the smaller firms only 13 per cent.[41] The likelihood that a specific drug preparation made by any small firm will be inspected is therefore about 6.9 times as great as in the case of any large firm. It must be conceded, however, that during this period the average large firm had 381 samples inspected; the average small firm, 7.2. Each large firm is virtually certain of one or more samples per year; a small firm may hope to go uninspected for a year or more. (3) Most small firms buy the drugs in bulk form from large firms, and merely tablet and bottle the finished dosage forms. Pejorative comments by large firms, therefore, often imply at least some criticism of their own bulk drugs. (4) The United States Pharmacopoeia sets tolerance intervals above and below 100 per cent of labelled strength for the active ingredient in many drugs. If the lower limit is, for example, 95 per cent, it has been claimed that the producer might aim of 95 per cent strength and thereby achieve economies. For a small firm, however, the cost of goods sold may average about two-thirds of sales[42] and the cost of raw materials may constitute about half of the total cost of goods sold[43] so that raw materials costs may be in the neighborhood of one-third of total costs for a small firm. Hence a reduction of 5 per cent in raw material input would cut total cost by only about 1⅔ per cent, or by much less than it would require to begin to justify a procedure which would result in turning out a substantial number of tablets below the 95 per cent lower limit of tolerance.[44] (5) It is claimed that low priced sellers economize on quality control. Again, there seems to be little room for cost savings, for the cost of quality control is probably no more than 2½ to 3 per cent of the total of all costs[45]—surely not enough to justify a procedure which would make the violation of the drug laws a certainty.

Perhaps the best argument why quality differences might be expected to exist between higher and lower priced drugs is the contention that the Food and Drug Administration is understaffed and cannot make enough inspections. It is true that insufficient inspections are made with regard to both large and small firms. From January, 1950, to June, 1960, 7,699 samples of drugs produced by large firms ($10 million or more in annual sales) and 9,298 samples from small firms were inspected. During the same period, 84 incidents of irregularities developed in connection with drugs made by large firms, 79 of which were handled by the "drug recall" procedure and five of which led to legal actions. For small firms, 690 such irregularities developed, 206 of which involved drug recalls, and 484 of which led to legal actions. The ratio of legal actions is almost 100 to one, while the ratio of drug recalls is only five to two. Clearly, those irregularities involving large firms are much more frequently negotiated than those involving small firms.[46] For the large firms, there was a ratio of 1.1 percent of irregularities to total samples inspected. For the small firms, the ratio was 7.4 percent. The difference is a matter of degree; both figures are too high. The remedy is not to prohibit or to discourage by propagandistic activities the sales of drug at

[41] Data presented by Food and Drug Administration Commissioner G. P. Larrick, *id.*, pt. 22, at 12147.

[42] The only data available are 68 per cent for Panray Corporation. *Id.*, pt. 16, at 9375.

[43] The only data furnished by any one company for any product show a 52 per cent ratio for Carter's meprobamate. *Id.*, pt. 16, at 9157, 9161.

[44] The products of large firms commonly sell at prices as much as several hundred per cent above those charged by small firms, as has been indicated in the case of reserpine. Small firms can undercut large ones by economies in selling costs without any risk of violating the food and drug laws. Large firms spend about 25 per cent of sales revenue in sales promotion, according to data submitted to the Senate Subcommittee by the major firms during the hearings. It is clearly preferable to save 20 to 25 per cent of total cost by foregoing sales promotion in favor of price competition, than to save 1⅔ per cent in raw materials cost and risk a violation that might result in a fine large enough to put a very small firm out of business.

[45] Panray Corporation's quality control costs were 3 per cent of sales revenue; its profits before taxes were about 10 per cent of sales. Hence quality control for this small firm accounted for about 2.7 per cent of total cost. That this is adequate is evident from the fact that no samples of Panray products have been judged violative by Food and Drug Administration inspectors. Hearings on Administered Prices, pt. 16, at 9375, 9378.

[46] It must not be assumed that irregularities involving legal action were more serious, on the average, than those settled by drug recall. If anything, the reverse is true. The nature of 46 violations taken to court, for 32 large and small firms appearing in the record of the hearings, had to do almost entirely with deficiencies or excesses of the active ingredient; only three samples in 46 contained adventitious deleterious substances. Of 285 drug recalls, most were for lack or loss of potency, but several very serious irregularities appeared. For small firms, there were four instances of contaminated drugs, and one instance where the drug was suspected of causing agranulocytosis. For large firms, there were six instances of contaminated drugs, and one instance of suspected agranulocytosis, three instances where the drugs had caused liver damage or jaundice, one instance of induced acidosis, and one instance (again a recall, not a legal action) where polio vaccine had caused widespread paralytic poliomyelitis. *Id.*, pt. 22, at 12137–61.