HARRY F. DOWLING, M. D.
208 BLISS LANE
GREAT FALLS, VIRGINIA 22066
TELEPHONE 759-3120

December 19, 1973

Prof. and Mrs. Alvin Zander
3 Harvard Place
Ann Arbor, Michigan 48104

Dear Mr. and Mrs. Zander:

I have no objection to your quoting what I wrote, so long as you make it clear that it is my opinion and not what I consider to be proved fact in every case. For instance, most pediatricians believe that chloramphenicol is the drug of choice for H. inluenzae meningitis, because many articles have been written about its use and they consider tetracycline more toxic for infants than chloramphenicol. Also, everyone does not agree that blood counts may not predict the onset of aplastic anemia in time to keep the full-blown disease of aplastic anemia from developing.

In answer to your question, I do not believe that working for a stricter U. S. label would be very valuable in controlling labelling abroad. Rather, since the U. S. label now contains statements that should be on labels abroad, the best thing to do is to push for them.

With regard to the longer monograph, I have the following criticisms:

(1) The second paragraph on page 1 does not distinguish between in vitro susceptibility and clinical effectiveness. It starts off talking about bacteriostatic effect and ends with a clinical judgment, that it is particularly effective against Salmonella typhi and Hemophilus influenzae. This gives the impression that the drug should be used for any of the conditions in the total list.

(2) On page 2, under indications, the statement is made that "chloramphenicol is specifically indicated for" and this is followed by some specific indications, such as typhoid and rickettsial infections and some very general categories, such as bacterial meningitis. It is of course not specifically indicated in all types of bacterial meningitis. The same criticism applies to intraocular infections and septicemias due to gram negative organisms. The next list of infections should be headed, "It is sometimes clinically effective in:..... The last paragraph about infective conditions in ophthalmology, otology and dermatology is so loose as to be almost ludicrous.

In other words, I do not think this monograph as it stands is the proper basis for good labelling.

Sincerely,

Harry F. Dowling

Harry F. Dowling