ROLE OF REGULATION

Mr. Chairman, let me turn at this point to the possible role of regulation in addressing this overall problem. The FDA is responsible for regulating drug advertising and labeling, and I believe we do that well. On the other hand, we also have a responsibility not to restrict legitimate educational materials which are not under the authority of the Federal Food, Drug, and Cosmetic Act.

I would like to make one point unequivocally clear. Any scientist, physician, or other person can say or write anything he wants about a drug, so long as this effort is not subsidized by the drug industry. The Federal Food, Drug, and Cosmetic Act poses no threat whatsoever to scientific communication and debate on drugs, to the reporting of research on drugs, or to the voicing of any medical opinion on drugs, providing industry funding of that communication is not involved.

Once a drug firm distributes written or audio-visual material about a drug, or in association with one of its drugs, however, that material comes under the labeling provisions of the law. Labeling has been defined quite broadly in the Federal Food, Drug, and Cosmetic Act and by the Courts and includes virtually all printed materials about drugs placed into interstate commerce and supported by a drug firm.