Without such a determination, the Government will interfere unjustifiably with the physician's clinical experience and judgment and will abrogate the right of medicare and medicaid patients to be treated in the same manner as nonsubsidized private patients. Substituting its judgment for that of the physician, the Government assumes an obligation to assure that there is no therapeutic difference between the products it will pay for and those that would have been prescribed absent a MAC program. To date, no such assurances have been given that such determinations would be made.

Senator ABOUREZK. Mr. Trygstad, could I interrupt you for just a minute and ask you a question.

Yesterday the Secretary of HEW told this subcommittee that, and I am quoting:

> Essential to the success of the MAC program is our ability to assure that drug products covered by the program all meet the same high standards of quality.
>
> I would like to take a few moments to discuss programs that the Food and Drug Administration has undertaken and will undertake to provide this assurance.

The Secretary then went on to describe FDA's drug quality program, their plant inspection progrm, their drug product surveillance program, and other programs, as well as bioequivalence regulations which will soon be published.

Are you saying that the Secretary was not telling us the truth when he said that the currently ongoing activities of the Government do not need substantial change before the MAC program can be implemented for selected drugs?

Mr. TRYGSTAD. No. I certainly would not say that the Secretary was not telling the truth about his intentions and what they plan to do. However, this MAC program is proposed for implementation now. The Secretary was talking in part about what the Food and Drug Administration has been doing in the past, which was inadequate. Everybody knows it is inadequate.

Senator ABOUREZK. Everybody but the Secretary.

Mr. TRYGSTAD. Well, if it was adequate in the past, then the proposals he is making for the improvements that are to be made, and he enumerated a whole page full of them, must be superfluous. The things that he plans to do and he proposes to do are very essential. They partly fulfill the recommendations of the OTA Committee in improving Good Manufacturing Practices, the compendial standards, inspections, product testing from the raw material to the finished product, including in-process testing, which is not now required.

There are many things that, if carried out by FDA, probably would go a long way toward improvement of the drug supply and the dangers now in it. All of these measures do not exist today.

Mr. GORDON. Now wait a second.

Mr. TRYGSTAD. This (MAC) program is proposed to be put into effect now. They are talking about what they will do in the future.

Senator ABOUREZK. What they have done, what they are doing now, and what they will do. That is a more accurate statement.

Mr. TRYGSTAD. Of course.

Mr. GORDON. And what dangers? You talk about the dangers. What dangers are you talking about?

Mr. TRYGSTAD. Well——