Have you gotten this reaction from other State medical societies?

Dr. EDWARDS. As I attempted to indicate a moment ago, the reaction has been mixed. We have had some very nice things said about what we have done. Some other people that have been very critical of what we have done. And I do not know just exactly, as we have not really surveyed the profession in a meaningful sort of way, what the overall reaction is, nor do I think the gentleman who wrote that article really had a sample that was meaningful that would allow him to make a statement quite like he made.

I think we have to communicate the fact to the medical profession that our ultimate aim is to assure the physician that when he prescribes a drug, on which certain claims are made, that he can depend on those claims. I mean, he can depend that these claims will be fulfilled by the drug that he is prescribing. So it really is in the best interests of the profession that they support us and support the National Academy as well.

Senator NELSON. I have not had the opportunity to look at the professional journals. How have they handled the continuing release of the information respecting NAS–NRC studies and the decisions made by the FDA respecting these drugs?

Dr. EDWARDS. I think their handling to date has been pretty much a straightforward reporting job. I do not think there has been a great deal of editorializing.

Do you want to comment on that, Dr. Simmons?

Dr. SIMMONS. Generally, the journals that report this information, specifically the AMA Journal, the Journal of the American Medical Association, and also the Journal of Internal Medicine, merely report what has been said without editorializing. If you ask what kind of support there has been in the medical community generally, I would echo the Commissioner's statement that it varies from faint praise to loud damning.

The New England Journal of Medicine recently ran an editorial stating that with all the difficulties the FDA had in these drug evaluations and other things, the title of the editorial was, "Homage to the FDA," that even with this difficult job the profession did look to it for that kind of guidance. I think generally what it might be reasonable to say is that if anybody thought of going back to the old system before FDA had authority to look to efficacy, almost no one would be willing to go back to that system.

We know that change is difficult to accept.

Senator NELSON. Go ahead, Doctor.

Dr. EDWARDS. I would now like, Mr. Chairman, to speak briefly about the drug efficacy review per se. The Drug Amendments of 1962 required that drugs be proven effective for their intended uses, as well as safe. Thousands of drugs introduced between 1938 and 1962 had been marketed on proof of safety alone with no obligation upon the manufacturer to prove the truth and validity of their promotional claims of effectiveness.

Surely the most important provision of the 1962 Amendment was to define the kind and the quality of medical evidence that is to be required both to justify the introduction of any new product and to sustain the continued marketing of products already on the