NEW LABELS VS. OLD LABELS.*

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As early as 1849, Congress sought to prevent importation of adulterated drugs into this country. This effort was intensified in 1852, the year of the organization of the AMERICAN PHARMACEUTICAL ASSOCIATION. Indeed, one of the expressed objects of the ASSOCIATION was to assist the United States Government in its undertaking in that field. It was not, however, until 1906 that Federal legislation of a general nature was enacted in an attempt to free the channels of interstate commerce from adulterated and misbranded drugs. In that year, the "old" Food and Drugs Act was enacted into law. While that law accomplished a great deal, measured by the then existing evils in the sale and distribution of drugs and medicines which had been curbed thereby, it was woefully inadequate for the purpose intended when measured by the abuses which subsequently developed or were continued thereunder. The new Federal Food, Drug and Cosmetic Act of 1938 constitutes a radical departure of the Act of 1906 and is intended to stamp out the many abuses which had been in evidence during the 32 years of the operation of the old law. While the law also prohibits adulteration and regulates introduction of new drugs, it is popularly considered by retailers mainly as a "labeling law," that is, the provisions with regard to labeling seem to be the paramount topic of discussion. It steals the show, so to speak. "Have you seen the new labels?" or "what about the new labels?" and similar expressions seem to typify retailers' current concern in and discussion of the Act—hence, the title of this paper "New Labels *vs.* Old Labels."

Rather than set out in detail all of the labeling requirements under the law, let us discuss a few specific practical features of it of interest to retailers. To begin with, a medicine for human medication containing any of certain enumerated narcotic or hypnotic substances, like codeine or barbituric acid, for example, must be labeled so as to indicate the presence of such substances both qualitatively and quantitatively with the added legend "Warning—may be habit-forming." You can readily appreciate that such information on the label will in many instances seriously affect the volume of sales of preparations containing such narcotic or hypnotic ingredients—the warning phrase acting as a scarecrow. The practical result of it may be that the customer will either ignore it, or shift to another patent medicine without such warning phrase on the label or ask the pharmacist for an extemporaneous preparation of his own, or abandon entirely self-medication in favor of a physician's diagnosis and prescribed individual medication, the latter two results being decidedly advantageous to the profession.

Secondly, a non-official medicine containing two or more active ingredients must be labeled so as to indicate the presence of each active ingredient at least qualitatively, and in the case of certain enumerated ingredients, like alcohol and bromides, for example, quantitatively as well. Here again the practical result of

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that may be the same as in the case of the patent medicines containing a narcotic or hypnotic ingredient; that is, the customer will either ignore it, or shift to another preparation which does not contain the ingredient deemed objectionable or ask the pharmacist to recommend an extemporaneous preparation of his own, or abandon entirely self-medication in favor of a physician's diagnosis and prescribed medication, the latter two results—as already stated—being decidedly advantageous to the profession. In other words, all of this professional information on the label at least in the case of the masses of scientifically uninformed buyers of self medications, and those are by far in the majority, will serve to initiate a conversation or discussion between the customer and the pharmacist regarding a given product which, in many instances, will undoubtedly lead to either of the two aforementioned favorable results from the standpoint of the pharmacist, namely, an acceptance of the recommended extemporaneous preparation of the pharmacist, or a shift to a physician's diagnosis and prescribed medicine.

Another so-called new label problem of particular concern to the retail pharmacist is the "repacking" provision of the misbranding regulations. Pharmacists frequently buy from manufacturers located in different states familiar bulk goods, like Elixir of Terpin Hydrate with Codeine, Compound Syrup of Cocillana or Cheracol, for example, in gallon lots and resell it on call over the counter (as well as on prescriptions, of course) in small quantities. The manufacturer may in such cases omit from the label on the gallon bottle the directions for use by placing thereon the statement "Caution: to be used only by or on the prescription of a physician." The pharmacist, however, in reselling such product on call over the counter, even though such sale is intra-state only, so long as the purchase of the gallon lot was made across the state line, must label the two- or three-ounce bottle which he sells, in full compliance with all of the provisions of the Federal law, including name, formula disclosure, warning against habit-forming, directions for use, etc., the same as the manufacturer would have had to label it had he shipped it to the customer in a two- or three-ounce bottle directly from his plant located in a different state. Of course, if the gallon goods are purchased from a local manufacturer within the state, no interstate commerce is involved at any stage of the transaction and the labeling requirements of the Federal law are not applicable.

Lastly, the labeling requirements of the law in the case of medicines dispensed on physicians' prescriptions, are not as favorable as many pharmacists feel they ought to be. While an attempt has been made to create an exemption in such cases, the provision is so worded as to make the exemption meaningless in the case of "refillable" prescriptions. For example, a prescription calling for 3 fluidounces of Elixir of Terpin Hydrate with Codeine, which is generally and legally considered a refillable prescription, would (if the bulk Elixir were purchased in interstate commerce or if the prescription were to be shipped in interstate commerce) have to be labeled so as to meet all of the detailed labeling requirements of the Federal law referred to above, including the phrase, "Warning—may be habit-forming," in addition to the usual and customary prescription labeling. While it is the writer's opinion that such result was never intended, nor necessary, nevertheless the provision of the law is as indicated above; and it is hoped that the administration will place a saner interpretation on it than the language permits.

Retailers have repeatedly asked the question "What about old label mer-

chandise remaining on our shelves after the law takes effect?" *Drug Topics* has already very effectively answered that question with a dramatic picture on the cover of a recent issue in which retailers were appeased and advised not to worry about the G-man getting after them. It should be added that reputable manufacturers will undoubtedly work out some practical plan in the handling of their old label merchandise, particularly after their new package has been advertised and introduced to the public, in order to avoid unnecessary explanation and possible sales resistance at the drug counter. Of course, some difficulty may be encountered with the adjustment of old label merchandise of questionable manufacturers, and retailers should guard themselves against it in advance. But, on the whole, the problem of old label merchandise remaining on the retailers' shelves after the law takes effect, could hardly be considered as a serious one.

In conclusion, we should not be blinded into the belief that the new law will prove a panacea to all the ills which were prevalent under the old act. Far from it. It must be borne in mind that the "misbranding" section, as drastic and as all-inclusive and sweeping as some of us may think it is, is nothing more than a "labeling statute" covering only information which may or may not, or must, be given on the label and accompanying literature in the sale of foods, drugs, devices and cosmetics, and even then only in the case of such as are shipped or introduced for shipment in interstate commerce. The law does not cover the manufacturing or production angle of such commodities except indirectly in the case of "new drugs" within the meaning of the Act. In other words, it is not what a manufacturer puts into the bottle, so long as it is not adulterated, but what he says about it in the labeling on and accompanying it, that determines whether or not he committed an unlawful act under the law. The public first commences to enjoy the benefits of its provisions only after the product had been manufactured, labeled, shipped in interstate commerce, seized, analyzed, found to be either adulterated or misbranded, or both, and the enforcement machinery had been set in action and successfully concluded—but not before. Until all of these things had taken place—and in the case of many products it may either never take place or only after the wrong had been committed—the public remains unprotected under this law.

The writer is not prepared to say whether Government control and regulation of the manufacturing or production of foods, drugs, devices and cosmetics, as in the case of production and bottling of "bonded whiskeys," for example, is legally possible or generally desirable or necessary. That is a matter which requires serious and careful consideration as well as a study of a number of factors in the light of existing laws, experiences, necessities and circumstances. From an abstract viewpoint, however, it would appear that in order to afford the maximum protection to the public—particularly the masses of unintelligent buyers of foods, drugs, devices and cosmetics—authoritative regulation and control at the point of manufacture or production of these products is equally, if not more, essential than that provided under the Act.
