GOVERNMENT Rx's

FDA proposes important revision

According to a recent FDA-proposed regulation on labeling (package insert), a food, drug, device, or cosmetic is "misbranded" if the labeling does not reveal:

1. facts that appear in other statements (et al) about the product;
2. consequences which may result from using the product (either as prescribed or as it is usually used).

However, the regulation's prohibitions are more important than its requirements. Material facts do not, according to the FDA, "*permit* or require a statement of *differences of opinion* with respect to warnings (including contraindications, precautions, adverse reactions, and other information relating to possible product hazards) required in labeling for food, drugs, devices or cosmetics under the act." (Italics ours.) Furthermore, the proposed regulation does not "*permit* or require a statement of differences of opinion with respect to the effectiveness of a drug unless each of the opinions expressed is supported by substantial evidence of effectiveness . . . ."

In the regulation's preamble, the FDA gives us significant insight into why they have made the above proposal. The current regulation states that "the existence of a difference of opinion among experts qualified by scientific training and experience, as to the truth of a representation made or suggested in the labeling is a fact (among other facts) the failure to reveal which may render the labeling misleading if there is a material weight of opinion contrary to such representation." (In other words, according to the regulation they want to revise, differences of opinion are required.)

In 1971, the FDA published a notice that the labeling for oral hypoglycemic drugs used in the treatment of adult onset diabetes must contain a warning against cardiovascular consequences reportedly associated with the use of these drugs. Later that year a group of physicians petitioned the FDA to withdraw or modify this requirement, because they believed that the warning was unjustified, and that if it were required, it should be accompanied by a statement of the differences of opinion among experts about the necessity for the warning. The FDA Commissioner denied the petition, and manufacturers of oral hypoglycemic drugs had to include the warning in their labeling. The FDA felt that an undiluted statement was justified, since there was significant clinical evidence to support the warning, and that the physicians who presented the petition did not have enough evidence to dispute the need for the warning. The physicians then brought suit to enjoin the labeling change on the grounds that, by not including the difference of opinion, the drug would be misbranded according to the above regulation.

The FDA contended that since statements of drug effectiveness and truthful labeling were supposed to be based on "substantial evidence" rather than medical opinion, the labeling suggested by these physicians would be misleading. However, the district court entered a preliminary injunction prohibiting the FDA from requiring the warning because, the court concluded, there was a reasonable likelihood that the labeling proposed by the FDA did not comply with current regulations.

When the FDA appealed, the United States Court of Appeals cited the inconsistency between the way the current FDA regulation reads and the "substantial evidence" requirements that had been added to the Food