15470 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

therapeutic benefit. Government regulatory bodies tend towards policies which take absolute safety as the dominant note, while independent scientists tend to evaluate a drug more on a riskversus-results basis with the individual physician determining the applicability of the particular drug to a particular case. Second, there is the basic doubt as to a universal and automatic competence of the FDA or any other governmental agency in all matters it touches. Rigid acceptance of FDA controls, with appeal or review difficult and very expensive, makes for a unsatisfactory system. Political pressures are significant in drug control regulation when they should not be, and there is sometimes too much short-sighted action taken just to get rid of an immediate problem. This results in an ever increasing body of industry rules which tend to develop into a rigid formula for establishing black and white, without any regard for the vast gray area which exists in medical procedures.

It would seem that one of the best ways that is now available to evaluate a new product, or a new use of an old one, is to try it in a market where there is some latitude permitted in promotion efforts. This is not to justify in any way exploitation of a product for indications known to be wrong, or without warning of possible side effects that have been established by previous use elsewhere. Full disclosure is <u>always</u> essential. Absence of conscious deception is <u>always</u> essential. Acknowledgement of