PARKE, DAVIS & CO., DIRECTOR'S LETTER, UNITED STATES AND CANADIAN SALES DEPARTMENT, DECEMBER 22, 1952, LETTER NO. 3

To members of the professional service staff.

Gentleman: The summary of last summer's special survey by the Food and Drug Administration of the relationship of Chloromycetin to reported blood dyscrasias has been published in the December issue of "Antibiotics & Chemotherapy."

We are sending to you a quantity of reprints of this article for distribution to physicians. Attached to this letter is a specimen reprint marked to call your attention to *significant facts which should be kept in mind* when evaluating the contents.[1]

Here are some questions which you may be asked relative to this report together with factual answers which are vital to a full understanding of the points developed in the survey.

Question. What did the recent investigations show?

Answer. Several hundreds of case records, collected from hospitals and physicians throughout the country by members of the FDA field staff, were reviewed. Of 539 in which classification was possible, in only 198 (37 per cent) was there evidence that the development of blood dyscrasia was associated with the use of Chloromycetin either alone or in conjunction with other drugs.

Question. Was Chloromycetin the only drug administered in these 198 cases?

Answer. No. Chloromycetin was the only drug administered in 55 of the 198 patients. Other drugs had been given in the remaining 143 cases.

Question. What "other drugs" were involved?

Answer. These were numerous; in some instances they were mentioned specifically, but in most they were mentioned only by categories. Included were: analygesics, anticonvulsants, antihistaminics, antipyretics, antibiotics (other than Chloromycetin, of course), antimalarials, antibacterials, and other chemotherapeutic agents.

Question. What safeguards protect patients against blood distorders?

Answer. Judicious use of potent therapeutic agents in the hands of the physician; careful observation of the patient; avoidance, when possible, of prolonged or intermittent use; and adequate blood studies, especially during prolonged or intermittent therapy when required. There is no known method permitting determination in advance of those in whom blood dyscrasias are likely to develop.

Question. What were the conclusions of the official agency (FDA) regarding further availability and use of Chloromycetin as a result of the survey?

Answer. The F.D.A. concluded that serious blood dyscrasias following the use of Chloromycetin are uncommon. The report specifically stated that Chloromycetin is a valuable drug which, however, should not be used indiscriminately or for minor infections. When prolonged or intermittent administration is required, adequate blood studies should be carried out. Attention of the physician is invited to these points through a warning on the label and through a statement in the literature on Chloromycetin.

Question. What are the present indications for Chloromycetin?

Answer. *These are not changed.* Chloromycetin is effective and is indicated in a wide range of bacterial, viral, and rickettsial infections, including: urinary tract infections; brucellosis; bacterial and primary atypical pneumonias; pertussis; enteric fevers (salmonelloses, including typhoid fever); dysenteries (shigelloses); rickettsial infections (Rocky Mountain spotted fever, typhus fever, scrub typhus fever); acute gonorrhea; granuloma inguinale; and lymphogranuloma venereum.

Very truly yours,

GRAYDON L. WALKER.

PARKE, DAVIS & CO.,
June 16, 1954.

Letter No. 8

To all sales representatives:

An important highlight in the development of up-to-date information on the antibiotics was presented in a symposium on antibiotics held in Washington this winter. A number of papers dwelt on the matter of safety and efficacy of Chloro-

[1] Retained in committee files.