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 re-scheduling 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 under way 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