LETTERS

Generic Prescriptions

The article "Large drug firms fight generic substitution" (News and Comment, 30 Nov. 1979, p. 1054) is something of a paradox. In it, numerous cases are cited where generic drugs were found to be substandard or inequivalent to the prototype products. But rather than voicing surprise or concern about this, the author proceeds to quibble about the means by which we, the manufacturer, have attempted to draw attention to the problem.

For example, reference is made to Antivert (meclizine) advertising material which reported on chemical analyses of several generic "substitutes" for Antivert. It is pointed out that the initially reported results incorrectly stated that 10 of 17 tested generics failed these tests and that the correct figure should have been 11 of 65. [In fact, a recent audit of these data, soon to be provided to the Food and Drug Administration (FDA), indicates the true figure is 22 of 62.] However, the actual number of products that failed the test is not the central issue, for, even using the most favorable figures, the conclusion remains clear—a very substantial number of generic meclizine products are on the market today that fail to pass the compendial tests that provide threshold quality assurance for this product. Therefore, many prescriptions written for Antivert are being filled with clearly substandard meclizine.

In another portion of the article, the author refers to the dispute between Barre-National and Pfizer regarding Barre-National's generic version of Pfizer's Marax Syrup. As the author correctly points out, the chemical assays performed on the generic product yielded spurious results due to the presence of a preservative, methylparaben, not present in the FDA-approved prototype formulation—our Marax—which interferes with the established assay for quality assurance on this product. But, while the *Science* article focuses on the resultant discrepant assay results, it misses the obvious point: What about the preservative present in the generic product? Since the original product for which a New Drug Application was approved has no such preservative, the products are clearly not identical. But the more important issue is what the effect of this added chemical might be upon the allergic pediatric patient for whom Marax Syrup is typically prescribed. To our knowledge, there are no human stud-

ies demonstrating the effects of this chemical on immunologically sensitized children.

Human studies showing safety and efficacy must be performed with products like Marax that are approved under the New Drug Application procedure. The anticipated results of Marax in patients are based on such clinical data. To condone and promote substitution of "generic drugs" that are, in fact, qualitatively different from the clinically tested product is really a rejection of our whole system of regulatory preapproval of prescription drug products. Remember, it was the tragic inclusion of just such an untested, "inert" excipient that led to the Pure Food and Drug Amendments of 1938 in the first place.

Finally, the author discusses a recent film, *Pharmacy and the Law*, distributed by Pfizer. In that discussion, the author fails to focus on the underlying facts expressed by the legal experts in the film. The implication of a generic substitute in a situation where a patient has experienced a serious side effect, or a lack of therapeutic effect, will surely add a new dimension to product liability litigation. The product liability expert in the film pointed out that he would certainly include generic substitution as an additional cause of action in a complaint against those involved in such a case.

Pharmacists, after viewing the film, may indeed be more sensitive to the possible legal implications of substitution, but I believe this to be a prudent consideration. All aspects of the decision to substitute one drug for another should be weighed by the physician, when he or she authorizes the substitution, and the pharmacist, if he or she decides to make the substitution. Instances of substandard or nonequivalent generics on the market, as documented in the *Science* article, can only underscore the importance of such professional prudence.

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Near-Infrared Microscopy

In a recent issue of *Science* (Research News, 23 Nov. 1979, p. 918), Thomas H. Maugh II announces that near-infrared microscopy is useful for a number of biological problems, including observation of living photoreceptor cells in the dark-adapted state. Since workers on vision in vertebrates and invertebrates have used microscopes fitted with infrared image converters for more than 20 years, Maugh's discovery comes late. In fact, we have in our laboratory a still quite useful image converter made for the British Army and bought in an electronic junk shop in London in 1955 for $10. Much better ones, of course, are sold to amateur astronomers by surplus dealers in the United States for about $200, and quite good new ones with miniature high-voltage supplies are available from at least two American manufacturers for about $700, or about one-tenth the cost of the instrument described by Maugh.

It is true that standard achromatic and apochromatic microscope objectives give rather poor images in the 800- to 900-nanometer spectral region in which most work with photoreceptors is done. Such optics are designed for minimum spherical and chromatic aberration near 450 to 600 nanometers, and their corrections fall apart badly in the near infrared. But we have found that achromatic fluorite objectives, available from several manufacturers, give infrared images whose resolution and contrast are consistent with the longer wavelengths used. Some of these objectives are available for phase microscopy. A standard laboratory compound microscope with fluorite objectives, an image converter at its eyepiece, and an infrared-transmitting filter (such as a Wratten 87) on its light source gives micrographs comparable to those published in Maugh's article and at a much lower price than $6900. In view of this I suggest that future articles like Maugh's be labeled "advertisement."

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Priority?

Gartner and McGuirk (Articles, 14 Dec. 1979, p. 1272) propose a short but intensive drought in the latest Cretaceous to explain, in part, the extinction of the dinosaurs. I cannot resist pointing out that this same theory was proposed more than 30 years ago by Disney, in the animated classic *Fantasia*, which vividly portrays the great animals succumbing to thirst in the desert. Further study of this reference may be in order.

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