

DRUG PRODUCTS—THE LAW AND THE LABEL.

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How to make a statement of the strength, quality or purity on a label for drugs which differ from the official standards, in such manner as to be plain, has never been judicially determined. It is claimed by some that a simple declaration of the actual strength is sufficient, while others contend, that some qualifying statement should also be made in order that the purchasers may not be misled.

The labels employed by some manufacturers and dealers give evidence of their conviction, that a simple statement of the strength of the drug, in such cases, does not comply with the law. Examples:

"Aconite Root

Standard Strength U. S. P. 0.5% Aconitine
Assayed Strength 0.485% Aconitine

"Elixir of Ammonium Valerate

Alcohol, 17%

Each Fluidounce contains

Ammonium Valerate 16 grains
Tincture of Vanilla 2 minims

This elixir is preserved with alcohol and glycerin. The chloroform of the N. F. preparation has been omitted and the elixir colored with carmine."

"Beef, Wine and Iron

Alcohol 18%

This preparation should not be confused with that of the National Formulary, as it is made from a different formula.

Each fluidounce represents 15 grains of Extract of Beef in Sherry Wine with about 4 Grains of Iron and Ammonium Citrate."

Section 7 of the Federal Food and Drugs Act provides: "That no drug defined in the United States Pharmacopœia or National Formulary shall be deemed to be adulterated * * * if the standard of strength, quality, or purity be plainly stated upon the bottle, box or other container thereof, although the standard may differ from that determined by the test laid down in the United States Pharmacopœia or National Formulary."

Section 8 provides: "That the term 'misbranded,' as herein used, shall apply to all drugs, or * * *, the package or label of which shall bear any statement, design, or device regarding such article, or the ingredients or substances contained therein which shall be false or misleading in any particular."

The label for a drug sold under an official name, which is either above or below the standard, having upon it a declaration of strength only, is plainly misbranded, because a single declaration of strength does not provide a plainly stated declara-

tion of the quality. Moreover, when such a label carries a guaranty, the label is misleading. The standard is stated and the drug guaranteed. Nothing appears on the label to show the purchaser what the standard should be. He does not know what the standard is and, naturally, concludes that the article is guaranteed of standard strength, but is sadly misled. In fact just such a case as this was brought to light in the work of the Pennsylvania Board of Pharmacy.

A prescription for Essence of Pepsin, N. F. was sent to a pharmacist who filled it with a nearly half-strength drug. Later this pharmacist was cited for a hearing before the board, at which he set up the claim that he was in the right and safe from prosecution because the essence he used was guaranteed by a reputable manufacturer. The difference in a guaranty *for what the product is sold for*, and a guaranty that the product is of *official standard of strength and quality*, misled him. This would not have been possible, if a declaration of the quality had appeared upon the label of the article, or a statement such as appears on the label for the beef, iron and wine, or the elixir of ammonium valeriate quoted herein.

It may very properly be said that a pharmacist should be sufficiently familiar with official standards, to readily detect a drug of deficient strength when a simple statement of strength appears upon the label. But is this law for the protection of the pharmacist only? How about the physician and the general public, are they expected to know the standards? What constitutes a plain statement of the standard of strength, quality, or purity, within the meaning of the law?

For our answers to these questions we must look to the intent or purpose of the provision. It can have no other purpose than to protect the consumer and acquaint him with the fact, when he is sold an article that is not standard. A label bearing a statement of strength by which only the pharmacist may determine the actual strength and quality of the drug it represents, and that, perhaps, after making a careful calculation, cannot possibly afford the protection this provision is intended to give, to the ordinary every day purchaser of the product for his own consumption. The following illustrations will show how some manufacturers attempt to comply with this very important provision as to the label, and how the public may be misled thereby.

"Essence of Peppermint

Contains 80 percent PURE PROOF SPIRIT
19.75 percent Distilled Water
Pure Oil of Peppermint and herb, a trace.
Guaranteed under the Food & Drugs Act, June 30, 1906."

"Tincture of Iodine

Contains 45. percent Pure Alcohol.
3.51 percent Pure Iodine
0.5 percent Pure Potassium Iodide.
Guaranteed under the Food & Drugs Act, June 30th, 1906."

Under labels as above, drug products are not guaranteed for their PRIME quality. They are really guaranteed to be of inferior quality. The labels are not plain as to this, but what average purchaser of such 10 percent bottled prod-

ucts as these were taken from would ever know how utterly deficient in strength and quality they were?

The labels declare the strength, but say nothing plainly about the quality. They are not adulterated drug products, within the meaning of the law, but they are misbranded, which is, also, a violation of the law.

It is evident that there is need for a court decision in this matter and a possibility of a common sense rendition, as to what a plain statement for sub-standard drugs should consist of, is apparent, when we consider what Chief Justice Claybaugh, in the Antikamnia case, says regarding regulations, viz.:

"Conceding for the purpose of the statement of this case, that this is not a quasi-criminal statute, but purely a remedial one, if that be true then it is the duty of the court to construe it as to give effect to the purposes and objects for which it was passed.

"I have no doubt that these secretaries could, with great propriety, make regulations that would more effectually carry into execution the purposes and intent of the law makers. That being so, what is the fair construction of the act, or does it need any interpretation?

"The right to interpret an act in conformity to the purposes and objects of that act applies only where the act is not perfectly plain or is not perfectly apparent.

"Then the courts can give such interpretation to it as will carry out and gratify the purposes of its passage. Interpretation, as I understand it, does not mean that the court can add anything to language which is plain."

This would seem to encourage a hope that the position taken by the Pennsylvania Board may be sustained when properly presented to the courts.

Regarding regulations. The Federal law does not provide for a guaranty and serial number; nor does it provide, that a label shall make reference to a guaranty; nor does it provide that a guaranty shall be filed with the department of agriculture, but the regulations adopted, do provide for, not only the guaranty and serial number, but also the manner in which these are to be stated. It was found when left to themselves, manufacturers misapplied the object of the guaranty and made their labels read "Guaranteed by the U. S. Government."

Now if it is legal and proper to adopt regulations as to the manner in which a guaranty shall be made, and stated, it is reasonable to hold that regulations may be adopted which shall provide for a plain statement for labels on sub-standard drug products, in order that purchasers may not be misled.

SOME PHASES OF A PHARMACIST'S DUTY TO THE PUBLIC.

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It is fair to suppose that all men realize that they owe something to the community in which they live. They believe that it is their duty to be good citizens but the ideas of what constitute good citizenship are as far apart as the poles. It is without doubt too often true that men think it is sufficient to be honest and honorable in their dealings with others, to pay their debts and keep out of the penitentiary. There is a considerable number who do not even feel it a duty to exercise the right of suffrage. In brief, it is a passive sort of good citizenship