very limited number of drugs for an extended period of years. He may, but it is just not within the realm of possibility for the finest of brains in the world to do that as against the collective knowledge of the expert pharmacologists and clinicians and controlled studies over a period of years. And yet as a result of the procedure we follow, we had the fixed dose antibiotic combinations in the market for 15 years, widely prescribed, despite the fact that the AMA's Council on Drugs and every distinguished pharmacologist and clinician in the country said it was irrational to prescribe them. It never got through. They had all the reason in the world to read the literature and all the literature was against the fixed dose antibiotic combinations, yet they were the biggest sellers in the country, among the 200 most frequently prescribed drugs.

Now, whatever explanation one may have, the method followed was a total failure. We have moved 15 years later through the NAS–NRC after a prolonged fight by the great and distinguished Senator Estes Kefauver, who said you have to prove effectiveness, and then after he got that law through, we finally start coming up with the formal judgments under the law by the Government which is now taking them off the market. We would have gone on prescribing them despite what the literature said.

So, in the face of this, it seems to me, there is a grave responsibility in the medical profession, the DOD, and in Public Health Service, to say these drugs are proven ineffective and we are not going to put them in our armamentarium.

I do not know how you achieve that unless there is some really vigorous leadership at all levels from the American Medical Association, DOD, Public Health Service, medical schools and everything else .

Dr. STEINFELD. And by the hospitals in the review of the various patients' records after the patient leaves the hospital, by the doctor's own peers. I agree with you that it is not right and I think our new regulations from Food and Drug Administration will require demonstrated effort to determine a basis for the synergism or a number of other factors before a new combination drug will be permitted on the market.

Senator NELSON. If we follow the rules of rational prescribing as stated by HEW's Task Force on Prescription Drugs, most of this would not happen.

Dr. STEINFELD. I think most of this has already happened. What we have got to do is get rid of the bad things and prevent any more from occurring.

Senator NELSON. There is a long article in the August 10 issue of the Journal of the American Medical Association saying what has been said by many clinicians and pharmacologists for a long time. It is entitled, "Propoxyphene Hydrochloride, A Critical Review", and it states that a review of studies shows that "propoxyphene is not superior to codeine or aspirin in terms of analgesic effect. * * * It appears that factors other than intrinsic therapeutic value are responsible for the commercial success of propoxyphene." I consider that a rather masterful understatement. In any event, it concludes as the Medical Letter has already done, that it is no better than