

15428 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

Chloramphenicol is an antibiotic which is well known to this Committee because of the Committee hearings on the subject in 1967 and 1968, and the subsequent hearings on antibiotics, particularly in 1972.

Chloramphenicol marketed in the United States since 1949, is unquestionably a potent antibiotic. But because its use may result in serious adverse effects, including fatal blood dyscrasias (aplastic anemia, thrombocytopenia and granulocytopenia) it must not be used when less dangerous drugs will be effective.

In the United States the Food and Drug Administration (FDA) limits approval of the conditions for which it may be promoted by manufacturers to infections caused by Salmonella typhi sensitive to chloramphenicol, and the following serious infections caused by susceptible strains:

- Salmonella species;
- Hemophilus Influenzae, specifically meningococcal infections;
- Rickettsia strains;
- Lymphgranuloma-psittacosis group;
- Various gram negative bacteria causing bacteremia, meningitis or other serious gram negative infections; and
- Other susceptible organisms that have been demonstrated to be resistant to all other appropriate antimicrobial agents.

In spite of these clear indications and the fact that chloramphenicol can be dispensed in the United States only on a physician's prescription, there is still significant misuse and overuse. In a recent study in Tennessee, for example, it was found that half the chloramphenicol prescriptions for Medicaid patients were