assurances furnished by the Merrell representative which persuaded me to use Kevadon. . . . When first approached by the Merrell representative with regard to my trying out Kevadon, I made it clear to them that I was not going to keep any records or furnish them with any written reports. I was informed that reports would not be necessary.

I explained that I was not setup to do research or provide clinical data because I deal with paying patients in a private practice. I urged the representative to seek their data from a clinical which had the personnel, equipment and facilities to do justice to a valid research program. It was my impression that reports were not required. . . . To reiterate, I felt that verbal and written assurances on the safety of Kevadon were valid, or else I would never have used the drug. It is my practice to use experimental drugs. The manufacturer never asked that I pay for any Kevadon which I received. With this in mind, I felt that the Wm. S. Merrell Company wanted me to participate in a program which was not to supply data as to the safety and efficacy of Kevadon since such had already been demonstrated in Europe, but to familiarize myself with the drug and test patient acceptance. . . ."

Donald J. Nenno, M.D., 490 McKinley Parkway, Buffalo, New York, Obstetrician-Gynecologist, signed an affidavit quoted in part "Mr. Rose represented Kevadon as being absolutely safe in that according to him it had been proven safe through wide spread use in Europe and was superior to other hypnotic drugs such as barbiturates and that it was impossible to be used for suicidal purposes and was not habit forming. However, Wm. S. Merrell Company advised me not to give the drug before administering anesthesia as the effect of the drug with anesthesia had not been documented even though they were certain it was safe. I accepted the drug on these representations. From our discussion with Mr. Rose, I had no idea that Kevadon was an experimental drug, the safety of which had not been cleared by the U.S. Food and Drug Administration. I thought it was simply for clinical comparison study. I have many drugs offered to me by pharmaceutical companies for my determination if their effects are superior to competitive products on the market. Kevadon was represented to me as just another one in that category. . . . To the best of my knowledge I never signed a clinical investigator statement. Mr. Rose supplied me with the evaluation forms on which the attending nurse could record how the patient felt about the drug. Mr. Rose said that these forms were provided to keep the information on, but it was not necessary to return them. . . ."

R. C. John Pearson, D.O., 3416 S. W. Webster, Seattle, Washington, General Practitioner, signed an affidavit which is quoted in part "The Merrell detailer stated that he had a new sedative preparation named Kevadon. He strongly indicated a human lethal dosage had not yet been determined and even gross amounts consumed in suicidal attempts had not been fatal . . . that this was an important drug since it was a highly effective sedative yet non-toxic. . . . During Mr. Cowles' visit of 11/3/60, I agreed to evaluate Kevadon in my hospital practice to learn if the drug was as effective a sedative as indicated by the detailer and the above brochure. The studies were undertaken on the basis that it was an effective sedative and non-toxic. From Mr. Cowles approach, I considered the use of Kevadon as an opportunity to determine its efficacy and not to determine its safety since I had no facilities for this type of study . . . I gave him my verbal report . . . I do remember receiving a letter dated August 21, 1961 from the Wm. S. Merrell Co. where it states among other things 'Nulsen administered Kevadon to expectant mothers with a sleep problem without effects on the newborn infants.' . . ."

Roy J. Phillip, M.D., 44 W. Main Street, Carbondale, Illinois, Internist, signed an affidavit which is quoted in part, "Mr. Howard informed me his firm had a new sedative, a drug name Kevadon and gave me a brochure on the drug. He informed me to note in this brochure that the drug had no LD50. He also stated that he would have his firm send me an investigator's statement to sign. He made no representations as to safety of the drug and other claims except that I should note or read the information under the safety data. . . . But after reading the brochure I was impressed with the statement under the caption of safety data that LD50 could not be determined. This specifically persuaded me to under-