Mr. GORDON. Does that not constitute a pretty good record, though?

Dr. BERLINER. Oh, on the whole I think the record for drugs is pretty good generally.

Mr. GORDON. Is it your judgment, then, that the Department of HEW with proper procedural safeguards can move safely ahead with its MAC program?

Dr. BERLINER. Emphasizing the proper procedural safeguards I certainly think so.

Mr. GORDON. Well, you heard Secretary Weinberger this morning. Do you think those measures that they are adopting are proper?

Dr. BERLINER. I think they are quite proper and reasonable. I want to see, however, what the list of drugs looks like before I give a final opinion.

Mr. GORDON. I would like to read to you from some documents that come from the files of the Abbott Co. dealing with bioequivalency. One of the memos has this paragraph, and I am quoting:

> The main point that we wish to make is that Upjohn is using bioavailability studies for promotional purposes. To do this they are designing their bioavailability studies to be biased in favor of their product and negatively biased toward competitive products. Certainly, we feel this is a prostitution of the science of bioavailability and does little credit to scientists who allow such distortion to occur. Such use of bioavailability data tends only to create confusion in the minds of the hospital and retail pharmacists, who are usually not sufficiently knowledgeable of the science of bioavailability to detect the effect of these protocol designs.

There is no sense in my reading any more. You get the drift of it. And then it ends up by saying:

> Since the Upjohn studies are consistently done with these built-in biases, it is obvious it is not accidental or unintentional. We consider this action of Upjohn unscientific and unconscionable.

We will put this material into the record,[1] and I would like to ask you the following question. Would you agree that this issue has been largely a manufactured issue? When Dr. Charles Edwards, as Assistant Secretary for Health, came before this subcommittee last year Senator Nelson asked him:

> 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?

And Dr. Edwards answered:

> Mr. Chairman, I have said from the very beginining that I have thought that bioavailability or equivalency as it relates to our pricing policy, has no relevance. I think it is being used more or less as a smokescreen by those who prefer not to have a pricing policy.

Would you comment on these statements?

Dr. BERLINER. Well, since the one I heard last was Dr. Edwards', I can comment on that first. I would disagree when he says it has no relevance. I think it has some relevance, limited, but definite. It has some relevance because of the questions that come up with things like digoxin and a few other compounds, so it has some relevance. But for the most part, differences in bioavailability, as I indicated

[1] See Abbott comments on Upjohn studies, page 11815.