Now those physicians know what is being stocked in the hospital. They observe the effects of those drugs on their patients. There is no mystery about what their patients are getting; and if the drug turns out to be not effective or not to work as the physician expects it to, or to have side effects, he can immediately do something about it. If any of these conditions are observed, that hospital will change to a different drug. Now in contrast to that, in a program such as MAC, you have a situation with a committee sitting in Washington deciding what should be made available to physicians throughout the country. If the physician does not have control of what is going to be dispensed on his prescription, he has no way of knowing whether the drug that his patient will be getting is satisfactory or not for his particular patient.

The CHAIRMAN. Well, what puzzles me a bit about that though, is that, as I understood the main thrust of your argument was that: No. 1, a doctor ought to be able to prescribe for his patient what he decides ought to be prescribed, and that if somebody is going to interfere with that, he ought to be required to prove that the drug the MAC regulations say should be prescribed, is better than the one the physician selected. No. 2, as I understood your argument, there ought to be bioavailability studies done on all of them. I do not have any quarrels with the idea that all be done in the course of time. Three, there ought to be clinical studies showing therapeutic equivalents.

Now, the therapeutics committees or the formulary committees do not conduct bioavailability studies. They may sometimes, but as a general practice that is not the way they set up a formulary. They do not conduct any trials on therapeutic equivalents. Yet they do tell the doctor that this is the formulary and to prescribe outside of the formulary he would have to present a specific valid reason if it is a well-run therapeutics committee. The doctor can not just say I like it better that way. The doctor is going to have to say that I have a patient who, in taking this particular drug, does get a reaction. I have found that with this other brand this patient does not get that reaction. He can not just say I prefer it.

So, I do not quite understand how you approve a therapeutics committee and formulary committee making all these decisions which you say should not be made by HEW based upon advice and consultation with clinicians, since the formulary committee, the therapeutic committee is not going to go through all this protocol that you believe they ought to go through.

Now, I am not saying it is not good protocol if you could do it. If you could have controlled clinical tests on every single brand of every compound in the marketplace, perhaps that would be good for medicine. We can not quite do that, at least in this stage in history But HEW can call upon the most distinguished clinicians in the country in the same way that the FDA called upon the National Academy of Sciences-National Research Council to set up the panels on all the various classes of drugs, and select for them distinguished, reputable, and knowledgeable clinicians from these various fields all over the country and followed their advice on them.

So, it seems to me what you are approving for the formulary committee and the therapeutics committee is the same principle that HEW is saying we ought to apply nationwide. I realize it is not in one hopsital and in one locale; but it seems to me the principle is the same,