requesting special brands of a particular drug. If it doesn't, then we might have to go to a prospective rather than a retrospective review of the claim or the request.

But I would hope we could avoid that because if we had to set up a prospective kind of review, I think that is the kind of review that would require a fairly sizeable staff and organization.

We also plan that those exemptions to Maximum Allowable Cost will be defined very narrowly. We do not expect many physicians will find it necessary to specify that their patient can only tolerate a specific brand. If the exemptions are abused we will, of course, appropriately, as I mentioned, alter the policy.

Other issues involving package size, dosages and a host of other problems have to be taken on. The Department has been working diligently to determine the most equitable way to devise these regulations and to anticipate all relevant issues. I hope from this discussion of these very complex issues that it will be fully realized that this policy is a tremendous undertaking on the part of the Department which has required the expenditure of considerable effort. It is a challenge that we have welcomed and one that we are hopeful we are meeting rather rapidly.

We are now at the stage in the preparation of the regulations when we can begin to consult with various interested groups regarding the issues we have discussed today. We feel this is only fitting when one considers the impact that these regulations will have. Again, I would like to emphasize that by undertaking such consultation we are not in any way attempting to further delay the regulations. We believe it will be useful and productive to provide the many interested groups with an opportunity to informally comment on our proposal as now developed. We believe this consultation can be conducted within a period of 2 to 3 weeks and, furthermore, we believe that the regulations can then be issued shortly thereafter.

Mr. Chairman, this concludes the formal parts of our presentation and we would be delighted to attempt to answer any questions that you have.

Senator NELSON. I have a couple of miscellaneous issues that have been raised in recent hearings. Dr. Schmidt testified on the bioavailability question when he was here a short time ago.

The industry itself keeps raising the question about the terrible problem of bioavailability, potential and real, and so forth. Just what do you think about the issue of bioavailability that continues to be raised respecting assurance of comparability of drugs?

Dr. EDWARDS. Mr. Chairman, I have said from the very beginning that I thought that bioavailability or equivalency as it relates to our pricing policy has no relevance. I think that it is being used more or less as a smoke screen by those who prefer not to have a pricing policy. I am not for a moment suggesting that bioavailability doesn't represent a potential problem, but, nevertheless, in reviewing the records of the Food and Drug Administration, I think the number of major bioequivalency or bioavailability problems has been small. It certainly is an issue to which the FDA is going to