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All authors who are involved in developing therapeutic guidelines for ASHP are asked beforehand to complete a conflict-of-interest disclosure report. In the report, the author is asked to list financial benefits, including grants, honoraria, consulting fees, and gifts received during the past year. Disclosure is limited to awards of $10,000 or more and those that exceed 10% of the author’s gross annual income. Potential authors are also asked whether they have participated on a health-related advisory panel, regulatory board, or similar program within the past year or have contributed to non-ASHP publications.

The survey was mailed to 192 authors of 44 clinical practice guidelines describing the management of common diseases, such as pneumonia, coronary artery disease, asthma, and hypertension. All of the guidelines in the study had been endorsed by at least one major North American or European society on common adult diseases. Although the survey’s questions dealt with authors’ relationships with drug companies, the guideline topics were not restricted to drug therapy but also described diagnosis and other aspects of disease management.

A total of 100 authors representing 37 clinical practice guidelines completed the survey. The guideline authors were not promised that their responses would remain anonymous, a factor that the survey team conceded may have lowered the response rate.

All 44 guidelines were examined to determine whether they included a conflict-of-interest statement. All but two of the published guidelines lacked a statement indicating whether the authors had declared a potential conflict of interest. One guideline contained a statement that the authors had personal financial dealings with the pharmaceutical industry. Another guideline declared that none of the authors had a conflict of interest.

One fourth of the 44 clinical practice guidelines that were examined contained a declaration that a pharmaceutical company had sponsored the guideline. Nine guidelines received support from “nonindustry organizations.”

Fifty-nine percent of the 80 respondents who returned a follow-up survey acknowledged having a relationship with one or more companies whose drugs were considered in the guideline. In all but two cases, the relationship with the sponsor predated the creation of the guideline.

A subset of nearly 70 guideline authors offered their opinion of how the relationship with a drug company influenced the guideline-creation process. Five said that the relationship influenced their personal recommendations, but 13 said that such relationships influenced the recommendations of their colleagues.

One of the guidelines used for the study was produced by ASHP, but the report did not provide a breakdown of individual guideline or author data.


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Recent changes to FDA-approved labeling

Amiodarone hydrochloride tablets (Cordarone, Wyeth): The occurrence of myopathy, hemolytic anemia, and aplastic anemia since the initial marketing of the drug has been added to the Adverse Reactions section.

Brimonidine tartrate ophthalmic solution (Alphagan, Allergan): Prevention of a postoperative increase in intraocular pressure in patients undergoing argon laser trabecuoplasty was added as an indication. Also, information on adverse events in pediatric patients with glaucoma was added; somnolence developed more frequently in children 2–6 years old (50–80%) than those 7 years or older (25%) during a clinical study with 0.2% brimonidine tartrate solution.

Imatinib mesylate capsules (Gleevec, Novartis): Treatment of patients with CD117+ inoperable or metastatic malignant gastrointestinal stromal tumors was added as an indication. The recommended dosage is 400 or 600 mg once a day.

Levalbuterol hydrochloride oral inhalation solution for nebulization (Xopenex, Sepracor): Treatment or prevention of bronchospasm in children 6–11 years old with a reversible obstructive airway disease, such as asthma, was added as an indication. The recommended dosage is 0.31 mg of levalbuterol three times a day, with a maximum dosage of 0.63 mg three times a day. A new strength, 0.31 mg of levalbuterol in 3 mL of a ready-to-use preservative-free solution, will be available in unit dose low-density polyethylene vials. Results of the study that supported the new indication appeared in the December 2001 Journal of Allergy and Clinical Immunology.

Levofoxacin tablets and injection (Levaquin, Ortho-McNeil): A warning about corticosteroid-taking patients, especially the elderly, perhaps having an increased risk of tendon rupture has been added.

News Briefs

• About 39% of HMOs had inhouse pharmacies in 1999, up from 20% in 1990, according to Managed Care Trends Digest 2001, part of an annual four-part series by Aventis Pharmaceuticals. The percentage of HMOs that used a mail-service pharmacy stayed the same, about 83%, from 1998 to 1999. Of the medical group practices that are members of the American Medical Group Association (AMGA), Aventis’s Medical Group Practice Digest reported, 41% had an inhouse pharmacy

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