4. Publish follow-up efficacy notices on DESI drugs for which data have been submitted in response to a previous notice.

PRO: This appears inescapably logical from an administrative point of view.

CON: Nothing.

DISCUSSION

1. Assumptions

The assumptions noted on p. 6 of this memo appear largely self-explanatory, but can be debated. We believe, first, that a "class action" is fairer in an administrative sense, and more valid scientifically. The last is particularly true with respect to drugs with abuse potential, for unless action is taken on a broad front, addicts may abandon the restricted drug merely to begin to abuse similar drugs not yet scheduled.] Piecemeal action might appear "conservative" but we believe it fails to take account of such considerations as the great lag between abuse and documentation of abuse.

The second assumption may appear partially inconsistent with the first, in that we suggest limiting action to anorectics rather than extending them, for example, to all sympathomimetic amines.

While this may neglect for the moment such abusable drugs as mephentermine, it is a valid assumption with respect to efficacy and to the way in which the drugs are used, i.e., orally and subacutely. Moreover it limits our actions to a manageable size and to drugs sharing a common indication. In addition, decisions on efficacy in treating obesity involve a number of policy decisions, independent of the scheduling questions.

The third assumption, that actions should not be deferred, appears far preferable to any compromise or delaying action. New Drug Applications have been submitted and will continue to be submitted, and they should be acted on. Early decisions are also required with respect to determinations of "medical need" for anorectics and manufacturing quotas of scheduled substances.

The fourth assumption, to leave aside discussions of minimal brain dysfunction (MBD) and narcolepsy, is a logical determination in terms of the scope of the memo. If we wish, we will have the opportunity to revise our position on MBD later since there is ongoing discussion of the place of CNS stimulant drugs in treating MBD; a current consultant task force should help us here if necessary.

The fifth and last assumption is that a decision can be made generically for all amphetamine drug products. This appears a sound approach, because clinical experience and clinical trials have used various drug products without results suggesting differences.

2. Recommended actions and arguments in support of them

Briefly we recommend the following actions, discussed at greater length above, together with their alternatives: (The letters and numbers in paranthesis refer to alternatives discussed above—in the ALTERNATIVE COURSES OF ACTION SECTION.)

(A.1.) Base approval of anorectics for which NDA's are currently under review on demonstrated superiority to placebo in relatively short-term (e.g., 4–12 weeks), trials of weight reduction. Further testing of some sort, e.g., for abuse potential, would be a desirable corollary.

(B.1.) Label amphetamines to exclude use in obesity.

(C.1.) Place all anorectics except fenfluramine in Schedule II, and fenfluramine in Schedule IV.

(D.1.) Require further testing of anorectics with respect to abuse potential.

(E.1.) Prohibit marketing of parenteral formulations of anorectic drugs for obesity.

(E.2.) Reject NDA's recently submitted for amphetamine-sedative combinations and withdraw approval from older DESI's combination NDA's for which efficacy supplements were submitted.

(E.3.) Require anorectic drug labeling to detail more explicitly the limitations and hazards of use.

(E.4.) Require fenfluramine labeling which balances decreased abuse potential against other possible increased adverse effects.

(F.1–4.) Make the actions public through the *FDA Drug Bulletin* and two SPI's as well as through appropriate DESI notices and follow-up notices.

In summary, arguments in support of these recommended actions are as follows: The actions are consistent with the best available data. They establish and implement a comprehensive policy for a difficult class of drugs. They pro-