MATERIAL SUPPLIED FOR THE RECORD BY
SENATOR GAYLORD NELSON

ACTIONS BY THE FOOD AND DRUG ADMINISTRATION AND DRUG ENFORCEMENT AGENCY SINCE TERMINATION OF HEARINGS

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20852 20857

Honorable Gaylord Nelson
Chairman, Subcommittee on Monopoly
Select Committee on Small Business
United States Senate
Washington, D.C. 20510

FEB 16 1977

Dear Senator Nelson:

In response to a request from Mr. Benjamin Gordon of your staff, I am writing to outline our current thinking in regard to amphetamines.

We presented the issue of the need for amphetamines in the treatment of narcolepsy and minimal brain dysfunction to our Neurologic Drugs Advisory Committee on February 3, 1977. It was the view of this group that there are alternate safe and effective, but not fully equivalent, treatments for minimal brain dysfunction. Therefore, the withdrawal of amphetamines from the market would have a deleterious effect on the treatment of patients with minimal brain dysfunction. They further stated that there are alternatives to the amphetamines for the therapy of narcolepsy, but these are not equivalent, let alone superior to the amphetamines. Thus, the Committee concluded that the withdrawal of amphetamines from the market would have a deleterious effect on patients with narcolepsy. Additionally, the Committee considered that, although there may be safe and effective alternatives to the use of amphetamines in certain forms of epilepsy and in alleviating the sedative effects of anticonvulsants, withdrawal of the amphetamines from the market would have a deleterious effect on the treatment of some patients with seizure disorders.

Given the above advice from our Neurologic Drugs Advisory Committee, it seems unlikely that total removal of the amphetamines from the market would be in the interest of good medical care for patients with these serious conditions.

Our current plan is to present our overall approach for relabeling amphetamines and promoting their proper use in medical care at a public meeting in April or May. At that meeting, we would present the final data received from the Drug Enforcement Administration (DEA) and the National Institute on Drug Abuse (NIDA) and solicit testimony by experts in the field of drug abuse. We would also invite members of medical professional associations, State Boards of Medicine, and the interested public. Regulatory action on our part would then be based on the data submitted as well as expert advice related to those data. We will, of course, include in our deliberations the testimony of the expert witnesses who appeared at your Subcommittee meetings last November.