of the person prescribing, provided he is required by those laws to be so registered.

§ 54-524.67. A pharmacist, acting in good faith, may sell and dispense drugs to any person pursuant to a prescription of a practitioner as follows:

(a) A drug listed in Schedule II shall be dispensed only upon receipt of a written prescription that is properly executed, dated and signed by the person prescribing on the day when issued and bearing the full name and address of the patient for whom, or of the owner of the animal for which, the drug is dispensed, and the full name, address, and registry number under the federal laws of the person prescribing, if he is required by those laws to be so registered. If the prescription be for an animal, it shall state the species of animal for which the drug is prescribed. Provided, however, that:

(1) In emergency situations, as prescribed by the Board by regulation not inconsistent with the federal law, such drugs may be dispensed pursuant to an oral prescription;

(2) Whenever a pharmacist dispenses any drug listed within Schedule II on a prescription issued by a practitioner, he shall affix to the container in which such drug is dispensed, a label showing his name, address, and registry number, or the name, address, and registry number of the pharmacy; the name and address of the patient or, if the patient is an animal, the name and address of the owner of the animal and the species of the animal; the name, address, and registry number of the practitioner by whom the prescription was written; and such directions as may be stated on the prescription.

(b) A drug controlled by Schedule III or Schedule IV shall be dispensed upon receipt of a written or oral prescription as follows:

(1) If the prescription is written, it shall be properly executed, dated and signed by the person prescribing on the day when issued and bearing the full name and address of the patient for whom, or of the owner of the animal for which, the drug is dispensed, and the full name and address of the person prescribing. If the prescription be for an animal, it shall state the species of animal for which the drug is prescribed.

(2) If the prescription is oral, the practitioner shall furnish the pharmacist with the same information as is required by law in the case of a written prescription for drugs and compounds, except for the signature of the prescriber. The pharmacist who fills such a prescription shall be required to comply with all the provisions of law.

§ 54-524.68. Prescriptions may be refilled as indicated:

(a) A prescription for a drug in Schedule II may not be refilled.

(b) A prescription for a drug in Schedule III may not be filled or refilled more than six months after the date on which such prescription was issued and no such prescription may be authorized to be refilled, nor be refilled, more than five times, except that any prescription for such a drug after six months after the date of issue, or after being refilled five times, may be renewed by the practitioner issuing it either in writing, or orally, if promptly reduced to writing and filed by the pharmacist filling it.

(c) A prescription in Schedule IV may not be refilled, unless authorized by the practitioner either on the face of the original prescription or orally by the practitioner. Oral instructions shall be reduced promptly to writing by the pharmacist and filed on or with the original prescription.

§ 54-524.69. The pharmacist filling or refilling any prescription shall record the date of filling or refilling and his initials on the prescription.

§ 54-524.70. Possession Prohibited; Exceptions.—No unauthorized person shall have in his possession a drug the dispensing of which is restricted to prescription by law unless such person shall have obtained such drug on a prescription, or such drug has been delivered by a practitioner lawfully practicing his profession.

§ 54-524.71. Persons and Corporations Exempted.—The provisions of this article restricting the possession and having control of drugs shall not apply to a person delivering a bona fide prescription, to common carriers or to warehousemen, while engaged in lawfully transporting or storing such drugs, or to any employee of the same acting within the scope of his employment.

§ 54-524.72. The following drugs controlled by Schedule IV may be sold without a prescription by persons other than pharmacists: drugs of the sulfonamide group, hormones, or hormone drug preparations and antibiotics in forms which are unacceptable or unfit for treatment of humans, antibiotics in medicated feeds and hormones or hormone drug preparations in medicated feeds, manufactured for use in the control of animal diseases when sold in the original, unbroken packages of the manufacturer, plainly labeled to indicate their veterinary nature, and giving directions for their use and adequate caution as to the dangerous character of such drugs.

§ 54-524.73. No person shall sell, give away or dispense in any manner to a consumer any biological product capable of producing a disease in an animal that may be transmissible to man or other animals, including, but not limited to, the following vaccines: rabies, hepatitis, or fox encephalitis, swine erysipelas, leptospirosis, equine encephalomyelitis, anthrax, brucellosis, live hog cholera virus and bovine exthyma, except on the prescription of a practitioner, lawfully practicing his profession, and licensed by law to prescribe or administer such biological products, but nothing herein contained shall apply to vaccines used in treatment of canine distemper.

§ 54-524.74. It shall be lawful for a pharmacist to sell, or offer to sell, or otherwise dispose of any Schedule V drug to consumers.

§ 54-524.75. A preparation listed pursuant to Schedule V may be dispensed

(1) that the preparation is dispensed only by a pharmacist directly to the person requesting the preparation;

(2) that the preparation is dispensed only to a person who is at least eighteen (18) years of age;

(3) that the pharmacist requires the person requesting the preparation to furnish suitable identification including proof of age when appropriate;

(4) that the pharmacist does not dispense to any one person, or for the use of any one person or animal, any narcotic drug preparation or preparations, when he knows, or can by reasonable diligence ascertain, that such dispensing will provide the person to whom or for whose use, or the owner of the animal for the use of which, such preparation is dispensed, within forty-eight consecutive hours, with more than one hundred and thirty milligrams of opium, or more than three hundred twenty-five milligrams of codeine, or more than one hundred and thirty milligrams of dihydrocodeine, or more than sixty-five milligrams of ethylmorphine or more than thirty two and five tenths milligrams of diphenoxylate.

(5) In dispensing such a narcotic drug preparation, the pharmacist shall exercise professional discretion to insure that the preparation is being dispensed for medical purposes only.

(6) Any pharmacist shall, at the time of dispensing, make and keep a record

showing the date of dispensing, the name and quantity of the preparation, the name and address of the person to whom the preparation is dispensed, and enter his initials thereon. Such records shall be maintained pursuant to § 54-524.56.

§ 54-524.76. Fraud, Deceit and Forgery.—(a) No person shall obtain or attempt to obtain any drug or procure or attempt to procure the administration of any drug: (1) by fraud, deceit, misrepresentation, or subterfuge; or (2) by the forgery or alteration of a prescription or of any written order; or (3) by the concealment of a material fact; or (4) by the use of a false name or the giving of a false address.

(b) Information communicated to a physician in an effort unlawfully to procure any drug, or unlawfully to procure the administration of any such drug, shall not be deemed a privileged communication.

(c) No person shall furnish false or fraudulent information in or omit any information from, or willfully make a false statement in, any prescription, order, report, record, or other document required by this Chapter.

(d) No person shall use in the course of the manufacture or distribution of a controlled drug a license number which is fictitious, revoked, suspended, or issued to another person.

(e) No person shall, for the purpose of obtaining any drug, falsely assume the title of, or represent himself to be, a manufacturer, wholesaler, pharmacist, physician, dentist, veterinarian or other authorized person.

(f) No person shall make or utter any false or forged prescription or false or forged written order.

(g) No person shall affix any false or forged label to a package or receptacle containing any drug.

(h) This section shall not apply to officers and employees of the United States, of this State or of a political subdivision of this State acting in the course of their employment, who obtain such drugs for investigative, research or analytical purposes; or to manufacturers or laboratories, their agents or employees acting in the course of their employment, who purchase such drugs for investigative, research or analytical purposes in connection with the sale or dispensing of such drugs, but not for human use.

§ 54-524.77. Admissibility in evidence of chemist's certificate of analysis.— In any prosecution for a misdemeanor under this article, the certificate of analysis of the chemist performing such analysis for the Board when duly attested by the chemist, shall be admissible in evidence as evidence of the facts therein stated and the results of the analysis referred to therein, provided that the certificate of analysis of the drug or drugs shall be made available to the defendant, or his attorney, at least twenty-four hours prior to the trial.

§ 54-524.78. Disposal of Seized Drugs.—All drugs, the lawful possession of which is not established or the title to which cannot be ascertained, which have come into the custody of a peace officer, shall be forfeited and disposed of as follows:

(a) Except as in this section otherwise provided, the court or magistrate having jurisdiction shall order such drugs forfeited and destroyed. A record of the place where such drugs were seized, of the kinds and quantities of drugs so destroyed and of the time, place, and manner of destruction, shall be kept, and a return under oath, reporting such destruction, shall be made to the court or magistrate and to the Board by the officer who destroys them.

(b) Upon written application by the State Board of Pharmacy the court or magistrate by whom the forfeiture of drugs has been decreed may order the delivery of any of them, except heroin, to the Board, for distribution or destruction, as hereinafter provided.

(c) Upon application by any hospital within this State, not operated for

private gain, the Board may in its discretion deliver any drugs that have come into its custody by authority of this section to the applicant for medicinal use.

(d) The Board shall keep a full and complete record of all drugs received and of all drugs disposed of, showing the exact kinds, quantities, and forms of such drugs; the persons from whom received and to whom delivered; by whose authority received, delivered, and destroyed; and the dates of the receipt, disposal, or destruction.

## ARTICLE 6

#### Standards and Schedules

§ 54-524.79. The Board shall control the distribution of all drugs listed within, or pursuant to, this act. Unless otherwise provided, any drug not listed within this act shall be listed pursuant to regulations promulgated by the Board; the listing of such drugs shall be based on the criteria set forth in the act. The drugs listed in Schedule I, Schedule II, Schedule III and Schedule IV include the controlled drug listed or to be listed by whatever official name, common or usual name, chemical name, or trade name designated.

§ 54-524.80. Schedule I. In determining that a drug shall be listed within Schedule I, the Board shall find:

- (1) a high potential for abuse, and
- (2) no accepted medical use in the United States.

(a) Any of the following drugs, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation, are included in Schedule I:

- (1) Acetylmethadol.
- (2) Allylprodine.
- (3) Alphactylmethadol.
- (4) Alphameprodine.
- (5) Alphamethadol.
- (6) Benzethidine.
- (7) Betacetylmethadol.
- (8) Betameprodine.
- (9) Betamethadol.
- (10) Betaprodine.
- (11) Clonitazene.
- (12) Dextromoramide.
- (13) Dextrorphan.
- (14) Diampromide.
- (15) Diethyliambutene.
- (16) Dimenoxadol.
- (17) Dimepheptanol.
- (18) Dimethyliambutene.
- (19) Dioxaphetyl butyrate.
- (20) Dipipanone.
- (21) Ethylmethylthiambutene.
- (22) Etonitazene.
- (23) Etoxeridine.
- (24) Furethidine.
- (25) Hydroxypethidine.
- (26) Ketobemidone.
- (27) Levomoramide.
- (28) Levophenacylmorphan.
- (29) Morpheridine.
- (30) Noracymethadol.
- (31) Norlevorphanol.
- (32) Normethadone.

- (33) Noripipanone.
  (34) Phenadoxone.
  (35) Phenampromide.
  (36) Phenomorphan.
  (37) Phenoperidine.

- (38) Piritramide.(39) Proheptazine.
- (40) Properidine.
- (41) Racemoramide.
- (42) Trimeperidine.

(b) Any of the following opium derivatives, their salts, isomers and salts of isomers, unless specifically excepted, whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation:

- (1) Acetylcodone.
- (2) Benzylmorphine.
- (3) Codeine methylbromide.
- (4) Codeine-N-Oxide.
  (5) Desomorphine.
  (6) Heroin.

- (7) Hydromorphinol.(8) Methyldesorphine.
- (9) Methylhydromorphine.
- (10) Morphine methylbromide.
- (11) Morphine methylsulfonate.
- (12) Morphine-In-Oxide.
  (13) Myrophine.
  (14) Nicocodeine.

- (15) Nicomorphine.
- (16) Normorphine.(17) Thebacon.

(c) Any material, compound, mixture or preparation which contains any quantity of the following hallucinogenic substances, their salts, isomers and salts of isomers, unless specifically excepted, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

- (1) Bufotenine.
- (2) Diethyltryptamine.
- (2) Diethyltryptamine.
  (3) Dimethyltryptamine.
  (4) 4-methyl-2, 5-dimethoxyamphetamine.
  (5) Ibogaine.
  (6) Lysergic acid diethylamide.
  (7) Marijuana.
  (8) Mescaline.
  (9) Deutete

- (9) Peyote.(10) Psilocybin.(11) Psilocyn.
- (12) Tetrahydrocannabinol.

§ 54-524.81. Schedule II. In determining that a drug shall be listed within Schedule II, the Board shall find:

(1) a high potential for abuse, and

(2) currently accepted medical use or currently accepted medical use in the United States with severe restrictions, and

(3) abuse may lead to severe psychic or physical dependence.

The following controlled drugs are included in Schedule II:

(a) any of the following drugs, except those narcotic drugs listed in other schedules, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by combination of extraction and chemical synthesis:

- 1. Opium, coca leaves, and opiate;
- 2. Any salt, compound, derivative or preparation of opium, coca leaves or

3. Any salt, compound, derivative, or preparation thereof which is chemically equivalent to or identical with any of the substances referred to in clauses 1 and 2, except that these drugs shall not include decocainized coca leaves or extraction of coca leaves, which extractions do not contain cocaine or ecognine; and shall not include the isoquinoline alkaloids of opium;

4. Opium poppy and poppy straw.

(b) Any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters and others, unless specifically excepted, whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation:

- 1. Alphaprodine.
- 2. Anileridine.
- 3. Bezitramide.
- 4. Diphenoxylate.
- 5. Fentanyl.
- 6. Isomethadone.
- Levomethorphan.
   Levorphanol.
- 9. Metazocine.
- 10. Methadone.
- 11. Methadone-Intermediate, 4-cyano-2-dimethylamino-4, 4-diphenyl butane.
- 12. Moramide—Intermediate, 2-methyl-3-morpholino-1, 1-diphenyl-propane carboxylic acid.
- 13. Pethidine.
- 14. Pethidine—Intermediate—A, 4-cyano-1-methyl-4-phenylpiperidine.
- 15. Pethidine—Intermediate—B, ethyl-4-phenylpiperidine-4-carboxylate.
- 16. Pethidine Intermediate C, 1-methyl-4-phenylpiperidine-4-carboxylic acid.
- 17. Phenazocine.
- 18. Piminodine.
- 19. Racemethorphan.
- 20. Racemorphan.

§ 54-524.82. Schedule III. In determining that a drug shall be listed within Schedule III, the Board shall find:

(1) A potential for abuse less than the drugs listed in Schedules I and II; and,

(2) Approved medical use in the United States; and,

(3) Abuse may lead to moderate or low physical dependence or high psychological dependence.

The following classes of drugs are included in Schedule III:

(a) Any material, compound, mixture, or preparation which contains any quantity of the following drugs having a potential for abuse associated with a stimulant effect on the central nervous system:

- 1. Amphetamine, its salts, optical isomers, and salts of its optical isomers.
- 2. Phenmetrazine and its salts.

3. Any substance which contains any quantity of methamphetamine, including its salts, isomers, and salts of isomers.

4. Methylphenidate.

(b) Any material, compound, mixture, or preparation which contains any quantity of the following substances having a potential for abuse associated with a depressant effect on the central nervous system:

1. Any substance which contains any quantity of a derivative of barbituric acid or any salt of a derivative of barbituric acid, except those substances which are controlled by other Schedules.

- 2. Chloral betaine.
- 3. Chloral hydrate.
- 4. Chlordiazepoxide.
- 5. Chlorhexadol.
- 6. Diazepam.
- 7. Ethchlorvynol.
- 8. Ethinamate.
- 9. Glutethimide.
- 10. Lysergic acid.
- 11. Lysergic acid amide.
- 12. Meprobamate.
   13. Methyprylon.
   14. Paraldehyde.
   15. Petrichloral.

- 16. Phencyclidine.
- 17. Sulfondiethylmethane.
- 18. Sulfonethylmethane.
- 19. Sulfonmethane.
- (c) Nalorphine.

(d) Any material, compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, or any salts thereof:

1. Not more than one and eighty one-hundredths grams of codeine per one hundred milliliters or not more than ninety milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium.

2. Not more than one and eighty one-hundredths grams of codeine per one hundred milliliters or not more than ninety milligrams per dosage unit, with one or more active, non-narcotic ingredients in recognized therapeutic amounts.

3. Not more than three hundred milligrams of dihydrocodeinone per one hundred milliliters or not more than fifteen milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium.

4. Not more than three hundred milligrams of dihydrocodeinone per one hundred milliliters or not more than fifteen milligrams per dosage unit, with one or more active, non-narcotic ingredients in recognized therapeutic amounts.

5. Not more than one and eighty one-hundredths grams of dihydrocodeine per one hundred milliliters or not more than ninety milligrams per dosage unit, with one or more active, non-narcotic ingredients in recognized therapeutic amounts.

6. Not more than three hundred milligrams of ethylmorphine per one hundred milliliters or not more than fifteen milligrams per dosage unit, with one or more active, non-narcotic ingredients in recognized therapeutic amounts.

7. Not more than five hundred milligrams of opium per one hundred milliliters or per one hundred grams, or not more than twenty-five milligrams per dosage unit, with one or more active, non-narcotic ingredients in recognized therapeutic amounts, except that camphorated tincture of opium shall be controlled by Schedule V (a).

8. Not more than fifty milligrams of morphine per one hundred milliliters or per one hundred grams with one or more active, non-narcotic ingredients in recognized therapeutic amounts.

e. The Board shall by regulation list any compound, mixture, or preparation containing any stimulant or depressant drug listed in paragraphs (a) and (b) of this Schedule. Any compound, mixture, or preparation containing a stimulant or depressant drug in combination with one or more active medicinal ingredients not having a stimulant or depressant effect on the central nervous system shall be exempt from Schedule III and subject to the requirements of Schedule IV. Provided, that such admixtures shall be included therein in such combinations, quantity, proportion, or concentration as to vitiate the potential for abuse of the drugs which do have a stimulant or depressant effect on the central nervous system. Any compound, mixture or preparation exempted from Schedule III shall be controlled by Schedule IV.

§ 54-542.83. Schedule IV. The following classes of drugs shall be controlled by Schedule IV:

(a) Any compound, mixture, or preparation containing any stimulant or depressant drug exempted from Schedule III.

(b) Every drug or device, not included in Schedules I, II or III, which 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 generally recognized among experts qualified by scientific training and experience to evaluate its safety and efficacy as safe for use except by or under the supervision of a practitioner licensed by law to prescribe or administer such drug or device.

(c) Any drug or drug preparation, not included in Schedules I, II, or III, required by federal law to bear on its label the legend: "Caution: Federal Law Prohibits Dispensing Without Prescription."

§ 54-524.84. Schedule V. The following controlled drugs are included in this Schedule:

Any compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, which shall include one or more non-narcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation, valuable medicinal qualities other than those possessed by the narcotic drug alone:

1. Not more than two hundred milligrams of codeine per one hundred milliliters or per one hundred grams;

2. Not more than one hundred milligrams of dihydrocodeine per one hundred milliliters of per one hundred grams;

3. Not more than fifty milligrams of ethylmorphine per one hundred milliliters or per one hundred grams;

4. Not more than two and five-tenths milligrams of diphenoxylate and not less than twenty-five micrograms of atropine sulfate per dosage unit;

5. Not more than one hundred milligrams of opium per one hundred milliliters or per one hundred grams, or not more than five milligrams per dosage unit; except that this shall not be construed to prohibit the dispensing of a quantity of camphorated tincture of opium not to exceed thirty milliliters.

# ARTICLE 7

# Misbranded and Adulterated Drugs and Cosmetics

 $\S$  54-524.85. The following acts and the causing thereof within this State are hereby prohibited:

(a) The manufacture, sale, or delivery, holding or offering for sale of any drug, device, or cosmetic that is adulterated or misbranded.

(b) The adulteration or misbranding of any drug, device, or cosmetic.

(c) The receipt in commerce of any drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

(d) The sale, delivery for sale, holding for sale, or offering for sale of any article in violation of  $\S$  54-524.95.

(e) The dissemination of any false advertisement.

(f) The refusal to permit entry or inspection, or to permit the taking of a sample, or to permit access to or copying of any record as authorized by  $\S$  54-524.99.

(g) The giving of a guaranty or undertaking which guaranty or undertaking is false, except by a person who relied on a guaranty or undertaking to the same effect signed by, and containing the name and address of the person residing in this State from whom he received in good faith the drug, device, or cosmetic.

(h) The removal or disposal or a detained or embargoed article in violation of 54-524.88.

(i) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to a drug, device, or cosmetic, if such act is done while such article is held for sale and results in such article being adulterated or misbranded.

(j) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by regulations promulgated under the provisions of this Act or of the federal act.

(k) The using by any person to his own advantage, or revealing, other than to the Board or its authorized representative or to the courts when relevant in any judicial proceeding under this Act, of any information acquired under authority of this Act concerning any method or process which as a trade secret is entitled to protection.

(1) The using, on the labeling of any drug or in any advertisement relating to such drug, or any representation or suggestion that an application with respect to such drug is effective under § 54-524.95, or that such drug complies with the provisions of such section.

(m) In the case of a drug distributed or offered for sale in this State, the failure of the manufacturer, packer, or distributor thereof to maintain for transmittal, or to transmit, to any practitioner licensed by applicable law to administer such drug who makes written request for information as to such drug, true and correct copies of all printed matter which is required to be included in any package in which that drug is distributed or sold, or such other printed matter as is approved under the federal act. Nothing in this paragraph shall be construed to exempt any person from any labeling requirement imposed by or under other provisions of this Act.

(n) (1) Placing or causing to be placed upon any drug or device or container thereof, with intent to defraud, the trade name or other identifying mark, or

imprint of another or any likeness of any of the foregoing; or (2) selling, dispensing, disposing of or causing to be sold, dispensed or disposed of or concealing or keeping in possession, control or custody, with intent to sell, dispense or dispose of, any drug, device or any container thereof, with knowledge that the trade name or other identifying mark or imprint of another or any likeness of any of the foregoing has been placed thereon in a manner prohibited by subsection (1) hereof; or (3) making, selling, disposing of, or causing to be made, sold or disposed of, or keeping in possession, control or custody, or concealing any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any drug or container or labeling thereof so as to render such drug a counterfeit drug.

(o) The doing of any act which causes a drug to be a counterfeit drug, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit drug.

(p) Dispensing or causing to be dispensed a different drug or brand of drug in place of the drug or brand of drug ordered or prescribed without the permission of the person ordering or prescribing.

§ 54-524.86. In addition to the remedies hereinafter provided the Board is hereby authorized to apply to the circuit or corporation court of the county or city wherein the violator has his principal place of business for, and such court shall have jurisdiction upon hearing and for cause shown, to grant a temporary or permanent injunction restraining any person from violating any provision of § 54-524.85; or any Board regulation promulgated under this Act; irrespective of whether or not there exists an adequate remedy at law.

§ 54-524.87. (a) Any person who violates any of the provisions of § 54-524.85 shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than six months or a fine of not more than five hundred dollars, or both such imprisonment and fine; but if the violation is committeed after a conviction of such person under this section has become final, the person shall be subject to imprisonment for not more than one year, or a fine of not more than one thousand dollars, or both such imprisonment and fine.

(b) No person shall be subject to the penalties of subsection (a) of this section, for having violated § 54-524.85 (a) or (c) if he establishes a guaranty or undertaking signed by; and containing the name and address of, the person residing in this State from whom he received in good faith the article, to the effect that such article is not adulterated or misbranded within the meaning of this Act, designating this Act.

(c) No publisher, radio-broadcast licensee, or agency or medium for the dissemination of an advertisement, except the manufacturer, packer, distributor, or seller of the article to which a false advertisement relates, shall be liable under this section for the dissemination of such false advertisement, unless he has refused, on the request of the Board to furnish the Board the name and post office address of the manufacturer, packer, distributor, seller, or advertising agency, residing in this State who caused him to disseminate such advertisement.

§ 54-524.88. (a) Whenever a duly authorized agent of the Board finds, or has probable cause to believe, that any drug, device, or cosmetic, is adulterated, or so misbranded as to be dangerous or fraudulent, within the meaning of this Act, or is in violation of § 54-524.95 of this Act, he shall affix to such article a tag or other appropriate marking, giving notice that such article is, or is suspected of being, adulterated or misbranded or in violation of § 54-524.95 of this Act and has been detained or embargoed, and warning all persons not to remove or dispose of such article by sale or otherwise until permission for removal or disposal is given by an authorized agent or the court. It shall be unlawful for any person to remove or dispose of such detained or embargoed article by sale or otherwise without such permission. (b) When an article is adulterated or misbranded or is in violation of § 54-524.95 of this Act it shall be liable to be proceeded against by petition of the judge of the police, county, or circuit court in whose jurisdiction the article is located, detained, or embargoed for a libel for condemnation of such article. When an authorized agent has found that an article which is embargoed or detained is not adulterated or misbranded, or in violation of § 54-524.95, he shall remove the tag or other marking.

(c) If the court finds that a sampled, detained, or embargoed article is adulterated or misbranded, or in violation of § 54-524.95, such article shall, after entry of the decree, be destroyed at the expense of the claimant thereof, under the supervision of an authorized agent, and all court costs and fees, and storage and other proper expenses, shall be taxed against the claimant of such article or his agent; provided, that when the adulteration or misbranding can be corrected by proper labeling or processing of the article, the court, after entry of the decree and after such costs, fees, and expenses have been paid and a good and sufficient bond, conditioned that such article shall be so labeled or processed, has been executed, may by order direct that such article be delivered to claimant thereof for such labeling or processing under the supervision of an agent of the Board. The expense of such supervision shall be paid by the claimant. The article shall be returned to the claimant and the bond shall be discharged on the representation to the court by the Board that the article is no longer in violation of this Act, and that the expenses of such supervision have been paid.

§ 54-524.89. It shall be the duty of each Commonwealth attorney to whom the Board reports any violation of this Act, to cause appropriate proceedings to be instituted in the proper courts without delay and to be prosecuted in the manner required by law. Before any violation of this Act is reported to any such attorney for the institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views before the Board or its designated agent, either orally or in writing, in person, or by attorney, with regard to such contemplated proceeding.

§ 54-524.90. Nothing in this Act shall be construed as requiring the Board to report for the institution of proceedings under this Act, minor violations of this Act, whenever the Board believes that the public interest will be adequately served in the circumstances by a suitable written notice or warning.

§ 54-524.91. Any added poisonous or deleterious substance, or any color additive, shall with respect to any particular use or intended use be deemed unsafe for the purpose of application of § 54-524.92(A) with respect to any drug or device, or § 54-524.96 (a) with respect to any cosmetic, unless there is in effect a regulation, promulgated under this Act by the Board limiting the quantity of such substance, and the use or intended use of such substance conforms to the terms prescribed by such regulation. While such regulations relating to such substance are in effect, a drug or cosmetic shall not, by reason of bearing or containing such substance in accordance with the regulations, be considered adulterated within the meaning of § 54-524.92 (A) or § 54-524.96 (a).

§ 54-524.92. A drug or device shall be deemed to be adulterated—(A) (1) If it consists in whole or in part of any filth, putrid or decomposed substance; or (2) (a) if it has been produced, prepared, packed, or held under insanitary conditions whereby it has been contaminated with filth, or whereby it has been rendered injurious to health; or (b) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this Act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess, or (3) if it is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (4)

if (a) it is a drug and it bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of the federal act or § 54-524.91; or (b) it is a color additive, the intended use of which in or on drugs is for purposes of coloring only, and is unsafe within the meaning of the federal act or § 54-524.91.

(B) If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium. Such determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in such compendium, or in the absence of or inadequacy of such tests or methods of assay, those prescribed under authority of the federal act. No drug defined in an official compendium shall be deemed to be adulterated under this paragraph because it differs from the standard of strength, quality, or purity therefor set forth in such compendium, if its difference in strength, quality, or purity from such standard is plainly stated on its label. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homeopathic Pharmacopoeia of the United States it shall be subject to the requirements of the United States Pharmacopoeia unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the Homeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia.

(C) If it is not subject to the provisions of paragraph (b) of this section and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

(D) If it is a drug and any substance has been (1) mixed or packed therewith so as to reduce its quality and strength; or (2) substituted wholly or in part therefor.

§ 54-524.93. A drug or device shall be deemed to be misbranded:

(a) If its labeling is false or misleading in any particular.

(b) If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count, provided, that under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be allowed, in accordance with regulations prescribed by the Board.

(c) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(d) If it is for use by man and contains any quantity of the narcotic or hypnotic substances alpha-eucaine, barbituric acid, beta-eucaine, bromal, carbrom<sup>a</sup>l, chloral, coca, cocaine; codeine, morphine, opium, paraldehyde, or sulfonmethane, or any chemical derivative of such substances, which derivative, after investigation has been found to be and designated as, habit forming, by regulations issued by the Board under this Act, unless its label bears the name and quantity or proportion of such substance or derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

(e) (1) If it is a drug, unless (A) its label bears, to the exclusion of any other non-proprietary name (except the applicable systematic chemical name or the chemical formula), (i) the established name (as defined in subparagraph (2)) of the drug, if such there be; and (ii) in case it is fabricated from two or more ingredients, the established name and quantity of each active ingredient, including the kind and quantity or proportion of any alcohol, and also including, whether active or not, the established name and quantity or proportion of any bromides, ether, chloroform, acetanilid, acetphenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein, and (B) for any prescription drug the established name of such drug or ingredient, as the case may be, on such label (and on any labeling on which a name for such drug or ingredient is used) is printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug or ingredient; provided, that to the extent that compliance with the requirements of clause (A)(ii) or clause (B) of this subparagraph is impracticable, exemptions may be allowed under regulations promulgated by the Board.

(2) As used in this paragraph (e), the term "established name", with respect to a drug or ingredient thereof, means (A) the applicable official name designated pursuant to section 508 of the federal act, or (B) if there is no such name and such drug, or such ingredient, is an article recognized in an official compendium, then the official title thereof in such compendium or (C) if neither clause (A) nor clause (B) of this subparagraph applies, then the common or usual name, if any, of such drug or of such ingredient; provided, further, that where clause (B) of this subparagraph applies to an article recognized in the United States Pharmacopoeia and in the Homeopathic Pharmacopoeia under different official titles, the official title used in the United States Pharmacopoeia shall apply unless it is labeled and offered for sale as a homeopathic drug, in which case the official title used in the Homeopathic Pharmacopoeia shall apply.

(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; provided, that where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the Board shall promulgate regulations exempting such drug or device from such requirements; provided further, that articles exempted under regulations issued under Section 502(f) of the federal act may also be exempt.

(g) If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein; provided, that the method of packing may be modified with the consent of the Board, or if consent is obtained under the federal act. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homeopathic Pharmacopoeia of the United States, it shall be subject to the requirements of the United States Pharmacopoeia and labeling unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the Homeopathic Pharmacopoeia; provided further, that in the event of inconsistency between the requirements of this paragraph and those of paragraph (e) as to the name by which the drug or its ingredients shall be designated, the requirements of paragraph (e) shall prevail.

(h) If it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling or advertising thereof.

(i) If it is, or purports to be, or is represented as a drug composed wholly or partly of insulin, unless (1) it is from a batch with respect to which a certificate or release has been issued pursuant to Section 506 of the federal act, and (2) such certificate or release is in effect with respect to such drug. (j) If it is, or purports to be, or is represented as a drug composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other antibiotic drug, or any derivative thereof, unless (1) it is from a batch with respect to which a certificate or release has been issued pursuant to section 507 of the federal act, and (2) such certificate or release is in effect with respect to such drug; provided, that this paragraph shall not apply to any drug or class of drugs exempted by regulations promulgated under section 507(c) or (d) of the federal act. For the purpose of this subsection the term "antibiotic drug" means any drug intended for use by man containing any quantity of any chemical substance which is produced by micro-organisms and which has the capacity to inhibit or destroy micro-organisms in dilute solution (including, the chemically synthesized equivalent of any such substance).

(k) If it is a color additive, the intended use of which in or on drugs is for the purpose of coloring only, unless its packaging and labeling are in conformity with such packaging and labeling requirements applicable to such color additive, prescribed under the provisions of the federal act.

(1) In the case of any prescription drug distributed or offered for sale in this State, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that drug a true statement of (1) the established name, as defined in § 54-524.93 (e) (2) of this Act, printed prominently and in type at least half as large as that used for any trade of brand name thereof, (2) the formula showing quantitatively each ingredient of such drug to the extent required for labels under § 54-524.93 (e) of this Act, and (3) such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations issue under the federal act.

(m) If a trademark, trade name or other identifying mark, imprint or device of another or any likeness of the foregoing has been placed thereon or upon its container with intent to defraud.

(n) Drugs and devices which are, 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 packed shall be exempt from any labeling or packaging requirements of this Act, provided that such drugs and devices are being delivered, manufactured, processed, labeled, repacked or otherwise held in compliance with regulations issued by the Board.

§ 54-524.94. (a) 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 § 54-524.93 except subsections (a), (i) (2) and (3), (k), and (l), and the packaging requirements of subsections (g) and (h), if the drug bears a label containing 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, the name of the patient, and the directions for use and cautionary statements, if any, contained in such prescription.

(b) Nothing in this section shall be construed to relieve any person from any requirement prescribed by or under authority of law with respect to drugs now included or which may hereafter be included within the classifications of narcotic drugs or marijuana as defined in the applicable federal and State laws relating to narcotic drugs and marijuana.

§ 54-524.95. (a) No person shall sell, deliver, offer for sale, hold for sale or give away any new drug unless (1) an application with respect thereto has been approved and said approval has not been withdrawn under section 505 of the federal act, or (2) when not subject to the federal act, unless such drug has been tested and has been found to be safe for use and effective in use under the conditions prescribed, recommended, or suggested in the labeling thereof, and prior to selling or offering for sale such drug, there has been filed with the Board an application setting forth (a) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (b) a full list of the articles used as components of such drug; (c) a full statement of the composition of such drug; (d) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing and packing of such drug; (e) such samples of such drug and of the articles used as components thereof as the Board may require; and (f) specimens of the labeling proposed to be used for such drug.

(b) An application provided for in subsection (a)(2) shall become effective on the one hundred eightieth day after filing thereof, except that if the Board finds, after due notice to the applicant and giving him an opportunity for a hearing, (1) that the drug is not safe or not effective for use under the conditions prescribed, recommended or suggested in the proposed labeling thereof; or (2) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drugs are inadequate to preserve its identity, strength, quality, and purity; or (3) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; he shall, prior to the effective date of the application, issue and order refusing to permit the application to become effective.

(c) An order refusing to permit an application under this section to become effective may be revoked by the Board.

(d) The Board shall promulgate regulations for exempting from the operation of the foregoing subsections of this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs. Such regulations may, within the discretion of the Board among other conditions relating to the protection of the public health, provide for conditioning such exemption upon:

(1) the submission to the Board, before any clinical testing of a new drug is undertaken, of reports, by the manufacturer or the sponsor of the investigation of such drug, of preclinical tests (including tests on animals) of such drug adequate to justify the proposed clinical testing;

(2) the manufacturer of the sponsor of the investigation of a new drug proposed to be distributed to investigators for clinical testing obtaining a signed agreement from each of such investigators that patients to whom the drug is administered will be under his personal supervision, or under the supervision of investigators responsible to him, and that he will not supply such drug to any other investigator, or to clinics, for administration to human beings; and

(3) the establishment and maintenance of such records, and the making of such reports to the Board by the manufacturer or the sponsor of the investigation of such drug, of data (including but not limited to analytical reports by investigators) obtained as the result of such investigational use of such drug, as the Board finds will enable it to evaluate the safety and effectiveness of such drug in the event of the filing of an application pursuant to subsection (b).

Such regulations shall provide that such exemption shall be conditioned upon the manufacturer, or the sponsor of the investigation, requiring that experts using such drugs for investigational purposes certify to such manufacturer or sponsor that they will inform any human beings to whom such drugs, or any controls used in connection therewith, are being administered, or their representatives, that such drugs are being used for investigational purposes and will obtain the consent of such human beings or their representatives, except where they deem it not feasible or, in their professional judgment, contrary to the best interests of such human beings. Nothing in this subsection shall be construed to require any clinical investigator to submit directly to the Board reports on the investigational use of drugs; provided, that the Board may, in its discretion, promulgate regulations whether or not in accordance with regulations promulgated under the federal act. (e) (1) In the case of any drug for which an approval of an application filed pursuant to this section is in effect, the applicant shall establish and maintain such records, and make such reports to the Board of data relating to clinical experience and other data or information, received or otherwise obtained by such applicant with respect to such drug, as the Board may by general regulation, or by order with respect to such application, prescribe; provided, however, that regulations and orders issued under this subsection and under subsection (d) shall have due regard for the professional ethics of the medical profession and the interests of patients and shall provide where the Board deems it to be appropriate, for the examination, upon request, by the persons to whom such regulations or orders are applicable, of similar information received or otherwise obtained by the Board.

(2) Every person required under this section to maintain records, and every person in charge of custody thereof, shall, upon request of an officer or employee designated by the Board permit such officer or employee at all reasonable times to have access to and copy and verify such records.

(f) The Board may, after affording an opportunity for public hearing and judicial appeal, revoke an application approved pursuant to this section if he finds that the drug, based on evidence acquired after such approval, may not be safe or effective for its intended use, or that the facilities or controls used in the manufacture, processing, or labeling of such drug may present a hazard to the public health.

§ 54-524.96. A cosmetic shall be deemed to be adulterated—

(a) If it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling or advertisement thereof, or under such conditions of use as are customary or usual. Provided, that this provision shall not apply to coal-tar hair dye, the label of which bears the following legend conspicuously displayed thereon: "Caution— This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness," and the labeling of which bears adequate directions for such preliminary testing. For the purpose of this paragraph and paragraph (e) the term "hair dye" shall not include eyelash dyes or eyebrow dyes.

(b) If it consists in whole or in part of any filthy, putrid, or decomposed substance.

(c) If it has been produced, prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

(d) If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.

(e) If it is not a hair dye and it is, or it bears or contains a color additive which is unsafe within the meaning of the federal act or § 54-524.91.

§ 54-524.97. A cosmetic shall be deemed to be misbranded:

(a) If its labeling is false or misleading in any particular.

(b) If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; provided, that under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established by regulations prescribed by the Board.

(c) If any word, statement, or other information required by or under

authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(d) If its container is so made, formed or filled as to be misleading.

(e) If it is a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements applicable to such color additive prescribed under the provisions of the federal act. This paragraph shall not apply to packages of color additives which, with respect to their use for cosmetics, are marketed and intended for use only in or on hair dyes (as defined in the last sentence of  $\S$  54-524.96 (a)

(f) A cosmetic which is, in accordance with the practice of the trade, to be processed, labeled or repacked in substantial quantities at an establishment other than the establishment where it was originally processed or packed, is exempted from the affirmative labeling requirements of this Act while it is in transit in commerce from the one establishment to the other, if such transit is made in good faith for such completion purposes only; but it is otherwise subject to all applicable provisions of this Act.

§ 54-524.98. (a) An advertisement of a drug, device, or cosmetic shall be deemed to be false if it is false or misleading in any particular.

(b) For the purpose of this Act the advertisement of a drug or device representing it to have any effect in albuminuria, appendicitis, arteriosclerosis, blood poison, bone disease, Bright's disease, cancer, carbuncles, cholecystitis, diabetes, diptheria, dropsy, erysipelas, gallstones, heart and vascular diseases, high blood pressure, mastoiditis, measles, meningitis, mumps, nephritis, otitis media, paralysis, pneumonia, poliomyelitis (infantile paralysis), prostrate gland disorders, pyelitis, scarlet fever, sexual impotence, sinus infection, smallpox, tuberculosis, tumors, typhoid, uremia, venereal disease, shall also be deemed to be false, except that no advertisement not in violation of subsection (a) shall be deemed to be false under this subsection if it is disseminated only to members of the medical, dental, or veterinary professions, or appears only in the scientific periodicals of these professions, or is disseminated only for the purpose of public-health education by persons not commercially interested, directly or indirectly, in the sale of such drugs or devices; provided, that whenever the Board determines that an advance in medical science has made any type of self-medication safe as to any of the diseases named above, the Board shall by regulation authorize the advertisement of drugs having curative or therapeutic effect for such disease, subject to such conditions and restrictions as the Board may deem necessary in the interests of public health; provided, that this subsection shall not be construed as indicating that self-medication for diseases other than those named herein is safe or efficacious.

§ 54-524.99. (a) For purposes of enforcement of this Act, the Board or any of its authorized agents, are authorized upon presenting appropriate credentials and a written notice as to the purpose of the inspection to the owner, operator or agent in charge (1) to enter at reasonable times any factory, warehouse or establishment in which drugs, devices or cosmetics are manufactured, processed, packed or held for introduction into commerce or after such introduction or to enter any vehicle being used to transport or hold such drugs, devices or cosmetics in commerce; and (2) to inspect at reasonable times and within reasonable limits and in a reasonable manner such factory, warehouse, establishment or vehicle and all pertinent equipment, finished and unfinished materials, containers and labeling therein. In the case of any factory, warehouse, establishment or consulting laboratory in which prescription drugs are manufactured, processed, packed or held, the inspection shall extend to all things therein (including records, files, papers, processes, controls and facilities) bearing on whether prescription drugs which are adulterated or misbranded within the meaning of this Act or which may not be manufactured, introduced into commerce or sold or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported or held in any such place or otherwise bearing on violation of this Act. No inspection authorized for prescription drugs by the preceding sentence shall extend to (A) financial data, (B) sales data other than shipment data, (C) pricing data, (D) personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this Act), and (E) research data. Such inspection shall be commenced and completed with reasonable promptness.

(3) to have access to and to copy all records of carriers in commerce showing the movement in commerce of any drug, device, or cosmetic, or the holding thereof during or after such movement, and the quantity, shipper and consignee thereof; provided, that evidence obtained under this subsection shall not be used in a criminal prosecution of the person from whom obtained; and provided further, that carriers shall not be subject to the other provisions of this Act by reason of their receipt, carriage, holding, or delivery of food, drugs, devices, or cosmetics in the usual course of business as carriers.

(b) If the authorized agent making any such inspection of a factory, warehouse or other establishment has obtained any sample in the course of the inspection, upon completion of the inspection and prior to leaving the premises, he shall give to the owner, operator, or agent in charge a receipt describing the samples obtained.

§ 54-524.100. The Board may cause to be disseminated such information regarding drugs, devices, and cosmetics as the Board deems necessary in the interest of public health and the protection of the consumer against fraud. Nothing in this section shall be construed to prohibit the Board from collecting, reporting, and illustrating the results of the investigations of the Board.

### ARTICLE 8

#### Prohibited Acts and Penalties

§ 54-524.101. (a) Except as authorized by this Chapter, it shall be unlawful for any person knowingly or intentionally:

(1) to distribute, or to possess with intent to distribute, a controlled drug;

(2) to manufacture a controlled drug;

(b) Any person convicted of a violation of this Section with respect to:

(1) any drug classified in Schedule I, II or III shall upon conviction be imprisoned in the penitentiary for a period not less than five nor more than forty years, or fined not more than twenty-five thousand dollars, or both. For a second or any subsequent violation of § 54-524.101 (a) with respect to any drug classified in Schedule I, II or III, or where in case of a first conviction of violation of § 54-524.101 (a) with respect to any law of the defendant shall previously have been convicted of a violation of any law of the United States, or of this or any drug classified in Schedule I, II or III, and such violation would be punishable in this State if the offending act had been committed in this State, the defendant shall be imprisoned in the penitentiary for life or not less than ten years or fined not more than fifty thousand dollars, or both.

Provided, further, that if the violation of the provisions of this article consist of the filling by a pharmacist of the prescription of a person authorized under this article to issue the same, which prescription has not been received in writing by the pharmacist prior to the filling thereof, and such written prescription is in fact received by the pharmacist within one week of the time of filling the same, or if such violation consists of a request by such authorized person for the filling by a pharmacist of a prescription which has not been received in writing by the pharmacist and such prescription is, in fact, written at the time of such request and delivered to the pharmacist within one week thereof, either such offense shall constitute a misdemeanor and be punishable only by a fine not in excess of one hundred dollars.

(2) any drug classified in Schedule IV or Schedule V shall upon conviction be confined in jail for not more than one year, or fined not more than one thousand dollars, or both. For a second or any subsequent violation of § 54-524.101 (a) with respect to any drug classified in Schedule IV or V, or where in case of a first conviction of violation of § 54-524.101 (a) with respect to any drug classified in Schedule IV or V, the defendant shall previously have been convicted of a violation of any law of the United States, or of this or any state, territory, or district, relating to the distribution or manufacture of any drug classified in Schedules I, II, III, IV or V, and such violation would be punishable in this State if the offending act had been committed in this State, the defendant shall be imprisoned in the penitentiary for a period not less than one nor more than five years or fined not more than ten thousand dollars, or both.

(c) It is unlawful for any person knowingly or intentionally to possess a controlled drug unless such substance was obtained directly or pursuant to a valid prescription or order from a practitioner, while acting in the course of his professional practice, or except as otherwise authorized by this Act. Any person convicted of a violation of this subsection with respect to a drug classified in Schedule I, Schedule II, or Schedule III shall be deemed guilty of a felony and imprisoned in the penitentiary for not less than one year nor more than twenty years, or fined not more than twenty-five thousand dollars, or both.

For a second or any subsequent violation of § 54-524.101 (c) with respect to any drug classified in Schedule I, II, or III, or when in the case of a first conviction of violation of § 54-524.101 (a) with respect to any drug classified in Schedule I, II, or III, the defendant shall previously have been convicted of a violation of any law of the United States, or of this or any other state, territory or district, relating to the distribution or manufacture of any drug classified in Schedule I, II, or III, and such violation would be punishable in this State if the offending act had been committed in this State, the defendant shall be imprisoned in the penitentiary for not less than two years nor more than forty years or fined not more than fifty thousand dollars, or both.

§ 54-524.102. Conditional discharge for possession as first offense.—Whenever any person who has not previously been convicted of any offense under this Act or under any statute of the United States or of any State relating to narcotic drugs, marijuana, or stimulant, depressant, or hallucinogenic drugs, pleads guilty to or is found guilty of possession of a controlled drug under subsection 54-524.101 (c), the court may, prior to imposition of sentence by the court or jury and without entering a judgment of guilt and with the consent of such person, defer further proceedings and place him on probation upon such reasonable terms and conditions as it may require. Upon violation of a term or condition, the court may enter an adjudication of guilt and proceed as otherwise provided. Upon fulfillment of the terms and conditions, the court shall discharge such person and dismiss the proceedings against him. Discharge and dismissal under this section shall be without adjudication of guilt and shall not be deemed a conviction for purposes of disqualifications or disabilities imposed by law upon conviction of a crime (including the additional penalties imposed for second or subsequent convictions under § 54-524.101 of this Act). Discharge and dismissal under this section may occur only once with respect to any person.

§ 54-524.103. It shall be unlawful for any person who is at least eighteen years of age to knowingly or intentionally distribute any drug classified in Schedule I, II or III to any person under eighteen years of age who is at least three years his junior. Any person violating this provision shall upon conviction be imprisoned in the penitentiary for a period not less than twenty-five years nor more than fifty years or fined not more than fifty thousand dollars, or both. Any person convicted of a second or subsequent violation of this section shall upon conviction be imprisoned in the penitentiary for a period not less than twenty-five years nor more than fifty years or fined not more than fifty thousand dollars, or both. Imposition or execution of such sentence shall not be suspended and probation shall not be granted.

§ 54-524.104. Any person who attempts or conspires to commit any offense defined in this Chapter is punishable by imprisonment or fine or both which may not exceed the maximum punishment prescribed for the offense, the commission of which was the object of the attempt or conspiracy.

§ 54-524.105. Any penalty imposed for violation of this Chapter shall be in addition to, and not in lieu of, any civil or administrative penalty or sanction authorized by law.

§ 54-524.106. Any person who violates any provision of this chapter, for which no penalty is specified, shall be deemed guilty of a misdemeanor and upon conviction thereof shall be fined not more than one thousand dollars or shall be confined in jail not exceeding twelve months, or both, at the discretion of the court or the jury trying the case.

§ 54-524.107. Any person licensed by the Board who violates any of the provisions of this chapter, and who is not criminally prosecuted, shall be subject to the monetary penalty provided in this section. If, by a majority vote, the Board shall determine that the respondent is guilty of the violation complained of, the Board shall proceed to determine the amount of the monetary penalty for such violation, which shall not exceed the sum of five hundred dollars for each violation. Such penalty may be sued for and recovered in the name of the Common-wealth.

§ 54-524.108. Exceptions and Exemptions Not Required to be Negative.— In any complaint, information, or indictment, and in any action or proceeding brought for the enforcement of any provision of this Chapter, it shall not be necessary to negative any exception, excuse, proviso, or exemption, contained in this Chapter, and the burden of proof of any such exception, excuse, proviso, or exemption, shall be upon the defendant.

§ 54-524.109. If any provision of this Act is declared unconstitutional or the applicability thereof to any person or circumstances is held invalid, the constitutionality of the remainder of the Act and applicability thereof to other persons and circumstances shall not be affected thereby.

2. That Chapter 15 of Title 54 of the Code of Virginia consisting of §§ 54-399 through 54-524, as amended, is repealed.

3. The repeal of Chapter 15 of Title 54 upon the effective date of this act shall not affect any act or offense done or committed, or any penalty or forfeiture incurred, or any right established, accrued or accruing on or before such date, or any prosecution, suit or action pending on that date. Except as in this act otherwise provided, neither the repeal of such chapter nor the enactment of Chapter 15.1 of Title 54 shall apply to offenses committed prior to the effective date of this act, and prosecutions for such offenses shall be governed by the prior law, which is continued in effect for that purpose. For the purposes of this act, an offense was committed prior to the effective date of this act if any of the essential elements of the offense occurred prior thereto.

# **APPENDIX** (continued)

# LEGISLATIVE PROPOSALS

Π

Recommended amendment to add provision on sales of over-the-counter drugs.

## AMENDMENT TO PROPOSED BILL

(To add language to require that every preparation containing any quantity of any drug, or drugs, subject to the requirements of Schedule IV, be included in Schedule V, and controlled by the "Drug Control Act")

1. In § 54-524.84, at the end of the section, add the following paragraph.

(b) Every preparation containing any quantity of any drug, or drugs, subject to the requirements of Schedule IV, which may be dispensed without a prescription under federal law, which in its labeling bears cautions as to side effects, or contraindications when certain diseases exist or may exist with respect to the user, or which is capable of producing a drug incompatibility when used in conjunction with a prescription drug.