STATEMENT BY SENATOR GAYLORD NELSON

The President of the Pharmaceutical Manufacturers Association has recently complained to the Executive Branch of the Government as well as to some members of Congress that the new policy of refusing to use public funds for drugs for which there is at present no proof of efficacy, is unfair to the drug industry. His argument is that since the Food and Drug Administration has given the industry additional time—30 days—for "ineffective" drugs and 120 days for "possibly effective" drugs, the United States Government should continue to use these drugs as if they were really effective.

The Kefauver-Harris Amendments to the Food, Drug and Cosmetic Act, which requires that all drugs on the market must have *substantial* evidence that they are effective as well as safe, was enacted in 1962. The drug industry was put on notice at that time. Over eight years have elapsed and the required scientific evidence was not—or could not be—supplied to support the claims for many drugs.

Dr. Charles C. Edwards, Commissioner of the Food and Drug Administration in a recent letter to me stated that:

"In the real sense, the industry failed to mount any effort to provide the necessary evidence of effectiveness. Rather, they continued to request hearings, revise labeling, or otherwise avoid the issue of supplying substantial evidence of effectiveness. No drugs of any economic significance were voluntarily removed from marketing, except in those cases where the matter was resolved in the courts, such as some combination antibiotic products. We, therefore, considered it prudent to publish the decisions we made based on the NAS–NRC review."

Now the industry's trade association not only is asking for more time to come up with the evidence that such drugs are effective, but also insists that public funds be continued to be spent on them.

In reply to such requests Dr. Jesse L. Steinfeld, the Surgeon General, wrote to the president of the Pharmaceutical Manufacturers Association and I would like to read the last two paragraphs of Dr. Steinfeld's reply, for which I wish to commend him.

"The policy stated in my memorandum is intended to improve patient care in those programs supported with Federal funds. It does not constitute good medical practice to administer drugs that have not been shown to be effective for the purposes for which they are prescribed.

"I do not agree that the Departmental policy is unfair to the drug manufacturing industry as you allege. Even if it were, I would then have to weigh that against the unfairness of giving sick people drugs that have not been shown to be effective. I would have to decide in favor of the sick people."

SURGEON GENERAL,
PUBLIC HEALTH SERVICE,
DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
Washington, D.C., January 28, 1971.

Mr. C. JOSEPH STETLER,
President, Pharmaceutical Manufacturers Association,
Washington, D.C.

DEAR MR. STETLER: Your letter of January 21, 1971, requests me to modify my memorandum of December 11, 1970 stating Departmental policy about the use of Federal funds to purchase drug products classified as "ineffective" or "possibly effective." The request is based on your view that the result of the policy will be to effectively remove any "ineffective" or "possibly effective" products from the market. You also state your view that my memorandum is unfair to the drug manufacturing industries.

The policy stated in my memorandum will not effectively remove drugs from the market. It applies only to drugs purchased with Federal dollars and these make up a relatively small volume of the drugs sold in the United States.

The policy stated in my memorandum is intended to improve patient care