FDA Panel Backs Bronchial Thermoplasty Device

BY ELIZABETH MECHCATIE

GAITHERSBURG, MD. — A Food and Drug Administration advisory panel voted 6 to 1 that a novel device that uses thermal energy to ablate smooth muscle in the airway during bronchoscopy could be approved under certain conditions as a treatment for severe, persistent asthma in people aged 18 years and older.

At the meeting, members of the FDA's Anesthesiology and Respiratory Therapy Devices Panel agreed that there was reasonable evidence that the device was safe and effective for this indication, but stipulated several conditions for approval.

The conditions included requiring the manufacturer to enroll all patients treated with the device after approval in a registry, which would follow the durability of the therapeutic effects and safety; and not using the device in patients with impaired coagulation or on those who are on anticoagulant medication, because hemoptysis was reported in six treated patients in the pivotal study.

Other conditions for approval were that physicians who use the device be adequately trained, and that patients not be retreated with the device until clinical trial data on the effects of retreatment are available. The panel also unanimously recommended postmarketing studies of the device.

Components of the Alair Bronchial Thermoplasty system include a radiofrequency generator and a single-use catheter with an electrode basket at the tip that delivers radiofrequency (RF) energy to surrounding tissue. Treatment results in clinical improvements in people with severe asthma by using thermal energy "to reduce the airway smooth muscle responsible for airway constriction in asthma patients," according to the manufacturer Asthmatx.

The pivotal study conducted in six countries compared treatment with the device in 190 patients to sham bronchoscopy in 98 patients (where the catheter was deployed, without RF). Patients, whose median age was 41 years, had severe persistent asthma that was "not well controlled" (30%) or "very poorly controlled" (70%), and required high doses of inhaled corticosteroids and long-acting beta agonist therapy. Treatment was administered during three separate outpatient bronchoscopies 3 weeks apart.

The primary end point was the average of the changes in 6, 9, and 12 month Asthma Quality of Life Questionnaire (AQLQ) scores, a patient self-administered validated questionnaire, from baseline. Scores increased among patients in both groups, but the average of the three scores was 0.21 points greater among those in the active treatment group, compared with those in the sham group, which just missed statistical significance, according to the FDA's analysis.

The largest effects of treatment were seen at U.S. study sites, but in Brazil, improvements in the scores were somewhat higher among those in the sham group, which some panelists thought may have been due to the free maintenance medications received by all the patients enrolled at the Brazil sites.

Some of the study's secondary end points, including rates of severe exacerbations after treatment; days lost from work, school, or other daily activities due to asthma symptoms; and emergency room visits for respiratory symptoms, were lower among those treated with the device. Nearly 79% of those on Alair had a change in the AQLQ score of at least 0.5 (which the company said is the threshold for a clinically meaningful change), compared with 64.3% of those on sham treatment, the company reported.

Respiratory related-events, including asthma symptoms, were higher among those in the device-treated patients during the treatment phase (from the time of the first bronchoscopy through 6 weeks after the third bronchoscopy) but lower than among those in the sham group after that tine. A total of 6 patients (3%) treated with the device had hemoptysis, but there were no cases in sham-treated patients. There were no treatment related-deaths or withdrawals for worsening asthma in the study. ■

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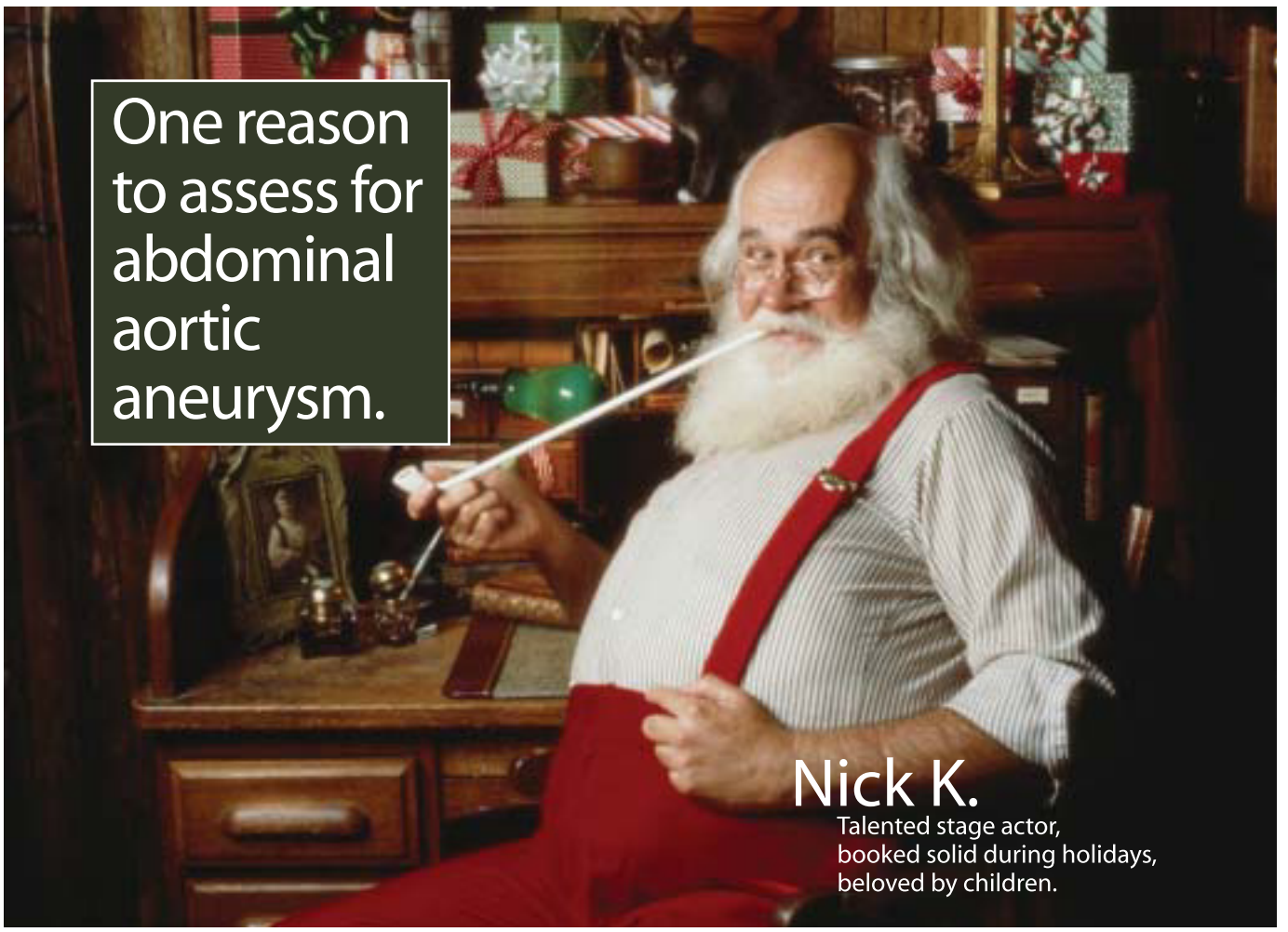

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