While I cannot be certain at this time, I suspect that our overall approach will include a proposal to withdraw the obesity indication for amphetamines and to include a patient package insert in all amphetamines emphasizing that their proper use is only in patients with minimal brain dysfunction, narcolepsy, or certain types of convulsive disorders. In addition, we may be in a position by then to recommend scheduling changes for other anorectic drugs should the data being gathered by DEA support such a position. We would also hope to have gathered the formal support of a number of medical organizations by that time so that any regulatory action on our part has broad support from the medical profession. It has become clear to us that combined Government-professional action is likely to produce the best result in limiting the use of amphetamines to their proper indications. While it will take longer than we originally predicted to develop such a combined program, we believe this will be time well spent in the long run.

In addition, we would expect that State level legislation (as in Maryland), vigorous activities of such groups as the Federal-State "Diversion Investigation Units" (supported by the Law Enforcement Assistance Administration (LEAA) and administered through DEA) and articles in the FDA Drug Bulletin and professional journals will be influential in keeping inappropriate prescribing of these drugs to a minimum.

We will keep you informed as to the outcome of our data review and the upcoming public meeting on this important issue.

Sincerely yours,

J. Richard Crout, M.D.

J. Richard Crout, M.D.
Director, Bureau of Drugs