would be—are there any bioequivalency or bioavailability problems with that drug? If the answer is no—and I think that would be the case—when we would pay $5.70 for 100—for a prescription of erythromycin. We would pay no more.

The CHAIRMAN. Thank you.

Secretary WEINBERGER. Our studies have made clear that drug acquisition cost is very hard to pin down. Quoted wholesale prices often do not reflect the real acquisition costs. The individual pharmacist, or the buyer for a large chain or a large hospital, may be able to get the drug at well below the so-called wholesale stated cost.

This would suggest that maybe we should look at the account books of the pharmacist. But here, too, precise information is difficult, especially if the drug supplier offers inducements, rebates, tie-in sales, or other products or considerations that actually lower the true acquisition cost.

We do not mention this to suggest that there is anything improper about such marketing practices, but merely to indicate that it is a difficult thing to figure actual acquisition costs. And so it is difficult for a public agency to know what is a fair reimbursement rate—fair to the pharmacist, fair to the taxpayer. A reimbursement system must give consideration to the cost of professional services involved in dispensing a drug and a reasonable return to the pharmacist who is, as any other health professional, interested and has to maintain the cost of his operations. That is a consideration that has to be borne in mind, too.

There are other issues that remain to be clarified, as the public comments on our proposed regulations quite properly indicate. I think we have made great strides toward developing a responsible and equitable program.

Before we go into that, we might mention this point of quality, which I think is uppermost—properly—in most peoples' minds. Essential to the success of this whole program is our ability to assure that drug products covered by the program all meet the same high standards of quality. We have some things that the Food and Drug Administration is doing that we think does assure that.

The Food, Drug, and Cosmetic Act requires that every drug firm be inspected every 2 years, and we do that. Those inspections are done primarily to determine whether the plan is operating in compliance with the Good Manufacturing Practices regulations. These regulations specify the basic standards the manufacturer must adhere to in order to control his production process. Stringent process control is essential to the manufacture of high quality drugs.

Considerable effort has been devoted to updating our regulations, and a late draft of these newly amended regulations is on display in the office of the Hearing Clerk at FDA, and will be published as a proposal in the Federal Register. It has some changes in it. This requires a description of manufacturing and control operations in written procedures. It says that appropriate statistical sampling techniques must be followed in quality control testing. A quality control unit must be established by the company with a director reporting to management, independent from those who are responsible for production. All drug products must carry an expiration date on their