FDA rules that researchers will have to disclose financial interest

Deborah Josefson, *San Francisco*

Drug companies submitting licensing applications to the Food and Drug Administration (FDA) in the United States will now have to reveal whether researchers involved in a drug trial have any financial interest in the company. The new regulations aim to eliminate possible data bias arising from financial considerations.

Effective from February 1999, the new rules will require companies to disclose whether clinical investigators have received stock and patent options, payments in the form of research grants, gifts of equipment, consultant fees, and honorariums from lectures.

Drug companies routinely recruit doctors and scientists to study their products and to conduct clinical trials. Clinical investigators may receive substantial compensation for participating in these studies, and these may then

be used to support an application to the FDA.

The liaison between academia and industry can be vital to a researcher's success in an era of diminishing federal and private grants. Drug companies also benefit, because they can get an independent scientist and leader in a field to research their potential product. Without financial compensation, it would be difficult to recruit researchers.

A spokesperson from the FDA, Dr Michael Friedman, said: "Although some have argued that there is nothing inherently wrong with scientists in the private sector having a financial interest in the products they study, the FDA must be aware of these relationships as it evaluates clinical data from those trials. The regulation will help ensure that the process is thoroughly open and above board."

Dr Sidney Wolfe, director of the consumer agency Public Citizen Health Research Group, said: "It's outrageous that these rules didn't exist before. If I were an investigator with a financial interest conducting one of these trials, there's nothing to stop me from designing these trials to favour a certain outcome. It's an incredible conflict of interest."

The FDA's deputy commissioner, Sharon Smith-Holstein, said: "We never had these rules before because we never felt there was a need. We always presumed there was a financial interest in any new drug application. The rule has been in evolution since 1991, when a committee on fraud and abuse in federal agencies found that the lack of financial disclosure rules in applications for FDA approval constituted a 'material weakness' or a 'highly vulnerable area.'"

She said that both the FDA and industry feel that it would be highly unusual for a relationship between a firm and an investigator to influence a study's outcome. However, a recent article in the *New England Journal of Medicine* (1998;338:101-6) found just the opposite. The researchers found that doctors who had a financial relationship with manufacturers of calcium channel blockers were more likely to consider them safe and promote them over competing antihypertensive treatments than those who lacked such relationships.

Dr Wolfe said that the new rules are a start but are inadequate. In particular, he faulted the high threshold for financial disclosure. Sums of \$25 000 (£15 600) or less do not have to be disclosed to the FDA. "Disclosure is not enough—we also must push for disqualification," he said. □

China recognises AIDS problem

Richard Tomlinson, *Beijing*

China is mounting an increasingly public fight against HIV infection and AIDS, with four ministries jointly drafting a new national prevention plan.

The turn of the century is now the target for ending the transmission of HIV through blood plasma and setting up a nationwide AIDS control network. Another objective is to limit the annual increase in cases of sexually transmitted diseases to less than 15%.

When HIV infection first came to China, the authorities were slow to realise the potential threat, preferring to dismiss the problem as a "foreigners' disease." There were few public

information campaigns. As the government started to learn about the pattern of infection in neighbouring countries, it began to take the subject more seriously.

Shen Jie, who is in charge of HIV/AIDS control at the ministry of health, said that the new joint plan would come into effect after approval by the state council. The programme will include public information and education campaigns.

China had officially recorded 8303 cases of HIV infection by the end of October 1997, with positive tests in all but one of China's provinces. About two thirds of those infections were through intravenous drug use. However, these official statistics represent only the tip of the iceberg. The official media admit to an estimated 150 000 to 200 000 cases of HIV by the end of 1996.

In January the ministry of health said that it was trying to

Chinese people are more sexually active in the post-Mao era

keep the number of HIV infections below 1.5 million by 2010, but Arthur Holcombe, resident coordinator of United Nations operations in China, warned that infections could rise to more than 10 million by 2010. China is still in

an early, pre-pandemic phase, say experts. But conditions are ripe for the infection. Drug dependence in the south west is rife, prostitution is thriving, and the country has a huge floating population of migrant workers. □