that all of the versions in the marketplace are equivalent, and then go on to problem drugs as the bioavailability regulations begin to take effect.

Senator ABOUREZK. Thank you very much.

Dr. NOVITCH. You are welcome.

Senator ABOUREZK. Mr. Trygstad, there is right now a live quorum going on, just preceding a cloture vote on the tax cut bill, and I think what I had better do now, rather than let you go on and interrupt when the vote itself is called, which will be in just a few moments, is just to recess for 20 minutes, until 11:30. By that time the vote should be over with, and Senator Nelson will return to continue the committee hearings.

I am very sorry for this interruption.

[A brief recess was taken.]

The CHAIRMAN [presiding]. The subcommittee hearings will resume. I apologize to the witnesses for the delay.

Unfortunately we had this series of hearings scheduled at a time which turned out to be the busiest period of the year thus far. I expect we may be interrupted by another rollcall very shortly. That was why Senator Abourezk did not return because he thought momentarily we will be voting, and we may very well be doing so.

I again apologize for imposing on your time. Why do you not just proceed. You are at page 4, the second paragraph, I understand.

Mr. TRYGSTAD. Yes, we were.

The CHAIRMAN. Go ahead, Mr. Trygstad.

Mr. TRYGSTAD. The proposed program fails in several important respects to assure that medicare and medicaid patients will receive high-quality, effective drugs. The rules that would govern MACs for drugs treat the problems of quality assurance and therapeutic inequivalence in a cavalier and offhand manner. The multiple source drugs to which the MAC policy will apply are to be identified by a Pharmaceutical Reimbursement Advisory Committee, on the basis of (a) dollar volume of actual or anticipated usage, and (b) the existence of products from more than one source at significantly different prices.

Provision is made for the Food and Drug Administration "to advise the Board of any pending or antcipated regulatory activity, including the establishment of a bioavailability requirement which would warrant delay in establishing a MAC for the drug." Nothing more. As a minimum, HEW should assure that all drug products eligible for reimbursement in a class for which a MAC has been established are therapeutically equivalent. No assurances of such intentions are given in the present proposal.

The CHAIRMAN. May I ask a question there? Just exactly how would they do that?

Mr. TRYGSTAD. How would they do that?

The CHAIRMAN. Yes.

Mr. TRYGSTAD. Well. there would have to be bioavailability standards adopted. There would have to be an improvement in the drug quality assurance programs. I think there has to be more clinical testing.