Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

26 June 2014

FDA Advisory

No. 2014-050

SUBJECT: FOOD AND DRUG ADMINISTRATION (FDA) ADVISORY ON PHARMACOVIGILANCE

The Department of Justice (DOJ) has issued a landmark decision upholding the reporting of potentially harmful drug products to the duly-constituted authorities. The ruling is in reference to the libel case filed by a pharmaceutical company against eminent members of the Philippine Society of Anesthesiology who submitted a report to the FDA after observing potentially harmful precipitation in the delivery device of a gas anesthetic agent being marketed by said company.

The regulation of drug products is essential to the protection of the public as no drug product exists that is one hundred percent safe and post marketing surveillance is an important aspect of the FDA's legally constituted mandate to monitor product defects arising from post approval manufacture and distribution. Pharmacovigilance relies on among other methods, reports submitted by clinical practitioners to generate early warning signals by which the FDA can pursue early investigations and actions so that the loss of lives can be averted. In this regard, the Philippines is among the lowest-performing countries in terms of pharmacovigilance reporting because practitioners, in general, fear of becoming targets of litigation.

The recent DOJ affirms the commitment of government to support the protection of the Filipino patient against potentially harmful drug products and should be a clarion call to all medical and paramedical practitioners to report adverse events that may be associated with any medical product.

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