

Study has led to a continuing series of actions and policy determinations. The following will illustrate FDA actions impacting on drug usage.

First, the NAS/NRC study clearly reflected the existence of a number of irrational, fixed combination drug products. To effectuate a more rational approach to drug usage, the FDA, after consulting widely with professional groups, has established guidelines for such products. A large number of widely prescribed antibiotic combinations were removed from the market after a major legal contest through the courts.

Incidentally, Mr. Chairman, that number I am advised is about 120 systemic antibiotic combinations, and irrational drug products continue to be removed as the individual items are evaluated.

Senator NELSON. These weren't all different entities?

Dr. FINKEL. No, they weren't all different entities; they largely include penicillin and streptomycin combinations.

Mr. SEGGER. Irrational drug products continue to be removed as the individual items are evaluated.

Senator NELSON. May I ask a further question on that?

Mr. SEGGER. Yes, sir.

Senator NELSON. Does your department have a list of those 120 drugs?

Dr. FINKEL. Yes; it does.

Senator NELSON. And does the department know what the total annual sales of those fixed combinations and anti-infectives were?

Dr. FINKEL. I think we probably don't, because for some of them we haven't received records and reports on for quite a while.

Senator NELSON. Do you happen to know whether the Food and Drug Administration has the amount of the total sales of those drugs?

Dr. FINKEL. I don't think so. Our figures relate to amount of drug distributed but we can certainly attempt to extrapolate sales figures from that information as well as obtain hard sale data on the most popular of the drugs.

Senator NELSON. Could you submit for the record the figures you do have on the total sale of the fixed combinations and anti-infectives.

Mr. SEGGER. Yes, sir.

Senator NELSON. Thank you.

(The subsequent information was received and follows:)

FDA does not have accurate sales data for all the 120 systemic antibiotic combinations which have been removed from the market. However, for 51 of these 120 combinations, data are available which show an approximate whole value of \$17,200,000 as of the year prior to their removal from the market.

Mr. SEGGER. The second category which I would like to mention is labeling. The labeling of a large number of drugs is being updated to delete indications evaluated as ineffective. A requirement became effective on May 15, 1972, which requires package inserts and advertisements to reflect indications evaluated as "probably" or "possibly" effective while clinical evidence is being sought to establish whether the drug is effective. This is to inform the prescriber of the best available scientific evaluation of these drugs.

Three, the abbreviated New Drug Application concept has simplified the procedures for manufacturers to obtain approvals to market certain new drugs. This procedure is designed to establish a mecha-