2. The therapeutic usefulness of anorectic drugs has been poorly and variably defined, and the definitions disputed.

3. Regulatory decisions regarding anorectic drugs appear to have been made in the past largely piecemeal; a broad explicit policy with consistent implementation has been lacking.

FACTS

Relevant to the issues above are a number of more concrete facts, old and new, scientific and administrative. The major background facts are listed below. It is suggested, however, that the material attached under Tabs "A" and "B" be read first, as easy and more extensive descriptions of the complex background.

ADMINISTRATIVE ACTIONS WITH RESPECT TO ANORECTIC DRUGS

1. Submissions of NDA's for Currently Marketed Amphetamines required by the Statement of Policy and Interpretation of 8–8–70

Of the anorectics, the most prominent group, the amphetamines, were considered "grandfathered" until August 8, 1970. At that time the FDA published a "Statement of Policy and Interpretation" (see Tab H) which essentially revoked grandfather status and required among other things the submission within a year of New Drug Applications for amphetamines. NDA's were submitted by sponsors, and are the principal documents on which formal action will be taken in implementation of future amphetamine policy. A few NDA's had been submitted a number of years ago for special amphetamine formulations or combinations and will also be acted upon.

The indications for which the amphetamines might be provisionally labeled were set forth in the announcement of August 8, 1970. The indications were: as an adjunct in the treatment of obesity: as a adjunct in the treatment of minimal brain dysfunction in children: narcolepsy. The first indication is the subject of this memorandum, the efficacy of amphetamines in the latter two being somewhat less controversial.

2. Review of currently marketed non-amphetamines by the Drug Efficacy Study (DESI)

All but one of the other, non-amphetamine anorectic drugs currently marketed in the United States are subject to review by the Drug Efficacy Study, so that decisions are pending on these drugs. The only anorectic DESI Notice published to date, (Tab I) on special formulations and combinations, listed the drugs effects as "possibly effective". Efficacy data have been submitted in response to the Notice, and these "E" supplements must be acted upon in implementing this policy on anorectics.

3. Submissions of NDA's for anorectic drugs not previously marketed

New Drug Applications have been submitted for three anorectic drugs not yet marketed: fenfluramine (Pondimin), mazindole (Sanorex), and clortermine (Voranil). These have purposely been held up in their processing with the agreement of the manufacturer, pending development of overall policy. These must be acted upon.

4. Revision of scheduling of anorectic drugs under the Comprehensive Drug Abuse Act

The Comprehensive Drug Abuse Prevention and Control Act (Controlled Substances Act; CSA), passed in October 1970, is designed to impose restrictions on use appropriate to the abuse potential of drugs. Schedule II of the CSA, the most restrictive for marketed drugs, requires non-refillable prescriptions, special records, and manufacturing quotas, among other things; Schedule III and IV have little but psychological impact on the practice of medicine, requiring only a special symbol on the labels and labeling and a practitioner's BNDD number on the prescription. The Schedules of the Act include three anorectics—methamphetamine, the amphetamines themselves, and phenmetrazine. Other anorectics, e.g., diethylpropion, are not included, although they are labeled as having abuse potential, (and almost certainly possess abuse potential).

The Schedules also exhibit other inconsistencies and omissions, and they require revision. Along these lines, the amphetamines and oral methamphetamine were moved from their original place in Schedule III to the more restrictive Schedule II in July 1971, following FDA recommendations. Phenmetrazine was moved from III to II in January 1972, again following FDA recommendations.