Under present law FDA has regulatory authority over some of the materials I have been using as illustrations. Cassettes which discuss a particular drug, for example, must meet standards for drug labeling and may not promote nonapproved uses of drugs, minimize hazards, or make comparisons not supported by evidence. This still does not, of course, mean that they are neutral educational materials as their formats might suggest.

PROPOSED FDA GUIDELINES

Recently, FDA was asked by a medical society whether a drug company could legally distribute a monograph prepared by the society without including prescribing information. The society objected strongly to the presence of such information because it would, they felt, have suggested that the monograph was promotional or prepared by the drug manufacturer when in fact it was not. In an attempt to define the circumstances in which we would consider informational material disseminated by a drug manufacturer not to be drug labeling, and thus not obliged to contain package insert information or to maintain strict conformance to the content of the approved package insert, we suggested the following five tests:

1. The material has been prepared solely for educational use and not with any intent that it be used for other purposes, e.g., sale to or distribution by the pharmaceutical industry.