tion in children—but we must also recognize there are alternative drugs for these indications. I cannot predict at the present time whether any new regulatory action in regard to amphetamines would involve simply removal of the indication for obesity or complete withdrawal of the drugs from the market. Neither can I predict whether phenmetrazine might be involved in any such action. Answers to these questions will depend on the extent of documented diversion and abuse with these agents found by DEA and the judgments of those on our scientific staff and advisory committees who will review the data.

I would again emphasize that a report from DEA and additional data from the National Institute on Drug Abuse are necessary for FDA to take a strong legal position, and our staffs are working together on this matter.

The withdrawal from the market of a previously approved drug on the basis of its risk to society, as well as to the patient, is an innovative position on which there is little legal precedent. But we believe such a position is legal and are prepared to defend it.

While the preliminary data available to us do not appear to indicate an important public health problem with the schedule III and IV anorectics, we will, as part of our review consider these drugs also. Again, on the basis of careful consideration of data from our sister Federal agencies and the medical research community, we will take whatever action on these drugs is indicated. Such action might range from recommendations for rescheduling to improvements in the labeling. I do not anticipate at the present time, however, any new review for effectiveness comparable to the anorectic review of 1972. In view of the importance of obesity as a national nutritional problem and the lack of any widely accepted, universally effective alternative therapy, we do not think it medically appropriate to question at this time the marketing status of those anorectic drugs now in schedules III or IV.

I would also point out that the Food and Drug Administration has underway two major programs which will ultimately affect many prescription drugs including the anorectic drugs: The prescription drug labeling review and the patient package insert proposal. In the very near future, we will issue final regulations on the format and context of package inserts for the physician and, over the next several years, all prescription drug labeling will come into compliance with these regulations. Various drug categories will be taken on a priority basis under this program, and we consider anorectic drugs as properly among the priority drugs.

We also anticipate issuing in 1977 proposed regulations relating to patient package inserts for prescription drugs. This proposal will undoubtedly stimulate extensive public comment and may well require another year or more for development of a final order. It is our intent to develop patient package inserts for specific drugs only in the context of this general statement on policy and procedure. In specific cases in which the public health requires a patient package insert on a prescription drug, for important safety reasons, we will take such action on an ad hoc basis as we have for oral contraceptives and estrogens. For most drugs, however, we believe it is wiser to develop general policy ahead of specific patient labeling. We, therefore, anticipate at the present time that specific patient labeling for anorectic drugs will not be developed in the near term.