Proposed US stroke centres under fire for planned use of alteplase

Jeanne Lenzer *New York*

Federal legislation to designate US hospitals as "stroke centres" only if they can administer alteplase within three hours from onset of symptoms is causing concern among doctors who question the drug's efficacy.

The opponents also say the plans are an attempt to short-circuit a scientific debate that should be settled by doctors, not politicians.

The Stroke Treatment and Ongoing Prevention Act, which is due to be considered by Congress, would authorise \$165m (£101m; €144m) in 2003 and about \$125m a year through to 2008 to establish the specialist stroke centres.

The American Heart Association has launched a campaign telling the public to call the emergency number if they have symptoms of a stroke and another directed at doctors to "get with the guidelines."

The association's decision in 2000 to move alteplase from an

optional to a highly recommended treatment for stroke was based on a five year trial by the National Institute of Neurological Diseases, published in the *New England Journal of Medicine* (1995;333:1581-7). After reports in the *BMJ* in 2002 saying that most of the association's experts had ties to the drug's manufacturers, the trial was reanalysed (7 June, p 326).

The panel, chaired by W Michael O'Fallon, a professor of biostatistics, said that analyses confirmed the trial's finding that alteplase, delivered according to its protocol, reduced disability in patients with acute stroke.

David Faxon, president of the American Heart Association, has countered claims of links to the drug's manufacturers, saying that "all those who developed the guidelines adhered to...stringent conflict of interest policies and procedures." But there still remains considerable concern over use of the drug.

The Society for Academic Emergency Medicine, for example, states: "Ongoing controversies surround the use of thrombolytic therapy for acute stroke... It is not yet clear whether the treatment risk is outweighed by the likely therapeutic benefit" (*Academic Emergency Medicine* 2003;10:805).

"Many physicians are very reluctant to prescribe tPA [alteplase] for acute stroke, so the proponents have decided to take a political approach and achieve their aims through legislation," said Dr Phillip Brewer, assistant professor of emergency medicine at Yale University and president of the Connecticut chapter of the American College of Emergency Physicians.

Connecticut has just enacted legislation to establish stroke centres, despite the recent publication of a study involving all stroke patients in the state who were treated with alteplase that showed that overall in-hospital mortality was higher in the Connecticut cohort (16/63 (25%)) than in the original National Institute of Neurological Diseases cohort (40/312 (13%)) (*Archives of Internal Medicine* 2002;162:1994-2001).

But advocates say that when the protocol is followed alteplase can work. Dr William Barsan, chairman of emergency medicine at the University of Michigan, said, "The Connecticut study would seem to support that the safe use of tPA for acute stroke is dependent upon following appropriate guidelines which are well established."

However, Dr Greg Henry, associate professor of emergency medicine at the University of Michigan and a nationally recognised medicolegal expert, said that the legislation is "totally political."

"It's a back door to find support for tPA," said Dr Henry, who is serving as an expert on about a half dozen malpractice cases against doctors who did not give alteplase for stroke.

Brigid O'Brien, spokeswoman for Congresswoman Lois Capps, who is the sponsor of the Stroke Treatment and Ongoing Prevention Act, said that her office was unaware of any controversy surrounding alteplase.

The American Heart Association and the American Stroke Association declined to respond to questions about their support for the act. □

Company plans to sell snuff as "smokeless tobacco"

Deborah Josefson *Nebraska*

A major US tobacco manufacturer, US Smokeless Tobacco, is planning to launch an advertising campaign that will exploit anti-smoking bans across the country.

The company is the largest producer of snuff—smokeless tobacco—in the United States. In the wake of tobacco related litigation settlements and negative publicity surrounding cigarette smoking, the company has produced a snuff that does not make the user spit. It wants to market the product as a safer and more socially acceptable alternative to cigarette smoking and has asked the Federal Trade Commission to review and comment on its new marketing techniques to avoid controversy.

Traditional snuff is moist

shredded tobacco that is sold in small tins like shoe polish tins. Users stuff a wad of the tobacco in their mouth and let it rest against the cheeks, where nicotine is slowly absorbed through the mucous membranes into the bloodstream.

In the United States use of moist snuff is associated with baseball players, racing car drivers, and rodeo riders, but it is not more generally used because users need to spit frequently. The new snuffs, as well as being spitless, feature more elegant packaging, non-tobacco flavours, such as mint, wintergreen, and cherry, and packets like tea bags.

US Smokeless is preparing to market one, Revel, nationwide shortly. It is seeking approval for advertisements that show an attractive couple arm in arm.

The advertisement reads, "I was a smoker but my wife hated the smoke. No secondhand smoke. Another reason to switch to Revel."

The new product's slogan is "Anytime, anywhere," to emphasise its accessibility. Although the planned campaign does not specifically tout snuff as safer

The proposed advertisement from US Smokeless for Revel

than cigarettes, US Smokeless is actively lobbying federal authorities to allow advertising that promotes snuff as a safer alternative to smoked tobacco products.

On 3 June US Smokeless presented a paper to the Congress subcommittee on commerce, trade, and consumer protection which argued that, unlike cigarettes, snuff was not associated with major lung diseases, such as cancer, and that secondhand

smoke was non-existent. The paper also claimed that snuff had a lower risk of cardiovascular disease than cigarettes and quoted an Institute of Medicine report that said: "Smokeless tobacco products are associated with oral cavity cancers, and a dose-response relationship exists. However, the overall risk is lower than for cigarette smoking, and some products may have no increased risk." □