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Announcement

The editors are pleased to announce the addition of Catherine P. Murphy, R.N., Ed.D., to the Editorial Advisory Board of *Nursing Law & Ethics*. Dr. Murphy is widely known for her research and writing in the area of nursing ethics. In addition to her doctoral dissertation on ethical reasoning in nursing and the effects of bureaucratic structures, she has written a chapter entitled "The Moral Situation in Nursing" in *BIOETHICS AND HUMAN RIGHTS*, edited by Bandman and Bandman (Little Brown 1978). Dr. Murphy is author of a forthcoming book, *ETHICAL PROBLEMS IN THE NURSE-PATIENT RELATIONSHIP*. For the past four years, Dr. Murphy has held the position of Assistant Professor at the Boston University Graduate School of Nursing, where she teaches a course entitled "Ethical Issues in Nursing."

New Drugs Continued

stance in other proportion is not a new drug.

5. The newness for drug use of any substance which composes such drug, in whole or in part, whether it be an active substance or a menstruum, excipient, carrier, coating, or other component.⁵

Thus, any chemical or substance not previously used in the treatment of disease is obviously a new drug; it has not been approved as safe and effective for anything by the FDA. It may be a drug that a doctor has made in a laboratory and tried out on himself, or an illegal drug such as cocaine or marijuana. More probably, it is a drug which a drug company (or an individual researcher) is clinically testing to find out whether it is in fact safe and effective enough for marketing to the public. The drug therefore is sometimes called an "investigational drug" or an "investigational new drug" or an "experimental drug." But it is confusing to interchange the term "new" with the term "investigational," because a doctor may be using a new drug for treatment purposes and not investigational purposes, or he may be investigating a drug which is not a "new drug." Since it makes more sense to refer to new drugs as either "investigational new drugs" or "treatment new drugs," these terms will be used when relevant.

Unapproved Combinations and Uses

Untested combinations of drugs, individually approved by the FDA, may also be regarded as new drugs. An example is a capsule containing penicillin and aspirin, both approved drugs, used for treatment of certain infections (the penicillin) and to allay fever and discomfort associated with the infection (the aspirin), because this combination has never been proven safe and effective. The use of a drug for conditions not set forth in the official, FDA-approved labeling makes the drug a new drug. Such unapproved uses may include a different dosage form, strength, or dose, such as aspirin dissolved in an alcohol and intended for administration by injection. A drug which is already approved by the FDA, but which is used for an unapproved purpose, such as anturane (which is approved for the treatment of gout) used for the treatment of heart disease, is a new drug. For many years propranolol, which was approved for hypertension, was used to treat migraine headaches, a condition for which it was not approved until recently. Propranolol was therefore a new drug when it was used for the unapproved purpose. A drug which is used for a different patient population is also a new drug.

Considerable confusion exists about a nurse's legal obligations in administering "new drugs" . . .

Physician Prescribing for Unlabeled Indications

Very little is known about the prescribing patterns of physicians for unlabeled indications. What data does exist, however, suggests that there is considerable prescribing for nonindicated uses for inpatients, and somewhat less for outpatients. A study of hospitalized patients, for example, showed that the three drugs under study were used very frequently for unlabeled uses: cephalexin (78% of the time), allopurinol (57%) and propranolol (66%). The authors concluded that physicians are not greatly influenced by the recommendations in the package insert, and, in the case of propranolol, that the package insert information was seriously out of date.⁶

In a more recent study of the charts of 500 outpatients, researchers found that approximately nine percent of all prescriptions written were for un-

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