

Clinton seeks heavy fines for breaching research ethics

Fred Charatan *Florida*

President Clinton is to ask Congress for authority to levy fines of up to \$250 000 (£156 000) on medical researchers who violate federal rules on human research, and up to \$1m on the universities that employ them.

Donna Shalala, Department of Health and Human Services secretary, said on 23 May: "The explosion in biomedical research has brought new challenges as more researchers are becoming involved in commercial ventures that may create new ethical dilemmas. Today's actions are designed to further strengthen government oversight of all biomedical research including gene transfer research, and to reinforce institutions' and

researchers' responsibility to follow internationally accepted ethical standards. Public confidence in clinical trials is essential to the continued advances in medicine we all hope to see in the next century."

While the Food and Drug Administration can currently issue warning letters or impose regulatory sanctions that halt research until problems are rectified, the new financial penalties, if authorised by Congress, will give the agency additional tools to punish research institutions, sponsors, and researchers who do not follow federal guidelines.

Reaction to the new proposals was mixed. Dr Nils Hasselmo, president of the American

Association of Universities, called them "a constructive action," but Dr Gerald S Levey, dean of the medical school at the University of California at Los Angeles, said, "It's radical and it's inappropriate ... it will drive people out of doing clinical research."

But the proposals were backed by others. Dr George Rupp, president of Columbia University, said, "The federal government doesn't have any intermediate action between dropping the atomic bomb and a wrist slap. This is clearly an effort to look for a more focused and discriminating level of penalty."

Dr Jane E Henney, commissioner of the Food and Drug

Administration, said, "We must ensure that patients are well protected and properly informed when they choose to enrol in a clinical trial. By maintaining high standards and requiring that all investigators adhere to them, we can be sure that the nation's biomedical research enterprise will continue to earn the trust of research subjects."

Dr Ruth Kirschstein, acting director of the National Institutes of Health, said, "We are constantly exploring new and effective ways to enhance systems to strengthen protections for human research subjects without unduly burdening institutional review boards." □

Unusable medicines "dumped" on Venezuela

Claire Wallerstein *Caracas*

Six months after devastating floods and landslides left up to 30 000 people dead or missing and 200 000 homeless, Venezuela is being inundated again—by a flood of unusable medical aid. Harrowing television pictures of the disaster last December in the coastal states of Vargas and Falcon, near Caracas, sparked a massive humanitarian response, and tonnes of medicines are still arriving from all around the world.

However, health workers helping the victims say that huge quantities of medical aid remain stockpiled in warehouses, and up to 70% of it will have to be incinerated. A report by the government's Pharmacological Production Service (Servicio de Elaboraciones Farmacologicas) says many products cannot be used

because they are out of date, unnecessary, have been partially used, or have no Spanish labelling. As a result, the government has already had to spend at least 10m bolivars (£10 000, \$16 000) to hire extra staff and increase working hours simply to classify what has been received.

Dr Francisco Griffin, director general of the service, said some companies had even deliberately sent expired products—considered as toxic waste—to evade the cost of having to deal with them themselves. The World Health Organization set guidelines to help improve aid provision after the war in Kosovo, where it was estimated that the cost of destroying unusable products exceeded their original value.

However, Dr Griffin accepted that the production service had not anticipated such a massive



A young evacuee is bundled onto a ferry to escape flooding in Vargas, Venezuela

international response to the landslides. When the disorganised nature of the donations—and the "titanic work" required to sort through them—became clear, adverts were belatedly posted on the websites of international organisations asking only for specifically requested products.

Meanwhile, a telephone helpline set up by a group of psychologists from Caracas University to help the victims, and which

went on to become a successful Samaritans-style support line for all the people of the capital, has had to close down. The service has run out of funds, and the Department of Health says it cannot afford to help. Fears are also growing that last year's disaster is set to recur, because hundreds of displaced people have returned to their collapsing shanties, built on steep hillsides in the poorest areas of Caracas. □