concern not only of manufacturers and physicians but of the public represented through the Federal Food and Drug Administration.

In the case of Chloromycetin, the matter of whether its marketing should be continued has been the subject of special reviews by Committees of the Division of Medical Sciences and of the National Research Council appointed at the request of the Food and Drug Administration. These Committees have decided that its benefits outweigh its possible risks and that its marketing should be continued.

You should know, perhaps, that bone marrow depression may occur without any known exposure and is also attributed to many agents other than Chloromycetin.

It is realized, of course, that this does not alleviate your personal situation or afford you any comfort. I do sincerely hope, however, that your husband experiences a recovery. In the meantime, perhaps you might be willing to let us know the name of your physician since we may wish to correspond with him.

Cordially yours,

JOSEPH F. SADUSK, Jr., M.D.

PARKE, DAVIS & Co.,
Detroit, Mich., September 19, 1967.

———, NEW YORK.

DEAR MR. NAME WITHHELD: Please accept my apologies for not replying sooner to your letter of August 21.

Review of the material so kindly sent on to us at your request by Drs. ——— does not enable us to make a positive determination that Chloromycetin was necessarily the cause of the terminal illness of your sister.

In this connection, may I point out that there does not seem to be any clear agreement among the physicians involved of the nature of the illness for which it was prescribed, the dosage directions or the duration of treatment. The situation is further obscured by the fact that acetophenetidin, an ingredient of Anacin (which your sister also received), has also on occasion been associated with the development of blood dyscrasias.

As indicated in my first letter to you, physicians are universally aware of the possible association between Chloromycetin and the development of blood dyscrasias. Under the circumstances, I do not see how any approach by us to Dr. Diez could be helpful or considered by him in any light other than as being critical of him. There is, of course, no reason why you should not write him directly if you so choose.

Cordially yours,

JOSEPH F. SADUSK, Jr., M.D.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
FOOD AND DRUG ADMINISTRATION,
Washington, D.C., July 10, 1967.

———, NEW YORK.

DEAR NAME WITHHELD: This refers to the copy of your letter to the manufacturer of Chloromycetin which you sent to us, describing your sister's illness and death after use of the drug.

We can certainly understand your personal concern and believe you will be interested in details on the re-evaluation of this drug as long ago as 1952, when the possible side effects became recognized as a serious problem, and again in 1961. We accumulated all available data on the drug and presented the facts to a special committee of outstanding medical experts appointed by the National Research Council. After careful deliberation, that committee concluded that Chloromycetin is a life-saving drug in certain illnesses where other safer drugs are not effective, and recommended that it be permitted to remain on the market for such purpose. They recommended that its labeling plainly warn physicians that the drug may cause serious blood disturbances and that it should not be used indiscriminately or for minor infections.

We are enclosing a photocopy of the news release and copy of the committee recommendations that issued at that time.*

Sincerely yours,

EDNA M. LOVERING,
Consumer Inquiries Staff, Office of Education and Information.

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*These copies are not enclosed, since I am sure all of this material is available to the committee.