

When a drug manufacturer maintains such a booth and promotes his drug there, that clearly falls under the drug labeling and drug advertising regulations.

In a separate section of the floor, or even in a separate room, there are booths where physicians or research scientists present their work as an alternate form of presenting their scientific discoveries. Sometimes people present their work as a speaker on a scientific program, and other times they will present it at a booth. So the scientific exhibit has always been viewed as equivalent to a scientific paper on a program.

The extent to which funding of the scientific exhibits has shifted to the pharmaceutical industry for support is a matter of concern and surprise to us.

Senator NELSON. Is that a recent phenomenon?

Dr. CROUT. Yes, that is a recent phenomenon.

I think the AMA memorandum points this out. Many of these were formerly supported by grant funds from NIH and so on.

Again, let me stress that I have no reason to believe that these industry-supported scientific exhibits represent anything other than the honestly-held beliefs and legitimate findings of the investigators involved. Many contain high-quality work. It is nevertheless a matter of great concern that most of the content of scientific exhibits is to a great degree selected by the drug industry. The exhibit committees of the conventions no doubt can eliminate the more frankly promotional exhibits, but they can do little to alter the fact that an exhibit unsupported by a drug company will usually not be produced and submitted for their review.

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 materials 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.

Senator NELSON. Are you saying that an article by a scientist—physician or otherwise—in a throwaway journal supported by the drug industry that make claims for drugs that were not supported by scientific evidence is controlled by the FDA, but if written for a