

Senator HAYAKAWA. Thank you, very much.

Senator NELSON. Any other questions?

Thank you very much, Dr. Lasagna, for taking the time to come here and present your testimony today. We appreciate it very much.

[The prepared statement of Dr. Lasagna follows:]

STATEMENT BY LOUIS LASAGNA, M.D., PROFESSOR OF PHARMACOLOGY AND TOXICOLOGY AND PROFESSOR OF MEDICINE AT THE UNIVERSITY OF ROCHESTER SCHOOL OF MEDICINE AND DENTISTRY, ROCHESTER, N.Y.

My name is Louis Lasagna. I am Professor of Pharmacology and Toxicology and Professor of Medicine at the University of Rochester School of Medicine and Dentistry. For over a quarter of a century I have engaged in research on analgesic drugs, and have written extensively in this area.

I appreciate this opportunity to share my thoughts with you in regard to the suggestion that propoxyphene constitutes a major drug abuse problem and an imminent hazard to the health of the U.S. public.

Propoxyphene is unquestionably an effective analgesic drug, either when given alone or in combination with such drugs as aspirin or acetaminophen. This judgment was reached by the Analgesic Drugs Panel which I chaired in the late 1960's for the National Academy of Sciences/National Research Council at the request of the FDA Commissioner, and is an opinion still supported by a review today of the world literature on pain-relieving drugs. It is unfortunate that some who are concerned about the euphorogenicity or toxicity of propoxyphene feel constrained to deny the ability of propoxyphene to relieve pain. Millions of patients have taken, and continue to take, propoxyphene for its analgesic properties. No placebo effect can explain its popularity.

It has been known for years that while propoxyphene, like any drug which affects the central nervous system (CNS), can be abused by some individuals, the risks of such abuse are minuscule. National and international expert advisory committees have repeatedly taken up this issue since the original marketing of propoxyphene, and have never seen a need to reclassify propoxyphene as a drug with high addiction liability.

More recently, drug-associated fatalities have been observed in individuals taking excessive doses of propoxyphene, especially in combination with alcohol and other CNS depressants. After an investigation of this new concern, the Eli Lilly Co. revised labeling for propoxyphene and undertook a campaign aimed at acquainting U.S. physicians with this important new information. When HEW recommended to the Justice Department that propoxyphene products should be placed in Schedule IV, so far as I know the manufacturer did not oppose the listing.

I believe that both the FDA and the several manufacturers of propoxyphene are cognizant of these new developments concerning this drug and have not shown any reluctance to take appropriate steps to inform the prescribing physician.

The data from the government-financed Drug Abuse Warning Network (DAWN), while far from a perfect representation of national drug abuse problems, nevertheless provides information which contradicts the allegation that propoxyphene abuse is increasing and constitutes an imminent hazard. I have followed the DAWN data for some years because of my interest in drug reporting systems.

The most recent reports available to me (Project DAWN VI and the January-March 1978 DAWN Quarterly Report) show, e.g., that there are more yearly mentions of aspirin in emergency room reports (7212) than of propoxyphene (4111). The crisis centers in the DAWN system reported a yearly total of 488 propoxyphene mentions, as opposed to 7243 for heroin/morphine, despite the much smaller number of people exposed to the latter narcotics. Propoxyphene is also mentioned less often than heroin/morphine in medical examiner reports in the DAWN system, with only 486 mentions of all sorts for the entire year.

More important, I believe, is the pattern of decreasing reports for propoxyphene when one looks at the data base recommended by DAWN itself for the best assessment of time trends, i.e., the so-called "consistent reporters." The number of emergency room drug mentions for propoxyphene peaked in October-December 1976 at 892 and has decreased to 753 for the January-March 1978 (the most recently analyzed) period.