I would also emphasize that every batch of antibiotics and of insulin is certified by the FDA before it is released. Such batches are now tested to assure, among other things, their potency, purity, and sterility. In the future, testing will include dissolution rates as requirements are established. The FDA certifies approximately 20,000 batches of antibiotics and 600 batches of insulin each year. The overall rejection rate is less than 1 percent, indicating a high degree of industry performance in this area.

Although the FDA has the authority to use strong enforcement measures such as seizure or injunction to remove defective drugs from the marketplace, such action is relatively uncommon today. Currently, the usual means of removing products from the market is the voluntary recall. I would like to submit for the record a list of recalls conducted by the FDA in FY 1974 and so far in FY 1975 (to February 28, 1975). This list includes all recalls of drugs with an actual or potential hazard to health which involved a quality control problem. The list includes 130 such recalls for FY 1974 and 94 for FY 1975. The list reveals the names of many major manufacturers as well as those not so well-known. FDA is unable to conclude from this list that there is any clear difference between these two groups based on recalls.