What we said was that some of the products included in the efficacy review by the Drug Research Board are still in debate. The question is whether or not data has been submitted that takes them out of the category of "relatively effective." Those products are going to be on the market, they are available to everybody. It is our position that they should be available for reimbursement from medicare and medicaid until these issues are adjudicated. And they are being adjudicated.

Mr. GORDON. You wanted reimbursement, you advocated reimbursement for drugs, even though there was no evidence of efficacy for these drugs?

Mr. STETLER. There is plenty of evidence of efficacy. They have been on the market for many years.

Mr. GORDON. That doesn't make them effective at all.

Mr. STETLER. It just means that they have not complied with the requirements of proof that have been established by regulation. What we are talking about now, if you will, is a new set of criteria. We firmly believe that the Food and Drug Act should be amended to require annual inspections, certification, or licensure before the manufacturer can put a product on the market. And for every product he has on the market, he should be required to submit proof. Only in this way can we get out of the guessing game as to whether he is doing his job or not.

The CHAIRMAN. What proof are you talking about?

Mr. STETLER. Proof of safety and effectiveness, and the bioavailability of his products. Now, there are plenty of products on the market, from big and small manufacturers, on which such data has not been submitted to the Food and Drug. And in the absence of it we are now making this assumption across the board. We say that it not proper, it is not scientifically valid.

Pharmaceutical research can provide and often has produced the best and most cost effective answers to abiding health problems. A MAC program which dilutes that capability will, in the longer term, increase total medical care costs by delaying better therapy.

If one were to study past therapeutic progress to determine those products whose sales financed the research that led to their introduction, rather few patented products would be found to have carried the entire burden. On the contrary, it appears that revenues from many drugs, both patented and nonpatented, shared the cost of developing the breakthrough agents of recent decades.

We firmly believe that the proposed program could result in the establishment of MAC prices at levels which would discourage research and development aimed at product improvement. Similarly, with respect to services, if MAC's are established at the level of the lowest price commodity supplier, the capacity of other suppliers to offer services, vital to public health, would be jeopardized. The MAC level should support a supplier's product recall capability and reflect cost justified and nondiscriminatory warehousing and distribution allowances.

Additionally, it is imperative that any program of this type be flexible enough to allow for varying pharmacy costs and services and to encourage growth and professional development. If necessary