Renewed Attention Regarding Drug Stability

An interview with an aeronautical engineer was recently published in a general circulation magazine. What made the interview unusual was the subject matter: namely, lighter-than-air vehicles, otherwise known as dirigibles, zeppelins, or just plain "balloons."

The engineer brought out the usefulness of such aircraft to harvest logs out of dense forests, to deliver construction materials to otherwise inaccessible sites such as mountain tops, to bring heavy beams or piers into place in constructing bridges or tall buildings, and an assortment of other such uses. But he also lamented the fact that the entire field of lighter-than-air craft has been virtually ignored for the past 40 years as the appeal and glamour of air travel has moved, in turn, from propeller planes, to jet aircraft, to rockets, and to space vehicles.

All of this is just human nature; people's attention and interest are naturally drawn to the new, the exciting, the complex. Thirty years ago, we used the "times tables" to perform our simple multiplications; 20 years ago, we used a slide rule for this purpose; 10 years ago, we were using pocket calculators; today, we have small computers to do the job for us.

In light of this trend, it is not surprising that the pharmaceutical research community has shown less interest in the chemical and physical stability of drug substances and of drug products than in bioavailability, pharmacokinetics, drug metabolism, bioequivalence, and the other new and more glamorous areas of research. These latter areas have captured the drug researchers' fancy and have been accorded the lion's share of interest for at least the past 10 to 15 years.

But just as in the case of lighter-than-air vehicles, there is much to be learned concerning drug stability, as well as much to be done in the way of potentially important applications of that knowledge.

We were particularly reminded of this situation when we reviewed a document issued by the World Health Organization in late Summer 1981. The paper was entitled, "Stability of Pharmaceutical Substances and Simple Methods of Detecting Their Degradation," and it was prepared by Dr. M. Perez of the Analytical Laboratories of Roussel-Uclaf in Romainville, France.

The paper is the second in a series and details the results of a stability survey conducted on an additional 132 pharmaceutical substances. The practical significance of such research was indicative in the finding that 59 of the substances in this latest study were determined to be degradable under the conditions employed, while the remaining 73 substances were judged to be stable under the standardized adverse conditions utilized.

Even more recently, we have read announcements or reports that indicate a renewed interest in drug stability on the part of several pharmaceutical groups in this country.

For example, in October 1981, the United States Pharmacopeia, the American Society of Hospital Pharmacists, and the Food and Drug Administration jointly announced that they would be proceeding to undertake a "program to learn more about the shelf-life stability of drugs under actual market conditions." The program is to be titled "The Drug Stability Testing Program," and it is based on the success of a pilot stability study conducted on digoxin tablets during the preceding year. The results of the latter study, and a description of the study procedure, were published in the December 1981 issue of the *American Journal of Hospital Pharmacy*.

In November 1981, the Extension Services in Pharmacy at the University of Wisconsin announced that their annual Industrial Pharmacy Management Conference, to be presented in late March 1982, would be devoted to the theme "Dating of Pharmaceuticals, Update 1982." This conference will attempt to examine and review all that has happened on this subject since it was initially addressed as the theme of the first Wisconsin conference when this pharmacy management series was launched in 1969.

Finally, in December 1981, the American College of Apothecaries adopted a resolution titled "Uniform Expiration Dating for Pharmaceuticals." The body of the resolution lends support to the proposal for nationwide uniform dating as a part of FDA's Good Manufacturing Practices regulations—all of this out of recognition of the variable stability among drugs and the importance of stability information in ensuring quality pharmaceuticals for the patient.

None of these individual actions or programs is particularly dramatic. Indeed, some of them are not even new.

Nevertheless, they are significant because they address an important subject that has been largely neglected in recent years. Consequently, we applaud such efforts. Moreover, we encourage all within the pharmaceutical community to give their moral and professional support to these and to similar efforts directed at (a) elucidating more information concerning drug stability and instability and (b) the application of this information for the benefit of patients and those practitioners who serve them.

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