

Senator NELSON. Are the instructions about the precautions in using it as widely disseminated there as here?

Dr. DAMESHEK. I would be inclined to doubt that they were. I am not sure that they even have any cautionary statements about the use of chloramphenicol in these countries.

Senator NELSON. In the——

Dr. DAMESHEK. In the literature or in the package. I am not sure about that. I do not believe they have, but I am not sure about it.

Some of the disturbances which may be related to aplastic anemia, and which I have observed, are acute leukemia, which has been shown to develop in some cases of aplastic anemia after some time. And the peculiar disorder known as paroxysmal nocturnal hemoglobinuria, PNH, which I do not think I would go on and explain to you because it is rather complicated.

But, a few months ago we did report in the New England Journal of Medicine three cases of myeloblastic leukemia following Chloromycetin therapy and in these two cases the patients had used the drug, had developed aplastic anemia which was followed by the development of leukemia.

Senator NELSON. Were these cases in which the drug should not have been prescribed, in which it was not indicated?

Dr. DAMESHEK. The first one I came in contact with was a woman from one of the most affluent families in this country. I will not mention the name. And her doctor in this elegant community had given her Chloromycetin for a head cold and had told her to use this drug for every sniffle that she might get in the future. She proceeded to follow this prescription regularly. Her colds disappeared. But later on she developed aplastic anemia and eventually leukemia.

And, in the two other cases I have here, one had a urinary disturbance where she was asked to take—cystitis, so-called—she was asked to take the drug whenever she had a little burning of the urination. Eventually she developed aplastic anemia and then leukemia.

The other one was a woman who had had simply a 6-week course of Chloromycetin for an infection. I do not have it specified here what the infection was. I guess we did not know about it. But, these are newer developments in the followup of aplastic anemia.

There was another case recently reported from California, the same sort of thing.

Senator NELSON. Are each of these cases ultimately fatal?

Dr. DAMESHEK. Yes. This kind of leukemia is always fatal.

Senator NELSON. Was the second case that you mentioned one in which it should have been prescribed for the condition?

Dr. DAMESHEK. Well, this woman had a urinary infection and a lot of people use this drug in urinary infections. Now, whether it should not have been prescribed I am not sure, but she used it whenever she had a little burning of urination. I think she used it rather indiscriminately. That is about as far as I can go on that.

I discussed in an editorial of the Journal of the American Medical Association of a few years ago some of the problems relating to responsibility and to precautionary measures.³ That is, who is responsible for this or whose responsibility is it?

³ See exhibit C, p. 2401, *infra*.