prevent pathological blood clots. Dicumarol has the same mechanism of action as warfarin. Dicumarol inhibits vitamin K epoxide reductase.

The package insert contained a warning, "Dicumarol passes the placental barrier. When pregnant women are treated with the drug, fetal bleeding ... may occur and cause fetal death *in utero* ... [t]herefore, the drug is contraindicated for pregnant patients ... [i]f anticoagulant therapy is required for such patients, heparin is considered the drug of choice, because it does not pass through the placenta."

The problem was that the physician supplied dicumarol to the patient for the treatment of phlebitis, even though he knew that the patient was pregnant. The patient gave birth to a child with brain damage and paralysis. A related problem is that the doctor had failed to read the package insert. In the words of the opinion, "[h]e did not consult the package insert or any other source of information on dicumarol before ordering it for Ms. Baker."

In the courtroom, the drug company argued that it should not be held liable, first, because its warning on the package insert was adequate, and second, because the doctor had ignored the package insert. Surprisingly, the court rejected the argument of the drug manufacturer. The court's basis for refusing the manufacturer's argument, was that the manufacturer should have gone a step further to warn the medical community, by transmitting "Dear Doctor" letters to the medical community, warning of the hazards of dicumarol to the fetus. This case has at least two take-home lessons. First, package inserts should provide warnings regarding ADRs. Second, even where the package insert does provide an adequate warning, this does not provide iron-clad defense against liability.

b. Opinion Regarding Kanamycin

Bristol-Myers Co. v. Gonzales (86), 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 ADR, for example, toxicity to hearing, it should include it in the package insert.

c. Opinion Regarding Dilantin

Peterson v. Parke Davis (87), 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, where the warning stated that, "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 greater serum levels of dilantin. And third, the doctor did not have blood serum tests done on the boy, even when the boy

[86]Bristol-Myers Co. v. Gonzales. 561 S.W.2d 801; 1978 Tex. LEXIS 302; 21 Tex. Sup. J. 179.

[87]Peterson v. Parke Davis & Co. 705 P.2d 1001; 1985 Colo. App. LEXIS 1062; 58 A.L.R.4th 1.