two that were reported in the OTA report and the attention that has been paid to this problem has arisen largely out of the clinical reports of therapeutic inequivalence.

Nevertheless, having said that, I would immediately say that they are few in number, and more importantly, the problems that have arisen we have been able to handle. I think the principal question is whether or not the Food and Drug Administration has, or can have, with our bioequivalency regulations, procedures in place to solve problems as they may come up. And I think the answer clearly is yes.

Mr. GORDON. This morning I submitted to you an advertisement for the Pharmaceutical Manufacturers Association which appeared in Time magazine and U.S. News & World Report. 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 that tells the true story?

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

Mr. GORDON. Thank you very much. Thank you very much, Mr. Secretary.

Secretary WEINBERGER. Thank you, Mr. Gordon.

Mr. GORDON. On behalf of the Chairman, I appreciate your coming to visit us this morning.

Secretary WEINBERGER. We are delighted to have been here. Thank you.

Mr. GORDON. We shall recess the hearings for about 10 more minutes until the Chairman comes back from voting on the floor.

[A brief recess was taken.]

The CHAIRMAN. Our next witness is Dr. Robert Berliner, Dean of the Yale University School of Medicine and Chairman of the Drug Bioequivalence Study Panel.

Dr. Berliner, the committee is very pleased to have you. Unfortunately, we are on the foreign aid bill so many of the members are on the floor and unable to be here to hear your testimony but it will be printed in full in the record and available to all of the members.

You may go ahead and present your statement however you desire.

STATEMENT OF ROBERT W. BERLINER, M.D., DEAN, YALE SCHOOL OF MEDICINE, AND CHAIRMAN, DRUG BIOEQUIVALENCE STUDY PANEL

Dr. BERLINER. Thank you, Mr. Chairman. My statement is relatively brief and with your permission I would like to read it.

As you indicated, it was my privilege to serve as Chairman of the Drug Bioequivalence Study Panel which rendered its report to the Office of Technology Assessment last July. It was Secretary Weinberger's statement of intent to establish the maximum allowable cost program that precipitated the request that led to our study, inasmuch as the matter of bioequivalence, or more specifically therapeutic equiv-