

strong U.S. warnings) but rejecting the U.S. method and principle of restricting unnecessary use and, in fact, in many subtle and some not-so-subtle ways encouraging such use in the Indications and Clinical Discussion sections, their initial description of the drug, and throughout the Monograph. The Monograph ~~both~~ implies many more Indications for use 1) in listing and discussing diseases in which Chloromycetin is "effective", "of value", and "useful", 2) by using much broader disease terms such as "intraocular infections", "infective conditions in ophthalmology, otology, and dermatology", "respiratory tract infections" and "surgical infections", and 3) sometimes by more specifically naming a disease that would not be included in the U.S. Indications such as "laryngotracheal bronchitis". Another way in which the Monograph encourages greater use is by omitting other important negative facts in the U.S. label which would restrict use, such as : 1) that blood studies do not preclude the later appearance of irreversible aplastic anemia, 2) that blood dyscrasias have occurred after both short-term and prolonged therapy, and 3) that there are reports of aplastic anemia attributable to chloramphenicol which later terminated in leukemia, and by omitting U.S. instructions: 1) that repeated courses of the drug should be avoided whenever possible, 2) that chloramphenicol must not be used as a prophylactic agent to prevent bacterial infection, and 3) that treatment should not be continued longer than required to produce a cure with little or no risk of relapse.

Important

We have also solicited the views of members of the medical profession to confirm or correct our judgment. The ~~two~~ doctors that have already responded have the same basic reaction to the Monograph as ours. A hematologist friend strongly criticized the Monograph mostly for its style, saying it is written more to sell Chloromycetin than to educate the physician in its proper use. He said if the company had wanted to educate the physician, they would have started the Monograph with a strong Warning and given more prominence to statements that it should not be used for trivial illnesses. The section on Indications is often only indicating where Chloromycetin is effective; for many of the conditions it should indicate use of other drugs if they had taken into account the risk/benefit ratio, in his opinion. He feels Parke-Davis misused the word Indications, often indicating conditions where it "may be useful" when other medicines should be used first. He calls attention to the fact that the U.S. label begins the Indications section with a capitalized statement of the very restrictive principles governing use of Chloromycetin, which is totally lacking in the Parke-Davis Monograph.

A physiologist friend also thinks the Monograph and the U.S. label are very different, saying that they not only differ factually on some important points but in particular and most important, they differ in tone; the Monograph essentially saying that there are lots of places to use Chloromycetin, it's a great drug and the U.S. label saying to be very careful, only use it under very special circumstances. He also says that many of the Indications (or implications for Indica-