

8764 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

In summary, the problems that currently exist are not the fault of any one group. Correction of the problems will require the combined efforts of all involved -- the Federal Government, the professional community, industry, and the public.

I would like to conclude with a report of the present status of the Drug Efficacy Study. Before doing so, as Commissioner I would like to publically commend the dedicated professional staff of the Bureau of Drugs who have worked so diligently to implement this very important study.

By July 1 of this year, we will have completed and published in the Federal Register our evaluation of all 3,000 drugs which were in the Drug Efficacy Study. During 1971, 142 drugs named in Federal Register announcements as "lacking substantial evidence of effectiveness," and 367 "related" drugs were effectively removed from trade channels, 64 by recall. To date, 452 ineffective drugs specifically covered by the publication of 102 final orders in the Federal Register are off the market. This has resulted in the removal from the market of 1473 additional related drugs. Of the 452 ineffective drugs specifically mentioned in the Federal Register statements, 338 were fixed combinations, and of the 1473 related drugs removed from the market, 1345 were fixed combinations.

In the months ahead, the drug industry will be carrying out, and the FDA will be assessing, the studies necessary on drugs which currently lack adequate evidence of efficacy. Drugs which are unable to provide adequate evidence of effectiveness will, as required by law, be removed from the