Now is there any reason in the world the Government should look at that and say, "Yes, if the doctor prescribes it the Government has got to prove that that drug he is prescribing is not better than the others."

This kind of price discrimination and rigging and brand name identification and widely publicized pushing of drugs has got to stop. And if at this stage in history the 26 companies that you represent do not understand that, I just tell you a half dozen years from now the picture will be a lot different. You are fighting a losing cause.

We finally get a conservative Republican administration and the Secretary of HEW, who is a very honorable, able, but very conservative man and who does not think the Government should interfere in hardly anything, came up here and said it has got to be done. And you are representing 26 big brand name companies who say, "Oh, no, we are going to throw dust in everybody's eyes on this one."

I just say to you you are in another century and you are going to lose your ball game, but go ahead. It baffles me. Mr. McKinley would be happy with you. But go ahead.

Mr. TRYGSTAD. The NPC understands that HEW proposes to exclude from its MAC program only those drugs in which bioavailability is considered to be an important factor, or for which unresolved problems of bioavailability are known to exist. The remainder would be eligible for immediate inclusion on the MAC list. Good reason exists, however, to believe that our present knowledge of bioavailability and therapeutic equivalence is deficient for many drugs.

The CHAIRMAN. Well, I want to let you finish. I am sorry, we have got another rollcall and I do not want to hold you up any.

Mr. TRYGSTAD. The necessary scientific studies have simply not been conducted. An assumption that drugs are equivalent based on the mere absence of data is unwarranted. Even as bioavailability problems are discovered, they cannot be effectively eliminated by Government-imposed standards until the standards themselves have been validated and correlated with clinical observations. To say that bioequivalence is unimportant in many drugs, for interchangeability, because of a wide range between an effective dose and a toxic one does not follow the same logic that is applied in requiring the labeled amount of an active ingredient, within tolerance limits, to be present in a pharmaceutical product. This would fail to distinguish, as an important consideration, between minimum and maximum effectiveness. The health and safety of medicare and medicaid patients must not be jeopardized while FDA uncovers problems of therapeutic inequivalence and promulgates bioavailability standards that may or may not assure the uniform effectiveness of drugs that are marketed as chemical equivalents.

In the end, the quality of care must depend principally on the professional skill and judgment of the practicing physician. He alone knows the clinical performance of a drug product for each patient he treats. The proposed regulations would recognize the paramount role of the physician by permitting him to certify a patient's need for a particular brand of drug. But they allow for such certification only when a specific manufacturer's product is the