training for FDA and industry alike. Many problems remain but much progress has been made toward the goal of better drugs and better therapeutics for the American people.

Thank you.

Senator NELSON. Thank you, Dr. Edwards.

You obviously feel quite strongly that the FDA had done a very effective job under the mandate of the 1962 Kefauver Act concerning efficacy. I would like to read to you an excerpt from an article that appeared in the National Journal in late 1971, commenting on the fixed-ratio combination drugs. The National Journal apparently took the position that the drug industry won the battle in respect to the combination drugs.

"Fresh from a victory with the administration over the regulation of combination drugs, the prescription drug industry is ready for any new challenges the Federal Government may send its way.

"The multi-billion-dollar industry, represented in Washington by the Pharmaceutical Manufacturers Association, has significantly strengthened its position with the Food and Drug Administration in the past year. The FDA backed away last summer from strict new requirements for combination drugs after the industry protested vehemently and cultivated extensive support among doctors and Members of Congress."

Skipping to another paragraph, "The agency was using powers it had received from the 1962 Drug Amendment to review drug efficacy. Its proposed guidelines were strict, following the advice of those academic medical experts who believe that reliance on fixed-combination drugs is more dangerous than prescribing custom dosages of each drug to best suit a patient's needs.

"But combination drugs are easier to prescribe, and they are very popular among doctors. The drug industry relied on this popularity in soliciting support from practicing doctors, who wrote letters of protest directly to the FDA and also to Members of Congress, who then sent inquiries to the agency.

"Besieged by this opposition, the FDA modified its guidelines before publishing a final version on October 15. Four major changes were made in deference to opposition from medical and drug interests. Over-the-counter drugs were removed from the guidelines and handled separately; suggestions that combination drugs are less desirable than individual dosages were eliminated; a requirement that the combination be effective for the duration of dosage was removed; and a requirement that the combination be advantageous for 'most' patients was changed to require that combinations be 'safe and effective for a significant patient population.' "

" 'We won the fight on combination drugs,' said William C. Cray, PMA's vice president for public relations. 'The final guidelines were quite reasonable.' "

What is your comment on that?

Dr. EDWARDS. I would say, Mr. Chairman, if they won the fight, I would like to lose more like it. I think we do, in fact, have a combination policy at this particular point that is perfectly acceptable to Dr. Simmons and his Bureau. There is no question about the fact that there was considerable interest in this original combination policy. Some of it was justifiable and some of it wasn't justified.