information be reiterated in more than one section of the package insert (81).

Moreover, in an analysis of about 70 package inserts, Fuchs and Hippius (82), found that package inserts can confuse patients where a page break occurs in the package insert in the middle of a dosing paragraph, or where doses are expressed in terms of milligrams, rather than in pill number. In general, package inserts in the United States tend to address the reading level of physicians, while package inserts in Europe tend to address the reading level of the patient (83).

The Canadian Public Health Association provides an account of readability of package inserts as it relates to patients, and recommends that parts of the insert that are especially relevant to the patient, for example, information on safety and dosing instructions, be written at the level of a 6th grader (84).

IX. PACKAGE INSERT MAY PROTECT MANUFACTURER FROM LIABILITY

The content of the package insert can protect the manufacturer from liability in the event of a drug-induced injury to the patient. The following published opinions illustrate situations where there was a drug-induced injury, where the patient filed a lawsuit, and where the manufacturer argued that the warning on the package insert satisfied its duty to warn the physician.

In some of these cases, the argument of the manufacturer succeeded. In other cases, the argument seemed to mitigate the manufacturer's liability. But in other cases, the argument failed.

Writing on package inserts plays a central role in liability cases. These cases serve as learning tools for medical writers needing to draft package inserts. The best sources of the case law from the state and federal courts are in databases from two vendors, LexisNexis®, Albany, NY, and Westlaw®, Eagen, 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 (antiepileptic), dicoumarol (anticoagulant), oxytocin (a naturally occurring hormone), and norethindrone (for treating endometriosis and a contraceptive).

a. Opinion Concerning Dicumarol

Baker v. St. Agnes Hospital (85), an opinion from a court in New York, involved dicumarol, an anticoagulant. Anticoagulants

[81]Kremzner ME, Osborne SF. An introduction to the improved FDA prescription drug labeling (68 pp.) (undated document obtained from www.fda.gov in February 2011).

[82]Fuchs J, Hippius M. Inappropriate dosing instructions in package inserts. Patient Educ. Couns. 2007;67:157–68.

[83]Fuchs J, Hippius M. Inappropriate dosing instructions in package inserts. Patient Educ. Couns. 2007;67:157–68.

[84]Canadian Public Health Assoc. National Literacy and Health Program. Ottowa, Ontario. Good medicine for seniors: guidelines for plain language and good design in prescription medication; 2002.

[85]Baker v. St. Agnes Hospital. 70 A.D.2d 400; 421 N.Y.S.2d 81; 1979 N.Y. App. Div. LEXIS 12729.