concerned about drugs with abuse potential. A vocal consumer group, *The Huntington* (Long Island) *Narcotics Council*, has publicly decried using CNS stimulant drugs to treat obesity, and on this basis has twice petitioned BNDD to reduce manufacturing quotas, once for amphetamine and once for phenmetrazine.

RECOMMENDATION

That the attached memorandum summarizing recommended actions be signed and forwarded to the Commissioner for concurrence.

DISPOSITION

After concurrence or revisions have been indicated by the Commissioner, the package should be returned to this office for preparation of implementing documents. DESI should be informed of the recommendations which they should implement.

TAB A—DRAFT ARTICLE FOR DRUG BULLETIN

AMPHETAMINES

This paper will serve as technical background for possible discussion on the control and distribution of amphetamines and other central nervous system stimulant drugs with abuse potential. It refers briefly to the history of amphetamine use and abuse, describes in some detail the recent control actions taken by HEW and the Department of Justice in the context of the Controlled Substances Act and refers to recent educational actions of FDA.

Racemic amphetamine and dextroamphetamine were introduced into clinical medicine in the early 1930's; their capacity for being abused was recognized within the same decade. The drugs were quite widely used for their stimulant effects by both sides during World War II; perhaps as a consequence more widespread abuse began to occur in the post-war years, with a particularly extensive and well documented epidemic of amphetamine abuse occurring in Japan. In the post-war years, clinical use of amphetamines also grew extensively, as the drugs became widely used in the treatment of obesity, and other conditions.

The abuse potential of amphetamines was not initially fully acknowledged by the general medical community. As it became so, the availability and distribution of amphetamines was progressively restricted. Benzedrine inhalers and other amphetamine products were placed on prescription; controls were applied under the Drug Abuse Control Amendments of the Food, Drug and Cosmetic Act in 1965. More recently, further controls were applied under the Controlled Substances Act.

The Controlled Substances Act, passed in October of 1970, as Title II of the Comprehensive Drug Abuse Prevention and Control Act, includes five "schedules" into which drugs with abuse potential are to be placed, each schedule differing somewhat in the degree of abuse potential of the drugs which it contains and in the degree of control which is applied to the drugs within it. The most stringent is Schedule I, restricted to investigational drugs. For marketed drugs, Schedule II applies the most severe controls and presumably contains drugs with the most severe abuse potential, while Schedule V applies minimal controls and penalties.

The Act when first passed included injectable methamphetamine in Schedule II. Oral methamphetamine as well as oral and injectable amphetamines were included in Schedule III, together with methylphenidate (Ritalin) and phenmetrazine (Preludin) two related stimulant drugs. Other anorectic drugs used in the treatment of obesity were not controlled at all, although possessing central nervous system stimulant activity.

Many people interested in the control of abusable substances both inside and outside government felt that the controls of Schedule III were inadequate for the abuse potential which the amphetamines had demonstrated in the past. Thus, relatively early in 1971, the Food and Drug Administration together with other units within the Department of Health, Education, and Welfare recommended that the oral amphetamines and methamphetamines be moved from Schedule III into the more stringent Schedule II. This was accomplished with the accord of the Department of Justice through its agency, the Bureau of Narcotics and Dangerous Drugs (now the Drug Enforcement Administration). Later in the same year, methylphenidate and phenmetrazine were also moved up into Schedule II.