

and I, for one, would hope that the subcommittee will look into that very carefully, and that the Department will too, because it is a very key point and I think it has been very much overlooked.

Secretary WEINBERGER. Well Senator, we do have as part of this proposal a recommendation—actually it will be a requirement under the regulation—to gather and disseminate pricing data to doctors so that they will have before them the knowledge that they can prescribe a bioequivalent therapeutic equivalent kind of drug or a medication at one price, but if they call for it under another name it might be much higher. We do not believe they have had all that information before them, and so one of the parts of this program would be to make that available to them as well as to pharmacists and others.

Senator JAVITS. I think that is excellent, and I would hope that going to increasingly loom in respect to the national health insurance the American physician will pay very strict attention to that as it is plan in which it would then become a critical cost factor.

Thank you very much.

Secretary WEINBERGER. Thank you, Senator.

When these monitoring activities reveal problems with an entire class or type of drug, we then put specific intensive programs into effect. The drug classes that have been studied includes such important drugs as digoxin, diuretics, antiarrhythmics, anticonvulsants, antibacterials, tranquilizers, oral hypoglycemics, bronchodilators, antiinflammatories, antihistamines, coronary vasodilators, and sedatives. Many of the multisource drugs in the list of the 200 most frequently prescribed products have been studied in that way. While some individual products have failed to meet standards, we do not have any evidence of any widespread industry problems of meeting appropriate standards of identity, purity, or potency.

Every batch, of course, of antibiotics and of insulin is certified by the Food and Drug Administration before it is released. Such batches are now tested to assure their potency, purity, and sterility.

The CHAIRMAN. And that applies to antibiotics that are imported from foreign countries?

Secretary WEINBERGER. Yes, sir. Dr. Schmidt assures us that is correct. That is my understanding. The Food and Drug Administration certifies approximately 20,000 batches of antibiotics and 6,000 batches of insulin every year. The overall rejection rate is less than 1 percent, which indicates a very high degree of industry performance in this area.

Although 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 rare. The usual method is the voluntary recall, and I would like to submit for the record a list of the recalls¹ which we have conducted in fiscal year 1974 and fiscal year 1975, and it includes all recalls of drugs with an actual or potential hazard to health which involved a quality control problem, 130 recalls in fiscal year 1974 and 94 so far this year. The list reveals the names of many major manufacturers as well as those not so well known. We are unable to conclude from this list that there is any

¹ See list of drug recalls, page 11965.