

Health Insurance, Consumer Ads Top AMA Agenda

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CHICAGO — Individual health insurance mandates, direct-to-consumer advertising, and changing the public's perception of salt were among the issues addressed at the annual meeting of the American Medical Association's House of Delegates.

On the heels of Massachusetts' new mandate that all individuals must obtain health insurance, AMA delegates voted to support a requirement that individuals and families earning more than 500% of the federal poverty level (\$49,000 for individuals

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and \$100,000 for a family of four) obtain a minimum level of catastrophic and "evidence-based" preventive health coverage. The new policy calls for using the tax structure to achieve compliance, although language about the exact tax consequences is vague.

"We've taken a bold shift here, and we want to help lead this discussion because we want to have comprehensive reform," said Dr. Edward L. Langston, a member of the AMA Board of Trustees, during a press conference at the meeting.

The recommendation would cover only a fraction of the more than 40 million uninsured Americans. About 11% of the uninsured had incomes that were more than 500% of the federal poverty level in 2004, according to an analysis by the Department of Health and Human Services. But the delegates' action gives AMA officials another tool with which to lobby for expanding the number of people with health coverage, said AMA Board of Trustees member Dr. Ardis D. Hoven.

The American College of Cardiology does not have a formal policy position on individual health insurance mandates. "The ACC has and continues to support reforms that would make health insurance coverage more accessible and more affordable for individuals and families," an ACC spokesperson said.

In other news from the AMA House of Delegates:

► **Direct-to-consumer advertising.** The delegates voted in favor of placing a moratorium on DTC advertising for newly approved prescription drugs and medical devices until physicians have become educated about the new products. Under the AMA policy, the length of the moratorium would be determined on a product-by-product basis by the FDA in consultation with the drug or device sponsor.

The guidelines are a response to the frustration many physicians feel when patients ask for specific drugs or devices that they have seen advertised, which may not be appropriate for them, said Dr. Ronald M. Davis, an AMA Board of Trustees member, during a press conference.

► **The need to scale back on salt.** In a series of actions, the AMA delegates voted to urge the FDA to revoke the "generally recognized as safe" status of salt, allowing the agency to develop limits on sodium in processed food and restaurant items.

The AMA called for at least a 50% reduction in the amount of sodium in processed foods, fast food products, and restaurant meals over the next decade. The delegates also instructed the AMA leadership to work with the FDA to im-

prove labeling of foods and meals so consumers can better understand the amount of sodium they consume. Patients are often unaware of how much sodium is in their diet, cardiologist J. James Rohack, an AMA Board of Trustees member, said during a press conference. Patients with hypertension will often say they don't add salt to food, but they don't realize the high sodium content of processed meats, he said.

► **Electronic medical records.** Delegates

voted for the AMA to support initiatives that minimize the financial burden to physician practices of adopting and maintaining electronic medical records, and they instructed AMA officials to get involved in efforts to define and promote standards for the interoperability of health information technology systems. However, the delegates also established as AMA policy that physicians should not be required to adopt electronic medical records by either public or private payers. ■

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Such research is vital, as acute heart failure is responsible for more annual deaths than leukemia and breast, pancreatic, and ovarian cancer.^{1,2} In addition, this condition has few approved treatment options and no known cure. That's why we're so committed to advancing heart failure treatment—and **keeping patient relief at the heart of what we do**.

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The **recommended dose** of NATRECOR® is an intravenous bolus of 2 mcg/kg followed by a continuous infusion of 0.01 mcg/kg/min.

IMPORTANT SAFETY INFORMATION

HYPOTENSION

NATRECOR® (nesiritide) may cause hypotension and should be administered only in settings where blood pressure can be monitored closely. If hypotension occurs during administration of NATRECOR®, the dose should be reduced or discontinued. At the **recommended dose** of NATRECOR®, the incidence of symptomatic hypotension (4%) was similar to that of IV nitroglycerin (5%). Asymptomatic hypotension occurred in 8% of patients treated with either drug. In some cases, hypotension that occurs with NATRECOR® may be prolonged. The mean duration of symptomatic hypotension was longer with NATRECOR® than IV nitroglycerin (2.2 versus 0.7 hours, respectively). NATRECOR® should not be used in patients with systolic blood pressure <90 mm Hg or as primary therapy in patients with cardiogenic shock. The rate of symptomatic hypotension may be increased with a baseline blood pressure <100 mm Hg, and NATRECOR® should be used cautiously in these patients. In earlier trials, when NATRECOR® was initiated at doses higher than the 2 mcg/kg bolus followed by a 0.01 mcg/kg/min infusion, the frequency, duration, and intensity of hypotension was increased. The hypotensive episodes were also more often symptomatic and/or more likely to require medical intervention.

NATRECOR® is not recommended for patients for whom vasodilating agents are not appropriate and should be avoided in patients with low cardiac filling pressures.

RENAL

NATRECOR® may affect renal function in susceptible individuals. In patients with severe heart failure whose renal function may depend on the activity of the renin-angiotensin-aldosterone system, treatment with NATRECOR® may be associated with azotemia. In the VMAC trial, through day 30, the incidence of elevations in creatinine to >0.5 mg/dL above baseline was 28% and 21% in the NATRECOR® and nitroglycerin groups, respectively. When NATRECOR® was initiated at doses higher than 0.01 mcg/kg/min, there was an increased rate of elevated serum creatinine over baseline compared with standard therapies, although the rate of acute renal failure and need for dialysis was not increased.

MORTALITY

In seven NATRECOR® clinical trials, through 30 days, 5.3% in the NATRECOR® treatment group died as compared with 4.3% in the group treated with other standard medications. In four clinical trials, through 180 days, 21.7% in the NATRECOR® treatment group died as compared with 21.5% in the group treated with other medications. There is not enough information to know if there is an increased risk of death after treatment with NATRECOR®.

See brief summary of full Prescribing Information on adjacent page.

References:

1. American Cancer Society (2005 estimates).
2. American Heart Association (2001 data).

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