Journal of Pharmaceutical Sciences

APRIL 1977

VOLUME 66 NUMBER 4

The *Journal of Pharmaceutical Sciences* is published monthly by the American Pharmaceutical Association at 2215 Constitution Ave., N.W., Washington, DC 20037. Second-class postage paid at Washington, D.C., and at additional mailing office.

Offices—Editorial, Advertising, and Subscription Offices: 2215 Constitution Ave., N.W., Washington, DC 20037. Printing Offices: 20th & Northampton Streets, Easton, PA 18042.

Annual Subscriptions—United States and foreign, industrial and government institutions $50, educational institutions $50, individuals *for personal use only* $30; single copies $5. All foreign subscriptions add $5 for postage. Subscription rates are subject to change without notice. Members of the American Pharmaceutical Association may elect to receive the *Journal of Pharmaceutical Sciences* as a part of their annual $60 (foreign $65) APhA membership dues.

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"ZERO-BASED" DRUG STANDARDS

President Carter has introduced the management approach of "zero-based budgeting" in reviewing federal programs and their financing. Indeed, so much has been said and written about this concept in recent months that few of our readers are probably unfamiliar with the term and its meaning. However, a brief explanation may be useful.

Basically, in contrast to taking last year's projects and programs and simply adding to them by way of staff, budget, and so on, zero-based budget calls for a complete reassessment of each such project or program to determine if the activity itself, as well as all of its components, can be currently justified. The premise is that there is a natural tendency for activities to be initiated which in time come to outlive their usefulness, in part or in whole. In the absence of any positive step to reassess their function and value by today's perspective, they drone on indefinitely.

The thought has long been with us that some such comprehensive reassessment would be highly desirable with respect to drug standards and specifications—particularly those appearing in the official compendia. Frequently, additions or revisions are made to *United States Pharmacopeia* or *National Formulary* monographs which interrelate with other elements within the compendia.

Those responsible for the compendial revision programs generally have done a good job of making whatever modifications were necessary to avoid any outright discrepancies or contradictions. However, in the absence of a "start from scratch" review, any process that introduces changes or new material in a piecemeal fashion will result in a patchwork product to some degree.

An example or two might help to explain both what we have in mind as well as how it happens to come about.

Effective April 1 of this year, a new standard requires that certain drugs be packaged in containers meeting specified criteria of "tightness." This significant advance now provides the compendia with objective procedures to test the tightness of containers and to specify well-defined limits of performance that the containers must meet. The drugs involved are all those whose individual monographs specifically include provision for such packaging. And, a review of the USP and NF reveals that a substantial number of monographs do call for use of either "well-closed" or "tight" containers.

However, such provisions were placed in most, if not all, of these drug monographs at a time when there was no real method for evaluating container tightness. Hence, the standard was more qualitative than quantitative.

The question now arises as to whether all drugs, for which there is a tightness requirement in the pertinent monographs, actually need this degree of protection now that we have defined it and have established methodology for its determination.

Compendia officials are well aware of this situation, but there is only one way that it can be rectified. That would require a drug-by-drug, monograph-by-monograph review, complete with stability data and the like, in order to conclude that the requirement may safely be deleted from certain monographs. But this review would necessitate considerable time and effort just to "clean up" the subject; that is, there is no risk or hazard with the present situation—it simply is one that, on purely scientific grounds, probably could not be justified as necessary to the extent that it applies.

Drug identification tests are another illustration of this problem. For many years, simple qualitative tests were included in compendia monographs to confirm the identity of a specimen. For example, such a test might describe a certain color change in a solution of the sample upon addition of a certain reagent.

With the introduction and wide application of infrared spectrophotometry—especially in conjunction with a reference standard—these antiquated spot tests and color tests became superfluous in the extreme. Yet they often were not deleted because certain parties—due to limitations in available equipment or misguided nostalgia—argued for their retention.

Again, there is nothing wrong *per se* with their continued presence. However, they have outlived their usefulness and they add a lot of undesirable "clutter" to what should be a concise set of drug standards.

All of these defects could be remedied by a start from scratch review of the entire USP and NF content. In line with President Carter's approach to budget development, it appears timely to consider a zero-based review of the compendial standards, with a goal of streamlining the monographs, eliminating duplication, correcting inconsistencies, and achieving uniformity of treatment.