In 1966, the U.S. Food and Drug Administration sampled 4,600 drugs from 250 manufacturers. About 2,600 were drugs sold by their generic names, and about 2,000 were drugs sold by brand names. The FDA found that 7.8% of the generic-named drugs were not of acceptable potency and 8.8% of the brand-named drugs were not of acceptable potency.

The Washington Post, May 7, 1967

One of the determinants of therapeutic response is potency—that is, whether a drug is of a required strength. A drug that is subpotent is a bad drug, even if it meets all the other requirements and is purer than pure. A year ago the Food and Drug Administration checked the potency of drugs from 250 suppliers. The products fell into 20 key categories but did not include antibiotics, whose quality is assured by the FDA's premarketing, batch-by-batch inspection. Of 2,600 samples sold under less expensive generic names 7.8 percent were found subpotent and therefore unacceptable. Of 2,000 brand-name samples 8.8 percent were below strength. (It should be understood that the difference between these percentages is very little, and under no circumstance should one conclude from the FDA findings that the quality of generics is necessarily higher than that of brand-name drugs.).

"The Handbook of Prescription Drugs," by Richard Burack, M.D.

"Not the least of the reasons forcing us to believe that brand-name drugs are not necessarily better than those sold by generic names is a finding made in the spring of 1966 by the United States Food and Drug Administration. At the direction of its new, no-nonsense Commissioner, Dr. James Goddard, the Agency sampled 4,600 drugs from 250 manufacturers. Quoting Mr. Winton B. Rankin, Deputy Commissioner, as he addressed the American College of Apothecaries on October 15, 1966, in Boston, Massachusetts: 'About 2,600 of the drugs were sold by their generic name only and about 2,000 by brand name. They represented 20 of the most important groups of drugs used in medicine—antihypertensives, oral antidiabetics, anti-infectives, digitalis and digitalis-like preparations, for example. Antibiotics were not included because every lot of antibiotics for human used is checked before sale'. Deputy Commissioner Rankin then went on to reveal to a hushed audience of pharmacists that '7.8 percent of the generic-named drugs were not of acceptable potency, 8.8 percent of the brand-named drugs were not of acceptable potency.' Later, in reply to a question from the audience, the speaker made it clear that the difference between the 7.8 and 8.8 percent figures is not large enough to allow one to conclude that genric drugs are necessarily better than those sold by brand name."

SUMMARY OF FDA DISCLOSURES, MAY, 1967

Products of 246 manufacturers were involved in the 1966 FDA survey. Of these, 84 are PMA members. Of the 84, 49 were found to have one or more violative products. (PMA has 138 members).

FDA reported on tests of 4,573 products. Of these, 1,933 were products of PMA members. Of the 1,933, 119 were found by FDA to be violative.

Overall, 8.2 percent of the products in the survey were found to be violative.

For the PMA-member products, the comparable percentage was 6.1.

SUMMARY OF PMA INVESTIGATION

(Please see attached questionnaire).

Responses to Question #12 are the most significant.

Forty-two firms, with 1,467 products in the survey, have undertaken internal reanalyses of their 100 products alleged to be violative. Results from 40 firms show that only 14 of these products were deficient, and that 80 were not. Reports on reanalyses of six products are pending. Two firms have not reported results to date.

Seven firms, with 146 products in the survey, have not reported undertaking reanalyses of their 19 products alleged to be violative.

Eight firms so far have reported that their in-house reanalyses were repeated by outside, independent laboratories. Results so far show that of 14 allegedly violative products among these eight firms, five have been found not violative, two were confirmed to be violative, and reports are pending on seven.