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- * Works quickly, usually in 24 to 48 hours
- * Gentle, osmotic effect
- * Indicated for acute and chronic constipation and has no restrictions on length of use*
 - *MiraLax™ is indicated for occasional constipation and should be used for 2 weeks or less or as directed by a physician†*
- * Taste-free, grit-free crystal formulation
- * Dissolves quickly in only 4 ounces of water
- * Available in convenient 10 g and 20 g single-dose packets
- * Rx only

Contraindicated in patients who require a low galactose diet. Initial dosing may produce flatulence and intestinal cramps, which are usually transient. Excessive dosage can lead to diarrhea with potential complications such as loss of fluids, hypokalemia, and hypernatremia. Nausea and vomiting have been reported. Use with caution in diabetics.

Please see brief summary of Prescribing Information.

*Elderly, debilitated patients who receive lactulose for more than 6 months should have serum electrolytes (potassium, chloride, carbon dioxide) measured periodically.

†MiraLax is a trademark of Braintree Laboratories, Inc.

Reference: 1. MiraLax [prescribing information]. Braintree Laboratories, Inc.; 2001.

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KRI-LIT-002T



A different kind of lactulose

- * No syrupy-sweet taste or stickiness

Brief Summary: Before prescribing, please see complete prescribing information. **INDICATIONS AND USAGE:** For the treatment of constipation. **CONTRAINDICATIONS:** Since KRISTALOSE® (LACTULOSE) For Oral Solution contains galactose (less than 0.3 g/10 g as a total sum with lactose), it is contraindicated in patients who require a low galactose diet. **WARNINGS:** A theoretical hazard may exist for patients being treated with lactulose who may be required to undergo electrocautery procedures during proctoscopy or colonoscopy. Accumulation of H₂ gas in significant concentration in the presence of an electrical spark may result in an explosive reaction. Although this complication has not been reported with lactulose, patients on lactulose therapy undergoing such procedures should have a thorough bowel cleansing with a non-fermentable solution. Insufflation of CO₂ as an additional safeguard may be pursued but is considered to be a redundant measure. **PRECAUTIONS: General:** Since KRISTALOSE® (LACTULOSE) For Oral Solution contains galactose and lactose (less than 0.3 g/10 g as a total sum), it should be used with caution in diabetics. **Information for Patients:** In the event that an unusual diarrheal condition occurs, contact your physician. **Laboratory Tests:** Elderly, debilitated patients who receive lactulose for more than six months should have serum electrolytes (potassium, chloride, carbon dioxide) measured periodically. **Drug Interactions:** Results of preliminary studies in humans and rats suggest that nonabsorbable antacids given concurrently with lactulose may inhibit the desired lactulose-induced drop in colonic pH. Therefore, a possible lack of desired effect of treatment should be taken into consideration before such drugs are given concomitantly with lactulose. **Carcinogenesis, Mutagenesis, Impairment of Fertility:** There are no known human data on long-term potential for carcinogenicity, mutagenicity, or impairment of fertility. There are no known animal data on long-term potential for mutagenicity. Administration of lactulose syrup in the diet of mice for 18 months in concentrations of 3 and 10 percent (w/w) did not produce any evidence of carcinogenicity. In studies in mice, rats, and rabbits, doses of lactulose syrup up to 6 or 12 mL/kg/day produced no deleterious effects in breeding, conception, or parturition. **Pregnancy: Teratogenic Effects: Pregnancy Category B:** Reproduction studies have been performed in mice, rats, and rabbits at doses up to 3 or 6 times the usual human oral dose and have revealed no evidence of impaired fertility or harm to the fetus due to lactulose. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed. **Nursing Mothers:** It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when lactulose is administered to a nursing woman. **Pediatric Use:** Safety and effectiveness in pediatric patients have not been established. **ADVERSE REACTIONS:** Precise frequency data are not available. Initial dosing may produce flatulence and intestinal cramps, which are usually transient. Excessive dosage can lead to diarrhea with potential complications such as loss of fluids, hypokalemia, and hypernatremia. Nausea and vomiting have been reported. **OVERDOSAGE: Signs and Symptoms:** There have been no reports of accidental overdosage. In the event of overdosage, it is expected that diarrhea and abdominal cramps would be the major symptoms. Medication should be terminated. **Oral LD₅₀:** The acute oral LD₅₀ of the drug is 48.8 mL/kg in mice and greater than 30 mL/kg in rats. **Dialysis:** Dialysis data are not available for lactulose. Its molecular similarity to sucrose, however, would suggest that it should be dialyzable. Rx only. **STORAGE:** Store at room temperature, 15°-30°C (59°-86°F).
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AMA Lends Hand to Drug Importation

BY JENNIFER SILVERMAN
Associate Editor, Practice Trends

ATLANTA — Delegates to the American Medical Association's 2004 interim meeting made a bold move to support prescription drug importation by wholesalers and pharmacies, provided that certain conditions are met to ensure patient safety.

"Prescription drugs should be available at the lowest price possible, and we must ensure quality and safety," AMA Trustee Edward Langston, M.D., said at a press briefing following the vote.

The policy approved by the House of Delegates states that the drugs must be approved by the Food and Drug Administration and must be subject to reliable "track and trace" technology and a closed distribution chain. The policy was swiftly approved by the house after much discussion in committee. The AMA also reaffirmed that it does not support personal importation of prescription drugs via the Internet until patient safety can be assured.

The policy urges the AMA to educate members regarding the risks and benefits associated with reimportation efforts.

"We're certainly gratified the AMA emphasized the need for safety" in its new policy, said Jeff Trewhitt, spokesman for the Pharmaceutical Research and Manufacturers Association. PhRMA, however, "remains convinced that importation is too riddled with problems to pursue."

The AMA's position on patient safety and reimportation could change once it reviews a forthcoming report from a task force of the Department of Health and Human Services, the policy stated.

The issue is certain to come up in the House of Delegates again. In committee debate, Erich Garland, M.D., AMA delegate from the American Academy of Neurology, urged the AMA to look into the cost discrepancy between Canada and other countries. Recently, "I was surprised to find that large insurance companies were reimbursing patients for medicines they got in other countries," Dr. Garland said. "We shouldn't need to reimport medicine."

Delegates backed another controversial issue—specialty hospitals—when they approved a board report encouraging competition among health facilities as a means of promoting high quality, cost-effective care. The report also opposed efforts to extend a federal 18-month moratorium on physician referrals to specialty hospitals in which they have an ownership interest.

Delegates approved several measures designed to address the influenza vaccine shortage, asking that physicians be allowed to form purchasing alliances for competitive purchasing of the vaccine comparable with large purchasers supplying pharmacy and grocery chain stores.

Language to study mechanisms to help the uninsured was also approved. Delegates in one instance broadened the scope of a board report, stipulating that federal legislation to authorize and fund state-

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based demonstration projects should include—but not be limited to—implementing income-related, refundable, and affordable tax credits.

In other actions, delegates voted to:

► Seek the replacement of the Medicare payment formula's sustainable growth rate with payment updates that reflect increases in the cost of medical practice.

► Pursue caps on noneconomic damages as a top priority in medical liability reform, with a request to the board of trustees to report efforts to reform the civil justice system, as part of its coalition-building activities.

► Support federal funding of comprehensive sex education programs that stress the importance of abstinence in preventing unwanted pregnancies and sexually transmitted diseases, and that also teach about contraception and safer sex.

► Create model state legislation for physicians who testify in medical liability cases, emphasizing that they must meet statutory expert witness requirements, such as comparable education, training, and occupational experience in the same field as the defendant.

"Junk science has no place in the courtroom," said Donald Palmisano, M.D., AMA's immediate past president.

The stance on prescription drug importation and specialty hospitals provided the House of Delegates the opportunity to flex its political muscle at a time when the AMA is struggling with its identity and appeal to younger physicians.

Delegates heard the evidence for themselves in video clips of young participants in focus groups, and in new survey data, where only 11% of 800 physicians identified the AMA as a leadership body to which they could relate.

"Physicians simply aren't clear about who we are and what we do," Michael Maves, M.D., the AMA's executive vice president, said during the meeting's opening session.

In addition, "the AMA is not getting credit from physicians for the advocacy work it does," said Ajay Gupta, a principal at McKinsey & Co., a management consulting firm that conducted the survey and the focus groups.

The survey reaffirmed a longtime trend that physicians prefer their specialty or state society to a broader umbrella organization. Only 19% of the survey participants thought the AMA increased opportunities for their voices to be heard on important issues, as opposed to specialty groups (49%) and state groups (30%). In comparing current member penetration, the AMA "was fifth in the wallet behind specialty, state, and county societies," Mr. Gupta said.

Lack of confidence in the AMA has manifested in declining membership rolls. The percentage of nonrenewals in AMA membership has doubled from 10% to 20% over the last decade, with young, active physicians accounting for most of the decline. "That amounts to 430,000 physicians who are no longer members," he said.

AMA could conceivably boost its membership by focusing on medical society activists and "positive" society supporters, two groups of physicians that embrace the idea of society medicine, Mr. Gupta suggested. About 290,000 physicians represent

these "joiner" segments, though most are mature physicians, not young ones, he said.

"Joiners" have "a remarkably uniform view of what they want us to deliver: focused advocacy on priority issues, opportunities for involvement, and communications about progress and results," Dr. Maves said.

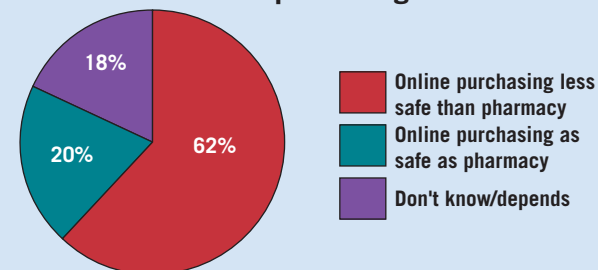
Targeting residents should be a key strategy, said Brooke Bible, the medical student representative to the AMA's political action committee. While

the AMA enjoys an excellent student constituency, "the residency period—where people get tired, jaded, or busy—is where we lose members."

The campaign begins in 2005, using surveys, town meetings, and other grassroots activities to connect with physicians, Gary Epstein, the AMA's new chief marketing officer, said in an interview. Patients in particular have always supported the AMA's charge, "and we need to leverage that" as a resource, he said. ■

DATA WATCH

Most Americans Do Not Trust Online Prescription Drug Market



Note: Based on a survey of 2,200 adults conducted May 14 to June 17, 2004.
Sources: Pew Internet & American Life Project, Princeton Survey Research Associates

KEVIN FOLEY, RESEARCH

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*From a single-dose study.

Reference: 1. Sunshine A, Olson NZ, Colon A, et al. Analgesic efficacy of controlled-release oxycodone in postoperative pain. *J Clin Pharmacol.* 1996;36:595-603.

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