very reputable scientist, pharmacologist; and Dr. Freis. I have not seen the actual document. All we have seen is what the Tribune says. Is it based on any study? Do they document any of their conclusions?

I don't quite understand what they are saying when they assert that FDA policy since 1962 has brought about a "stifling" of scientific creativity, escalation of research costs, and a "continuing decline in the number of new drugs entering the market in this country."

You could endorse all that if you interpreted it correctly. If unnecessary scientific work and duplication have been stifled by the 1962 act, fine. If costs are escalated in order to improve the safety and efficacy of the product, that is good. If there has been a decline, a continuing decline, in new drugs entering the market as a consequence of higher scientific standards, that is also good.

I wonder if that is the impression that the Dripps Committee is trying to create! If, however, it is an attack on the requirement that efficacy be proved, and if they are critical of the distinguished panel that handled this problem for the National Academy of Sciences-National Research Council, then, it seems to me, their charges ought to be documented.

Do you have any notion as to what they are talking about?

Dr. EDWARDS. This is one of the disturbing things. An individual, Dr. Dripps, in his position, you would have thought that at least he would have communicated with me in regard to these charges. But the fact of the matter is about all I have heard is what I have read from the Medical Tribune.

Senator NELSON. Have you seen any documents on which their claims may be based?

Dr. SIMMONS. We have some specific answers to the allegations.

Dr. EDWARDS. I do have a statement I would like to read at the appropriate time, that relates to this whole subject. We have recognized that we have some problems in the Food and Drug Administration, and we recognize there are some issues that need to be looked at very hard, and we are attempting to do that right now, but again, going back to the discrepancies, they were never discussed with us.

Senator NELSON. By any of the signers?

Dr. EDWARDS. By any of the signers.

May I read, Mr. Chairman, the short statement that I would like to have included in the record?

Senator NELSON. Go ahead.

Dr. EDWARDS. If there are problems with the system of the drug evaluation and drug regulation, then we are most interested, more interested than anyone, in seeing them corrected for the public interest, where it is involved.

However, we feel that existing laws and regulations governing these areas are scientifically sound and can allow necessary research and development while still adequately protecting the public. We are ready to do everything possible to help create a program for drug research and development, and we encourage it, but I would say for the past 2 years we have worked constantly to bring this about; with the help of outside consultants, we have reviewed all of our requirements, and in virtually all instances they have been sound and consistent with sound science.

We are working to streamline for maximum efficiency. We have added first-rate scientists to our internal organization. We have built