

15514 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

A gastroenterologist who believes that Chloromycetin should be used for the treatment of immediately life threatening infections such as typhoid fever and for no other infectious conditions unless the responsible organism is clearly identified, has been demonstrated as being sensitive only to chloramphenicol, and if the clinical situation is such that the risk of withholding treatment is greater than the risk of its administration yet realizes that there are conditions notably in Southeast Asia where there is a grave shortage of physicians and where different criteria may apply (though he hesitates to comment on these without local knowledge) but who does not see why restrictions on the use of chloramphenicol in U.S. law should be loosened when it comes to countries such as Germany, England or Spain where the problem of physician density and physician coverage is not strikingly different than it is in this country, makes the following comments on the new Parke-Davis materials: 1) As far as the new Monograph is concerned, in his judgment it is not sufficient to confine the indications to conditions which are "not trivial". Not trivial is one thing and life threatening is another. Moreover, in my judgment the Monograph is deficient in that it fails to make clear that in many instances alternative modalities of treatment may be available which are equally effective and safer. Since this is an area in which he is not an expert, he suggests our consulting an expert in infectious diseases. He is particularly concerned about bacterioides and pneumococcal infections. 2) As far as the new Spanish label based on the new Monograph is concerned, he says it contains a warning but it is neither loud nor clear. It's phrasing is not as cautious as that of the U.S. product and he sees no reason why it should not be. He also criticizes the closing statement "For complete instructions on prescribing consult the product Monograph available at the request of a physician.", saying that he feels that it is not the responsibility of the physician to have to write to the company at any time concerning adverse reactions, since this places the responsibility on the shoulders of the physician which is clearly that of the manufacturer. 3) He goes on to comment on the promotional material, in particular that of Chlorostrep, which appears to be a continued promotional campaign in which Chloromycetin is in fact combined with another antibiotic. A further concern of his is that the promotional material does not mention adverse reactions. He feels that if these adverse reactions are anything other than trivial it should, both in this and other instances. He pointed out that it seems useful to make a clear distinction between promotional literature such as that which and warnings inserted in the package however strong these warnings may be. In other words an aggressive promotional campaign cannot be offset by prominently displayed warnings once the package is purchased. The promotional material is seen by many, the warnings are seen by few. He found it difficult to understand why the promotional material should be allowed to continue in the manner in which it is done with Chlorostrep, for instance, in Spain. Package inserts may or may not meet the letter of the law, they rarely meet the spirit of the law. The experience with cigarette advertising may be used to illustrate the point. He considered the Spanish Chlorostrep poster particularly offensive and would warmly support that its publication over the name of Parke-Davis be brought to the attention of appropriate legislative authorities.