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What Nurses Should Know About Administering "New Drugs"

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Nurses often administer drugs to patients for treatment and research purposes, at the direction of physicians, without knowing their legal responsibilities. Following a doctor's orders is not an adequate defense for a nurse against a lawsuit based on the administration of a drug not approved by the Food and Drug Administration (FDA); administration of a drug approved by the FDA, but approved only for a different purpose; or administration of a drug without the informed consent of a patient. Considerable confusion exists about a nurse's legal obligations in administering "new drugs," and the purpose of this article is to provide some clarity.

All states have laws which allow registered nurses to administer drugs. For example, New York law defines the practice of nursing to include the "executing of medical regimens prescribed by a licensed physician,"[1] and Massachusetts law defines professional nursing as including "administering treatment or medication prescribed by a physician."[2] All states have adopted laws based on the Uniform Controlled Substances Act, and similarly define the term "administer" as follows:

> The direct application of a controlled substance [drug] whether by injection, inhalation, ingestion, or any other means to the body of a patient or research subject by
> (a) a practitioner, or
> (b) a nurse at the direction of a practitioner in the course of his professional practice, or
> (c) an ultimate user or research subject at the direction of a practitioner in the course of his professional practice.[3]

In administering drugs to patients, nurses will be *either* administering drugs that have been approved for safety and effectiveness by the FDA, and given in the manner prescribed, recommended, or suggested in the labeling, *or* they will be administering "new drugs." To determine what a "new drug" is, we must enter into the wonderland of clairvoyance inhabited by the FDA.

New Drugs

Federal law defines a "new drug" as any drug not generally recognized among experts (qualified by scientific training and experience to evaluate the safety and effectiveness of drugs) as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling. A drug recognized as safe and effective for use under certain conditions as a result of clinical investigations, but that has not been used to a material extent or for a material time under such conditions, is also a "new drug." Federal Food and Drug Regulations further define a new drug as follows:

1. The newness for a drug use of a combination of two or more substances, none of which is a new drug.
2. The newness of use of such drug in diagnosing, curing, mitigating, treating, or preventing a disease, or to affect a structure or function of the body, even though such drug is not a new drug when used in another disease or to affect another structure or function of the body.
3. The newness of a dosage, or method or duration of administration or application, or other condition of use prescribed, recommended or suggested in the labeling of such drug, even though such drug when used in other dosage, or other method or duration of administration or application, or different condition, is not a new drug.
4. The newness for drug use of the proportion of a substance in a combination, even though such combination containing such sub-

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