

10174 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

The very first object listed in both the APhA Certificate of Incorporation and the APhA Constitution is directly addressed to this matter. Specifically, object A of the Association's Constitution appears in my prepared statement. To save time I will not read it. But it addresses itself to the fact that the Association shall publish a compendium of standards and specifications known as the "National Formulary", and also will promote the safe use of drugs by taking certain steps as an Association in cooperation with other organizations to assure drugs of the highest quality.

Since its founding 122 years ago, APhA has pursued a consistent and relentless effort not only to ferret out and identify adulterated and misbranded drugs, but also to disseminate and publicize such information to the pharmacy profession. It has been our firm belief that such information is necessary if pharmacists are to practice their professions most capably and if the public is to be best served with pharmaceutical products which are both effective and safe. I have appended to my statement as submitted an exhibit A, which is an illustration of an article from the 1960 "APhA Journal" exposing unqualified drug manufacturers.

Moreover, the Association each month publishes lists of FDA drug recalls, complete with pertinent ancillary information pertaining to each recall, in order to ensure prompt and widespread dissemination of such information to practicing pharmacists. I have appended exhibit B to my statement as submitted, which is a tear-sheet from the February 1974 APhA "Journal".

At times, recall information either may not be sufficient or appropriate to communicate the peculiar problems which may relate to a certain drug, in which case APhA has prepared and published specially written articles, such as the recent series in connection with digoxin. And I have provided you with several examples of those.

Furthermore—

Senator NELSON. May I ask a question there?

Dr. FELDMANN. Yes, sir.

Senator NELSON. When did your organization become aware of the digoxin problem?

Dr. FELDMANN. Well, there have been two so-called problems involved with digoxin. One of these pertained to content uniformity, and the other an indication that there is a bioavailability problem involved with the product.

We became aware of the matter of the content uniformity problem in the late 60's, and as was testified to yesterday by Commissioner Schmidt, the USP adopted a content uniformity test, after which the FDA implemented it via a certification program in their St. Louis facility to batch certify digoxin.

More recently there has been indication that there is a problem involved with the bioavailability of the product. This came to the public eye with the so-called "Lindenbaum study", which was published in the "New England Journal of Medicine" along about late 1971. This has resulted again in USP taking action to adopt a dissolution test, which has been adopted by way of a recent interim