STATEMENT OF ROBERT H. FURMAN, M.D., VICE PRESIDENT, CORPORATE MEDICAL AFFAIRS, ELI LILLY & CO.

I am Robert H. Furman, M.D., Vice President, Corporate Medical Affairs, Eli Lilly and Company. With me are Edgar G. Davis, Vice President, Corporate Affairs, and John M. Holt, Secretary and General Counsel of the Company's Pharmaceutical Division. On behalf of the Company and my associates, I wish to express our appreciation for the opportunity to appear and state our views.

Lilly has been engaged in the manufacture of pharmaceuticals for the health professions since 1876. The Company maintains one of the largest private pharmaceutical research programs in the world. Lilly provides a broad range of products for human medical needs and backs them up with extensive programs of medical and technical support. Lilly was the discoverer and developer of propoxyphene products, which it markets under its Darvon trademark.

Extensive experience and study have demonstrated that propoxyphene products are safe when used as directed and that they are effective pain relievers. Lilly knows of no death that has occurred when propoxyphene was properly used, and no previous witness has testified to the contrary.

Like any drug, propoxyphene can be abused. The vast majority of patients who receive Darvon use it properly. But there are some people who take Darvon in excessive doses, and who take many drugs at one time—often along with alcohol. Frequently, their motives are suicidal. This kind of drug abuse is a medical and social problem that transcends the abuse of any one drug. If Darvon suddenly were to become unavailable, the problem would remain the same.

Lilly is deeply concerned about this problem of drug abuse. The Company believes that further study and educational efforts are needed to understand the problem and to help correct it. Available information indicates that the extent of propoxyphene abuse has in fact declined as physicians have become better informed about its abuse potential and since the drug was placed in Schedule IV under the Controlled Substances Act in 1977. The larger societal problem—of which propoxyphene abuse is only a part—remains, and Lilly is committed to work with the government and the medical profession in further efforts to ameliorate the problem.

The facts do not, however, support the Health Research Group's contention that propoxyphene products should be subjected to the more stringent controls of Schedule II, much less that they should be banned as an imminent hazard to the public health.

Propoxyphene is an analgesic for the relief of mild-to-moderate pain. Physicians precsribe it, alone and in combination with other analgesics, such as aspirin, for pain of the kind and severity that follows surgery and tooth extractions and that accompanies lower-back injuries, cramps following childbirth, and many other medical conditions.

It must be kept in mind that before Darvon was developed there was perceived a need for it. Lilly developed propoxyphene as the result of a national program of research, instituted in 1948, to find a synthetic substitute for the opium-derived analgesics (such as codeine) that would offer the therapeutically desirable properties of those drugs without causing addiction or drug-dependence. After extensive study, including clear-cut demonstration of pain relief in laboratory animals, Lilly introduced Darvon in 1957. Since then, the Company has continued to improve its propoxyphene products, study their effects, monitor their use, and disseminate information concerning them to physicians and pharmacists.

Over the past 21 years propoxyphene has been extensively studied. More than 865 scientific papers concerning the drug have been published.

Clinical research, as well as long experience in actual medical practice, have shown that propoxyphene products are safe when used as directed. Therapeutic doses of propoxyphene provide a wide margin of safety to the patient. Lilly has sold more than 20 billion doses of propoxyphene over the last 21 years, and the Company does not know of a single instance in which the use of its propoxyphene products in accordance with their labeling has caused death or serious injury. Propoxyphene's dependence liability is less than that of codeine.

Propoxyphene is an effective pain reliever. Its efficacy has been demonstrated in controlled, double-blind clinical studies conducted in accordance with rigorous scientific standards. The Food and Drug Administration has repeatedly confirmed the efficacy of propoxyphene products, as has an expert panel of the National Academy of Sciences-National Research Council. The efficacy of