drugs that may be marketed without preclearance provided they meet certain conditions. Some have said this will result in less effective Food and Drug Administration surveillance.

On the contrary, we think it will improve the conditions for the marketing of these drugs. The listing will trigger appropriate plant inspections, and that I think will mean again that we will have more frequent inspections in many of the firms. All such products must comply with the compendial standards and be produced in conformity with current good manufacturing practices and enforcement mechanisms to insure these are already in operation.

Manufacturers of these drugs will—that is with any bioequivalence requirements or special manufacturers problems—be required to obtain marketing preclearance through the submission of the abbreviated New Drug Applications.

Mr. GORDON. May I interrupt at this point? How is it determined that a drug has a bioequivalency problem? Would it be determined on the basis of a scientific study or individual complaints?

Secretary WEINBERGER. No, scientific studies. Dr. Schmidt may want to elaborate on that.

Dr. SCHMIDT. In general, I think that certain principles can be invoked that would allow one to anticipate where equivalency problems may arise. We do have some experience that has resulted from clincal experience that shows that certain classes of compounds, those with solubility problems, for example, may have problems. So I think we know enough to anticipate some problems.

We have clinical experience that would identify some problems. Then also drugs that you have identified before, those with a narrow therapeutic range, those that are terribly important, there is just one drug to treat a sort of disease—that kind of drug we would pay particular attention to.

All in all I think that we would very well be able to establish that list of drugs which should have as a requirement a prior marketing bioavailability study.

Secretary WEINBERGER. We now have over 1,100 employees working in drug quality with a public investment of about $25 million, and our analysis of industry performance in the recent past fails to show any systematic problem with any particular segment of the industry. Drug standards and Good Manufacturing Standards are increasing their specificity and their scientific excellence. Enforcement activitiese are becoming more stringent. Policies of the agency are becomng more demandng to insure single-standard performance, and I am reassured and I want to reassure you that the quality of drugs in this country is consistently high and will continue to remain so under current Departmental practices.

Now, with respect to the MAC proposal specifically, Mr. Chairman— we have three parts to it. The first is multiple source drugs, and it would, as I said, limit the Federal payment or cost-sharing to the lowest cost as which a drug is widely and consistently available to pharmacists throughout the United States. This would be termed the "maximum allowable cost" or the MAC for that drug. That would be established by a five-member Pharmaceutical Reimbursement Board which would be composed of Departmental officials re-