

REACH Notes

Recent Developments to Promote Judicious Antibiotic Prescribing

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Don't Forget.....

The webcast on *Challenges in the Diagnosis and Treatment of Acute Otitis Media: The Practitioner's Perspective* has been extended through May 7, 2003. Visit www.reachmass.org/access any time day or night -- it's available 24 hours a day! The program takes only about 40 minutes and is quite informative. AND you receive 1 CME credit for completing it. Contact Judith Chevarley at 617-509-9882 for more information.

NEW FDA LABELING FOR ANTIBIOTICS

On February 6, 2003, the FDA published new labeling requirements for all oral and intravenous antibacterial drugs intended for human use. Within one year, manufacturers must include statements in drug labels about the unnecessary use of antibiotics and the link between such use and the emergence of drug-resistant bacteria. This decision was based, in part, upon the CDC's analysis that half of the 100 million yearly antibiotic prescriptions written by office-based physicians are unnecessarily prescribed for the common cold and other viral infections. Further rulemaking for topical antibacterials, antiseptics, antimycobacterial drugs, and veterinary antibiotics are being considered. For more information, visit <http://www.fda.gov/bbs/topics/NEWS/NEW00736.html>.

Labeling Requirements for Antibacterial Drugs

1. **Immediately below the product name**, the label must state:

To reduce the development of drug-resistant bacteria and maintain the effectiveness of [this drug], it should only be used to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.

2. In the **Indications and Usage section**, the label must further state:

[This drug] should only be used to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection.

3. In the **Precautions section**, the label must state:

Prescribing [this drug] in the absence of a proven or strongly suspected bacterial infection or prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria. Patients should be counseled that antibacterial drugs including [this drug] should only be used to treat bacterial infections. They do not treat viral infections (e.g. the common cold). When X is prescribed to treat a bacterial infection, patients should be told that skipping doses or not completing the full course of therapy may decrease the effectiveness of the immediate treatment and increase the likelihood that bacteria will develop resistance and will not be treatable by X or other antibacterial drugs in the future.

Key FDA Points:

- 1) The new FDA labels should remind physicians that their individual prescribing decisions have a collective impact on the resistance problem.
- 2) Physicians should only prescribe antibiotics for infections proven or highly suspected to be bacterial in origin.
- 3) Physicians should use narrow spectrum antibiotics whenever possible. Normal flora exposed to an antimicrobial may become resistant to that agent and pass resistance genes on to more pathogenic bacteria.
- 4) Physicians should counsel patients that antibiotics are not effective against viral illness and that skipping doses or not completing the full course of an antibiotic can result in antibacterial resistance.