

14092 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

limits our regulations place on drug labeling or advertising, because they have been considered equivalent to scientific publications. As a result, such scientific exhibits frequently discuss new uses of drugs, drugs not yet approved, and comparative properties of drugs not made in approved labeling.

Recently, Agency action related to the regulation of drug labeling has raised serious questions about these exhibits. In an attempt to define ways in which a drug company could distribute independently prepared educational materials, such as standard textbooks of pharmacology, we suggested guidelines under which such information would not be considered drug labeling. For the most part, these guidelines attempted to assure that such materials were wholly independently developed and edited. We did not feel that materials which discussed products of a single manufacturer or which discussed drugs and were produced with drug company funds could avoid being labeling if a drug company distributed them.

We have discussed these guidelines with representatives of the American Medical Association and the Pharmaceutical Manufacturers Association who indicates that many scientific exhibits depend upon the support of individual pharmaceutical companies whose products are described in the exhibits.