

take the use of this drug as a sedative. . . . That I consider the use of the Kevadon drug as a means to familiarize myself with it and not as part of an investigational program to determine the safety of the drug."

Jere C. Robertson, M.D., 1110 S. Main Street, Hopkinsville, Ky., signed an affidavit which is quoted in part "I was approached by a Wm. S. Merrell detailman and asked if I would like a new type of sleeping pill to use in the clinic known as Kevadon. I remember specifically that the detailman stated that he could take as much as two bottles and not commit suicide. . . . I recall that the detailman emphasized the drug's safety. It was my understanding that the drug Kevadon was due to be marketed momentarily. . . . I believe that the detailman showed me charts and brochures to emphasize the safety and use of Kevadon. Because of this I did not believe it was an experimental drug which required clearance from Dr. D. S. Bayer, Head of the OB-GYN Section of the St. Thomas Hospital. I am almost positive that I did not sign an investigator statement before use of the drug. Any experimental drug or drug for investigational purposes require clearance from Dr. Bayer. I was lead to believe that this drug, Kevadon, was not in that category. No records of any kind were kept on the use of this drug and no reports concerning its use were rendered to the firm as it was my understanding that this was not necessary. I would not have been persuaded to use this drug had it not been for the assurances given me by this detailman that it was completely safe and had been thoroughly tested. . . ."

George P. Rosemond, M.D., 3401 North Broad Street, Philadelphia, Pa., Surgeon, signed an affidavit which is quoted in part, "The Merrell representative told me that this product Kevadon was not yet available for general use. He told me that his firm was interested in obtaining my opinion of the product. He told me that Kevadon had been studied quite extensively in Europe and that its safety had been well established. The latter point of established safety was well stressed. As I recall, he called to my attention to certain statements in a product brochure which stressed the safety of Kevadon. He left a copy of this brochure with me but I no longer have it available. As a result of this initial meeting, I decided to undertake the use of Kevadon tablet as a hypnotic convinced by the detailman that the safety of Kevadon had been well established by oral representations and statements made in the firm's brochure. The detailman had me complete a statement of investigator dated November 2, 1960, . . . a copy of a letter from Wm. S. Merrell Company dated August 21, 1962 addressed to me which states Nulsen administered Kevadon to expectant mothers with a sleeping problem without effects to the newborn infant. I believe I did receive this reference letter although I do not have my original copy. . . . I have not submitted any written or verbal reports covering my use of Kevadon to Wm. S. Merrell Company during the period of my use of the product. I had been told by the detailman during his initial contact that such reports were not necessary. It was my understanding that Kevadon was given to me to familiarize me with the product and was in no way associated with or considered as part of an investigational program. I am familiar with the procedures to be followed for clinical investigations of new drugs. Had I been told by the Merrell detailman that Kevadon was an investigational new drug I would have maintained more adequate records covering its clinical use. . . ."

Herbert F. White, M.D., 4741 Broadway N. E., Knoxville, Tenn., Internist, signed an affidavit which is quoted in part, "Mr. Hurley advised me that Kevadon was an excellent sedative with no side effects which had been used extensively in Europe. I was given to understand that Kevadon would be released in this country for general use very shortly and that Kevadon was the Merrell name for thalidomide. I was lead to understand that the drug had been thoroughly tested and was safe and at this time clinical evaluation was all that was being requested. It was my understanding that Kevadon was not to be considered an experimental drug in the true sense and that controlled experiments with laboratory testing was not required. Mr. Hurley had literature which he showed me during this first presentation which confirmed the above statement on the drug's efficacy. I agreed to use the product because of