

in databases from two vendors, LexisNexis[®], Albany, NY, and Westlaw[®], Eagan, MN. Courtroom opinions can also be found on Google Scholar[®]. The present commentary does not in any way constitute a comprehensive review of the applicable law. Where there is a desire to use published opinions as a source of guidance, guidance should be provided with the help of an attorney with experience in package inserts.

The drug-induced injuries from a small sampling of the available cases include brain damage, blindness, deafness, massive damage to the intestinal tract, and the case of a patient giving birth to a brain-damaged, paralyzed infant.

These courtroom cases do not involve obscure drugs that had never been widely marketed. These cases involve widely used drugs such as kanamycin (antibiotic), dilantin (anti-epileptic), dicoumarol (anti-coagulant), oxytocin (a naturally occurring hormone), and norethindrone (for treating endometriosis and a contraceptive).

a. Opinion concerning dicoumarol

Baker v. St. Agnes Hospital (37) an opinion from a court in New York, involved dicoumarol, an anti-coagulant. Anti-coagulants prevent pathological blood clots. Dicoumarol has the same mechanism of action as warfarin. Dicoumarol inhibits vitamin K epoxide reductase.

The package insert contained a warning, “Dicoumarol 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 dicoumarol 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 dicoumarol 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 dicoumarol to the fetus. This case has at least two take-home lessons. First, package inserts should provide warnings regarding adverse drug reactions. Second, even where the package insert does provide an adequate warning, this does not provide iron-clad defense against liability.

³⁷ *Baker v. St. Agnes Hospital*, 70 A.D.2d 400; 421 N.Y.S.2d 81; 1979 N.Y. App. Div. LEXIS 12729.