

## Drug Dosage Forms

Ecanow and Gold<sup>1</sup> incorrectly asserted that the Ocusert (pilocarpine) ocular therapeutic system is merely a dosage form delivery system containing a drug solution. They failed to make the distinction between a "dosage form" and a "controlled drug delivery system." The latter is a generic term for systems that go beyond conventional dosage forms in the sense that they are all specified by a drug delivery program—a predetermined rate and duration of drug delivery. The term "therapeutic system" is applied to controlled drug delivery systems that release a certain drug according to a temporal pattern designed for the therapy of a particular condition or disease state.

The therapeutic system functions according to this rate/duration program in automatic and uniform fashion. Moreover, the specification of rate and duration is based upon *in vitro* testing carried out under conditions that are predictive of the functioning of the therapeutic system *in vivo*. In contrast, a conventional dosage form is specified only by the weight or concentration of drug it contains. Thus, the distinction between dosage form and therapeutic system is clear from the labeling: the Ocusert system continuously delivers pilocarpine to the eye at either 20 or 40  $\mu\text{g}/\text{day}$  for 1 week; an eyedrop solution contains pilocarpine in concentrations of 1, 2, 4, *etc.*, percent. The essential difference lies between the words "delivers" and "contains." The former labeling specifies function, and the latter only specifies general content of

the bottle—not even the volume of the eyedrop is quantified.

We certainly agree with Ecanow and Gold that confusion can arise from ill-defined terminology. We propose, however, that the term "dosage form" be the broad description of pharmaceutical preparations intended for therapeutic use. This broad term encompasses various specific types of dosage forms such as tablets, capsules, suspensions, emulsions, solutions, semisolids, and controlled drug delivery systems. The drug delivery system can only be a specific entity (*e.g.*, a therapeutic system) if it is clearly distinguishable from other dosage types by definition, design, and function of the drug program.

"Dosage form delivery system," as proposed by Ecanow and Gold, would then be confined to the additional apparatus that may facilitate administration of dosage forms such as eyedroppers, syringes, and applicators. However, so restricted a meaning would create confusion and would be of dubious utility even when correctly employed.

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<sup>1</sup> B. Ecanow and B. H. Gold, *J. Pharm. Sci.*, 65 (8), viii (1976).