

The CHAIRMAN. You have raised a lot of smokescreens about bioavailability. You have misused the OTA study in paid advertisements. At least the Pharmaceutical Manufacturers Association's imprimatur is on the ads. You are misleading the public in your ads when you keep throwing up the bioavailability thing.

Mr. STETLER. I don't agree that we have misled the public. I maintain that our ads accurately state the basic conclusion of the OTA report.

The CHAIRMAN. All right, let's see what the Commissioner of the Food and Drug Administration says about the conclusions of the PMA, and then Dr. Berliner, the chairman of the OTA panel.

Mr. STETLER. They may have their opinions. But I disagree with them. And I could cite some others that agree with our point of view.

The CHAIRMAN. By just looking at the ad I would draw a conclusion absolutely different from one I would draw by reading the OTA study itself. This ad says—this is the Pharmaceutical Manufacturers Association—what is the date on that?

Mr. STETLER. It has run within the last 6 months or a year.

The CHAIRMAN. I don't have the date for it. It is this one I am reading from. "Recently the future of your health was debated. You won", is the title.

I will ask that the whole ad be printed at the appropriate place in the record.

But in any event, the ad says:

The Office of Technology Assessment, U.S. Congress, got the job of testing the argument and the suggestion. The first statement in the findings of the OTA's final report was crystal clear: "Current standards and regulatory practices do not assure bioequivalence for drug products."

In other words, the "same" medicines made by different companies aren't always comparable. Member companies of the Pharmaceutical Manufacturers Association support tougher regulations that would require *all* manufacturers to prove the reliability of their products.

Now, when Dr. Schmidt, Commissioner of the Food and Drug Administration, appeared before this subcommittee Mr. Gordon said:

This morning I submitted to you an advertisement of the Pharmaceutical Manufacturers Association which appeared in Time Magazine and U.S. News & World Report.

Incidentally, that is the ad I just read from.

The heading is: "Recently the Future of your health was debated. You won." Do you have it there?

Dr. SCHMIDT. Yes sir, I do.

Mr. GORDON. Would you please comment on that advertisement. Do you think it tells the true story?

Dr. SCHMIDT. Well, I remember seeing this when it came out, and I remember my reaction was one kind of as amusement. I think it is terribly good propaganda, but very bad science. It is incomplete, obviously, reporting of the OTA report, and it is quite selective and therefore misleading.

Now, then, we asked the question of Dr. Berliner, who was chairman of the panel that wrote the report that you quote as your authority.

Mr. STETLER. Right.

The CHAIRMAN. And Dr. Berliner repudiated your interpretation