COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

HEARINGS

BEFORE THE

SUBCOMMITTEE ON MONOPOLY

OF THE

SELECT COMMITTEE ON SMALL BUSINESS

UNITED STATES SENATE

NINETIETH CONGRESS

FIRST AND SECOND SESSIONS

ON

PRESENT STATUS OF COMPETITION IN THE PHARMACEUTICAL INDUSTRY

PART 6

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Mr. GORDON. That is not saying very much, however.

Dr. GODDARD. Well, I would like to ask you, Mr. Gordon, what it is you propose be done. I am at my wits' end as to what can be done within the authorities and the philosophy of what FDA is supposed to be doing.

Mr. GORDON. Well, for example, we discussed the possibility of re-restricting it to hospitals. We talked about the possibility of curtailing to a large extent, or abolishing, the promotional activities.

Dr. GODDARD. I have told you that in both instances we do not have the means to enforce those suggestions.

Mr. GORDON. I know now that you do not have the authority. But given this, it seems to me that we are not in very good shape.

Dr. GODDARD. What you are talking about basically is what protection do you have from your doctor—to put it in its baldest terms. Let us call a spade a spade. That is what you are talking about.

Now, I do not think you can legislate that. You are talking about one drug. You have to rely on the physician's judgment for every drug that he prescribes. And the physicians need good information. This committee is aware of the problem in that area. There needs to be greater self-regulation in the form of therapeutics committees, and a lot of these steps need to be taken.

But in the long run, I do not think you can regulate good practice of medicine.

Senator NELSON. I do not think anybody is suggesting that, really.

Dr. GODDARD. That is what it comes down to.

Senator NELSON. I think we are talking about an extra special case here in which—as you know—in a 15-year period, 35 to 40 million people in America have been givin a drug and have thus been exposed to a possibly lethal dose for a condition in which it is just not needed. And there is no disagreement at all about that. We should not be helpless in the face of that situation. And, certainly nobody could say it was an improper interference to say that there is a category of drugs which must be used only under certain circumstances.

I think that label ought to be a whole lot tougher. I think it ought to say "dangerous drug" at the top. I think it ought to say that medical evidence indicates that 90 to 99 percent of the people getting it should not be getting it, and great tragedies are occurring as a result. It should warn the doctor not to use it without making some careful investigations and studies. You ought to hit them in the teeth with it—hard. I do not see how we can expect to accomplish our goal with this new label. It contains a stronger warning, but physicians were not reading the last one.

Dr. GODDARD. Well, Senator, I am willing to consider your suggestions on rewording this. This is not the final copy yet. I do not think you have much faith in this either, even though it has been the strongest warning. These thoughts that you bring out are not unknown to the medical profession. There has never been a drug that has received the attention that chloramphenicol has in the form of editorials, news articles, tight language in the package circular, what is allowed in the ads and everything else.

Now, I do not see the difference between "dangerous drug," and saying "serious and fatal blood dyscrasia." The latter translates immediately to a physician that here is a drug to be reckoned with, or should.