In addition to these programs, we continue with the traditional approach to drug surveillance in the United States. This is routine inspection of drug plants by our field districts. We have 19 district offices, 95 resident posts, and 400 drug inspectors scattered across the Nation. They inspect drug firms to determine whether or not these firms are operating under current good manufacturing procedures. When necessary, evidence is gathered for possible legal action by FDA in the form of seizure, injunction, or prosecution.

These inspectors also monitor drug recalls to make certain defective products are actually removed from commercial channels. In 1972 we had 638 drug recalls. Of these, 291 were brand name and 347 generic products. Again, defects were encountered in big companies, small companies, brand and generic products.

In addition to our efforts to assure the quality of all drugs, brand and generic, developments are taking place in other areas. For years, the large brand name manufacturers have been major providers of generic drugs. Recent events indicate that more and more generics will be manufactured by traditionally brand name manufacturers. Also, as the number of drug substances increase, and as the expense involved in maintaining manufacturing facilities for a full line of drugs rises, more and more manufacturers—large and small, generic and brand—are selling to each other either bulk drugs or finished dosage forms.

This all makes it increasingly difficult for the average purchaser to know who really made the drug. In a number of instances, one manufacturer is providing to a large number of firms the same drug, which is then marketed under a wide variety of brand and generic names.

Thus it is difficult today for an individual health professional—and

"We cannot conclude there is a significant difference in quality between the generic and brand name product tested."

virtually impossible for the consumer—to really assess the quality of drugs. After all, each professional has limited experience with a particular drug. Evidence of some uncertainty is seen in the fact that some professionals prescribe the highest priced product when the same product is being offered at a substantial saving by equally large or experienced firms or offered by the same manufacturer generically at a lower price than the brand name drug would cost.

Some professionals seem to mistakenly equate "big manufacturer" or "brand name" with good, and "smaller manufacturer" or "generic" with bad. This impression is not borne out by the facts. Some of this confusion will be dispelled as we begin publishing the results of our national drug quality survey.

When this is done, I hope people will understand that a firm found to have produced a bad batch by these surveys should not necessarily be condemned or put out of business, because, as I have stressed, large and small have stumbled—and have corrected their defects and gone on to produce quality products. However, if a firm develops a pattern of poor performance or does not correct a defect once found, then corrective action will obviously be appropriate, and we will not hesitate to take such steps.

In summary, what does this all mean, where do we stand in total drug quality today?

In my judgment, the total quality of the Nation's drug supply is high and is constantly improving. Marginal drugs and manufacturers are being removed. Those that remain are better tested than they have ever been before. We exceed in quality the drug supply of any other nation in the world.

Is it good enough? Not yet.

Can it ever be perfect? Given the complexities of drug manufacturing, probably not.

Do we still find defective drugs? Yes, we do, but this should surprise no one, since it is humanly impossible in this less than perfect world to produce tens of billions of doses of a wide variety of drugs each year and not make a mistake.

Is a brand name a guarantee that a drug will be good while a generic name is an indication that the drug will be bad? In our experience it is not.

We at FDA plan to take further steps to strengthen our quality assurance program in the months ahead. We know we will find problems in the future. This is to be expected. When found, we will correct them, and thereby raise the standard of quality one more step toward the goal of consistent and uniform high quality drug supply for the American public.

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