

to agree upon what class of drugs should be placed in this special category?

Dr. HEWSON. Yes. I think the threshold decision of which drugs are to be placed in that category should come from the FDA, and I am sure they would make use of expert consultants from the profession.

Senator NELSON. They do not have that authority now.

Dr. HEWSON. I believe not.

To require a report on all cases of aplastic anemia or even of diseases treated by chloramphenicol from the individual physician would not be conscientiously followed, as our experience with venereal-disease reporting has shown. The procurement of more accurate evaluation of the incidence of blood dyscrasias following the use of chloramphenicol, as from hospital reporting, would be academically helpful but doubtfully help curtail use of the drug by the average practitioner, and probably would not be conscientiously followed. Placing the drug in the hands of the academically oriented, knowledgeable specialists, some of whom are available to virtually all hospitals, should be an effective, workable resolution of the problem.

That is the end of my statement, Senator.

Senator NELSON. If you are correct—and I assume you are—that the FDA presently does not have the authority to consult the profession and designate such a special category of drugs that should be administered only in hospitals or under specific circumstances, would you recommend that legislation be passed to authorize the FDA to do this?

Dr. HEWSON. I have never researched it, but I do not know of a drug being placed in such a category; so I just assume—it has never come up legally in my experience—that they do not have the power. Yes; I think it would be a most worthy addition to our control of drugs to authorize that power.

Senator NELSON. I do not know whether or not you read Dr. Dame-shek's testimony.

Dr. HEWSON. Yes; I did.

Senator NELSON. Two weeks ago he made a similar type of recommendation. And so did Dr. Lepper. Both suggested that some kind of limitation of supervision over its administration be required.

Dr. HEWSON. Definitely. As I say, I feel it has to be controlled from both sides. I think the physicians have to be controlled as well as the drug company and its promotional methods.

Mr. GORDON. Dr. Hewson, on page 5 you referred to Parke, Davis' "President's Letter," "Director's Letters," "Ideas and Suggestions" to its promotional staff, et cetera. I wonder if you could give these to us for insertion into the record at this point.

Dr. HEWSON. Certainly. I have them with me.

(The documents referred to follow :)

MARCH 12, 1952.

Newspapers recently carried a story of two children's deaths allegedly as a result of antibiotic therapy. One of two products mentioned was Chloromycetin. Within 24 hours retraction was made based upon more thorough investigation.

Rich, et al., [Ann. Int. Med. 33:1459 (Dec.) 1950] described clinical, laboratory, and autopsy findings in a patient who developed aplastic anemia while on Chloromycetin therapy; Herrell of Mayo Clinic [Amer. Journ. Surg. 82:638 (Dec.) 1951] cites the Rich report, and not any experience of his own, as basis for his generalizations against the use of Chloromycetin; and Loyd [Antibiot,