Regarding Analysis of Vaccines

TO THE EDITOR:

The March 1995 issue of the INTERNATIONAL JOURNAL OF LEPROSY (vol. 63, pp. 48–55) contains an article entitled "Analysis of Vaccines Prepared from Armadillo-Derived *M. leprae*; Results of an Inter-Laboratory Study Coordinated by the World Health Organization." This article describes the striking differences between preparations of *Mycobacterium leprae* provided by the World Health Organization for use in the leprosy immunoprophylaxis trial in Venezuela. Figure 3 of the article clearly appears to be mislabeled, since the gas chromatography figures do not correspond to the data presented in Table 3 nor to the statements in the text. Batches of *M. leprae* from Colorado (CSU) and Venezuela (IP2) contained at least 10-fold greater concentrations of arabinose and galactose than Wellcome Lot I; mannose and glucose differences were even greater (Table 3). Although it cannot be determined from the data presented whether Figure 3 (A) and (B) are correctly identified, since data in the table show similar concentrations of galactose and differing concentrations of glucose in the Colorado and Venezuelan preparations, it seems quite clear that Figure 3 (C) is mislabeled and does not correspond to Venezuelan batch IP2.

As stated in the text, ". . .it is hard to account for the extensive degradation–particularly the striking absence of simple sugar molecules–observed in the studies reported here." If "extensive degradation" were indeed a significant factor in the results presented in this article, one might surely have expected that phenomenon to be even more apparent when samples stored at −20°C and +4°C (Lot II) were compared with the original material from Lot II stored at −70°C; in fact, the differences are quite small (Tables 2 and 3).

We have often been asked why no evaluation was made in our laboratories of the vaccines sent to Venezuela. It seems appropriate to state here that the extraordinary measures taken to preserve the strictly coded nature of the trial precluded the possibility of performing these studies. In retrospect, we do not regret that decision. Nevertheless, we cannot deny the feeling of enormous frustration associated with the efforts and support of so many individuals at the Institute of Biomedicine, Venezuelan medical and paramedical field personnel, and the general population invested in a trial that we believe has not permitted a

fully adequate evaluation of the combined *M. leprae*-BCG vaccine.

Current enthusiasm with multidrug therapy in leprosy control is undeniable. Nevertheless, if our ultimate goal is eradication of the disease, as we believe it to be, it would be most unfortunate if that enthusiasm overwhelms and engulfs efforts to develop an effective vaccine. Much progress was made in the last decade in studies of the nature of the immune response in leprosy and in the identification of potentially important proteins with *M. leprae*-specific epitopes. The very nature of leprosy, with a subclinical, potentially contagious, latent period measured not in days or weeks but often many years, should provide sufficient stimulus for a vision that extends far beyond control by the year 2000. Hopefully, those who share that vision will continue to pursue the development of a safe and effective vaccine.

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In order not to delay publication of this issue, the Board of Directors of the JOURNAL has given its permission for the Index to Volume 63 to be published in the March 1996 issue of the JOURNAL. We hope this will not duly inconvenience readers who wish to bind their volumes promptly.—RCH