

form. I could suggest that. But that, to me, raises for serious discussion—What is the proper role of a Federal agency? This would represent a marked change in the philosophy behind FDA in terms of its role with respect to the practice of medicine. And it is not one that I would suggest to you. It is one that you may wish to explore. But I am loath to suggest it at this point in time.

Senator NELSON. Well, I must say it is most frustrating.

Dr. GODDARD. It is.

Senator NELSON. I have not come up with an answer. I have just been asking questions.

Every expert that I have heard, and the material I have read, all say basically the same thing: it should only be used in a hospital, because if you are sick enough to have it, you ought to be in the hospital. Then Dr. Gilman goes on to say that it should be used in the hospital, and if there is an exception, that there should be a specific agreement between the doctor and the patient that he would see that patient every 48 hours, and that continuous blood studies should be made.

Now, this is the opinion of experts as I gather it from all over the country. Yet, their recommendations are being violated wholesale. Are we supposed to sit here as toothless souls—our Government or anybody else—who cannot protest the country? This is incredible to me.

Dr. GODDARD. I agree it is incredible, Senator. But how are you going to stop this practice from occurring? I am as baffled by it as you are, as to what steps can be taken.

I know of no other drug that has been given the prominence in terms of warnings to the medical profession that this drug has over the past 18 years. And yet the sales indicate it is being more widely used today than ever before.

I do not know how you can control it, other than taking steps through legislation, which I raised with you as one of the possibilities. Because after we are through talking about all the things we are going to do, there still will remain in your mind, I am sure, as it must in mine, a serious question as to whether these new steps will be any more effective, other than temporarily, in reducing the amount used. And then you ultimately have to come back and say "What is it that can be done that can control the misuse of this drug?" And I submit to you, sir, that it would require a legislative change, the nature of which has not been made in our society before with respect to this profession. And I am loath—it would have to be explored, I think, in greater depth with the physicians, with the hospital association, with the pharmaceutical manufacturers themselves, because it has rather profound implications.

Senator NELSON. You have no present authority to say that it should be confined to hospital use?

Dr. GODDARD. We could in the labeling, and that is as far as we could go. And we cannot enforce that.

Senator NELSON. This is a fine state of affairs, where tragedies are occurring all over this country, and we do not have any creative ideas for doing something about it.

We are not attempting to interfere with anybody's rights. There is