THE NEWLY ENACTED FOOD, DRUG AND COSMETIC ACT, AND ITS RELATION TO PHARMACEUTICAL LEGISLATION.*

BY ROBERT L. SWAIN.[1]

The enactment of this law must be regarded as one of the most important events in the public health field in recent years, and it is certain to exercise a profound influence throughout the entire field of pharmaceutical legislation. The state food and drugs acts, almost without exception, are copies of the Federal Law passed in 1906. It was the avowed purpose of these state laws to supplement and complement federal legislation and thus the closest uniformity was practiced with respect to the actual language of the acts.

Obviously, the recently enacted law has thrown this arrangement out of gear and will necessitate a revision of the food and drugs acts of the several states, if the same continuity is to be preserved. This was, of course, to be expected and some thought has already been given to making the state acts conform to the new pattern.

Little thought, however, has been given to what the Federal Food, Drug and Cosmetic Act may mean to pharmacy laws, but it is my feeling that the new law affords an unusual opportunity for extending the authority of pharmacy laws and throws new light upon the whole effort now being made to modernize pharmaceutical legislation.

The Federal Food, Drug and Cosmetic Act clearly outlines the field in which it is to operate by comprehensive definitions of the subject matter to which it shall apply, and this fact alone should be seized upon as an essential factor to be considered in the revision of pharmacy laws. It is interesting to note that while pharmacy laws have to do almost exclusively with drugs, only a small minority of the state pharmacy laws attempt any definition of this term. In other words, the pharmacy laws proceed to discuss the rights and privileges of pharmacists with respect to drugs, the education which pharmacists must possess in order to deal intelligently and competently with drugs, and the prohibitions against others than pharmacists selling drugs, and yet, nowhere in the laws is there to be found any legislative pronouncement as to what the term "drugs" includes, and even in those few pharmacy laws in which an attempt is made to define the word "drugs," it will be found that the passage of the Federal Food, Drug and Cosmetic Act has rendered the definitions obsolete.

In order that we may truly appreciate the significance of the change which the new legislation has brought about, it will be helpful if we quote the definition of the term "drug" from the act originally passed in 1906, the definition as it now appears in the Federal Food, Drug and Cosmetic Act, and contrast this latter definition with the definitions of the term "drugs" as they appear in the pharmacy laws of the states given below.

FOOD AND DRUGS ACT OF 1906.

The term "drug," as used in this act, shall include all medicines and preparations recognized in the United States Pharmacopœia or National Formulary for

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[1] Secretary, Maryland State Board of Pharmacy

internal or external use, and any substance, or mixture of substances, intended to be used for the cure, mitigation or prevention of disease, of either man or other animals.

FEDERAL FOOD, DRUG AND COSMETIC ACT.

The term "drug" means (1) articles recognized in the official United States Pharmacopœia, official Homeopathic Pharmacopœia of the United States or official National Formulary, or any supplement to any of them; and (2) articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or animals; and (3) articles (other than food) intended to affect the structure or any function of the body of man or animals; and (4) articles intended for use as a component of any article specified in clause (1), (2) or (3); but does not include devices or their components, parts or accessories.

At this point it might be well to point out that the new definition recognizes the Homeopathic Pharmacopœia of the United States, as well as all supplements issued to the United States Pharmacopœia, National Formulary or Homeopathic Pharmacopœia, and brings within the classification of drugs, many new articles not heretofore specifically so regarded, such as articles used in the diagnosis and treatment of disease. Also, many articles, particularly those affecting body function and structure, such as "obesity cures," which heretofore were not regarded as drug products, in that they were not used in the cure, mitigation or prevention of disease, are now brought within this classification.

A study of the new definition in its entirety will impress one with the fact that the term "drug" has taken on a vastly expanded meaning and to the same degree has become of the greatest significance to the whole body of pharmaceutical legislation.

Let us now note the contrast between the state pharmacy laws and the Federal Food, Drug and Cosmetic Act in respect to the meaning of the words "drug" or "drugs."

Alabama.—"Drug" or "Drugs," where not otherwise limited, means any substance or substances used as medicines or in the preparation of medicines.

"Medicine" or "Medicines," where not otherwise limited, means a drug, drugs, chemicals, compounds or preparations thereof, in suitable forms for use as curative or remedial substances, either internally or externally by man or for animal.

"Chemical" or "Chemicals," where not otherwise designated or limited, means definite chemical compounds or the chemical materials of medicines.

Arizona.—The term "drugs," where not otherwise limited, means any substance used as a medicine or in the preparation of medicines.

The term "medicines," where not otherwise limited, means drugs or chemicals, or compounds, or preparations thereof, in suitable form for use as a curative or remedial substance intended to be used either internally or externally for man.

The term "chemicals," where not otherwise limited, means definite chemical compounds, or chemical compounds or materials or medicines.

Arkansas.—The term "drug," as used in this Act shall include all medicines and preparations recognized in the United States Pharmacopœia or the National

Formulary for substances intended to be used for the cure, mitigation or prevention of disease of either man or other animal.

"Medicine," when not otherwise limited, means a drug or preparation of drugs, in suitable form for use as a curative or remedial substance.

Iowa.—"Drugs and medicines" shall include all medicinal substances and preparations for internal or external use recognized in the United States Pharmacopœia or National Formulary, and any substance or mixture of substances intended to be used for the cure, mitigation or prevention of disease of either man or animals.

Minnesota.—The term "drug" shall mean all medicinal substances and preparations recognized by the United States Pharmacopœia and National Formulary or any revision thereof, and all substances and preparations intended for external and internal use in the cure, mitigation, treatment or prevention of disease in man and animals, and all substances and preparations, other than food, intended to affect the structure or any function of the body of man or animals.

The term "medicine" shall mean any remedial agent that has the property of curing, preventing, treating or mitigating diseases, or that is used for that purpose.

"Chemical" means all medicinal or industrial substances, whether simple or compound or obtained through the process of the science and art of chemistry, whether of organic or inorganic origin.

Nebraska.—For the purposes of this article "drugs and medicines" shall include all poisons, dangerous or deleterious substances and preparations for external or internal use recognized in the United States Pharmacopœia or National Formulary which are intended for the correction, mitigation or prevention of diseases of either man or animals, or any other poisonous, dangerous or deleterious substances and preparations intended for a similar purpose, except patent or proprietary medicines.

New Hampshire.—"Drugs," when not otherwise limited, means all substances used as medicines or in the preparation of medicines.

"Medicine," when not otherwise limited, means a drug or preparation of drugs in suitable form for use as a curative or remedial substance.

New York.—"Drugs," where not otherwise limited, means all substances used as medicines or in the preparation of medicines. "Crude Drugs," means drugs that have not been changed by manufacture except desiccation or comminution.

"Medicines," where not otherwise limited, means a drug or preparation of drugs in suitable form for use as a curative or remedial substance.

Oregon.—"Drug" or "Drugs," where not otherwise limited, means any substance or substances used as medicines or in the preparation of medicines.

"Medicine" or "Medicines" where not otherwise limited, means a drug, drugs, chemicals, compounds or preparations thereof, in suitable form for use as a curative or remedial substance, either internally or externally by man or for animal.

"Chemical" or "Chemicals," where not otherwise designated or limited, means definite chemical compounds or the chemical materials of medicines.

Pennsylvania.—The term "drug," as used in this act, shall include all medicines and preparations recognized in the latest revision of the Pharmacopœia of the United States, the latest edition of the National Formulary or the American Homeopathic Pharmacopœia, or any supplement to any of them official at the time of investigation, for the internal or external use and any substance or mixture of substances, intended to be used for the cure, mitigation or prevention of disease of either man or animals.

Rhode Island.—The terms "drugs," "medicines" and "poisons," as used in this chapter, shall mean and include all drugs and preparations sold under or by a name recognized in the United States Pharmacopœia or National Formulary, and of the standards of strength, quality or purity as determined by the test, if any, laid down in the United States Pharmacopœia or National Formulary.

South Dakota.—"Drugs," where not otherwise limited, means all substances used as medicines or in the preparation of medicines and such material as may be used in the treatment of disease.

"Medicines," where not otherwise limited, means drugs or chemicals, or preparations thereof, in suitable form for the prevention, relief or cure of diseases, when used either internally or externally by man or for animal.

"Chemicals," where not otherwise limited, means the chemical materials or (of) medicine.

Virginia.—The word "drug," as used in this chapter, shall include all medicines and preparations recognized in the United States Pharmacopœia or National Formulary for internal or external use, and any substance or mixture of substances intended to be used for the cure, mitigation or prevention of disease of either man or other animals.

Simply in passing, it is interesting to note that under the Nebraska definition, all articles intended for the correction of disease are classed as drugs, the same thing being true of poisonous, dangerous or deleterious substances and preparations intended for similar purposes. Most interesting, too, is the provision that patent and proprietary medicines are not drugs under the pharmacy law of that state.

A study of the above definitions will be found interesting and will afford much food for thought, but even a casual reading is sufficient to show that they are not as comprehensive and not as broad as the definition in the Federal Food, Drug and Cosmetic Act.

It must be apparent by this time that one of the major defects in our pharmacy laws is that of basic definitions, and it must be apparent, too, that the term "drugs" should have the same meaning in pharmacy laws as that ascribed to it in other related legislation.

There would seem to be no logical basis for defining the term "drug" one way in federal or state food and drugs acts, and another way in pharmacy laws, because there is a direct relation between pharmacy laws and food and drugs acts. The food and drugs acts set up standards for drugs and medicines, adopt prohibitions against their misbranding and adulteration, and prescribe penalties for violation. The pharmacy laws deal with the educational qualifications of those who shall prepare drugs and medicines, who may dispense them, and the conditions surrounding the compounding and dispensing of physicians' prescriptions for drugs and medicines.

There would seem every reason why the basic definition of drugs should be the same in the pharmacy laws and in the food and drugs acts. This point is emphasized because in the past, there has been no disposition to adopt uniform definitions, even in the food and drugs act and the pharmacy law of the same state. This, no doubt, has contributed toward a lack of coöperation between enforcement agencies concerned with the administration of the food and drugs acts and those charged with the administration and enforcement of pharmacy laws.

It is my judgment that an attempt should be made to bring about uniformity so that the pharmacy laws may be broad enough and comprehensive enough to encompass that field of drugs and medicines which is covered by the food and drugs acts. I believe this will result in greatly expanding the scope and authority of pharmacy laws, will have a tendency to more sensibly limit the distribution of drugs and medicines to pharmacists, and will afford the public a much greater degree of protection in this highly important matter. At any rate, it opens up a new field of study and one which should receive the very closest consideration of all interested in a modernization of pharmacy laws in a real and modern sense.

MUST ONE KEEP OPEN AT NIGHT TO COMPOUND PRESCRIPTIONS?*

BY FRANK A. DELGADO.[1]

An invitation to spend the week-end with friends at their summer cottage near East Hampton, L. I., was gladly accepted as it presented an opportunity to escape the heat wave that had been raging in New York. That evening some neighbors called, and introductions followed. My host said "Meet Mr. Doe. He is a pharmacist but like yourself has not actively practiced it for many years." I asked Mr. Doe what was his occupation at present, and what led him to give up the drug business. He informed me that he was now in the hardware business and I was to learn later that Fortune had smiled upon him, and that he not only possessed a splendid business which netted him an excellent income, but that furthermore he was getting the most out of life. He had a fine home, two new automobiles and some income property. He and Mrs. Doe visited New York City frequently to attend the theater and otherwise amuse themselves. He had two splendid sons of whom he had reason to be proud. His business while most profitable did not prevent him from enjoying the society of his family, and indulging in fishing and outdoor sports of which he was very fond. He decided to quit the drug business, he said, when one night after one A.M. he was awakened by a customer who asked would he compound a prescription. He slid into some clothes and still half-awake accompanied the supposedly sick man to the drug store. Switching on a light he read the prescription, and to his anger and amazement found that it was of the tonic variety, and furthermore bore a date that showed the patient had been carrying it around in his pocket for two or three days. It was precisely at this moment that Mr. Doe decided to seek his livelihood in some other field.

The incident just related may be exceptional; however, I venture to say that a study of the prescriptions dispensed after six P.M. would show that a substantial

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[1] 34–24—82nd St., Jackson Hts., New York City.