

submitted evidence to us for efficacy of these compounds have been unable to show it and we have turned them down. There are a few, though, who have been able to pass our requirements and have a reliable product on the market, but there are very few.

The majority of those currently on the market have not provided adequate evidence to the task and under the drug efficacy study of NAS-NRC we are requiring that they provide such evidence. It is a very difficult field and we would agree with your statement that in general they appear to be quite unreliable.

Mr. GORDON. Now, with respect to advertising? Are you planning to include in your requirements that when a firm advertises a particular drug which has been rated "probably" or "possibly effective" by the NAS-NRC, that that statement will appear in the advertisement?

Dr. EDWARDS. Yes. We have published our original Federal Register document indicating that we were going to require this, I think it was in October, and we will be republishing again indicating that we will require of the manufacturer that the National Academy of Sciences classification be included in any promotional information on the drug.

There are several drawbacks to this because, for instance, a particular drug can be advertised as long as reference is not made to the particular claim that was declared possibly or probably effective or ineffective and, in that case, the advertisement does not have to contain the rating by the National Academy of Sciences. But all of the drugs are going to be required to do this. Mr. Goodrich, would you want to add anything to that?

Mr. GOODRICH. No, other than that we did receive comments, about 20 in number, covering a great many pages and as you can imagine most of them came from the pharmaceutical manufacturers, the proprietary association and drug companies, challenging both the legal basis for such a requirement and the factual justification for it.

We were satisfied of the legal basis when we first published. We are still satisfied. We are in the process of working out a final document on it.

Mr. GORDON. Consider this situation: claims have been made in the past, that is, before the NAS-NRC reports were published. These claims have been inculcated to a large extent upon the minds of physicians. As I understand it, from what you said, the firms can still advertise but as long as they do not advertise the claims again, they do not have to put in the rating of the NAS-NRC, is that correct?

Dr. EDWARDS. If they use an acceptable label, one that is acceptable to the Food and Drug Administration, then, of course, this in effect is what we are trying to accomplish, that is, to make more meaningful the labeling on these particular drugs, so if they clean their labeling up and remove less than effective claims, the NAS-NRC rating need not be included. Mr. Goodrich, am I correct in that?

Mr. GOODRICH. Yes. What he has in mind is that if an ad is made for a drug that had some claims rated "effective," some "possibly effective," some "probably effective," and some "ineffective" and the only claim advertised is the one for which the drug was found effective, you need not have the possibly effective, the ineffective and the other claims in there with the disclaimer. We are striving to the end