[From the Medical Tribune, April 12, 1972]

BEHIND PROPOSAL TO HOUSE SUBCOMMITTEE—GROWING THERAPEUTIC GAP WORRIES AMERICAN SCIENTISTS

(Medical Tribune Report)

NEW YORK.—The developing therapeutic gap in American medicine was underscored here by scientific leaders as one of the major reasons behind their call for a Congressional "review" of American drug regulatory policies (MEDICAL TRIBUNE, April 5).

In exclusive interviews, several of the top medical scientists who took part in making the unprecedented proposal to a House health subcommittee noted that Europe has moved ahead of the United States in the number and usefulness of new drugs available to the clinician. They warned that the gap would widen unless there is a complete overhaul of Food and Drug Administration procedures.

"In England, a third of the drugs now in use have been introduced in the last five years. In this country, the corresponding figure is about 10 per cent," said Dr. Robert D. Dripps, Vice-President for Medical Affairs, University of Pennsylvania. "In the four-year period between 1966 to mid-1971, there were 70 products on the market in England not available to practicing physicians here. Many of these are not important therapeutic agents, but if there is only one vital agent available in England and not available here, it is one too many. Japan and Italy are also making great progress in drug research."

Dr. Dripps and others noted that, ironically, the decline in the number of new drugs introduced in the United States has occurred at a time when American drug research capacities are at an all-time high.

In their statement to the House Subcommittee on Public Health and Environment, the scientific group, which is headed by Dr. Dripps, asserted that FDA policies since 1962, when the Kefauver Amendments went into effect, have led to "stifling" of scientific creativity, escalation of research costs, and a "paradox" that finds the FDA working harder, U.S. research capacity greater, and productivity continually decreasing.

In wide-ranging interviews, several leaders of the group asserted that these results stemmed from protracted and, in their view, often unwarranted drug regulatory policies. They made these points:

o Fewer and simpler requirements abroad have given foreign medicine the benefit of more drugs with no loss of safety.

o Increasing costs of bringing a drug to market in the U.S., resulting in part from the need to comply with complex regulations, have brought about a slowdown in research.

o Limited manpower and dollars are being diverted to a large-scale review of old drugs at a time when the need is to develop promising new compounds.

o The Government's regulatory agency has gone beyond its mandate by actions that seek to dictate medical practice.

NO REVERSAL OF TREND SEEN

Dr. Dripps, commenting on the "steady decline in new products introduced in this country," noted that the FDA itself has acknowledged that "it sees no reversal of this trend in the near future."

He continued: "Whatever the reason is for this, we know that the time and cost of new product development has increased greatly and that money and personnel are being diverted from research and development into research required to clarify the status of old, already marketed ethical or proprietary medicines.

"Every dollar spent proving that Tums affects gastric acidity or that potent tranquilizers relieve neurotic anxiety represents dollars and man-hours not spent forging new weapons against disease."

Dr. Dripps stressed that the committee was not calling for "an immediate investigation [of FDA] by Congress," in the pejorative sense that term implies. "We are asking, however, the appropriate committee of the Congress to mandate an effort to develop a reliable body of information to provide a background for public policy decisions affecting new drugs," he declared.

Dr. Walter Modell, Professor of Pharmacology at Cornell University and editor of Clinical Pharmacology and Therapeutics, told MEDICAL TRIBUNE that