

Dr. MILLER. I have had access to Dr. Modell's statement, and from the way it was worded it might have been so interpreted; in fact, some of those who were in the hearing room at the time gained that impression on their own, and they suggested that I take this opportunity to dispel any misapprehensions that may have been given by Dr. Modell. I know he did not intend to give that impression, but the wording of his reference to the USP might have possibly been misinterpreted to mean that USP is supported by the industry. I will deal at some length with that.

Senator NELSON. I see. I didn't have that impression.

Dr. MILLER. Good, I am glad you didn't.

Senator NELSON. My interpretation of the references made by the various witnesses was that the USP was an independent, highly reliable source of information, and so I was curious where your impression came from.

Dr. MILLER. Thank you. It was a matter of precaution rather than apprehension on my part.

By the simplest definition, a pharmacopeia is a book that lists medicinal substances but the term is now generally restricted to drug lists that include standards of strength and purity, which in addition are produced under recognized authority. Thus the current U.S. Pharmacopeia is a book of some 1,200 pages. I have a copy here, that describes about 900 articles of therapeutic significance and provides for them appropriate tests and standards. This latest edition, USP XVII, was compiled, as were preceding editions, by a revision committee composed of 60 elected but unpaid medical and pharmaceutical experts who serve on the revision committee. These experts, and many others, take part in USP work not only because they are public-spirited but also because the Pharmacopeia is recognized as a legal compendium. That is, the USP standards are designated in the Federal Food, Drug, and Cosmetic Act for use by the Food and Drug Administration. As a result of this recognition by the Congress, the U.S. Pharmacopeia is regarded as an authoritative, quasi-legal compendium and no effort is spared to make it scientifically sound and accurate.

The revision program, incidentally, is supported not by tax funds, grants or contributions but rather by the sale of the Pharmacopeia and from fees charged for USP Reference Standards that are used in the laboratory in conducting the USP tests. The Pharmacopeia and the Reference Standards are used in all parts of the world. About two-thirds of the Pharmacopeias are bought by pharmacists, while nearly all of the Reference Standards are used in testing laboratories of the Government and the pharmaceutical industry.

I mention that fact to show the source of our support.

The organization responsible for this program is a nonprofit corporation that is constituted anew every 10 years by delegates from all of the colleges of medicine and pharmacy in America, from State and national medical and pharmaceutical associations, from several units of the Government, and from a limited number of professional and trade associations. Without doubt, the USP stands on a foundation of deeper roots and broader representation in medicine and pharmacy than anything else of its kind.

The revision program is entirely the concern of the USP Revision Committee, which is made up of 20 medical specialists and 40 special-