

15468 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

In the record of hearings of this Committee are two significant explanations offered as to just how these promotional differences between countries are explained or rationalized. One approach is the one set forth by the president of a major pharmaceutical house that whatever standards, indications, or claims for a drug are approved by the in-house scientific staff of his organization as to the "medical positioning" of a product, that is their standard of guidance, everywhere in the world. He stated further and specifically that they would not use the standard of what is approved by FDA for that drug in this country if there should be any difference. The more you think about this approach the more puzzling the ethical implications become. It takes quite a bit of self-confidence, and perhaps even arrogance, to be able to ignore completely any findings by the FDA contrary to your own. While the track record of the FDA includes some questionable judgments in the past that have not held up to the test of time, certainly the vast body of its findings and its regulation are sound, and probably are the production of the most advanced system of drug review operating in the world today. However, if such a policy were actually used there would be no variation in promotion among different countries except where regulation required some limitation. It would appear from testimony given here that is never the case, and variation exists in the promotional claims for the same product among countries which have no virtually regulations at all. Therefore it is