

US anger over accusations of trafficking in infant organs

Washington

THE US State Department has reacted with outrage to a resolution passed by the European Parliament last month that accuses the United States of trafficking in organs from human infants. US officials maintain that the 'baby parts' issue is part of a Soviet disinformation campaign, and has no basis in fact.

Todd Leventhal, a policy officer at the US Information Agency, says the first occurrence of the organ trafficking story appeared in a Honduran newspaper on 2 January 1987, attributed to Leonardo Villeda Bermudez, the former secretary general of the Honduran Committee for Social Welfare. The story at the time was that there were special fattening houses where babies were raised, and then their organs harvested for sale in the United States. Leventhal says Bermudez denied the reports attributed to him the next day, but his denial is never mentioned in subsequent stories. Similar stories have surfaced involving Guatemala.

The parliament resolution, introduced by a French Communist member, "condemns in the strongest terms practices of this kind", and calls on governments to hold inquiries into the affair.

Richard Schifter, Assistant Secretary of State for Human Rights and Humanitarian Affairs, in a letter dated 8 October to Karel de Gucht, chairman of the parliament's human rights subcommittee, expresses outrage over the "gullible acceptance by the Parliament of a totally untrue statement". US officials admit that there do exist illegal adoption services in Latin American countries that try to sell babies for adoption in the United States. Leventhal says the Soviet Union has used this fact to insinuate that the baby's organs are being marketed as well. He says the baby parts campaign is reminiscent of a similar campaign that claimed that AIDS was the result of a US biological weapon experiment gone awry.

US irritation over the AIDS campaign prompted the cancellation of several visits between US and Soviet health officials to discuss AIDS issues. Ironically, just days after Schifter sent his letter, the US Institute of Medicine and the Soviet Academy of Medical Sciences signed a five-year protocol for joint research programmes. The new protocol calls for cooperation on research on AIDS, environmental release of radiation, alcohol and drug dependence, and polio.

Joseph Palca

NIH delay first gene transfer

Washington

JAMES Wyngaarden, director of the National Institutes of Health (NIH), has decided to defer approving the first human gene transfer experiment. Although the NIH Recombinant DNA Advisory Committee (RAC) approved the experiment at a meeting earlier this month (see *Nature* 335, 577; 1988), Wyngaarden in a letter dated 18 October to RAC chairman Gerard McGerrity wrote that he wanted the protocol reevaluated on the basis of "unresolved questions" raised by the RAC's human gene therapy subcommittee and the NIH Institutional Biosafety Committee.

The experiment, proposed by W. French Anderson of the National Heart Lung and Blood Institute and R. Michael Blaese and Steven A. Rosenberg of the National Cancer Institute, involves putting a bacterial antibiotic-resistance gene into human lymphocytes specially selected for their ability to attack cancer tumours.

These 'tumour infiltrating lymphocytes' are grown in culture, activated with interleukin-2, and then injected into the patients from whom they were originally obtained. The bacterial gene provides no direct benefit for the patient, but will enable researchers to track how well the lymphocytes re-infiltrate their target tumour.

The gene therapy subcommittee was established to evaluate the details of the Anderson, Blaese and Rosenberg protocol, and at a meeting on 29 July it asked for additional data about the experiment. On 29 September, the subcommittee met and concluded that it had not yet received sufficient data to reach a decision on the proposal. But five days later, Anderson presented the additional data to the full RAC, and the experiment was approved. Anderson explained at the time that he had not provided the subcommittee with complete, written answers to its questions because he felt that to do so might jeopardize his prospects for subsequent publication in a scientific journal.

In his letter to the RAC, Wyngaarden says that "although this does not constitute gene therapy *per se*, gene transfer must be regarded as a prelude to such experiments and thus subject to the identical review process". Wyngaarden asks that the subcommittee re-evaluate the protocol quickly. No timetable has yet been established for this review.

In addition to the re-review by RAC and its subcommittee, the protocol must also be approved by the institutional review boards of the two NIH institutes involved, and the NIH Institutional Biosafety Committee.

Joseph Palca

Conflict of interest over Harvard drug

Boston

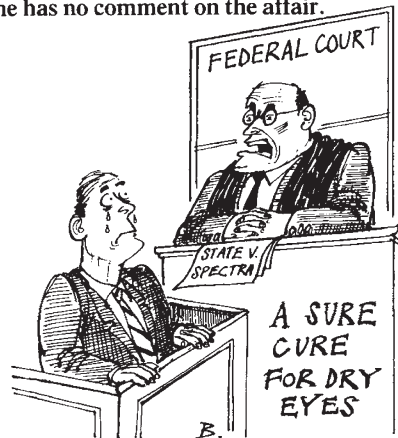
IN an unusually candid statement released last week by Harvard Medical School, Dean Daniel C. Tosteson acknowledged that a "significant conflict of interest occurred" in a drug study undertaken by a former Harvard researcher. The study, involving an experimental ophthalmic ointment, occurred three years ago, but it has been the focus of continuing investigation since then and has heightened concern about the effect of financial interests on biomedical researchers.

The researcher involved, Scheffer C. G. Tseng, and several of his colleagues and relatives, have apparently made large profits from the therapeutic promise of the ointment, using for the purpose an arrangement with a small company they set up called Spectra Pharmaceutical Services, Inc.

The drug, called Tretinoin, is an ointment containing vitamin-A. The medication was purported to cure dry-eye conditions caused by a family of ophthalmic diseases, including *keratoconjunctivitis sicca*. Ten million people are estimated to be afflicted with dry eyes in the United States alone.

Harvard says Tseng violated university research guidelines by administering the

drug in clinical trials without proper authorization. Tseng, who left Harvard more than two years ago for the University of Miami Medical School, refused several requests for an interview, and says he has no comment on the affair.



Harvard's statement about the incident says that Tseng failed to make "timely and complete disclosures" about changes in his study and his financial interest in the drug. The university also concedes that Tseng received "insufficient" supervision and that his study was run "without sufficient safeguards to protect [against] potential bias".

Seth Shulman