Conclusions

Dr. Perman: In this conclusion to the workshop, I want to look back at what we have done with a view to discussing how we provide the general community with the results of our 3 days of discussion and of the work that is represented in the chapters. I want to have an open discussion about these issues. But before I do, I want, on behalf of Jean Rey and me, to acknowledge the work of Dr. Steenhout, who was so instrumental in organizing this workshop. Thank you very much for all your efforts.

I don’t intend to summarize the meeting as part of this conclusion. There have been so many points that to try to highlight important points would do many a disservice. The title of this workshop was “Clinical Trials in Infant Nutrition.” As a first point of discussion, it seems to me that if we were to give this title to the monograph, it would not really reflect the work that we have done. That title suggests to me a compendium of clinical trials in infant nutrition. To be sure, we have heard original research during the 3 days of this meeting, but much of that was presented as illustration. It seems to me that what we have really done here is to have a vigorous discussion of the conduct of clinical trials in infant nutrition. I don’t know that we need to settle what we should call the ensuing volume right now, but I think that Dr. Steenhout, Jean Rey, and I would be very happy to hear your comments on this matter. It seems to me that what we want is a publication that serves not only the medical community interested in nutrition but also clinical investigators, ethics committees, aspiring clinical investigators, members of staff of regulatory bodies, and editorial staff of journals that publish in clinical nutrition.

Dr. Glinzmann: Certainly a large portion of this was not really didactic in terms of how you do a clinical trial. A lot of it dealt with the claims issue and the purposes of clinical trials and their sponsorship, so I think the claims context should be reflected in the workshop.

Dr. Hamburger: I agree that the title as listed in the cover of the workshop announcement is misleading and does need changing. Perhaps a title of “Clinical Trials in Infant Nutrition” with a subtitle using some of the section heads such as methodology, ethics, statistics, and claims should be considered.

Dr. Walter: I had the reaction that I think you did, that referring to this workshop as being entirely on clinical trials is inappropriate. Many people, when they see the words “clinical trials,” think of randomized clinical trials almost automatically, but in fact, much of the evidence that we have seen here was related to observational studies, and so the title might be construed as misleading. I wonder whether it should
be something like "Research in Nutrition" or "Recent Results in Clinical Nutrition" to make it much broader.

Dr. Uauy: I don't think we should put "clinical trials" as a sole purpose of the meeting because we have been very selective, mainly concentrating on methodology, ethics, and statistics.

Dr. Perman: I agree that we ought to say in the title what is inside the covers, without making it unwieldy. Are there any other thoughts about promulgating some of the points that we have covered? We are not organized as any kind of an official body, but I would like to give everybody the opportunity to comment. There were some very important points made over these 3 days that deserve the attention of members of ethics committees and regulatory bodies. So there should be a broader audience than the medical and scientific community only.

Dr. Hamburger: After publication of the first book in the Nestlé Nutrition Workshop Series, Nestlé decided to produce a more readable version for the average physician in the form of a small monograph for wider distribution to pediatricians. I think that was a very effective vehicle for getting the message to where much clinical research is being done these days—not by experts but by practitioners in the field. They need to see the results of a meeting such as this.

Dr. Steenhouw: We publish 40,000 booklets of each workshop and distribute them all around the world, and in different languages: English, French, German, and Spanish, and this booklet will be also published in Chinese.

Dr. Perman: On behalf of Jean Rey, the organizers from Nestlé, and myself, I want to express our deep gratitude for the time and effort that you have put into making this workshop a success. Thank you all very much.