vide a reasonable basis for approving drugs, the approvability of which in the past has depended upon rather arbitrary value judgments. The most controversial use of the most controversial drugs, the amphetamines, is eliminated. The actions restrict the use of other drugs with respect to abuse so far as current statutes permit, but maintain the availability of drugs for those practitioners who depend upon them. They inform the practitioner of the limitations of use and of the risks associated with these drugs. Most practically, they are consistent with the closest approximation to a consensus of experts and practitioner which we can strike, with the exception of the ampetamines, and even there we may still expect much professional and lay support. In short, the actions represent the policy which best balances the limited but demonstrated efficacy of anorectic drugs against their potential for abuse.

3. Problems with recommended actions

In acting on an entire class of drugs used in a condition as prevalent as obesity, and with a special hazard of abuse potential, we should expect multiple problems in implementing any policy; it should be clear that no action or set of actions will satisfy all sectors. We can anticipate problems that will almost certainly result from the recommended actions and no doubt others, as yet unforeseen, will arise. But we believe that a clear stand on the major problems we can expect which are discussed below will put us in an optimal position. (Minor problems are discussed only above, in the section entitled ALTERNATIVE COURSES OF ACTION.)

a. The central problem appears to be that of according formal recognition of efficacy to a disputed class of drugs. Some authorities object to calling drugs effective if they do not alter the long-term course of obesity. We believe, however, that this is an unreasonable requirement in view of a demonstrated effect on weight loss over the short term, and in the absence of more effective alternative therapy.

b. A second problem will result from eliminating the indication of obesity from amphetamines labeling. Academic medical figures and many practitioners will criticize us for over-reacting or for depriving physicians of a useful drug with which they are familiar. We will be going against the advice of our small consultant group.

c. A third major problem will be the recommendation to schedule in Schedule II. We wish to make it quite clear that a *basic issue in drug scheduling is involved*, that is, whether we await evidence that a drug is being abused before scheduling it or attempt to predict abuse potential. Data here are imperfect and spotty, as they so often are, and we can be challenged on individual drugs. But the overall picture is one of drugs that are more alike than dissimilar. They all possess CNS stimulant activity and appear very likely to be attractive to addicts, particularly if previously preferred drugs were in Schedule II. In addition there are scattered reports of actual abuse for almost all the non-scheduled drugs. Of all the currently non-scheduled drugs diethylpropion is the one for which evidence of *abuse*, as well as of abuse *potential*, is best documented.

d. A fourth problem is that of quotas. Quotas must be established for almost all anorectics in the near future, if they are put in Schedule II, and we are uncertain how to establish them. This however, appears only one more manifestation of a problem which should remain secondary to the primary consideration of restricting abuse. We are developing techniques for projecting medical needs and quotas.

e. The fifth major problem is that of fenfluramine. Fenfluramine will receive a marked competitive advantage if, as proposed, it is the only anorectic drug not placed in Schedule II. It seems unreasonable however to fly in the face of pharmacologic data for reasons of marketing. The proposed labeling will help slightly to place the probable decreased abuse potential in perspective.

4. Political implications

Congressman Pepper, Senator Bayh, and Congressman Rogers have all been interested as Congressional Sub-committee chairmen in the use of CNS stimulant drugs to treat obesity. The stand of Congressman Pepper has been formally to oppose such use; the latter two tend towards such a stand but until now have been content to await FDA policy.

These Sub-committee chairmen quite certainly represent the opinion of a substantial portion of the electorate, which vaguely disapproves of "diet pills", considered obesity to stem from lack of will power, and of course is extremely