

the opinion. Opinions are published for several reasons. One goal is to memorialize the decision of the court, enabling that particular decision to be enforced. Another goal is to establish stare decisis, that is, the custom in all aspects of law, where the court bases its decision on earlier decisions that concern similar issues. Still another goal is to provide society with guidelines as to how it should behave and carry out its business. For example, quality control units in pharmaceutical companies are required to comply with the Barr decision (44). The Barr decision held that lots or batches of drugs must not be tested and re-tested until the data somehow, that is, by chance, complies with the specifications. The opinion from the Barr decision is read, for example, by directors of regulatory affairs and directors of quality control in pharmaceutical companies. Where a pharmaceutical company wants to ensure that a package insert is consistent with the case law the company should consult an attorney with experience in the case law, as it applies to package inserts.

#### **IV. PACKAGE INSERT COMPARED WITH CONSENT FORM**

A context for understanding package inserts can be provided by comparing package inserts with consent forms. Consent forms are read by study subjects before the study drug is administered to humans for the first time. In contrast, package inserts are read by physicians and patients, after FDA approval of the drug, and long after the clinical trials have been completed. Consent forms and package inserts are both regulated by the Code of Federal Regulations.

Another similarity is that, during the course of a clinical trial, the consent form may need to be changed in view of newly observed adverse drug reactions, and study subjects may be required to sign a re-consent form, while package inserts of sometimes changed, in view of adverse event reporting through the MedWatch device.

#### **V. RELATION BETWEEN PACKAGE INSERTS TO THE STANDARD OF CARE, AND TO OFF-LABEL USES**

A further understanding of package inserts can be acquired by a knowledge of what a package insert is not. The dosing instructions and indications on a package insert are not the “standard of care.” Also, the dosing instructions and indications on the package insert are not an off-label use. Hermann and Bownas (45) describe the relations between the package insert, the standard of care, and off-label uses.

<sup>44</sup> United States of America v. Barr Laboratories, Inc. 812 F. Supp. 458; 1993 U.S. Dist. LEXIS 1932.

<sup>45</sup> Herrmann M, Bownas P. Keeping the label out of the case. *Northwestern Univ. Law Rev Colloquy*. 2009;103:477-489.