Mr. GORDON. But the compendium that we are discussing today is not going to include anything on relative efficacy either, is it?

Dr. GODDARD. No.

Mr. GORDON. Well, how is a doctor going to know which is the best drug to prescribe for a particular illness from a relative point of view?

Dr. GODDARD. Well, the physician has to make those judgments all the time. And the information contained in the compendium would be a useful guide to him. But there would not be a direct comparison of this product to that product, is the point I am trying to make.

Mr. GORDON. And yet the doctors who have come before our committee, who are from the academic field and who are connected with large and important hospitals have stated that the problem of relative efficacy is of extreme importance and should be covered by somebody some place.

Dr. GODDARD. Look, efficacy is a function of looking at the drug with respect to the claims that can be supported for it in one sense.

Now, this National Academy report and the material that is embodied in the compendium will be restricted as far as claims are concerned—I mean, the claims have to be substantiated. So in that sense, yes, relative efficacy does get into it. But we have to be careful that we do not get in the business of this antibiotic versus that antibiotic, and permit the same claims for both.

What we are saying is that the claims have to be substantiated, and thus the physician can draw conclusions about relative efficacy.

Senator NELSON. Go ahead.

Dr. GODDARD. Another pressing consideration is whether or not the package insert should be completely done away with in view of the compendium, or merely the requirement of distributing it with each package. As complete labeling is the basis of new drug approval, we recommend that such labeling be retained, and additionally, the package insert type of information should remain available for persons, such as clinical researchers, who are in need of more exhaustive data. In a few instances, it probably will not be possible or even desirable to provide for an exemption from distributing the package insert. For example, I mention the biologicals. That information needs to get to the physician for his views at the time of administration.

Another factor which prompts our endorsement of the compendium is that it will list all drugs, thereby increasing the physician's prescribing range and, of course, pricing information could be included in a supplement thereby fostering more economic prescribing.

However, listing in the compendium should not be construed as governmental approval. As I mentioned before, we are not in a position to guarantee the therapeutic equivalence of all drugs or hence their quality. We are striving toward this goal.

And I mentioned, also, the important role the efficacy review being carried out by the Academy will play.

Now, with sufficient funds—and we estimate about $5 million a year—we could publish such a compendium. We could also provide that listing in the compendium would satisfy the requirements of full disclosure. Although the project could be achieved without increased authority, it would not be the most advantageous manner, in my opin-