clear difference between these two groups of manufacturers, and we find no basis from the Food and Drug Administration's experiences with its product surveillance program to believe that the currently ongoing activities of the Government need any substantial change before this MAC program can be implemented.

Obviously, we will search for improvements. We will make them whenever we can, whenever they seem to be necessary, but we are confident that the basic soundness of our approach to quality assurance is there and there will be fundamental success of its current operation.

The recall list shows that mistakes do occur, and it is important that we have a mechanism for identifying those products rapidly. The Food and Drug Administration in 1970 established a Product Defect Reporting System to accomplish this. It relies on practicing pharmacists and nurses in hospitals, pharmacists in community pharmacies to report such things as deformed tablets, leaky vials, or cloudy solutions to the United States Pharmacopeia and the FDA.

We have had over 13,000 such reports and these reports have precipitated recalls and plant inspections. About 75 percent of these reports have concerned products of well-known manufacturers. Since well-known manufacturers hold the major share of the market, that would be an expected percentage. The data does not reveal any clear difference between the various segments of th prscription drug industry.

New regulations relating to bioequivalency have been promised for some time by the Food and Drug Administration. It is a very complex matter. We want to try and be as right as we can, and we have delayed publication to provide for full consideration of all of these products. The regulations will be published in the near future, probably the end of April or May as a proposal, and they will definitely appear before the MAC regulations are published as a final order. Specific procedures will be proposed for the establishment of the bioequivalence requirements for individual drugs whenever there is evidence that products made by the manufacturers are not bioequivalent, or where there is any clear potential for bioinequivalence.

The requirement, once established, will require testing of absorption in humans, in vitro testing of the dissolution rate of each batch by the manufacturer, and the approval of an abbreviated New Drug Application as a condition of marketing.

On old drug monographs, we have the "generally recognized as safe and effective," and that is now known, as you know, as generally "old drugs," and that includes most of the over-the-counter preparations and most older prescription drugs.

The law has always permitted any registered manufacturer to market those well-established old drugs without obtaining any preclearance from FDA. FDA has felt for some time it was necessary to develop a monograph system for prescription drugs in the old drug category, and the major regulations relating to old drug monographs will be published as proposals later this year.

In anticipation of this, we will announce that certain well-established prescription drugs which do not have bioequivalence or special manufacturing problems in the future will be considered as old