STATEMENT BY FDA OFFICIALS CONCERNING THE POTENCY SURVEY

1. Commissioner James L. Goddard in an address to the Drug and Allied Products Guild, Ellenville, N.Y., June 8, 1966:

"Between March 24 and June 3 of this year, the Food and Drug Administration collected almost 4,200 drug samples in 20 major therapeutic categories—corticosteroids, anticoagulants, antihypertensives, diuretics, nitrates, and so on, 7.6 percent of them deviated to a material extent from declared potency—they failed to meet USP or NF limits, or in the case of non-official drugs their potency fell outside the range of 90–110 percent of declared potency.

"On the average, then, we have to conclude that one out of every 14 drug units manufactured is violative just on potency alone . . .

"* * * These are facts of life—of human life and of economic life. But I must tell you that the Food and Drug Administration is interested first and foremost in the facts that protect human life . . ."

2. Deputy Commissioner Winton B. Rankin, in an address to the American College of Apothecaries, Boston, Mass., October 15, 1966:

"We collected about 4,600 (sic) samples of drugs last spring representing the output of about 250 manufacturers. We examined these samples for potency . . . The quality of a drug was judged by applying the potency limits of the USP or the NF [United States Pharmacopeia or the National Formulary] if it was an official drug. Otherwise, it was considered acceptable if it contained 90 to 110 percent of the active ingredient declared on the labeling. 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 . . . Manufacturers who would like to avoid increasing demands for extension of batch-by-batch Government testing of additional drugs would be well advised to clean their own house rather than waiting for the Government to do it . . . The main issue is: If a drug manufacturer cannot put out good drug, then he will have to get out of the drug business . . ."

3. FDA news release, for A.M.'s January 31, 1967:

"* * * There were 4,537 drug samples collected in the survey. Analysis showed that 376 samples—or 8.2 percent of the total—were above or below acceptable potency levels. The 376 samples came from 127 different firms . . . Follow-up action on violations of potency standards included the collection and examination of additional samples, re-inspection of manufacturing plants, recall or seizure of products, or citation of the manufacturer . . ."

4. Dr. Goddard, in an address to the Philadelphia Chapter, Defense Supply Association, February 9, 1967:

"* * * Altogether there were 4,573 drug samples collected. On just potency levels alone we learned that 8.2 percent of the total survey—that is, 376 drug samples—were above or below acceptable potency levels. As a physician—and, every now and then, as a patient, too—I regard 1 percent as the outside limit."

5. Dr. Goodard, in an interview in the February, 1967 issue of *D.O.*, publication of the American Osteopathic Association:

"* * * Well, you can quibble about minor differences; you can talk about whether this sample was statistically significant—it did have more than 4,500 drugs in it—about half of them were trade names, about half of them generic drugs. But you can't argue away the fact that about one out of twelve (sic) drugs didn't measure up on potency . . . In one out of twelve instances the patient isn't getting what the physician intended . . ."

STATEMENTS FROM SOURCES OTHER THAN FDA ABOUT THE POTENCY SURVEY

Senator Philip A. Hart, Senate Floor Speech, October 21, 1966

Mr. President, last Saturday the Deputy Commissioner of the Food and Drug Administration, Winton B. Rankin, pointed out that if doctors and pharmacists are attempting to supply patients with the best drugs, they might be better advised to use generics over brandname drugs.

A quality check by FDA of 4,600 samples of 20 of the most important groups of drugs—generic and brandnames—Mr. Rankin reported, showed 7.8 percent of the generics not of acceptable potency. But 8.8 percent of the brandname drugs failed to meet standards.

The percentages, admittedly, are still too high in both categories and demonstrated, as **Mr. Rankin said:**