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 ADRs, 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 (88), 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."

The injury to the patient (the mother), which occurred some time after the child's healthy birth, took the form of severe damage to the mother's intestinal track and rectum. The damage to the mother could not be reversed by surgery.

The issue in the courtroom was whether the warnings given were adequate. The court found that the warnings were, in fact, adequate, and the manufacturer was found not liable. The take-home lesson is that the package insert should warn of possible ADRs. This case also implies that package inserts should also state, where relevant, that specially trained personnel should be consulted before administering the drug.

e. Opinion Regarding Oral Polio Vaccine

Tenuto v. Lederle (89), which took place in New York, involved Orimune®, an oral polio vaccine. The patient was an infant receiving the vaccine, but the person who suffered the ADR was the infant's father. The infant received the vaccine in May 1979. At this time, the infant was 5 months old.

Morbidity and Mortality Weekly Report is a publication of the Centers for Disease Control and Prevention (CDC) (90). The Oct. 7, 1977 issue of this publication disclosed a danger of Orimune called contact polio. Contact polio refers to situations where a patient receives the Orimune vaccine, and where another person touches the patient, or touches the patient's feces, and where the other person contracts polio.

Contact polio is what happened to the infant's father. After the infant received the vaccine, the father touched the infant's feces, possibly while changing her diapers, and he contracted polio and became permanently paralyzed. According to the published opinion, "[f]rom October of 1977, when Lederle knew of the federal government's recommendations regarding vaccination of adults who may be in close contact of children receiving Orimune, until the 1979 Orimune package insert, there is no indication that [the drug company] took any steps to bring that knowledge to the attention of the medical profession."

[88]Fornoff v. Parke Davis & Co. 105 Ill. App. 3d 681; 434 N.E.2d 793; 1982 Ill. App. LEXIS 1712; 61 Ill. Dec. 438.

[89]Tenuto v. Lederle Laboratories. 2010 NY Slip Op 50255U; 26 Misc. 3d 1225A; 907 N.Y.S.2d 441; 2010 N.Y. Misc. LEXIS 309.

[90]The CDC is a United States federal agency encompassed by the Department of Health and Human Services. The applicable rules (regulatory laws) are found in Title 45 of the Code of Federal Regulations (CFR).