and Drug Act by Congress in 1962. The court then voided the injunction and gave the case back to the FDA for "further determination."

Now the FDA had to either allow inclusion of conflicting opinions about the oral hypoglycemics drug warning or revise the regulation. They decided to revise the regulation.

According to the 1962 Food and Drug Act:

> "If an article is alleged to be misbranded because the labeling is misleading, then in determining whether the labeling is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling relates under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual."

And:

> "Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users: Provided, That where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement."

The law also (as everyone probably knows by now) states that a new drug may not be approved for marketing if it is unsafe or ineffective for the conditions for which it is supposed to be used.

The FDA finds the use of the word "may" (underlined in the quotation above) particularly significant, since it implies lack of universal agreement among experts. The word "may" thus is supposed to make it unnecessary to include the specific medical controversy surrounding the warning. The FDA comments that warnings have been required on drug

(continued on p. 82)