EDITORIAL

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FOOD AND DRUG LEGISLATION.

THE FOLLOWING resolutions adopted unanimously at the Dallas (1936) and the New York (1937) meetings, respectively, concisely express the position of the ASSOCIATION with reference to this legislation.

"*Resolved*, that the AMERICAN PHARMACEUTICAL ASSOCIATION restates its profound conviction that the present Federal Food and Drugs Act is too limited in its scope to afford the public necessary protection in the matter of foods, drugs and cosmetics and that the ASSOCIATION urges the prompt enactment of legislation substantially the same as Senate Bill No. 5 as it was passed by the Senate in 1935;

"*Resolved further*, that the ASSOCIATION strongly opposes any provision in the proposed legislation which will lessen enforcement efficiency; and

"*Resolved further*, that additional delay in the enactment of food, drug and cosmetic legislation is unjustifiable and should be looked upon as a flagrant disregard of the public welfare."

"*Resolved*, that the ASSOCIATION express its profound dissatisfaction with the failure of Congress to enact food, drug and cosmetic legislation based upon a sound understanding of public health and designed to give the public adequate and immediate protection against adulteration of drugs, foods and cosmetics, and against all forms of misbranding and misstatement in labels and all forms of advertising."

After the lengthy study and full discussion of the subject during the last four years, there should be no real difficulty in deciding on the necessary and important provisions of the bill and in arriving at agreements with respect to them, between the various interests affected. Less important provisions should not be permitted to delay the legislation but should be deferred for such consideration at a later date as they deserve. Furthermore, it is practically impossible to compile a completely satisfactory bill; any measure adopted will probably have to be amended in the light of the experience gained in its enforcement.

This is not an approval of the hasty or ill-considered legislation. It is a plea for the adoption of improved food and drug legislation by the Congress at the coming session and an appeal to every national, state and local pharmaceutical association to place its influence squarely back of such action.

To say the least, S. 5 and Committee Print 3 provide the basis for satisfactory legislation at the coming session of the Congress.—E. F. K.

THE "ELIXIR OF SULFANILAMIDE" EXPERIENCE.

SO MUCH publicity has been given to the tragedy which followed the manufacture, distribution and use of this product and to the report with respect to it which the U. S. Department of Agriculture submitted to the Congress on November 26, 1937, that it is unnecessary to here review the former or to quote the latter. Every one joins in heart-felt sympathy to those who were in any way injured and in thanks and commendation to those who acted so promptly and so effectively to prevent greater harm.

It is important to place the responsibility for the tragedy and to punish those who are found to deserve it. It is much more important to take all possible steps to prevent a recurrence of such a tragedy by placing the necessary safeguards around the preparation, distribution and use of drugs and medicines.

In the report referred to above, it is recommended that in order "to protect the public from drugs which, like the elixir, are dangerous because of their inherent toxicity," legislation be enacted to provide at least the following:

1. License control of new drugs to insure that they will not be generally distributed until experimental and clinical tests have shown them to be safe for use. The definition of what constitutes a new drug should include (*a*) substances which have not been used sufficiently as drugs to become generally recognized as safe, (*b*) combinations of well-known drug substances where such combinations have not become generally recognized as safe, and (*c*) well-known drug substances and drug combinations bearing label directions for higher dosage or more frequent dosage or for longer duration of use than has become generally recognized as safe.

Exemption should be made for new drugs distributed to competent investigators for experimental work. A board of experts should be provided who will advise the Secretary of Agriculture on the safety of new drugs.

2. Prohibition of drugs which are dangerous to health when administered in accordance with the manufacturer's directions for use.

3. Requirement that drug labels bear appropriate directions for use and warnings against probable misuse.

4. Prohibition of secret remedies by requiring that labels disclose fully the composition of drugs.

With the purpose of the recommended legislation, this ASSOCIATION is in complete accord. To provide the control that is required without imposing a burden which even the Federal government will find it difficult to discharge, will require careful consideration and the profession and industry should contribute every possible assistance to the proper solution of this problem.

In response to these recommendations Senator Copeland introduced S. 3073 in the Senate on December 1, 1937, and it was referred to the Committee on Commerce. It provides "That (*a*) in order to safeguard the public health against the distribution of drugs which have not become generally recognized as safe for use, no person shall introduce or deliver for introduction into interstate commerce any drug composed, in whole or in part, of any substance or combination of substances, which substance or combination is not generally recognized as safe for use in the dosage and with the frequency and duration prescribed, recommended or suggested in the labeling thereof, unless the packer of such drug holds a notice of a finding by the Secretary that such drug is not unsafe for use."

The other sections provide for the enforcement of the legislation but do not include a penalty.

It is to be hoped that hearings on the bill will be held at an early date and that adequate legislation will be enacted during the coming session of the Congress.—E. F. K.