A Drug Is A Drug—Or Is It?

A matter of significant recent controversy is referred to by the public news media as "the use of prescription drugs in executions." Indeed, this subject has become so controversial that the matter is to be weighed by the U.S. Supreme Court this fall.

Capital punishment is also a controversial issue in itself, but the question of using "prescription drugs" to carry out the process of execution is a completely separate and distinct matter.

The current issue at hand was concisely summarized in a recent issue of APhA's weekly newsletter, *apharmacy weekly:*

"The court (U.S. Supreme Court) will hear oral arguments in a suit filed against the federal government by eight Texas and Oklahoma prisoners awaiting executions by lethal injection. The inmates are asking FDA to ban the use of prescription drugs for other than medical purposes.

"Currently, 14 states permit such executions, though only two (Texas and North Carolina) have carried any out. The executions typically involve the use of potassium chloride to stop the heart, a muscle relaxant to stop breathing, and a barbiturate to cause unconsciousness.

"To date, FDA has tried to sidestep the issue, saying it has an enforcement role only in instances which endanger the public health or involve fraud."

Other press reports have gone on to state that the prisoners have further claimed that FDA should not permit such use of these "drugs" because there has not been clinical demonstration of their effectiveness and safety for this particular use, as required by federal law for any new use of an otherwise approved and marketed drug.

Years ago, the *United States Pharmacopeia* and the *National Formulary* were faced with similar dilemmas. Substances such as sodium chloride, sucrose, rose water ointment, magnesium trisilicate, microcystalline cellulose, polysorbate, saccharin, carbon tetrachloride, and so on, all had multiple uses. They all had certain distinct uses as drug dosage form ingredients: either for the physiological activity they provided *per se*, or as pharmaceutical adjuncts that contributed to the overall suitability and activity of various drug dosage forms. But, in addition, they had certain other commercial uses that were clearly "non-therapeutic" or "non-drug" in nature: as foods, cosmetics, solvents, cleaning agents, and so on.

However, neither the drug laws nor the USP-NF made any distinction; in fact, the law as well as the official compendia appeared to specifically blanket all such substances under the broad obligation of meeting USP-NF standards and specifications. The wording in the General Notices section of both compendia read that: "The standards apply equally to articles bearing the official titles ... whether or not the added designation 'USP' (or 'NF') is used."

When the officials responsible for revising the compendia and maintaining their currency became aware of this unintended broad interpretation, they promptly introduced a clarifying new statement reading: "Articles listed herein are official and the standards set forth in the monographs apply to them only when the articles are intended or labeled for use as drugs or medical devices and when bought, sold, or dispensed for these purposes."

This means that a box of sodium chloride—whether it is labeled "USP" or not—must meet USP standards if it is intended for use as a drug or therapeutic agent. If, however, it is intended for use as a food, or as an agent in ice cream manufacture, or to melt road ice, then it is not obliged to meet the compendial standards.

Similarly, barbiturates are used as drugs and also as laboratory buffering agents; certain anticoagulants are used therapeutically and also as rat poison; and other examples might be cited as well. In each such case, it is the intended use of the substance—rather than what it is chemically—that determines whether it is a "drug," and therefore must meet the applicable drug requirements.

Applying this line of reasoning, the situation with regard to the substances used for execution *via* lethal injection seems quite obvious; namely, the substances are not drugs because their intended use is clearly otherwise, despite the fact that these same substances may also be labeled and used as drugs under another set of circumstances.

Ironically, however,the FDA itself is largely responsible for confusing what should be a clearly differentiated situation. Approximately 20 years ago, the FDA seized shipments of paper disks impregnated with various antibiotic agents which were intended for clinical laboratory use in determining whether cultures of isolated organisms were inhibited by one or more of the antibiotic agents. This FDA enforcement action was challenged by the manufacturer (Difco Laboratories), and the case went to trial.

In the personal view of this writer, the antibiotic-impregnated disks were only a diagnostic aid at most—they were not used in any therapeutic manner and, hence, were not drugs. Although they happened to contain trace amounts of antibiotic substances, their use made them no different than other reagents used in the clinical laboratory. On this basis, we testified as an expert witness in Federal District Court on behalf of Difco Laboratories and in opposition to the position taken by the FDA.

The case was a most difficult one, and was eventually decided by the U.S. Supreme Court in a landmark decision. The FDA had fought tenaciously to protect all aspects of its antibiotic certification program which was then in effect—but which has recently been abolished—and convinced the court of the necessity of "certifying" these test disks. In turn, this required the court to determine that the disks were "drugs" although they never came near the patient, and in themselves have no effect on the course of the patient's disease or condition of the patient.

It appears to us that the conclusion of the court was terribly erroneous and that many absurd interpretations mutually follow when the court's general conclusion is applied to other articles and to other situations that have subsequently arisen.

Perhaps the court, in reviewing the lethal injetion tissue, will see fit to review the Difco decision. If so, we believe that the wise course of action would be to reverse the unfortunate conclusion reached by an earlier panel of jurists some 15 years ago.

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Editor's Note: Dr. Feldmann's editorials are an expression of personal opinion and do not necessarily reflect views or policies of APhA. The editorials are intended to be provocative and to stimulate thinking. Readers having reactions, either pro or con, are invited to submit them for publication in the Open Forum section.

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