Lancet editor defends decision to publish GM research paper

Phyllida Brown *London*

The editor of the *Lancet*, Dr Richard Horton, this week defended his decision to publish a controversial paper on genetically modified foods as "absolutely the right thing to do" amid continued criticisms that he had simply fuelled public confusion over the issue.

The paper, a research letter describing the effects of various diets containing potatoes on the intestines of rats, is based on experiments that have already been reviewed by the Royal Society and condemned as flawed. One of the paper's authors, Arpad Pusztai, was suspended last year from the Rowett Research Institute in Aberdeen for making claims about the lack of safety of genetically modified foods that were not supported by data.

Dr Pusztai and Stanley Ewen of the University of Aberdeen fed rats with potatoes containing a snowdrop lectin, a substance that helps plants to resist attack from insects. Some rats were fed potatoes that had been genetically modified to express the lectin; others were fed ordinary potatoes spiked with the lectin; and still others were fed normal potatoes.

The researchers found that the mucosal linings of the small intestine were altered in the animals fed genetically modified

potatoes, and concluded that the process of genetic modification was probably responsible for some of the changes.

However, there are several problems with the way the experiments were designed, says Hub Noteborn of the Dutch National Institute for Quality Control of Agricultural Products at Wageningen University, who wrote a commentary on the research in the *Lancet*.

There were too few animals in each group for the findings to be interpreted. Animals were fed either raw or boiled potatoes, which complicated the analysis. All the diets—including those containing only normal potatoes—were unusually low in protein, so some of the changes may have been due to starvation.

The researchers were not "blinded" to which group of rats had received which diet. And there was no systematic attempt to examine the relation between the amount of lectin expressed by the genetically modified potatoes and the biological effects observed in the rats fed with these potatoes.

Professor Sir Aaron Klug, president of the Royal Society, said that the *Lancet's* decision to publish had only one effect—"to sow confusion" in the public's mind about the safety of genetically modified foods. In fact, he

Dr Arpad Pusztai: at the centre of the controversy over publication of "flawed" research on genetic modification

said, nothing could be concluded either way from the experiments. "It's a total waste of everybody's time," he said.

Professor Klug contested Dr Horton's argument that publication would help to encourage sensible debate. "The whole point of journals is that in having a refereeing system they can act as a filter on material," he said.

This paper—even accompanied as it was by critical commentaries—had been given authenticity by the *Lancet*, he said. And he said that an accompanying research letter showing the effects of lectin on human cells was irrelevant and its conclusions already known.

Dr Horton emphatically denied seeking publicity for the *Lancet*, saying that he had spent an entire day defending the decision. He has repeatedly said that the decision to publish does not vindicate Dr Pusztai but sim-

ply gets the data on the table so that the "phoney debate" can end and proper debate begin.

Most of the journal's referees had said that the paper should be published. Had he rejected their advice, he said, then "it would be legitimate to accuse us of backing off from a controversial issue, or, at worst, censorship."

Dr Horton said that it was common practice for medical journals to publish controversial papers with critical commentaries alongside. "If scientists really want a public debate they should welcome publication," he said, suggesting that some were under "extreme" commercial pressures to keep quiet.

Dr Pusztai contested most of the criticisms of his experiments, calling them "ill-conceived and inappropriate." For example, the number of animals was adequate and no rats were starving, he said. □

Sertraline approved for post-traumatic stress disorder

Scott Gottlieb *New York*

The US Food and Drug Administration's psychopharmacologic drugs advisory committee voted six to one to recommend that the agency approve the use of the popular antidepressant drug sertraline for treatment of post-traumatic stress disorder.

If the drug gains approval it will be the first drug officially available for the disorder. It is

likely to carry labelling, however, noting that its efficacy has not been established in men.

The agency will probably follow the panel's recommendation when it decides whether to expand sertraline's approval to include post-traumatic stress disorder. Sertraline is already approved for treating depression, obsessive-compulsive disorder, and panic disorder.

Symptoms of post-traumatic stress disorder include avoiding event reminders, survivor guilt, flashbacks, numbing of emotions, insomnia, and nightmares after a life threatening event, such as sexual or physical assault, childhood abuse, military combat, and natural disaster.

Women are twice as likely as men to experience the disorder, and their symptoms typically last several years, compared with one year in men. Men with the disorder have a high incidence of drug and alcohol misuse.

About half of the people with the illness are also clinically depressed, according to Dr Charles Marmar, vice chairman of the psychiatry department at the University of California in San Francisco. Dr Marmar testified before the agency's panel on behalf of Pfizer, sertraline's manufacturer.

Pfizer presented the panel with four unpublished studies that each enrolled about 200 patients. Half of the patients in each trial received sertraline, the

other half a placebo. One of the studies enrolled only military veterans.

Two studies showed a significant improvement in symptoms in patients taking sertraline, particularly among women, whereas the other two studies showed no benefit for either sex. Agency panel members said that the company needs to conduct more studies on the drug to examine why men did not seem to respond as well.

Pfizer "failed to show that it is effective in males," said panellist Dr Robert Hamer, associate professor of psychiatry at R W Johnson Medical School at the University of Medicine and Dentistry of New Jersey. □