

John V. Hummel, M.D., 273 S. Bellevue, Memphis, Tennessee, Obstetrician and Gynecologist, signed an affidavit which he first wrote out himself and which is quoted in part, "I was first approached about Kevadon in the winter of 1960 when Mr. James M. Walker, representative for the Wm. S. Merrell Company was visiting our office. . . . He was our friend and called on us often. He told us of a new drug called Kevadon that Merrell had and was waiting to get approval before putting this drug on the market. He wanted to know if we would like to have some to try to see if we liked it, how the patients liked it, and so we could be using it by the time it came on the market. He told us the fundamentals of the drug. We said that we would try the drug. He sent us a large folder containing a full account of the drug and stressed how safe it was, that it was of the same strength as the barbiturates and there was no contraindications that I can remember. . . . This was not done as a clinical investigation, but as a friendly personal basis so that we would get an impression of the drug before it was put out on the market as a sleeping pill. . . ."

S. Bruce Kepart, M.D., 303 S. Main Street, Bluffton, Indiana, Obstetrician-Gynecologist, signed an affidavit which is quoted in parts, "I did discuss Kevadon with Mr. Brenner on/or about November 28, 1960. Probably at that time, I was supplied with the Wm. S. Merrell Company's statement of investigator which I signed. Inspectors Glassner and Maciejewski showed me a copy of this signed statement. The phraseology under the section 'Brief description of proposed investigation indicating facilities namely evaluation of above' . . . facilities is not mind. Under the section animal and human experiments appears the type response 'animal.' I had no intention of conducting any animal experiments on Kevadon nor do I have experimental animals available. . . . Regarding the safety of Kevadon, I received the aforementioned letter from Mr. Brennan dated November 19, 1960 which indicated that the drug had no fatal dose, that fatal toxicity was not known. Also, the preliminary medical brochure described above stated that Kevadon was not addicting and was not habit forming; that tolerance had not been a problem; that no withdrawal symptoms had been experienced; that very large dosages had not produced respiratory depressions; that Kevadon had been administered to expectant and nursing mothers and that all of the babies were born or nursed without any abnormality or harmful effects from the medication; that Kevadon resulted in a very low in side effects; that Kevadon produced no measurably impairment of the functions of the vital organs. . . ."

"As a result of the representation made to me as described above, I concluded that I would try Kevadon in my practice, because (1) it would not be a hazard in the medicine cabinet in the patient's home in the event of accident ingestion of over-dosage and because of its non-habit forming property. (2) Its reported effectiveness in producing normal sleep and not a deep sleep from which a nursing mother would not be easily aroused to nurse her baby. (3) Because it was as effective as the most active barbiturate. (4) I was told either by the Merrell detailman in the fall of 1960 or by Mr. Brenner on/or about November 28, 1960 that Kevadon was soon to be made commercially available and that it was already being sold in Canada . . . I was not aware at any time of instructions from Wm. S. Merrell Company or its representative that reports from me were unnecessary, similarly I did not have the impression that the reports from me were required. In my use of Kevadon, I was not testing its safety; I was not conducting a basis testing program. I was determining its efficacious application so as to be able to report my experience with its use . . ."

Richard W. Miller, M.D., 1265 Union Avenue, Memphis, Tennessee, Surgeon, signed an affidavit which is quoted in part, "When first approached, the Merrell representative supplied me with both verbal assurances and literatures attesting to the safety of Kevadon. The majority of this literature comprised reprints of clinical studies, information as to dosage, contraindications, etc. . . . It was my distinct impression that Kevadon was not considered an experimental drug since it had been tested and widely used in Europe and since the literature and verbal assurances of the Merrell representative pointed up the safety of the drug. I definitely feel that the manufacturer sought my participation in this program not to supply clinical evidence but to familiarize myself with Kevadon and to test the patient acceptance of the drug. It was these verbal and written