Individually and collectively we sincerely believe, on the basis of our professional experience, that dextropropoxyphene should at least be placed in Schedule III to minimize its use and abuse, but preferably placed in Schedule II with the hope that its use would be greatly discouraged.

Yours truly,

PAGE HUDSON, M.D.,
Chief Medical Examiner.
ARTHUR J. McBAY, Ph. D.,
Chief Toxicologist.

Senator NELSON. We thank you very much for your testimony, Dr. McBay.

Dr. McBAY. Thank you.

[The prepared statement of Dr. McBay follows:]

STATEMENT BY ARTHUR J. McBAY, PH. D., CHIEF TOXICOLOGIST, OFFICE OF THE CHIEF MEDICAL EXAMINER, PROFESSOR OF PATHOLOGY AND PHARMACY, UNIVERSITY OF NORTH CAROLINA, CHAPEL HILL, N.C.

My appearance here is with the permission of the North Carolina Division of Health Services and the Chief Medical Examiner; however the opinions I volunteer are my own as a private citizen and do not represent an official stance or policy of the state of North Carolina.

Propoxyphene had been the most frequently prescribed analgesic until 1976 when Tylenol with codeine (CIII), and until 1977 when Empirin Compound with Codeine (CIII), exceeded it in popularity (*1*). It was the second most frequent prescription in 1971 and 1972. It has been reported that 33.5 million prescriptions were dispensed in 1977 containing propoxyphene.

In our opinion the acute adult oral lethal dose is about 12–20 65-mg doses or over 800 mg. In those deaths where the number of prescribed doses were reported, the smallest was for 20, 65-mg capsules, the largest 240 (more than 20 times the lethal dose). The majority were for 40 or more; 100 or greater was common. Several patients had a refill or a second propoxyphene prescription. The prescription of 120 or more doses was most frequent at Veteran Administration Hospital (*2*). There is obviously great danger in allowing a patient to have access to large amounts of this drug.

Although we are mainly concerned with deaths resulting from overdoses of this drug, something should be said about the value of this drug as an analgesic. If it were a unique and valuable analgesic which was useful where other analgesics could not or would not be efficient, then the benefits of this drug might outweigh the costs. Of the many reports of this substance as an analgesic, there are practically no adequately controlled studies which demonstrate a significantly greater analgesic effect than other analgesics such as aspirin, actaminophen and codeine; some studies report the drug as not significantly more efficient than a placebo.

In the past 5 years in North Carolina 183 deaths were attributed to propoxyphene, 26 were attributed to salicylates (aspirin), 3 to codeine and none to acetaminophen. We believe these data are similar to those from the relatively few communities having adequate death investigation systems including toxicology. In our opinion overdoses from these other drugs which are used more frequently than propoxyphene are much safer at least as far as fatalities are concerned.

The most serious problem with dextropropoxyphene is that overdoses often lead to death. With the advent of better analytical methods it soon became apparent that deaths were being attributed to this drug. In our laboratory the following numbers of cases were documented: 1970–3, 1971–2, 1972–21, 1973–21, 1974–30, 1975–50, 1976–34, 1977–36, 1978–31. In the last 5 years 183 deaths have been reported in North Carolina which as a population of about 5.5 million. If the death rate for the entire United States was the same there would be at least 1200 deaths yearly. The reported deaths are those that are discovered. There is no way ascertaining how many deaths are due to the drug that are not attributed to the drug.

Propoxyphene is ranked as third in frequency of occurrence in deaths reported in DAWN VI. It is preceded by alcohol in combination and heorin/morphine. In North Carolina and in 7 standard metropolitan areas it is a more frequent cause of death than "heroin", as it probably is in most of this country.