If I were back in practice and read this statement, I might cautiously give Drug X a try.

But what are the facts?

Actually, 127 patients were treated with Drug X in clinical trials. Of these 127, just five had only temporary reductions in the size of the tumor mass.

But the proposed label said: "effective in a few."

Is this being "effective?" Not at all. This kind of evidence is no basis for offering the drug for the treatment of every cancer patient.

Here is another example, involving a diuretic. The label should be clearly marked: "Warning—Dangerous Drug." We suggested this to the company and added that they should reinforce the warning with the phrase "unparalleled potency."

The company returned with a label that used the phrase "unparalleled potency" with the phrase "unusual effectiveness" and produced an effect that was clearly promotional rather than precautionary. This is the language of advertising, not the language of danger. This is not in the spirit of science.

It is clear that this particular drug should not be prescribed by physicians except in special cases where other diuretics have failed. But the company wants a good seller, a drug that will be prescribed for cases other than those few special ones for which it was specifically designed.

The company forgot about the patient. But I cannot forget.

We have ruled, as you know, on several long-acting sulfonamides already available. We have an NDA for another long-acting sulfa in our Bureau of Medicine before us now. We have asked the sponsoring company to tighten its labeling language so that the physician will use it only for that part of the human system—the genito-urinary tract—for which clinical evidence shows it would be effective.

The company, however, wants to tell physicians that clinical studies are still going on involving other uses.

It wants to include a reference to imply that the drug can be prescribed to treat acne.

And it has asked for other language that would leave the physician somewhat in doubt as to the full extent to which he might prescribe this drug—this long-acting sulfonamide—this drug which even the most careful physician, given the proper warnings for restricted diseases, would use with some risk to his patients.

The company clearly wishes to promote—by subterfuge—wider therapeutic use for this drug. In the short run, this threatens the patient. And in the long run, it threatens the very fabric of your industry.

And what of advertising? Of the 8,000 or so companies in the drug industry, about 1,000 do some advertising.

Of the 4,000 biomedical publications in the field, approximately 200 can be considered major publications through which hospitals and practicing physicians get their drug information. Some of these publications come out once a month; others, twice a week.

A two-man medical advertising staff has, during the past year, passed on to our Bureau of Regulatory Compliance a number of complaints involving nearly one-third of the membership of the PMA.

Some advertising cases have been quite abusive of regulations. They have trumpeted results of favorable research and have not mentioned unfavorable research; they have puffed up what was insignificant clinical evidence; they have substituted emotional appeals for scientific ones.

These cases are well-known among you. The FDA is moving against them.

But what of the less well-known cases? Why did they happen? I think I know the answer: I think some of you have been led to believe that facts don't sell drugs.

Gentlemen, if I'm right, then you have been led astray—astray of the law and astray of what physicians need and want to know. Facts do sell drugs, facts presented in a professional way for professional men to read with care and respect.

Maybe I am talking about tone, professional tone. For example, no drug categorically "relaxes both physical and emotional tenson" all by itself. Your doctors know better than that and so do ours. But a drug can help relax these conditions or can often relax these conditions.

And then there is the flat statement that, frankly, would make any responsible physician cringe—although it might make advertising copywriters puff with pride. I'm thinking of such headlines as "The One Tranquilizer That Belongs in Every Practice" and the now classic "Is Peritrate Life-Sustaining?"