

Administration will not propose any legislation to go beyond what you have said this year?

Dr. GODDARD. That is correct.

Mr. GROSSMAN. Can I ask you one other thing.

What portion, do you feel, of the number of patients who get this drug should be in the hospital? You have talked here about typhoid fever, as well as people living in rural areas who might not be able to get into hospitals.

Now, wouldn't it be a fairly high proportion of these people who would be in hospitals, if we are talking about a very serious indication?

Dr. GODDARD. Yes, sir. But let us just take an example. Take a clinic, which characteristically sees patients on an out patient basis. They have good laboratory diagnostic facilities. They do sensitivity testing. They culture the urine, let us say, and recover an organism. They find a particular infection that the patient has is due to an organism that is sensitive to chloramphenicol and not sensitive to other broad spectrum antibiotics.

Now, a kidney infection is a very serious thing, and yet it is not necessarily one which requires the patient to be hospitalized. The urinary tract infection in general must be viewed as a serious infection, and yet in many instances these are treated on an outpatient basis.

Now, having said that, let me say that I would guess—and it is only a guess, based on what I have read, other experts' testimony, and my own limited knowledge of this—that perhaps 80 percent of the patients who require Chloromycetin would in fact be hospitalized during the acute phase of this illness. Now, that does not include follow up treatment that is often required.

Mr. GROSSMAN. But—this is another area where there are no statistics.

Dr. GODDARD. No statistics at all; no, sir.

Mr. GORDON. Dr. Goddard, do you have authority to take a drug off the market?

Dr. GODDARD. Yes, sir.

Mr. GORDON. You have done so in the past?

Dr. GODDARD. Yes, sir.

Mr. GORDON. Have you found that it has interfered with medical practice?

Dr. GODDARD. Of course. And I have said on a number of occasions that Congress gave us certain authorities which in and of themselves must be viewed as, in part, interfering with the practice of medicine. We make decisions on which drugs will enter the marketplace, and which drugs are to be taken out of the marketplace. And that was what Congress said we should do.

Mr. GORDON. All right. How about taking this drug off the market? Do you have the authority to do that?

Dr. GODDARD. Yes, sir. And we have discussed that on every occasion that this drug has been reviewed by eminent groups of scientists, who have advised us—either through the National Academy of Science or directly—and in every instance there is unanimous agreement, as far as I know, that the drug should not be taken out of the market.

Mr. GORDON. These people do not represent the public. The FDA represents the public.