

# Fertility pioneers face 'misconduct' charges

**San Diego.** A world-renowned group of fertility specialists at the University of California (UC) at Irvine is being investigated for scientific misconduct, including the charge that members performed research on patients without their knowledge or consent.

Other allegations being investigated by federal and state agencies are that they used human oocytes said to have been discarded for research, also without consent, and smuggled into the United States an unapproved drug that was then sold to women patients to stimulate the production of eggs.

Two of the physicians involved — Ricardo H. Asch and Jose P. Balmaceda — are known internationally for developing in 1984 a technique known as gamete intrafallopian transfer (GIFT) while at the University of Texas at San Antonio. Asch is originally from Argentina, while Balmaceda and the third physician, Sergio C. Stone, are from Chile.

The allegations of misappropriation of human eggs and embryos centre on Asch. University officials say medical records indicate that eggs or embryos of at least 35 women may have been used without their consent, and that at least six children were born to unsuspecting parents as a result of the procedures used.

In one case, according to the records, eggs were taken from a young woman undergoing a fertility procedure, mixed without her knowledge with the sperm of a man, and the resulting fertilized embryo implanted in the man's wife, who had suffered a premature ovarian failure. A former administrator of the fertility clinic, Debra Krahel, who discovered some of the alleged irregularities before being forced by the university to resign last year, has called this practice "biomedical rape".

None of the three physicians is prepared to discuss the allegations with the press, but all have, through their lawyers, denied any impropriety. Asch blames some of the problems on poor record-keeping, and has claimed on occasion that allegations that embryos were misappropriated originated from an attempt to extort money from him.

The physician's lawyers acknowledge

some research was carried out without the required approval of the UC Irvine human subjects committee. But they claim this resulted from a misunderstanding of university policies. At least six research articles were published from this research, involving three retrospective studies and three studies involving drug trials or embryo-freezing.

According to the report of an investigation carried out by the university, Asch has acknowledged dispensing the unapproved hormone medication, HMG Massone. But both Balmaceda and Stone have contended in public statements that they have been smeared by university officials who, they claim, have been carrying out an unfair investigation based on what Balmaceda, at a hearing before state legislators, has described as "untested allegations".

Early in June, university officials closed down the physicians' primary clinic, the Centre for Reproductive Health, which was adjacent to UC Irvine Medical Center in Orange, California, and Asch resigned from the hospital's medical staff.

All three physicians were placed on paid administrative leave from their faculty appointments at the university, while the University of California at San Diego (UCSD), at which Asch operated a 'satellite' fertility programme, did not renew his unpaid appointment.

A subsequent audit of 155 patients' records at UCSD, the results of which were released two weeks ago, revealed that the eggs of three patients may have been used in donations to two other patients with proper consent. In addition, university officials found 17 cases in which egg/embryo records were either unclear or incomplete, and that records on the retrieval of eggs may be missing for up to 50 patients.

"We are determined to learn the truth regarding any improprieties, breach of ethics or violation of patient trust," says Thomas Moore, acting chief of reproductive medicine at UCSD.

But the researchers are not the only ones under fire. After details of the scandal became public in May, there was harsh criticism of UC Irvine officials, who were

accused of having moved too slowly and of silencing whistleblowers with hush money.

Last year, when three administrators — including Krahel — attempted to investigate some allegations against the physicians, they were forced by the university to resign, awarded more than \$900,000 in settlements, and told not to publicize the case.

This move has prompted outrage from some state officials, including Lieutenant Governor Gray Davis. "It is absolutely unac-



ceptable for this publicly funded university to throw this kind of hush money around," Davis has said.

But Sidney H. Golub, executive vice-chancellor of UC Irvine and himself a physician, denies such allegations. "The university administration responded to accusations of misconduct, no matter how sensitive the issue, with thorough investigations," he says. "Protecting the privacy of the patients, getting to the truth and ensuring due process have been and continue to be our main objectives."

Despite Golub's reassurances, the university decided in late June, in an administrative shake-up prompted by the debacle over the fertility clinic, to dismiss the medical centre's senior executive, Mary Piccione. She is now contesting the termination of her contract, contending it was improper.

In the wake of the affair, officials at the American Medical Association are examining professional standards for US fertility clinics, which are largely unregulated.

Meanwhile, UC Irvine nervously awaits the results of various federal and state investigations. The federal Office for Protection from Research Risks, for example, is looking into the allegations about research techniques, while the Food and Drug Administration is investigating the allegations that unapproved drugs were used.

University officials are also examining allegations the physicians may have siphoned off tens of thousands of dollars paid in cash for the fertility treatment, not usually covered by health insurance. **Rex Dalton**

## Report criticizes costly industry LINK scheme

London. A British government scheme to promote research partnerships between industry and universities has been criticized in a report published last week by the National Audit Office (NAO).

The LINK initiative, one of eight such schemes intended to support innovation and industrial competitiveness, has been described as costly and subject to unnecessary administrative delays, according to the report on all eight schemes.

LINK has supported 570 projects since

its launch in 1986. But, according to the NAO report, more than half of the grants allocated, constitute "deadweight expenditure" — funding in excess of the minimum needed to ensure a project proceeded.

Peter Dukes of the Medical Research Council, which announced the launch of two LINK research programmes on the same day as the NAO report, pointed out, however, that an earlier internal review of LINK had already identified areas that needed improvement. **E. M.**