What we did, in fact, was to clarify our position. In retrospect, I should say it was badly in need of clarification. There was a tremendous number of inquiries by practicing physicians, unfortunately, and others that had received misinformation because of misinformation that had been provided to them by others.

I think that our record speaks for itself. I doubt if any other administration that I know of in the Food and Drug Administration has ever acted as vigorously as we have in regards to the drug industry. We have got other things to do, things that I wish we could have acted more rapidly on, but nevertheless our record shows that we have been very vigorous, but we certainly—I think any statements like that are inaccurate and not founded. I don't think they bothered to look in the record.

Dr. SIMMONS. Mr. Chairman, we have a sound combination drug policy but unfortunately some people still misunderstand it. I suspect this may be the case with the author of the articles which you just discussed. I think our policy makes eminent good sense, and a number of fine scientists of this country helped us develop it.

Our basic position is that since all active drugs have a potential for harm as well as benefit, no patient should be exposed to or have to pay for a drug he does not need. Each drug in the combination must contribute to the therapeutic effect. It must make sense to use the drugs together, that is, the combination should provide rational concurrent therapy for a significant proportion of the target population. Neither drug should decrease the safety or effectiveness of the other drugs in the combination.

Senator NELSON. The requirement is that the producers of the drug demonstrate by adequate and scientifically controlled investigations conducted by qualified experts, that each drug in the combination makes a contribution, and, in effect, that the drugs in combination are at least additive. Is that correct?

Dr. EDWARDS. That is correct.

Dr. SIMMONS. That is right.

Senator NELSON. And under this policy, the panels selected by the National Academy of Sciences-National Research Council recommended removal of all fixed combination anti-infectives; is that correct?

Dr. EDWARDS. No; not all of them. There are still several—Dr. Simmons?

Dr. SIMMONS. No, they didn't. They spoke most strongly about penicillin combinations, which had to be removed from the market, but there is a combination drug for tuberculosis, which we are going to leave on the market.

Senator NELSON. Is that an anti-infective drug?

Dr. SIMMONS. Yes, sir. In general, they ruled against a fixed combination for a variety of drugs.

Mr. GORDON. I would like to ask you about your "freedom of information" proposal. I note on page 9135 of the May 5 *Federal Register* the following statement:

(d) Unless otherwise publicly disclosed, no safety and effectiveness data and information submitted with or incorporated by reference in an NDA file are available for public disclosure until the Food and Drug Administration withdraws approval of the NDA or determines that the drug is not a new drug or may be marketed pursuant to an abbreviated NDA. All such data and in-