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:

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

Two: The material is not promotional in nature taken as a whole, and is in the form of balanced educational materials. For example, the material may not contain any significant emphasis on uses for drug products that are not approved by the Food and Drug Administration as safe and effective, such as use for unapproved indications or in derogation of required contraindications and warnings. Although the material may contain occasional references to such cases, such references may not be frequent or be given major consideration or importance.

Three: The material has been prepared independently; that is, the pharmaceutical industry has not participated in the preparation of the material and has not exercised editorial review over the content of any of the material.

Four: The material covers a number of different drugs, and does not support use of one particular drug or the drugs of a particular pharmaceutical company.

Five: The material is not associated in any way with a promotional campaign for any drug product by the pharmaceutical firm supporting the exhibit. The material may contain reference to support by a pharmaceutical firm.

These tests, let me stress, were intended to permit truly independently prepared educational materials which do not have an overall promotional message to be distributed by drug manufacturers. When we were asked about scientific exhibits, we suggested essentially the same criteria.

We are currently drafting an extensive revision of our drug advertising and labeling regulations, and we expect to include guidelines such as those noted above in these proposed regulations. We are concerned that both the American Medical Association and the Pharmaceutical Manufacturers Association believe that these criteria would virtually eliminate scientific exhibits and industry-sponsored symposiums. These regulations could thus have an enormous impact on postgraduate medical communications and we would not take such a step lightly. We expect extensive comment on these regulations and will consider such comments carefully. At the same time, the extensive influence of the drug industry in these educational media is well illustrated by the profound effect our suggested guidelines could have.