

trials carried out by drug manufacturers and submitted to FDA as part of various applications. The data on safety were a more heterogeneous assemblage of different sorts of evidence - chemical, animal and human - which might have some bearing on abuse potential and other safety questions. The efficacy review involved an unprecedented re-examination of all individual patient data sheets, representing 70,000 patient visits, computerization of the data, and FDA re-analysis of the data, using its own computers and statisticians - who deserve much credit for the massive job.

In making the final decisions on the drugs, the FDA was advised by a consultant panel headed by Dr. Thaddeus Prout. The former Council on Drugs of the American Medical Association, headed by Dr. Harry Shirkey, also gave us its opinion on the proposed actions. The institutional FDA decisions were embodied in a comprehensive memorandum proposing various alternatives with the pros and cons of each, the final decisions being initialed by the Commissioner of Food and Drugs. In carrying out the decisions, the FDA itself implemented decisions with respect to marketing approval and relabeling. Decisions on controls to be imposed because of abuse potential were and are the primary responsibility of the Bureau of