b. Opinion regarding kanamycin

Bristol-Myers Co. v. Gonzales (38) taking place in Texas, involved kanamycin. Kanamycin is a common antibiotic. This drug kills bacteria. The package insert contained a warning, but the warnings were not adequate. The warning on the package insert failed to recommend that less toxic antibiotic drugs be used where appropriate. Moreover, the package insert failed to warn that the patient's hearing should be tested. The case turned on evidence showing that the manufacturer knew of the potential toxic effects to hearing (ototoxicity). In writing the opinion, the judge wrote, "[i]f a manufacturer knows or should know of potential harm to a user because of the nature of its product, the manufacturer is required to give an adequate warning of such dangers." The take-home lesson is relatively simple. If a company is aware of an adverse drug reaction, for example toxicity to hearing, it should include it in the package insert.

c. Opinion regarding dilantin

Peterson v. Parke Davis (39) which took place in Colorado, concerns dilantin, a drug for treating epilepsy. The patient was a 17-year-old boy with epilepsy. The package insert contained a warning that stated, "if toxic effects occurred, the drug dosage should be reduced or discontinued."

But there were three problems. First, the doctor had failed to read the package insert. Second, the doctor switched from administering dilantin in capsule form (absorbed slowly) to dilantin in liquid form (absorbed quickly). This was a problem, because the liquid form results in a greater serum level of dilantin. And third, the doctor did not have blood serum tests done on the boy, even when the boy showed signs of dilantin toxicity. The result was that the boy suffered brain damage.

The drug manufacturer was held not liable. The take-home lesson is that medical writers need to disclose adverse drug reactions, and to provide instructions on dose reduction or on discontinuing the drug. The package insert was, in these respects, sufficient and adequate.

d. Opinion concerning oxytocin

Fornoff v. Parke Davis (40) which took place in Illinois, involved oxytocin, a drug for inducing labor in pregnant mothers. Oxytocin stimulates the uterus to contract. The package insert warned that administration of the drug "must be adapted to the patient's response." The package insert warned that, "administration of oxytocin…in untrained hands is dangerous…[m]aternal deaths…and fetal deaths due to various causes have resulted from the injudicious use of parenteral oxytocic drugs."

[38] Bristol-Myers Co. v. Gonzales. 561 S.W.2d 801; 1978 Tex. LEXIS 302; 21 Tex. Sup. J. 179.
[39] Peterson v. Parke Davis & Co. 705 P.2d 1001; 1985 Colo. App. LEXIS 1062; 58 A.L.R.4th 1.
[40] Fornoff v. Parke Davis & Co. 105 Ill. App. 3d 681; 434 N.E.2d 793; 1982 Ill. App. LEXIS 1712; 61 Ill. Dec. 438.