

ists in pharmacy, chemistry and biology. A nine-member board of trustees handles all business affairs of the USP Convention.

At the time our statement was made in 1960, the 16th revision of the Pharmacopeia had just appeared; now, in 1967, the 17th revision has been out 2 years and work is well along on the next edition. These editions are not mere reprints; they are almost totally rewritten from cover to cover. The fact that the USP comes out at regular, 5-year intervals, with supplements intervening, and one just recently came out for the edition that is in force, amply supports the first point we wish to stress; namely that USP standards are kept current and are responsive to everyday needs.

Senator NELSON. May I interrupt?

Dr. MILLER. Surely.

Senator NELSON. How often does the supplement come out?

Dr. MILLER. Supplements come out as needed. This latest one came out after the main volume had been in effect for 18 months, so that generally we come out with two or three supplements during the 5-year period. There is no regular schedule for supplements. It is just that as we accumulate some 40 pages of material, we make the effort to publish it. The supplements incidentally are sent free to all holders of the Pharmacopeia who return a postcard in the back of the book that lets us know where they are, so that there is no excuse for anyone's not having a current supplement.

An outline of how the standards are revised may be helpful. To start with, the USP headquarters office in New York stands ready at all times to receive inquiries and suggestions, compile data, and develop sources of aid for the revision committee. If laboratory testing is needed, it may be carried out by a revision committee member himself or by the drug standards laboratory, a fully-equipped laboratory facility maintained here in Washington by three-way financial support from the U.S. Pharmacopeia, the American Medical Association, and the American Pharmaceutical Association Foundation.

The prestige of the USP is such that the revision committee has free access to the Nation's most competent experts on any relevant matter. There is no hesitancy in seeking expert opinion outside the revision committee; advisory panels are set up, often jointly with the National Formulary where the problem is common to both compendia. Possibly the fact that industry scientists are often consulted on drug assay problems had led to the notion that the revision committee is industry-dominated. In refuting the suggestion, we need only mention that we also consult FDA scientists often and receive invaluable aid from them. Revision committee members are drawn from industry and academic laboratories alike, but it is clearly understood that all members serve as individual experts and not at all as representatives of their colleges or companies. Of the 60 members, only 13 are now in the employ of pharmaceutical firms. And one of them is retiring at the end of this month.

Senator NELSON. The drug standards laboratory is maintained and staffed by the scientists by that laboratory?

Dr. MILLER. Yes; the funds come entirely from the USP, the AMA, and the American Pharmaceutical Association.

Senator NELSON. But the testing is done by the employees of the drug standards laboratory, and not by employees of the pharmaceutical industries?