Direct Heating of Samples

In reference to the paper[1] "Effect of Vehicles and Other Active Ingredients on Stability of Hydrocortisone," one important point should be made.

In the *Preparation of Assay Solution* section, the sample mixture was heated to boiling on a hot plate. No data were shown to verify that direct heating is harmless to the integrity of hydrocortisone in the sample mixture. In a stability study, the proper preparation of the assay solution from a dosage form is a key factor in obtaining meaningful and reliable data. Therefore, a stability test of hydrocortisone in the sample mixture by direct heating is necessary to be sure the reported data are accurate.

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[1] V. D. Gupta, *J. Pharm. Sci.*, **67**, 299 (1978).

1978 Drug Regulation Reform Act

At the recent annual meeting of the National Association of Boards of Pharmacy[1], a presentation dealt with the Drug Regulation Reform Act of 1978 (H.R. 11611 and S. 2755, 95th Congress, Second Session). Unfortunately, program scheduling did not allow for a question and answer period.

The speaker alleged that a major reason for revising the Food, Drug, and Cosmetic Act was to update the current law, making it more reflective of recent advances in medical science and technology. A similar justification has been offered by Secretary of Health, Education, and Welfare Joseph Califano[2]. One then wonders why this proposed legislation continues to recognize as official the anachronistic Homeopathic Pharmacopeia and the "drug entities" and "drug products" contained therein.

The "Section by Section Analysis" of the Act contains such mystifying statements as "Homeopathy is analogous to (but in fact quite distinct from) the theory of immunization." Subpart 8, Sec. 145 (b) of the Act states: "Any drug entity or drug product that is represented to be a homeopathic drug entity or homeopathic drug product shall . . . (3) meet the standards and specification set forth for such drug entity or drug product in the official Homeopathic Pharmacopeia as of the date of enactment of this title." This Pharmacopeia, in fact, contains no standards and specifications. The seventh edition (1964), which appears to be the latest edition, bears no relationship to a book of standards. It is more reminiscent of an early 19th century drug compendium.

The Analysis also states: "By restricting the definition of homeopathic drugs to drugs in the official Homeopathic Pharmacopeia on the date of enactment, the bill assures that future homeopathic preparations will be processed through the monograph system." This presumably means that all new homeopathic preparations will be subjected to the same rigorous requirements (IND's, NDA's, proof of efficacy, *etc.*) that affect all new drug products used in allopathic medicine. Why not require proof of efficacy of homeopathic preparations currently on the market?

The Analysis Report further states that "homeopathic drugs have never been fully subjected to the requirements of the current FD and C Act, and should be distinguished from allopathic drugs under the Drug Regulatory Reform Act. Any other approach would probably not be cost-effective in protecting the public health, given the present role of homeopathic medicine in the United States." This, in my view, is poor justification for retaining the official status of the Homeopathic Pharmacopeia.

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[1] 74th Annual Meeting, NABP, New Orleans, La., Apr. 22–26, 1978.
[2] "Section by Section Analysis, Drug Regulation Reform Act of 1978," Department of Health, Education, and Welfare, Washington, D.C., Preface, pp. 122–125.

Propoxyphene Bioavailability

After having written three letters to the authors requesting additional data and having received no response, and having been very disturbed even by the initial publication of this article, I find it necessary to respond to the tactics employed in the article "Generic Propoxyphene: Need for Clinical Bioavailability Evaluation"[1].

Not only was the conclusion "clearly" not supported by the data, but the clever manner of presenting the data to disguise the fact that they were dealing with laboratory formulations proved confusing to the public, to the press, and to state and federal legislators. Careful examination of the article was necessary to determine that: (*a*) the article was not dealing with marketed generic formulations, and (*b*) the conclusion was totally unsupported since the studies dealt only with laboratory lots. If the claim is to be made that bioavailability testing should be required, then data *must* be presented from marketed generic products to support this conclusion. I strongly believe such data do not exist.

Furthermore, I believe that politically oriented articles such as this one have no place in a scientific journal. I have made three attempts to obtain the formulation information supposedly available on request, but these data have not been supplied. I trust that the publication of this letter will bring forth the data, but I believe the damage has already been done and cannot be repaired.

I find it comforting that the MAC Board, state legislators considering DPS legislation, and the Division of Biopharmaceutics at FDA were not swayed by these tactics.

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[1] K. A. DeSante, R. G. Stoll, D. G. Kaiser, and A. R. DiSanto, *J. Pharm. Sci.*, **66**, 1713 (1977).