

were judged to be effective and to have an acceptable benefit-to-risk ratio, that is, narcolepsy, minimal brain dysfunction, and short-term adjunctive therapy in obesity. These conclusions were published in the December 1972 issue of the FDA Drug Bulletin which was distributed to some 600,000 health professionals.

2. We determined there was no place for parenteral amphetamines in medical practice and these products were removed from the market in 1973.

3. We took the position that preparations containing amphetamines in combination with other drugs—such as barbiturates, vitamins, and tranquilizers—failed to meet FDA's combination drug policy and were, therefore, ineffective as fixed combinations. Beginning in March 1973, procedures were begun to remove these from the market. A group of small manufacturers brought legal action to contest this action, but on December 28, 1973, the U.S. Court of Appeals for the Eighth Circuit upheld FDA's order. (*North American Pharmacal v. Department of Health, Education, and Welfare*; 491 F2d 546.) At the same time, several other manufacturers sought formal hearings on the withdrawal of their products from the market. Two products in this category remain unresolved at the present time. The agency has denied a hearing on one of them, Dexamyl, but this denial is stayed pending judicial review. The hearing request on the other product, Eskatrol, is still under review.

4. We recommended to DEA in 1973 that all of the drugs in the anorectic class be scheduled under the CSA. Previous to this recommendation, only the amphetamines and phenmetrazine were under the CSA; these were in schedule II. The advisory group headed by Dr. Prout had recommended, as I mentioned, that all of the anorectics, with the exception of fenfluramine, also be controlled in schedule II. After reviewing all of the information, however, we felt that the medical and scientific facts available at that time could not support this position since evidence of significant street abuse was not available for all drugs in the anorectic class. Consequently, the agency recommended that seven of the anorectics be controlled in schedule III on the basis of abuse potential even in the absence of clear evidence of significant abuse. These drugs were chlorphentamine, benzphetamine, phenmetrazine, chlortermine, mazindol, diethylpropion, and phentermine. Ultimately, the latter two drugs were placed by DEA along with fenfluramine in schedule IV. Given the nature of the data available at that time, we believe our scheduling recommendations were medically proper and responsible. Additional information has, of course, been steadily accruing since that time, some of which, for example, Dr. Jasinski's studies at NIDA's Addiction Research Center, have been discussed in recent testimony before this subcommittee. DEA is in the process of analyzing this new information on the anorectics and we look forward to their report.

Since 1973, the FDA has developed a mechanism—through the use of the National Prescription Audit and National Disease and Therapeutic Index—for monitoring the utilization of certain drugs