

15508 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

4. Dr. Harry Dowling's "opinions, not proven facts" on the new Monograph.

Note: These are Dr. Dowling's opinions and not what he considers proven fact in every case.

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

Dear Mr. and Mrs. Zander:

I apologize for taking so long to answer your letter, but I have been on an extended vacation since it came and have just gotten to it.

In general, pharmaceutical firms are not likely to restrict their claims in labels and advertisements unless they are specifically required to do so. Pressure from the medical profession and the public has some effect, but usually not as much as that which results from the requirements of a regulating agency. As I have shown on page 252 of my book, "Medicines for Man" (Knopf, 1970) advertisements in the leading journals in England were not as completely informative and balanced as advertisements for the same drugs in this country. Although professional ethics and social consciousness are at as high a level in England, their regulatory agencies do not have control of advertising. In the southern European countries, such as Spain, one has the impression that almost anything goes with respect to advertising of drugs. Public opinion and professional attitudes lag well behind those of Great Britain, Holland, the Scandinavian countries, Canada and the United States. This is reflected, as you have indicated, in the advertisement for chloramphenicol which you sent me.

The opening statement that chloromycetin has therapeutic activity against a great variety of pathogenic micro-organisms would probably not be allowed in an advertisement by the FDA because, leading off as it does, it immediately gives the impression that the antibiotic should be used in many infections.

The information about the gray syndrome (paragraphs 5, page 1, and 6, page 2) is not adequately explained. It results from the fact that the kidneys of infants do not have the capacity to metabolize chloramphenicol, thus allowing it to build up in the blood to dangerous concentrations. Full disclosure requires that doctors be warned not to use it in this age group unless absolutely necessary and then only if the concentration in the blood can be monitored. (In this respect, the American version is probably deficient). The symptoms of the condition should be given in detail.

The rarity of the blood dyscrasias is stressed in the Spanish labeling, without a parallel explanation of the fact that aplastic anemia following the use of chloramphenicol is almost always fatal, and, as you indicate, usually continues even if administration of the antibiotic is stopped.