labels by the Food and Drug Administration when there is significant medical evidence of a possible health hazard without waiting for a causal relationship to be established by definitive studies, which in some instances may not be feasible or would take many years. It states that in this way, physicians are fully informed of known potential dangers and the public is better protected.

These warnings must be stated in clear and unambiguous terms without disclaimers or qualifications that the FDA says would undermine or destroy their meaning and usefulness, and that all such warnings are by their very nature, about *possible* danger only. These warnings are often the subject of intense debate, but the FDA has never permitted drug labeling to reflect such debate, and, they say, this debate and disagreement should appear in professional journals and symposia but not in drug labeling. The prescription drug label warning is only for the guidance of a physician—it does not constitute a legal requirement and, the FDA adds, a physician does not violate federal law when he prescribes a drug contrary to a warning in its approved labeling.

In 1938, when the Federal Food and Drug Cosmetic Act was passed, personal expert judgment was the standard for determining drug effectiveness. The only way to satisfy that standard when the experts' opinions differed was to state both sides of the issue in the labeling for the drug. In the regulation preamble, however, FDA states that by 1960, the scientific principles of modern drug testing using statistically valid controlled studies had become fully developed and accepted, and claims of drug effectiveness (and thus the truthfulness of drug labeling) should be determined by adequate and well-controlled investigations, including clinical investigations by qualified experts.

The stated purpose of requiring scientific studies was to eliminate individual clinical observation and opinion as the measure of a drug's effectiveness, since the opinions of individual physicians reflecting their personal experience, empirical observation, and traditional practice do not satisfy the requirements of sound scientific investigation and thus do not conform to the standards established by the Drug Amendments of 1962. FDA notes that the Drug Amendments of 1962 are clearly intended to supersede the earlier reliance on medical opinion, and that therefore regulations should reflect the new standard.

In commenting on the concept of "fair balance" argued by the physicians in attacking the labeling for oral hypoglycemic drugs, FDA states that a draft of proposed new regulations will soon be published in the *Federal Register*. These regulations will implement "fair balance" for prescription drug labeling in the same way that present regulations do for prescription drug advertising. In both advertising and labeling, the required "balance" refers to how information on drug safety and effectiveness is presented and not to differences of judgment about that information.

The FDA concludes that the present regulation is inconsistent with current legal requirements and with contemporary medical and scientific principles. Since Congress has determined that the effectiveness of new drugs must be established by substantial evidence, the FDA thinks that a difference of medical opinion about labeling claims of effectiveness is not legally sufficient and is not a material fact unless the opinion is supported by evidence which meets the legal standard. The FDA goes on to say that some controversy exists in the medical profession about most statements in prescription drug labeling, and that permitting or requiring statements of these opinions on all such matters would destroy the present usefulness of prescription drug labeling.

The Commissioner thus concludes that there is no justification for presenting differences of medical opinion in any warning statements relating to possible product hazards. The FDA feels that the law presupposes a difference of medical opinion, since warnings of drug dangers will be required even though the danger itself may not be established but merely potential. Furthermore, they think there is no reason to allow these warnings to be discounted by including an opinion that the warning is really not necessary at all.

For these reasons the FDA proposes that the standing regulations be revised. (39 *Federal Register* 33229, Sept. 16, 1974)