Package Insert, Drug Labeling and Standard of Care

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"Package Insert (in FDA approved drugs) is the document defining information that is supplied with prescription drug products by the Marketing Authorization Holder,"[1] whereas "Patient Information Leaflet is the document defining information that is supplied with non-prescription drug products by the Marketing Authorization Holder."[2] The Patient Information Leaflet is intended for use by patients and is written in layman's language.[3] On the other hand, "labels and labeling materials are the primary sources of information for consumers. They provide useful information such as those dealing with the safe and effective use of a drug product (e.g. indication(s), pharmacologic class and dosage), and information dealing with quality (e.g. manufacturing and expiration dates, registration number, and manufacturer)."[4] "Drug labeling is part of a comprehensive regulatory scheme inextricably connected to drug approval."[5] Take note that (FDA) approval "doesn't play a part in defining the drug's standard of care or how it is prescribed".[6] Furthermore, when the FDA approves a drug or device for sale and marketing, it does so only with respect to the indicated uses.[7]

In the case of Lucas, et. al. v. Dr. Tuaño[8] complainants alleged that respondent physician did not heed the warning stated in the literature (package insert) of the drug and thus should be held liable for the resulting injuries. However, the Supreme Court dismissed the case pointing out that petitioners' complaint for damages is merely anchored on a statement in the literature (package insert). If no standard is established through expert medical witnesses, then courts have no standard by which to gauge the basic issue of breach thereof by the physician or surgeon. Another court[9] reached the same conclusion - the Physicians' Desk Reference (PDR) and package inserts does not standing alone establish a standard of care, but rather, (only) prima facie[10] proof of proper use ..." but when it is offered in conjunction with expert testimony xxx that combination may be sufficient to establish the standard of care.

Even granting, for the sake of argument, that a doctor deviated from the drug manufacturer's recommendation, such deviation from such recommendations is (only) prima facie evidence of negligence . . . ."[11] This is so, because the term "negligent act or omission" consistently has been used to refer only to breach and never to causation.[12] Hence, without further explanation, an alleged "breached of the standard of care" but without any foundation to establish causation will not be enough to compel the court to rule against a respondent doctor.

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This is not to say that other FDA labeling must be ignored. "The FDA-approved label may also include `contraindications' and `warnings and precautions.' A `contraindication' is a `situation () in which the drug should not be used because the risk of use . . . clearly outweighs any possible therapeutic benefit.' `Warnings and precautions' are descriptions of 'clinically significant adverse reactions . . , other potential safety hazards . . . , limitations in use imposed by them . . . , and steps that should be taken if they occur,' as well as any other -information regarding any special care to be exercised by the practitioner for safe and effective use of the drug..."[13]

References

1. **Revised Rules and Regulations Governing the Generic Labeling Requirements of Drug Products for Human use,** AO – 2016-ooo8, Office of the Secretary, Department of Health, Republic of the Philippines.

   Marketing Authorization (MA) - an official document issued by the competent drug regulatory authority (DRA) for the purpose of marketing or free distribution of a product after evaluation for safety, efficacy, and quality, and containing, inter alia: the name of the product; the pharmaceutical dosage form; the quantitative formula (including excipients) per unit dose; the shelf-life and storage condition(s); and packaging characteristics, specific information on which authorization is based (e.g. "The product(s) must conform with all the details provided in the application and as modified in subsequent correspondence."), the product information approved for health professionals and the public, the sales category, the name and address of the holder of the authorization, and the period of validity of the authorization. In the Philippines, the MA is in the form of a Certificate of Product Registration (CPR).

   Marketing Authorization Holder (MAH) - the company or corporate or legal entity in the field of pharmaceuticals in whose name the MA for a drug product has been granted. This party is responsible for all aspects of the product, including quality and compliance with the conditions of the MA. The authorized holder must be subjected to legislation in the country that issued the MA, which normally means being physically located in that country. In the Philippines, the MAH may either be a manufacturer or distributor (exporter, importer or wholesaler).
2. **Definition of Terms, (32), id.**
3. **Definition of Terms, (33), id.**
4. **I. Rationale, id.**
5. **Kurer, et. al. v. Parke, Davis & Company, and Warner-Lambert Company 679 N.W.2d 867 (2004)**
6. **"On-Label vs. Off-Label Drug Prescribing" by Heather Claverie, 29 IG Living | December-January 2016 | IGLiving.com**
7. **Mark Herrmann and Pearson Bownas; "Keeping the Label out of the Case", 103:477, Northwestern University Law Review Colloquy 2009**
8. **G.R. No. 178763, April 21, 2009**
9. **Harvey v. O'Donoghue, 530 A.2d 1141 (1987)**

10. Prima facie evidence is defined as:
Evidence good and sufficient on its face. Such evidence as, in the judgment of the law, is sufficient to establish a given fact, or the group or chain of facts constituting the party's claim or defense, and which if not rebutted or contradicted, will remain sufficient. Evidence which, if unexplained or uncontradicted, is sufficient to sustain a judgment in favor of the issue it supports, but which may be contradicted by other evidence (emphasis supplied). Wa-acon v. People of the Philippines, G.R. No. 164575 December 06, 2006.
11. Winkjer v. Herr, 277 N.W.2d 579 (1979)
12. Grier v. AMISUB of South Carolina, Inc.,725 S.E.2d 693 (2012)
13. Mark Herrmann and Pearson Bownas; "Keeping the Label out of the Case", 103:477, Northwestern University Law Review Colloquy 2009