

Senator NELSON. Are you skipping to the last paragraph on page 19?

Admiral ETTER. I am starting "On 31 March"?

Senator NELSON. Yes, sir.

Admiral ETTER. On 31 March, 1 and 2 April 1969, the Drug Information Association, in collaboration with the American College of Clinical Pharmacology and Chemotherapy, American Medical Association, American Therapeutics Society, and the American Society for Pharmacology and Experimental Therapeutics conducted a symposium on "Formulation Factors Affecting Therapeutic Performance of Drug Products."

Dr. Don Harper Mills, M.D., JD, Clinical Professor of Forensic Medicine and Pathology, School of Medicine, University of Southern California at Los Angeles, presented a paper which stated most succinctly the problem of the medical practitioner. Dr. Mills notes the significant increase of malpractice suits in recent years, and speculates that certain statistics project that theoretically, "a physician who practices for ten years faces a 100 percent chance of being sued."

It is the duty of the physician to exercise judgment, to select, to choose—he determines what laboratory test, to consult or not consult, which consultant, what diagnosis, and finally, what therapy. It is the exercise of his judgment in the latter area which is of concern to us today. In his paper, Dr. Mills emphasizes that the duty of the physician to choose a drug which, of his own knowledge, is effective, safe and proper, is an affirmative one, and must be susceptible of proof in court. Dr. Mills includes as a fact requiring personal knowledge, the therapeutic equivalency—or biological availability—of the chemically equivalent drugs available.

Senator NELSON. May I interrupt.

Doesn't this indicate that your physicians in the hospital would be better off if a formulary was established by qualified people? In all these cases we named here, such as Darvon, Librium, and others, if we had a lawsuit, the doctor couldn't present any evidence about the therapeutic equivalency or biological availability because he does not have any. The basis of the selection of the drug for your type of classification is that the doctor uses it.

We have recited the examples here where the Medical Letter says in controlled tests they either are inferior or not superior.

In addition, how can the individual physician, as Dr. Mills says, depend on his own personal knowledge—susceptible to proof—to select from a therapeutic category the best drug for a particular purpose?

Obviously, of this list of available drugs I submitted, there is no test that proves that according to the Medical Letter or the National Academy of Sciences-National Research Council.

Admiral ETTER. No. I think here is a—it is primarily a matter of the physician having confidence in a particular drug for one reason or another. He has—

Senator NELSON. What I am getting at, the doctors who requested Darvon and these various other drugs I cited, didn't have any knowledge of therapeutic equivalency or biological availability. They just