

Public Citizen

Buyers Up • Congress Watch • Critical Mass • Global Trade Watch • Health Research Group • Litigation Group
Joan Claybrook, President

October 26, 1995

David A. Kessler, MD, JD
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Kessler:

Less than a month after we wrote to you requesting that you investigate the pharmaceutical company Bayer for sponsoring a "Dear Doctor" letter concerning the widely-prescribed calcium channel blocker drug nifedipine (Adalat, Adalat CC) without disclosing that they had orchestrated and paid for the letter's mailing, we are writing about a similar circumstance, this time involving Allergan, the makers of Polytrim ophthalmic solution. We have learned that the investigation of Bayer is now under way; we request that a similar investigation of Allergan be initiated immediately.

In a Dear Doctor letter dated September 18, 1995 (see attached), four Sacramento, CA ophthalmologists described Polytrim as "an excellent first line choice" for uncomplicated conjunctivitis, and questioned the usefulness of the drugs produced by competitors. The letter, which was sent at a minimum to pediatricians in Sacramento and San Francisco, made no mention of sponsorship by any pharmaceutical company.

However, in a telephone conversation with us on October 13, 1995, Dr. Denise Satterfield, one of the ophthalmologists who signed the letter, informed us that a detail person from Allergan had solicited the letter. In fact, the detail person had actually written the first draft of the letter and, after receiving comments from Dr. Satterfield, had copied and mailed the letter. Dr. Satterfield stated that she and her colleagues were not paid for writing the letter.

Ralph Nader, Founder

1600 20th Street NW • Washington, DC 20009-1001 • (202) 588-1000

In the space of just one month, at least two pharmaceutical companies have stooped to the same illegal tactic to promote their products. We believe it is time for those Dear Doctor letters that have as their primary purpose the promotion of drug sales to become the focus of particular scrutiny by the FDA; this could be accomplished by requesting all such letters to be submitted to the agency prior to being sent out. We look forward to hearing from you as soon as possible about the Bayer investigation and your decision regarding the investigation of Allergan we have requested in this letter.

Yours sincerely,

Peter Lurie, MD, MPH
Research Associate
Public Citizen's Health Research Group

Sidney M. Wolfe, MD
Director
Public Citizen's Health Research Group

September 18, 1995

Dear Colleague;

As primary care providers, you are often the first to treat children for conjunctivitis. It is often impossible to tell if the conjunctivitis is bacterial or viral, and even if it is viral, there can be an overlying bacterial component. There are numerous topical ophthalmic antibiotics from which to choose. Here are our recommendations.

We as Pediatric Ophthalmologists recommend that you choose one of the broad spectrum antibiotics as your first line drug. In infants under two months of age, an ointment is often easier to apply, and Erythromycin is a good first line choice. In toddlers and other children, a drop is easier. Some drops, such as sulfacetamide, sting on application, and make compliance suboptimal. Polytrim ophthalmic solution is an excellent first line choice for these children. It is broad spectrum in coverage and has only a 2% incidence of stinging, so it is much easier on everyone! Furthermore, Polytrim can be used for children as young as two months of age and causes no toxicity to the cornea as some of the aminoglycosides do. If a child is not responding after a week, or if you have other concerns about the eyes, then you can have the child seen by an ophthalmologist.

Although other drugs such as the fluoroquinolones (i.e., Ocuflax and Ciloxan) are also effective in treating conjunctivitis, we feel it is better for patient care to reserve these medicines for more serious ocular infections, in which case, the child should be seen by an ophthalmologist. In addition, mixtures containing steroids (such as Tobradex) can worsen some eye infections (such as Herpes simplex), and are therefore not safe in the primary care setting.

We hope this information is helpful to you. Please feel free to call if you have any questions.

Byron Demorest, M.D.
Denise Satterfield, M.D.
James Ruben, M.D.
Richard Zipf, M.D.

Pediatric Ophthalmologists
Sacramento, CA

(Dr. Debbie Alcorn, the Director of Pediatric Ophthalmology at Stanford, is also available to answer any of your questions regarding the use of anti-biotics in children. You may reach her at 415/497-8880.)