Mr. Chairman, we find no basis from FDA's experiences with its product surveillance program, its certification program, or its recalls to believe that the currently ongoing activities of the Government need substantial change before the MAC program can be implemented for selected drugs. We have always asserted, and I will assert again, that improvements can and will be made, whenever necessary. But I am equally confident of the basic soundness of our approach to quality assurance and the fundamental success of its current operation.

Product Defect Reporting System

As the recall list reveals, mistakes do occur and defective products may on occasion appear on the market. It is, therefore, important that we have a mechanism for identifying such products rapidly. In 1970, the FDA established a Product Defect Reporting System to accomplish this. The system relies on practicing pharmacists and nurses in hospitals and in community pharmacies who report defects such as deformed tablets, leaky vials, and cloudy solutions to the United States Pharmacopeia and the FDA. To date, over 13,000 such reports have been received. Recalls and plant inspections are frequently precipitated by the reports.