CURRENT DEVELOPMENTS AND ISSUES: A SUMMARY

GENA COREA

Institute on Women and Technology, P.O. Box 338, North Amherst, MA 01059, U.S.A.

and

CYNTHIA DE WIT

Swedish National Environmental Protection Board, Box 1302, S-171 25, Solna, Sweden

IN VITRO FERTILIZATION

IVF called experimental, risky and often disappointing

About 3500 women have tried IVF in Canada, resulting in approximately 365 babies.

A *Globe and Mail* survey of Canada's 12 IVF clinics conducted by journalist Ann Pappert also found:

- "Clinics do not inform women of any risk involved. At least one clinic director asserted that a major study on abnormalities in IVF babies showed a lower rate of problems than in babies conceived naturally, when the study actually reported an increased incidence of abnormalities in IVF babies.
- "Some Canadian clinics operate for years without a single pregnancy or birth." For example, the first IVF clinic in Canada, at Laval University in Quebec, was in operation for six years before it had its first baby. The Queen Elizabeth Hospital's IVF clinic in Montreal, open since 1983, shut down last summer. The clinic had never had a birth.
- "The Government of Ontario, the only one in the world to finance IVF clinics, has spent more than \$7 million in two years on four clinics. During that time, a little more than 200 babies have been born, at a cost of \$35,000 a baby."

Pappert telephoned the 12 Canadian IVF clinics in December 1987, claiming to be a prospective IVF patient seeking information.

"Seven of the clinics reported success rates far in excess of their actual birth rates," Pappert reported. "Only when asked did most clinics admit the rate was based on pregnancies and not births."

Pappert wrote: "The Toronto Fertility and Sterility Institute, a private clinic run by Dr. Firouz Khamsi, said it has a 20 to 25 per cent success rate, 'like everybody else's,' and some births. Dr. Khamsi later refused to answer repeated questions about how many babies had been born. But Dr. Allan Zerafa, an associate at the institute, said the clinic had two pregnancies and no births in two years of operation."

The IVF clinic at Chedoke–McMaster Hospital in Hamilton, Ontario, which has treated 250 women and had 22 pregnancies and 17 births, is now conducting the world's first random trial comparing the success of IVF with spontaneous conception, Pappert reports.

Of the more than 150 IVF clinics in the United States, half have never had a birth, and only a handful have had more than five. Fifty percent of all the US test tube babies come from three clinics, Pappert notes.

ANN PAPPERT. 1988, February 6. In vitro in trouble, critics warn. Critics worry women not told of fertilization program risks. *Globe and Mail*, Toronto. February 8. Success rates quoted by in vitro clinics not what they seem. *Globe and Mail*.

High IVF failure rates exposed in Australia

"... a fertile woman who is fitted with an intrauterine contraceptive device has almost as much chance of becoming pregnant as does an infertile woman of having a healthy baby after an in vitro fertilization treatment cycle," writes Dr. Ditta Bartels in an analysis of IVF pregnancy statistics in *The Medical Journal of Australia*.

Australia has a national registry of IVF pregnancies run collaboratively by the Perinatal Statistics Unit at the School of Public Health and Tropical Medicine at the University of Sydney and the Fertility Society of Australia.

Bartels notes that the IVF team at Monash University in Melbourne is the most successful IVF team in Australia and possibly worldwide. But even so, she writes, according to the data from the national registry, "a woman who undergoes an in vitro fertilization treatment cycle only has a 7.9 percent chance of giving birth to a live and healthy baby. At the other in vitro fertilization centres, this chance decreases considerably, so much so that it comes into the range of failure rates for contraception with an intrauterine device!"

In her article, Dr. Bartels, lecturer in the School of Science and Technology Studies at the University of New South Wales in Sydney, reports the following:

For the period 1979 to 1985, the Perinatal Statistics Unit recorded a total of 1510 IVF pregnancies. Of these, 251 ended in a pre-clinical abortion, 292 ended in a spontaneous abortion and 65 pregnancies were ectopic. This left 902 viable pregnancies. Of these, 22.2 percent were multiple, with 169 of them twin and 32 triplet pregnancies.

In 47 of the 902 pregnancies, the babies were dead at birth or soon afterward. In 25 more pregnancies, the babies had major congenital defects. And in a further 112 pregnancies, the babies were severely premature and weighed less than 2000 g.

In total, there were an estimated 140 problematic pregnancies.

If that figure is added to the 608 nonviable in–vitro fertilization pregnancies that resulted in preclinical or spontaneous abortions, or pregnancies that had to be terminated because they were ectopic, "it can be seen that only 762 or half the total number of in vitro fertilization pregnancies in fact resulted in the birth of babies who were not dead, or seriously underweight or who did not have major congenital defects."

Bartels points out that "enormous resources have been spent by the Australian community on unsuccessful in vitro fertilization treatments and on the care of seriously underweight and deformed congenitally in vitro fertilization babies. In the light of the shrinking resources that are available for medical care, it is important to consider whether the sums that are spent on in vitro fertilization programmes and the intensive care of in vitro fertilization babies could not be better spent on more pressing health needs."

DITTA BARTELS. 1987, November 16. High failure rates in in–vitro fertilization treatments. *The Medical Journal of Australia* 147: 474–475.

Physicians ask themselves: "Are we exploiting the infertile couple?"

A group of physicians actively engaged in infertility treatment have written an editorial in *Fertility and Sterility* to address what they call a creeping problem in American gynecology: exploitation of the infertile.

The physicians address several areas of infertility practice that are susceptible to exploitation, including inappropriate use of credentials.

They note the proliferation of courses dealing with various topics in infertility, including IVF and laser surgery. Most of these courses are short, do not provide significant clinical training and do not objectively evaluate what the participants have learned.

"However," the physicians write, "the course brochures often advertise 'certificates suitable for framing' after course completion."

Patients may assume that physicians displaying these certificates have special competence in such areas as IVF and laser surgery, the group warns. But the courses do not train the physician in the appropriate application of the technology. The physician may return to the community and begin applying a technology in which he or she is inadequately trained, which may lead to exploitation of the patient.

The group writes that the "lack of standards and absence of a credentialing process with IVF" is "disturbing."

It writes: "It has become commonplace for practitioners to visit academic or private IVF programs for a short time and then return to their hospitals and attempt to open IVF or GIFT programs. The motive for establishing such programs may not be a strong interest in IVF or the desire to fill a void in the community, but an attempt by a hospital corporation to increase its market share. Considering that half of the IVF programs that have been established in the country have no pregnancies, it would seem that the standards of practice are variable."

In a section on the misuse of new reproductive technologies, the group writes that physicians have been using IVF to treat patients who have been incompletely evaluated. Physicians, they write, should guard against putting a patient through IVF, GIFT, or laser surgery unnecessarily and prematurely.

The authors note that each of them has observed the occurrence of pregnancies *independent of treatment* in couples who have undergone or are contemplating advanced infertility therapies. Before moving on to advanced therapy, physicians should make sure that the previous treatments have been systematic and thorough and that enough time has been left for those treatments to work.

The physician's preoccupation with pregnancy rates for IVF may confuse and mislead patients, the authors write.

They object to the following practices:

• Claiming a high pregnancy rate based on a limited number of chemical pregnancies ("misleading," particularly when it is take home baby rates that the patients are interested in).

- Quoting a high pregnancy rate based on young patients with only tubal disease and applying it to patients of all ages and diagnoses ("deceptive").
- Quoting the pregnancy rate for a limited time period when results are particularly favorable.

"We believe that patients should be told the respective IVF center's pregnancy and birth rates for their particular problem and age group," the authors write. "Conversely, patients who are unlikely to conceive with IVF should be accepted into the program, and should not be excluded to protect pregnancy rates."

RICHARD E. BLACKWELL, BRUCE R. CARR, R. JEFFREY CHANG, ALAN H. DECHERNEY, ARTHUR F. HANEY, WILLIAM R. KEYE, JR., ROBERT W. JOHN ROCK. REBAR. A. ZEV ROSENWAKS, MACHELLE M. SEIBEL, and MICHAEL R. SOULES. 1987. Are we exploiting the infertile couple? Fertility and Sterility 48(5): 735-739.

Ethicist calls IVF experimental

At an Anglo–American conference on biomedical ethics, ethicist Arthur L. Caplan said that IVF can be considered safe for the babies produced through it, but can by no means be considered effective and nonexperimental.

According to Dr. Veasy C. Buttram Jr., president of the American Fertility Society (AFS), the AFS voted nearly three years ago at their annual meeting that IVF no longer be considered investigational.

But Dr. Caplan, of the University of Minnesota Center for Biomedical Ethics, Minneapolis, said that the usual measure used by insurers to evaluate a treatment's efficacy is a 50 percent success rate over a five-year period, based on the performance of all providers.

If the birth of a normal baby is considered "success," he said, then even at the most experienced centers, this is achieved only 10 to 15 percent of the time.

Ob. Gyn News, reporting on Caplan's speech, stated: "The failure to view IVF

as experimental leads to a 'regrettable indifference' on the part of many in the field to the need for creating adequate international data bases."

1987, September 1. Calls IVF safe but questions efficacy rates. *Ob. Gyn News* **22**(17), 3.

Bacterial infection of eggs during in-vitro fertilization

Bacterial infection of eggs may occur during IVF, say Dr. Soon Chye Ng and associates at National University Hospital in Singapore.

The egg from a 40-year-old woman undergoing IVF became infected with the bacteria *Klebsiella*, probably the first reported case of its kind. Neither the husband's sperm nor contamination were probable sources of the infection. The woman may have had sub-clinical *Klebsiella* infection of the urinary tract.

Ob. Gyn News reports: "Bacteremia may result in its seeding in the growing and highly vascularized follicle. The *Klebsiella* may then have spread in vitro through the four spermatozoa–containing tubes into which the oocytes were introduced."

Oocytic bacterial infection during invitro fertilization. 1988. *Ob. Gyn News* **23**(4).

New freezing technique for human eggs

One woman became pregnant and subsequently delivered a child after invitro fertilization using an egg frozen by a new technique. The slow-freeze and slow-thaw technique used on that egg may improve the survival of frozen, unfertilized eggs and may lead to a greater number of successful pregnancies, say Dr. J. F. H. M. van Eum and associates at the University of Erlangen-Nuremberg in the Federal Republic of Germany.

Ob. Gyn News reports: "In the new technique, the oocyte is reduced in size by needle dissection of the cumulus incubated, and then placed in a computer–controlled freezing device that permits ice crystals to form at the ideal temperature

range around the freezing point of the medium. This approach, called self–seeding, minimizes the damage of the freezing process."

Of 28 human eggs frozen in this way, 7 survived. After in–vitro fertilization of the cryopreserved eggs, embryos were transferred into.two women. One woman who, *Ob. Gyn News* notes, "had previously failed a standard in–vitro fertilization procedure," came through this time and delivered a daughter.

New techniques may improve survival of frozen oocytes. 1988. *Ob. Gyn News* **23**(4), 49.

New egg bank coming

Physicians at the Toronto East General Hospital's in–vitro clinic will start a donor egg program this spring, making it only the second of its kind in North America. (The first is the egg bank at Cleveland Clinic Hospital in Ohio.) The clinic plans to circulate a pamphlet to physicians asking women to donate their eggs to women who do not produce eggs of their own.

Dr. Peter Leung, medical and scientific director of the lab at the IVF clinic, told reporter Ann Pappert: "If they have a patient undergoing a hysterectomy or a tubal ligation, she might volunteer to donate her eggs."

He expects a good response because, he said, "Women tend to be more sympathetic than men."

Pappert reports: "Women who volunteer will be given hormones to produce extra eggs. Surgery to retrieve the eggs from the donor would be coordinated with the menstrual cycle of the woman selected to be the recipient... There are no plans to pay the women for donor eggs, although Dr. Leung said the recipients may be charged for the costs of the hormone therapy for their donors."

ANN PAPPERT. 1988, February 9. New technology poses ethical dilemma. *The Globe and Mail*, Toronto.

Egg donor programs proliferating

Donated embryo transfer programs are proliferating, reports Nadine Brozan of *The New York Times*. In January, new ones were scheduled to begin at Pennsylvania Hospital in Philadelphia and at the University of Washington School of Medicine in Seattle.

In the following few months, programs will begin at New York Hospital–Cornell Medical Center, Cedars Sinai Medical Center in Los Angeles, Mount Sinai Medical Center in New York, and Mount Sinai Medical Center in Chicago.

Centers with programs already underway include the Albert Einstein College of Medicine, which runs the program at the Women's Medical Pavilion in Dobbs Ferry, New York; the Jones Institute of Reproductive Medicine in Norfolk, VA; the Fertility Institute of New Orleans; the University of California at Irvine; Beth Israel Hospital in Boston; the Cleveland Clinic Hospital; and the Yale University School of Medicine in New Haven, CT.

Brozan reports: "No one knows how many pregnancies or babies have resulted."

Women in IVF programs have become reluctant to give up their extra eggs for donation, according to one IVF clinic director, so other egg sources have had to be found.

Some programs will only take women who bring their own donors. Others use women who are having tubal ligation. The Cleveland Clinic recruits women from the public at large through publicity.

Egg donors must take hormones – mainly Pergonal and Clomid – for about a week in order to increase the production of eggs.

"Both medications are widely used for people with problems," Dr. Edward E. Wallach, chairman of obstetrics and gynecology at Johns Hopkins University School of Medicine, said. "But now we are using them for people without problems."

At the University of Washington, egg donors will receive \$500.

"It is for time and inconvenience," Dr. Michael Soules, director of the division of reproductive endocrinology there, told Brozan. "A donor goes to a lot of trouble. She has to have a procedure that is based on her menstrual cycle and not on a schedule, she must have five to eight days of injections, she must have blood drawn three times, she must have ultrasound, she must have 30 minutes of anesthesia. Nobody would do this for the money, and some people have told us it is not nearly enough."

NADINE BROZAN. 1988, January 18. Babies from donated eggs: growing use stirs questions. *The New York Times*, 1.

New IVF guidelines in Britain

"Pressure for rapid legislation on in vitro fertilization and embryo research is mounting in Britain following the flouting by a London clinic of voluntary guidelines," reports Nature's Simon "The Hadlington. privately funded Humana Hospital Wellington ignored guidelines imposed by the Voluntary Licensing Authority (VLA) by transferring more than four eggs at a time. The hospital has been struck off the VLA's list of approved clinics but remains free to continue to practice because the VLA has no statutory powers."

The VLA is thinking about changing its position on one of its guidelines. It previously ruled that a relative of an infertile woman would not be allowed to donate eggs to her. The VLA may allow this in the future.

SIMON HADLINGTON. 1987. IVF rules under pressure to change. *Nature* **329**: 474.

Woman suffers anguishing pregnancy with IVF quintuplets

Michelle L'Esperance gave birth to the first IVF quintuplets in the United States January 11, 1988. At the time of birth, she had three children. They are her children (aged 7 and 5) by a previous marriage, and her husband's 2-year-old son by his previous marriage. The couple wanted a child of their own but L'Esperance's fallopian tubes had been removed after her second pregnancy. She entered the IVF program at William Beaumont Hospital in Royal Oaks, Michigan.

The hormones given L'Esperance – first to stimulate her ovaries during the IVF procedure and later, during the last four months of pregnancy, to prevent miscarriage – caused her extreme emotional upset.

L'Esperance and her husband reacted differently to the news that she was carrying five fetuses.

"When they said, 'Five,' Ray walks out with his chest all puffed up, and I'm in tears," she said. "He thinks he did something real special and all I could think was, 'Oh my God, now what?""

By the second month, L'Esperance was bedridden and unable to work. Her husband switched to evening shifts so he could care for the children during the day. They moved to her parents' home because she needed care.

During the fourth month, she was given intravenous drip when she began hemorrhaging. From that point on, she remained in the hospital. As the babies grew, L'Esperance became increasingly uncomfortable, she said.

"Four of the babies were lying on one side and two of them had their heads on my diaphragm, so it was hard to breathe...Then there was Alexandria, who was in the birth canal the last three months... As time went on and they ran out of room, they got more active. It felt like I had aliens inside me."

As the fetuses grew, there was considerable pain for L'Esperance. Doctors progressively prescribed Tylenol, Tylenol with codeine, Demerol, and finally morphine. She became irritable at this point.

"I told my doctors they weren't treating me as a person but as a stomach with babies in it. I kept telling all of them, 'You're not listening to me. I can't take it anymore."" By the end of the pregnancy, she had gained 60 pounds, her scars from a tummy tuck were tearing, her bladder and cervix were pushed out of place, and she was unable to sleep because of the kicking.

She said: "Somebody was always up, and I'd just lie there watching the clock all night long. They would give me Nembutal to sleep but it wouldn't affect me. The only reason I took it was because it would knock the babies out."

With L'Esperance under full anesthesia, five babies were delivered by Caesarean section. She cried for three days following delivery.

The L'Esperances now face financial difficulties.

L'Esperance says: "Nobody in their right mind asks for quintuplets. But I'll tell you this: I feel real special because I feel that whoever is running things upstairs doesn't give anyone anything more than they can handle. And if he thinks I can handle this job then I must be special. There must be some reason for these babies. Either that or he has a grim sense of humor."

Doctors say the babies may be released in a month.

JULIE GREENWALT. 1988, February 15. Thankful for five tiny blessings. *People*, 92–100.

Former prostitute appeals hospital

decision to remove her from IVF program A former prostitute failed in a High

Court appeal against her removal from a British IVF program because she was considered unsuitable as a potential mother.

Janet Harriott, 36, convicted in 1969 for prostitution and running a brothel, had been misled over the reasons for her removal. She had originally been told the hosptital could not treat her because of an infection her husband had and because she had a liver function abnormality.

Harriott was informed of the true reason in September 1985, after the Infertility Services Ethical Committee of St. Mary's Hospital, Manchester, met and presumably discussed her case.

Justice Schiemann ruled that neither the ethical committee nor the physicians involved had acted unreasonably or unlawfully.

Schiemann did express concern that Harriott should have been allowed to suffer the discomfort of a laparoscopy (part of the IVF procedure) if the policy all along had been to exclude women considered "socially unfit" to be mothers.

Roger Bell, attorney for the hospital's ethical committee, argued that what had happened was part of the "doctor-patient relationship" and was not subject to judicial review.

Sarah Boseley of the *Guardian* reports: "The judge asked whether it would have been open to challenge, as a matter of public law, if a woman had been removed from the programme because she was Jewish. Mr. Bell said it would not."

SARAH BOSELEY. 1987, October 21. Ex-prostitute says doctors unfair on testtube baby. *Guardian* (London). Former prostitute loses test tube baby appeal. 1987, October 27. *Guardian*. The right to a baby. 1987, October 28. *Guardian*.

Getting rid of "extra" fetuses produced by IVF

Pregnancy reduction is a technique used to reduce multiple fetus pregnancies most often resulting from IVF and fertility drugs. In the first trimester, the doctor guides a needle injecting potassium chloride into the fetus' chest.

The fetus dies and is eventually absorbed into the body.

Dr. Lawrence Platt of the University of Southern California Medical Center in Los Angeles says the procedure is "a risk to the mother and the continuing pregnancy." He explains possible complications: the woman could start bleeding or go into labor, losing all the fetuses; infection could develop; bleeding in the uterus could cause neurological damage to remaining fetuses.

George Annas, professor of health law at Boston University, asks how women can give informed consent to this procedure when no reliable data on effectiveness and safety exist.

GINA KOLATA. 1988, January 25. Multiple fetuses raise new issues tied to abortion. *The New York Times*, 1.

Fear grows that world trade in stockpiled embryos could grow

"Scientists fear that unscrupulous dealers may set up an international trade in frozen embryos from the 10,000 stockpiled around the world unless controls are introduced," Andrew Veitch of the *Guardian* reports.

Nearly 3000 embryos are stored in Britain at the Bourne Hall IVF clinic of Patrick Steptoe and Robert Edwards in Cambridge, at the private Cromwell Hospital in London, and at the American Medical International clinic at Nottingham.

Most of the rest are stored in France and Australia.

At a conference of the European Society of Human Reproduction and Embryology in Toulouse, Dr. Michelle Plachot of the Marignan clinic in Paris called for a European-wide code of practice to prevent a baby trade and put a time limit on embryo storage.

The numbers of stored embryos will grow because some patients never return, Robert Edwards, Bourne Hall clinic, told the conference. The women change their minds or the husband may die.

Women undergoing IVF can produce up to 47 eggs at a time but, in an attempt to avoid multiple pregnancies, most clinics won't transfer more than 4. The rest can be fertilized and frozen.

ANDREW VEITCH. 1987, October 5. Doctors fear world trade in stockpiled embryos. *Guardian*, 4.

GAMETE INTRAFALLOPIAN TRANSFER (GIFT)

GIFT proclaimed effective

After six of eight women with premature ovarian failure who underwent

GIFT with donated eggs became pregnant, Dr. Ricardo H. Asch declared that patients with this condition have an impressively high pregnancy rate when treated with GIFT.

Asch, speaking at the American Fertility Society annual meeting in Reno, Nevada, said three women have had babies and three more are in the second or third trimester.

The administration of 17 beta– estradiol and progesterone in increasing doses is central to the success of GIFT in treating premature ovarian failure, according to Asch, an obstetrician– gynecologist at the University of California, Irvine. These hormones create a hormonal environment similar to that of a spontaneously ovulating woman, he said.

The pool of women who might be candidates for oocyte donation and GIFT is reportedly sizable. Premature ovarian failure affects 1 to 3 percent of women of childbearing age and 10 percent of women with primary or secondary amenorrhea.

The donated eggs could come from excess eggs taken from women undergoing in-vitro fertilization or GIFT, as was done in Asch's study. Or the eggs could be obtained from women undergoing laparoscopic sterilization or diagnostic laparoscopy. These women would have to receive clomiphene and/or human menopausal gonadotropin from stimulation, Asch said.

Asch explained that the first step in the treatment was steroid replacement to establish a menstrual cycle. On days 12 to 15 of the treatment cycle, the GIFT procedure was carried out. The administration of steroids was stopped at 100 days' gestation.

Asch's study won the General Session Prize Award as the outstanding presentation at the meeting.

GIFT, donated eggs to treat ovarian failure. 1987. *Ob. Gyn News* **22**(23).

Physicians suggest new approach to egg donation

Egg donation does not require a complex steroid replacement regimen for women with primary or secondary ovarian failure, according to Drs. Paul F. Serhal and Ian L. Craft, of University College and Middlesex School of Medicine in England. Nor does it require a synchronized luteinizing hormone surge between recipient and donor for normally cycling women, they say.

A simpler approach consisting of estradiol valerate, augmented with either oral or intramuscular progesterone starting on the day preceding the egg harvesting, may be just as effecive as the standard approach, regardless of whether the women were cycling normally or had ovarian failure, they say.

They base their conclusions on experiences with 17 women undergoing either GIFT or IVF.

An advantage of the new approach is that all procedures could be performed on an outpatient basis, and the simplicity of the regimen leads to greater patient compliance.

The women may be kept on estrogen from two to four weeks. This, the investigators say, allows great flexibility in planning the procedure for both egg donors and recipients.

In a related development, the first pregnancy in the United States using nonsurgical donor egg transfer in a woman with ovarian failure has been reported. Dr. Mark V. Sauer of Harbor– UCLA Medical Center in Torrance, California, and his associates report on a 37–year–old woman with Hodgkin's lymphoma who experienced ovarian failure after chemotherapy.

The physicians placed her on ovarian steroid replacement and then synchronized her cycle with that of a 22– year-old donor. After insemination, the uterus of the 22–year–old woman was flushed out, a mature blastocyst was obtained and transferred into the uterus of the 37-year-old. After eight weeks, there is a pregnancy with fetal heart activity.

Ob. Gyn News reports: "These results suggest that donor ovum transfer may be

an attractive alternative for women experiencing ovarian failure."

Estradiol plus progesterone before ovum donation. 1988. *Ob. Gyn News* **23**(2), 22.

New variation on IVF: Intratubal insemination

After the birth of two children conceived through intratubal insemination, Dr. Gary S. Berger said that this method may become an alternative to gamete intrafallopian transfer.

The live birth rate was 7 percent for 28 treatment cycles in 20 women who underwent intratubal insemination.

The laparoscopic procedure, done under local anesthesia and I–V diazepam, was performed during ovulation cycles controlled with human menopausal gonadotropin and human chorionic gonadotropin approximately 34 to 36 hours after the HCG injection. Women were discharged about an hour after the insemination. No ovarian manipulation for follicle aspiration is involved in the procedure.

Intratubal insemination: Alternative to intrafallopian transfer? 1988. *Ob. Gyn News* **23**(1).

SEX PREDETERMINATION

Sex predetermination in livestock

Farmers may soon be able to choose the sex of livestock produced by embryo transfer, *New Scientist* reports. It quotes Joe Sreenan of the Agricultural Institute in Ireland as saying, "Sexing embryos is very close to being a commercial proposition."

New Scientist states: "Gary Anderson of the University of California at Davis...has recently sexed embryos of cattle, sheep and pigs with an accuracy of more than 80 percent. Several companies in the US are now developing kits that could determine an embryo's sex quickly on the farm. The kits will exploit the fact that only male embryos have a certain molecule on their surface...Sexing sperm remains a more distant prospect." GAIL VINES. 1987. Choosing sex to beef up cattle farming. *New Scientist* 17 September: 42.

SURROGACY

"Surrogate" mother dies in USA

Denise Mounce, 24, died of heart failure while in her eighth month of a "surrogate" pregnancy arranged by the surrogate broker, Gene Search, Inc. The woman, who was to have been paid \$10,000 when she turned her baby over to the sperm donor customer, had a history of heart problems. Many are now wondering why she was accepted onto a surrogacy program. Her parents are considering legal action against the surrogate broker, citing negligence.

CATHY GORDON. 1987, November 11. Secret surrogate. *Houston Chronicle*.

Surrogate agencies close in France

Michele Barzach, the French minister for health and the family has ordered that the three surrogacy agencies operating in France be closed down, *Nature* reports. He states that the agencies are breaking French law. He refers specifically to Clause 351 of the civil law that states that "it is an offence for an individual to incite a woman to enter into an agreement to abandon her child." The three agencies are Alma Mater, Sainte-Sarah and Anias.

PC. 1987. Surrogacy agencies shut. *Nature* **329:** 753.

Coalition in the Federal Republic of Germany succeeds in closing down surrogate mother business

Following a campaign by a large coalition of surrogacy opponents, a German court ordered the immediate closing of a North American surrogate mother business, United Family International, January 6. The court declared that the business, operating in Frankfurt, was contrary to the country's adoption laws and to basic moral principles. United Family International had denied promoting surrogate motherhood. All it did, it stated, was advise potential clients about opportunities for surrogacy in the United States.

The Minister of Youth, Family, Women and Health, Rita Sussmuth, had described the business as an affront to human dignity.

The ruling overturned a lower court decision that the Frankfurt authorities had failed to give sufficient reasons for closing the business.

United Family International, which opened October 1, 1987, was part of the Infertility Center of Michigan, the company that organized the controversial adoption of Baby M by the sperm donor against the wishes of the mother, Mary Beth Whitehead.

On October 9, the company was told that it was in violation of the German adoption law and was thus subject to being fined. According to *Nature's* Steve Dickman, United Family International representative Franklin Torch had maintained that "West Germany is powerless to challenge" his company, which signs no contracts with the wouldbe parents but rather refers them to its parent company in the US."

United Family International has supplied American women to sperm donors from France, Italy, Israel, Greece and Australia.

New York Times. 1988, January 7. German court shuts center for surrogate motherhood; STEVEN DICKMAN. 1987. West German ructions over US surrogacy company. *Nature* **329:** 577

FETAL TISSUE

Use of fetal tissues for transplantation spreading

There is considerable interest in using tissues from aborted fetuses for transplantation purposes. In Sweden, human fetal brain cells have been transplanted into rats with a disease similar to Huntington's chorea. Human trials of the method are expected to begin soon. According to *Newsweek*, "Dr. Robert Gale of the University of California, Los Angeles, USA, implanted liver cells from aborted fetuses into three of the victims he treated after the Chernobyl nuclear plant disaster in the USSR. Gale hoped the cells would multiply and replace the bone marrow that had been destroyed by high doses of radiation...but all three died from burns before the results of the therapy could be determined...Gale is doing more testing in animals before he tries again to implant fetal cells in humans."

Another physician, Dr. Kevin Lafferty of the University of Colorado, is experimenting with a new way to treat diabetes. He is now implanting preinsulin–producing cells from fetal pancreases under the skin of the groin in diabetic patients.

Surgeons in the Federal Republic of Germany recently transplanted fetal kidneys into three patients.

M. CLARK et al. 1987. Should medicine use the unborn? *Newsweek* September 14: 50–51.

GERMAN POLICE RAIDS

Protest rallies held against police raids of German technology critics

Thousands of people participated in rallies and meetings to express solidarity with feminists and others subjected to police raids and arrests in the Federal Republic of Germany December 18.

In numerous commentaries, the actions by the German equivalent of the FBI (the Bundeskriminalamt) were characterized as attempts to criminalize critics of genetic technology and reproductive medicine.

Massive rallies were held in support of the two arrested women – Ursula Penselin and Ingrid Strobl-in Hamburg, Cologne, and Berlin. Penselin and Strobl, both wellknown and highly respected writers and activists, are now in prison.

In an open letter to national and regional government officials, Green Party members of the German Congress (Bundestag) judged the police raids "an attempt to stamp women and groups who are critical of the technology as members of terrorist organizations and to hinder them in their work," *Gen-Ethischer Informationasdienst* reports.

The Association of Feminist Attorneys sent a letter to a minister of the North Rhein–Westphalen government protesting against the "illegal action of the attorney general." In May 1986, the Association rejected in-vitro fertilization, characterizing it as a new means of oppressing women. The attorneys fear that IVF offers the basic technology for selection, manipulation, and human breeding in the tradition of Nazi racism.

Police staged 33 simultaneous raids, many of them against feminists, throughout the Federal Republic of Germany December 18 at 4:30 p.m. A total of 430 heavily armed police were involved. Fifteen to 30 in a group, they swept into homes and workplaces of activists in Cologne, Dortmund, and Dusseldorf. In Essen, Duisburg, Bochum, and Hamburg, the raids were directed overwhelmingly against feminist critics of genetic and reproductive technology, according to Prozessgruppe Hamburg, a watchdog group.

The women raided were forced to undress. All "non-changeable marks" on the bodies-scars, moles, etc. – were noted down in police records.

The targeted critics have written and spoken on such issues as in-vitro fertilization, amniocentesis, sex predetermination, and genetic engineering. They have actively opposed surrogate motherhood. Many supported a massive coalition formed to stop North American Noel Keane's attempt to open a branch of his surrogate business, United Family International, in Frankfurt.

Operating under the law's Paragraph129a, "Support or Membership in a Terrorist Organization," the police conducted the searches to ascertain whether any of the individuals were members of a terrorist organization. They were specifically looking for a group called Revolutionaren Zellen (Revolutionary Cells) and its feminist wing, Rote Zora (Red Zora). Paragraph 129a, added to the laws in 1977, was expanded at the beginning of 1987. Critics of this law have feared for years that it could be used to criminalize unpopular political activity in general.

The arrests of Penselin and Strobl do not seem suited to lay such fears to rest, comments *Gen-Ethischer Informationsdienst.*

Noting that last year Paragraph 129a was used against opponents of atomic energy and that this year it is being used against critics of genetic technology, the oppression of women, and German policies on assylum seekers, the Cologne magazine *Stadt-Revue* asked: "Who, if you please, is next?"

Penselin has been active in two groups in Hamburg – Women Against Genetic Engineering, and another group critiquing population control policies. Strobl, a journalist for eight years with the national feminist magazine *Emma*, has been writing a book and contributing to radio programming. Both women have been charged under Paragraph 129a.

Today in Germany, the sheer criticism of something is enough to bring gangs of armed terrorist-hunting police to your door, feminists interviewed from Germany told *off our backs*.*

In a telephone interview from Essen, physician Beate Zimmerman, one of the women raided, said: "I opened the door of my office and bluum! They came in like a herd of animals. About 15 of them. They ran into every room and stood there with their guns drawn. I said, 'What are you doing here? There is nothing here.' There were two patients sitting and trembling. Nothing else."

Zimmerman is one of the six women (two physicians and four social workers) who founded the Gene Archive in 1982, an archive housing material on all aspects – scientific, legal and political – of reproductive and genetic engineering.

^{*}A monthly U.S. feminist newspaper based in Washington, DC.

This includes the development of genetic engineering in agriculture and medicine, and in the production of Pharmaceuticals.

"We are working quite openly," Zimmerman said. "Everybody can come and use the archive. In the last year, we've done a lot of work with the women's church groups that are beginning to deal with this question."

Trade unions, political parties, students and teachers also use the archive.

Zimmerman and her colleagues participated in and helped organize the many conferences on reproductive and genetic engineering that have been held throughout Germany since 1985.

"Last October, we organized the most recent meeting of the movement Women Against Genetic and Reproductive Engineering," Zimmerman said. "It was then, for the first time, we realized that the police were watching us. They put us under surveillance and followed us in their cars."

The archive is located next to Zimmerman's practice, in the same building. Before conducting the raid, police cordoned off the street.

"Most of the police were in the archives looking at every single paper, every picture," Zimmerman said. "They took photographs all over, of everything we had on the wall, even the map of the world."

In the nationwide raids, officials from the Bundeskriminalamt and local police confiscated materials from the archives and from private apartments and homes. They seized drafts of the women's speeches, material prepared for seminars, names and addresses of those attending seminars, published work, videos, tapes of radio programs, scientific articles, postcards, brochures, and private address books.

"From the archives, they took with them mainly materials about prenatal diagnosis and genetic counselling," Zimmerman said.

Last summer, she said, women's groups in Germany conducted an

information campaign on these practices, distributing material on the streets and entering hospitals and genetic counselling centers to talk with people there.

"The people were mostly interested in that and in one packet of material about developments in the pharmaceutical industry in genetic areas, and about the involvement of institutions and universities in this industrial development."

At the police station, Zimmerman said, the women had to take off their clothes.

"They wrote down my scars," she said. "They would put down, for example, 'One scar on the bottom, one on the back, another on the belly.' Every part of my body had a number and they described it. It's a criminalogical technique."

German feminists have developed a strong critique of the use of reproductive and genetic technology as a weapon of social control and of its role in the world marketing strategies of the multinational corporations.

Since 1985, the discussion and critique of reproductive and genetic engineering has moved well beyond the feminist movement into society at large. Trade unions, church groups, and political parties have become engaged in a critical discussion of these issues.

Last November, a group of Protestant women issued strong statements against reproductive and genetic engineering for the Kirchentag (National Association of Protestant Churches). They have organized many seminars and conferences on this issue.

Catholic women's groups have organized at least three different seminars and workshops. They also issued two resolutions – one in 1986 and another in 1987 – criticizing the technologies.

The Hausfrauen Bund (the Housewives' League) met to discuss this issue in Bonn on January 19.

On another level, in 1985 and 1986, the militant group Rote Zora attacked the facilities of the Gene Center in Heidelberg, the Max-Planck Institute for Reproductive Research in Cologne, and the Human Genetics Institute of the University of Munster.

The police raids appear to be an attempt to stop the widespread antigenetic technology movement in Germany by linking legal organizations with more militant ones, said Maria Mies, author of *Patriarchy and Accumulation on a World Scale* and professor of sociology at the Fachhochschule in Cologne, in a telephone interview with *off our backs* from her home.

"No concrete accusation or crime was being investigated," she pointed out. "This means that women doing 'Aufklarungsarbeit,' that is, researching reproductive or genetic engineering, or talking about it or giving seminars, are already doing enough to provide a pretext for the attorney general to launch such a police action."

Mies, an organizer of the world's first massive feminist conference against reproductive and genetic technology–the historic 1985 conference in Bonn – said of the police action: "We think it is an effort to criminalize and intimidate the whole protest movement of women against reproductive and genetic engineering and to frighten others away from participating in order to prevent the movement from spreading even more widely."

In a report on "Political Security News" July 24, 1986, the physicians' journal *Die Neue Arztliche*, warned against the critics of reproductive and genetic technology, stating that today they are practicing "verbal radicalism" (Verbalradikalismus), but that this might turn into an active radicalism.

"Many organizations in Germany discuss the benefits and risks of genetic technologies." reproductive and Zimmerman said. "But in the feminist movement, as well as here at our archives, we see no benefits. We have to warn about the risks. In this sense, we are We stand radical. clearly against reproductive and genetic engineering. We think they are trying to criminalize this position and say: If you are radical against this, then that's a verbal radicalism which

is very near to becoming an active terrorist."

According to Prozessgruppe Hamburg, the international Human Genetics Congress in Berlin in 1986 (for which eight Berlin women's groups organized a simultaneous five-day "Anti-Genetics Congress") tookplace under police watch. And when women's groups met in Marburg to work on the issues of reproductive and genetic engineering, the Bundeskriminalamt warned the Human Genetics Institute and the facilities conducting genetic technology research of the meeting.

Asked why he thought groups like Rote Zora did such things as attack facilities where genetic and reproductive technology was being developed. Bunderkriminalamt spokesman Alexander Prechtel told Gena Corea: "I think the real reason is that they don't like any government, any state, any authority. Because of that, they would like to have anarchy. Everything which is the state is their enemy and the biggest enemies of all are the United States and German governments and the German institutions that are representative of the United States and Europe. They see them as the enemy because there is authority there and they see a little bit oflaw and order. They want to have a state without rules, without law, so that everyone can do whatever he wants."

CHRISTIAN STERNBERG. 1988, February. Kritik an Gentechnik weckt Terrorismusverdacht. Gen-Ethischer Informationsdienst. 29. A.S. 1988, February. Was soll das? Emma; GENA COREA, 1988, March. German police raid activists, off our backs. 1988, January 1– February 29. Wer ist, bitteschon, die nachste? Stadt-Revue (Cologne).

CAESAREAN SECTIONS – MEDICINE AND THE LAW

Fewest births occurred on Sundays in the United States in 1985: Phenomenon linked to Caesarean sections More babies were born on weekdays than on weekends or holidays in the United States in 1985, according to a final analysis of government natality statistics for that year. On the peak day, Tuesday, an average of 26 percent more babies were born than on Sunday, the day that the fewest births occurred.

This phenomenon can be explained in part by the steadily increasing proportion of deliveries by a Caesarean section, *Ob*. *Gyn News* reports; repeat Caesareans typically are scheduled well in advance.

Childbearing hits high in unmarried women. 1987. *Ob. Gyn News* **22**(21), 2.

Young woman dies after forced Caesarean; court upholds hospital's right to operate on the woman against her will

A court issued a ruling in Washington last summer that forced a dying woman to have a Caesarean section in a failed attempt to save the fetus. The District of Columbia Court of Appeals affirmed that ruling in a written opinion.

"Angie C," 28, a terminally ill leukemia patient at George Washington University Hospital, Washington, was forced to submit to a court-ordered Caesarean section against her expressly stated wishes, the wishes of her family, and the judgment of her physician team. Hospital officials asked the D.C. Superior Court to order the surgery when they deemed that the woman had only two days to live and that there was a good chance of saving the 26-week-old fetus.

The baby girl died a few hours after the surgery. The mother died two days later.

Angie's father, Daniel Stoner, said at an emotional press conference: "For 14 years our daughter was considered terminally ill and what right did the court have to decide that her life was over?"

Appeals court Judge Frank Q. Nebeker, in an opinion filed last December to explain the appellate panel's ruling, wrote that "with an unborn child, the state's interest in preserving the health of the child may run squarely against the mother's interest in her bodily integrity."

At the press conference, Angie C.'s mother, Nettie Stoner, said that last June the hospital had telephoned her and her husband to tell them that Angie was not doing well. The couple called a priest and he gave Angie the last rites. A few minutes later, Stoner said, the hospital staff told them they were needed at a short meeting.

"They did not tell us it was a court hearing," Stoner said. "It took all day. Poor Angie, first she's told she's dying and the next thing everybody abandons her and leaves her alone in her room..."

"Then even before the hearing was over they started prepping her for surgery. She was already in so much pain."

"We told the judge she didn't want the surgery, that we didn't want her to suffer anymore, that we didn't think the baby would live. But they didn't listen. After the surgery and after they told her the baby was dead, I think Angie just gave up."

In November, a coalition of feminist, religious, civil rights, and medical groups asked the District of Columbia Court of Appeals to rehear the case.

American Civil Liberties Union attorney Lynn Paltrow commented: "This case sets precedent for court orders that could require pregnant women to stay in bed, to stay home from work, or to eat certain foods if such activities were beneficial to the fetus. It also sets a precedent to balance the life of any terminally ill person against another, and could force them to donate organs or other body parts for the sake of other people."

(See "At Issue" column by Janice G. Raymond for relevant commentary.)

1987, December 25. Drama in the womb: a matter of life and death winds up in court. *Los Angeles Times;* 1988, January 15, 5. Coalition opposes ruling that upheld court–ordered Caesarean. *Ob. Gyn News* **23**(2), 1.

POPULATION POLICIES

Breeding politics in Singapore

In 1983, the Prime Minister of Singapore tried to encourage female college graduates who were single to marry and have several children. At that time, many such women were remaining single or, if married, having only one child.

Two years later, the government had added a computer dating system to try to match up graduates of both sexes and introduced a system of broad benefits to female graduates having a third child.

Neither policy was popular and the birth rate is still declining.

In April 1987, the Singapore Medical Association held a conference on the theme "Reversing the falling birth rate."

New Scientist's Diana Smith writes that the prime minister's son "said that financial incentives alone might not be enough to bring about an increase in the number of babies being born in Singapore. He asked doctors to help to create a new social climate in which couples would put behind them their adherence to the 'stop at two' policy which had operated for the past 20 years. He urged doctors to increase the social pressure on couples 'who could afford it' to have more children...For example, he recommended that married women should be talked out of having an abortion even if they felt they were 'not ready' for another baby. Similarly, women who marry late should be encouraged to come forward for medical attention as soon as possible if they do not conceive."

DIANA SMITH. 1987. A question of breeding. *New Scientist* September 3: 70.

Family planning in China not succeeding

China has been trying to enforce a policy of one child per family with mixed results.

Most families in the countryside have two anyway, even if they have to pay penalties. The one-child policy became especially unpopular after zealous officials forced women to undergo abortions.

Women who have had two children are encouraged to have an IUD inserted to prevent a third.

At the same time, doctors are trying to treat childless couples since it is socially very difficult not to have a child in China. The Swedish doctor Karl–Gosta Nygren from Sofiahemmet in Stockholm is in charge of a WHO project in Peking. He has been treating 12 childless couples and is also instructing 50 Chinese doctors in fertility treatments.

GORAN LEIJONHUFVUD. 1987. Ffamilje-planering lyckas inte i Kina. *Dagens Nyheter* 29 September.

STERILITY AND MALE CONTRACEPTION

Scandinavian sperm getting worse

A new Swedish-Norwegian study of Scandinavian men shows that the sperm count in 30-year-olds had declined to half what it was 20 to 30 years ago. Because this seems to be correlated with living in large cities, environmental poisons are suspected. The researchers plan to study infertile couples to try to see what environmental factors they may have been exposed to.

GUN LEANDER. 1987. Spermierna var dugligare forr. *Dagens Nyheter*. 11 September.

Soybean diet may contribute to sterility

New Scientist reports that cheetahs in North American zoos have a high mortality and low birth rate and that a large number of baby cheetahs never reach adulthood. Cheetahs in South African breeding farms do not have these problems.

The difference seems to be related to diet. The cheetahs in South Africa eat carcasses whereas those in North America are fed a commercial cat food consisting of horse meat and soybean products.

The soybeans were found to contain chemical compounds that are similar to

estrogen. Estrogen is known to have effects on the liver as well as on reproduction (birth control pills contain estrogen) and the soybean estrogens are probably the cause of the cheetahs' problems.

These results have raised "questions about the possible effects on human physiology of the increasing amounts of soyabean products we are all eating."

Zoo diet to blame for cheetahs' sterility. 1987. *New Scientist* October 1:31.

Contraceptive pill for men seen on the horizon (again)

"A contraceptive pill for men is now nearer to reality," according to *New Scientist's* Sharon Kingman. One hundred couples at eight medical centers in different parts of the world will take part in the first clinical tests. The men will receive weekly injections of the hormone testosterone and doctors hope eventually to develop a long-lasting injection or a pill, Kingman writes.

Testosterone "suppresses the hormones from the pituitary, the gland at the base of the brain that controls the sex hormones and normally stimulates the production of sperm," she explains.

After the injections, the men produce little or no sperm. When tested in the laboratory, "the sperm of these men has proved unable to fertilize eggs," Kingman writes.

According to one of the doctors involved, "If all goes well with this trial ... it will be 10 to 15 years before anything will be available on prescription."

SHARON KINGMAN. 1987. Rising hopes for male contraceptive. *New Scientist* August 20: 14.

PRENATAL DIAGNOSIS

Umbilical blood sampling opens doors to treatment of fetuses

Percutaneous umbilical blood sampling (PUBS) during pregnancy is one of the "hot topics" in prenatal diagnosis because it opens the door to treatment of the fetus while in the mother's body, Dr. Michael L. Socol said at an ob. gyn. update in Traverse City, Michigan, USA. It offers the potential to deliver drugs to the fetus.

PUBS, which can be used to diagnose Rh isoimmunization and such in-utero infections as toxoplasmosis and rubella, will not have as great an impact as amniocentesis in terms of the numbers of women it will apply to, Socol, of Northwestern University Medical School in Chicago, said.

He has performed about 30 intrauterine transfusions and about 30 samplings for prenatal diagnosis using PUBS.

Under ultrasound guidance, the physician passes a 22–gauge spinal needle through the placenta (if necessary) and into the umbilical cord, obtaining approximately 4 to 6 cc of blood.

Possible complications are similar to those of amniocentesis and include a pregnancy loss rate in the range of 1 to 2 percent.

Method opens door to antenatal therapy. 1987. *Ob. Gyn News* **22**(21), 1.

Risk of infection in amniocentesis following chorionic villi sampling

A series of letters published in the British medical journal *The Lancet* concluded that amniocentesis after chorionic villi sampling may be associated with an increased risk of intrauterine infection attributable to either procedure. But the risk can be reduced by taking precautions during the sampling. Multiple insertions of the sampling device through the cervical canal should be avoided. The transabdominal route should be used whenever difficulties with transcervical sampling are expected.

Infection risk in amniocentesis following chorionic villi sampling. 1988. *Ob. Gyn News* **23**(3), 53.

Embryo screening on the horizon

Vogue reports that embryo biopsy, a new technique for detecting genetic

disease now being explored in London and Edinburgh, promises to revolutionize prenatal screening.

The embryo can be flushed out, screened in the laboratory for specific genetic or chromosomal abnormalities and, if the embryo passes the screening, returned to the woman's uterus. In IVF, the embryo can be screened and transferred only if there is no evidence of defect.

"This means the trauma of an abortion is avoided completely," *Vogue's* Susan Downie commented.

Researchers can now remove one or two cells from an eight-cell embryo, a procedure which reportedly has no adverse effects on the baby's development.

A team at the Hammersmith Hospital, London, plans to use the new method on volunteers in early 1988 to detect a very rare genetic defect, Lesh-Nyhan syndrome.

Vogue reports: "At Edinburgh University, researchers have established a technique for detecting the sex of embryos that will enable them to eliminate sex– linked diseases, such as haemophilia and Duchenne muscular dystrophy which are carried by the mother and only appear in male children."

SUSAN DOWNIE. 1987, December. Embryo Screening. *Vogue*.

BODY BANKS

Deepfreeze next step in controlling life?

Will Paul Segall become as famous as his fellow physiologist, Robert Edwards, the test tube baby king?, asks *New Scientist's* Donald Gould.

Segall noticed that Canadian frogs could tolerate being frozen over the winter. They secrete glycerol into their blood and tissues before winter and this acts as an antifreeze. (Glycerol is what sperm and embryos are treated with before they are frozen.)

Segall has exchanged blood with a glycerol mixture in hamsters and dogs, frozen them and then thawed them and

replaced their blood. They survived without any noticeable negative effects.

Segall plans to test monkeys next and he forsees the use of this method on humans such as "sufferers from dreadful maladies, like Alzheimer's disease and certain cancers" who could be frozen until a cure is found.

So what does this have to do with Robert Edwards, the co-lab parent of the world's first test-tube baby?

Gould writes: "In 1965, this then young and unknown physiologist published a paper in *The Lancet* describing the 'apparent fertilisation' of human ova by human spermatozoa'" in the laboratory.

The British researcher Sir Peter Medawar said at that time, "'Some people might look at this work and start thinking in terms of test-tube babies, but test-tube babies are out, and this isn't the importance of the discovery at all.' … Alexander Comfort said, There might well be an uproar, arising from the fear that we shall now start culturing human babies from embryos in test tubes, but people who protest will never ask themselves why anybody should want to do this. The normal method is more fitting.""

Gould continues: "So what's happened? Exactly! The moral is of course that once something can be done it will be done and no laws or pronouncements of committees or any other kinds of hinderance ...will stop the process. Thus we may confidently look forward to the establishment of ... body banks."

DONALD GOULD. 1987. Beyond the fringe. *New Scientist* August 6: 64.

GENETIC ENGINEERING

Fluorescent bacteria to be tested soon

According to Carol Ezzell, the U.S. Environmental Protection Agency (EPA) "approved the first field test of a recombinant organism to fall under the Toxic Substances Control Act."

The chemical company Monsanto will be allowed to test a strain of *Pseudomonas*

aureofaciens that has been manipulated to include a gene for fluorescence (it glows in the dark) and a marker gene so it can be tracked in the environment.

Monsanto plans to engineer the bacteria further by implanting genes for important proteins once it knows more how the bacteria move within the environment.

A previous release of a manipulated bacteria was approved by the EPA using another regulatory statute. In that case, EPA used the Federal Insecticide, Fungicide and Rodenticide Act to approve the release of "ice-minus" bacteria on a field of strawberries, classifying ice as a "pest."

New Scientist reports that the bacteria in the Monsanto test will be sprayed on winter wheat and later that soybeans and then winter wheat will be planted in the same field to see how long the bacteria survive.

CAROL EZZEL. 1987. Field test for bright bacteria to go ahead soon. *Nature* **329:** 757. Why engineered genes may glow in the dark. *New Scientist* October 29: 28.

New heart drug receives approval

The U.S. Food and Drug Administration (FDA) announced in November its approval of a blood clot dissolving drug called tissue plasminogen activator (TAP), according to *Nature* and *Science*.

Genentech, Inc. produces tissue plasminogen activator by genetic engineering methods. The drug is expected to be the first billion dollar product of the biotechnology industry.

Tissue plasminogen has been shown to disolve blood clots and is especially useful for heart attack victims. However, the FDA refused to approve the drug in June 1987 calling for more clinical data. According to *Nature*, the new data demonstrated the drug's efficacy and also showed that the side effects are not serious.

Science states that the new drug, called Activase, is ten times more expensive than

streptokinase, the current drug used to dissolve clots. But Activase is twice as effective as streptokinase.

Genentech has already had tissue plasminogen activator on the market in Austria, West Germany, France, New Zealand, South Korea, and the Phillippines via a foreign license to Boehringer Ingelheim, says *Science*.

MAJORIE SUN. 1987. New data clinch heart drug approval. *Science* **238**: 1031; CAROL EZZELL. 1987. TPA freed for US use at last. *Nature* **330**: 200.

Genentech wins broad patent

Nature reports that Genentech has received a "broad patent covering molecular biological tools used to create proteins from genetically engineered organisms." This may give Genentech the right to collect royalties from "every company selling products made by genetic engineering."

Genentech may use the patent to corner the biotechnology market by locking out its competitors.

CAROL EZZEL. 1987. Patent office decision puts Genentech out in front. *Nature* **330:** 97.

Drugs from milk?

"Genetic engineers in the US have created mutant mice that secrete a valuable human drug in the female's milk," *New Scientist* reports. "The scientists say their technique, the first ever to turn lactation into drug manufacture, could make goats, cows or any lactating mammals into protein factories."

The transgenic mice have been produced by Integrated Genetics and the National Institutes of Health and contain a human gene for tissue plasminogen activator (TPA). TPA is being produced by several companies but they all use bacteria or other manipulated microorgnisms. Transgenic animals "out produce bacteria by 10 to 100 times."

Lactating for drugs. 1987. New Scientist. October 29: 26.

European Commission recommends more biotech

"The European Commission is calling for a 14 million British pound expansion of its biotechnology programme to update information systems, improve training and make room for new European Community members Spain and Portugal," *Nature* states. "The present 39 million pound programme expires in 1989. A five-year follow-up is scheduled to start in 1990."

In *New Scientist* it is reported that "Britain has established two research centres to investigate the industrial aspects of biotechnology. They will receive 3.5 million pounds over the next four years to learn more about how to scale up biological processes from the laboratory to the factory.

S.L.H. 1987. Biotech expansion. *Nature* 330: 97; 1987 Funds for scaling up biotechnology. *New Scientist* October 29: 27.

Man convicted by DNA fingerprint

A British court convicted a man for rape based on the results of a genetic "fingerprint", *Nature* reports.

DNA fingerprinting is a method developed by a British scientist and is based on the fact that everyone has a unique combination of genetic material. This can be used for identification purposes, as in this case where

DNA samples taken from the victim matched the DNA of the rapist.

The method of DNA fingerprinting is owned by ICI (Imperial Chemicals Industries) and is now available as a kit. The company expects an increase in demand for the kits now that the method has been used successfully in court.

S.J.H. 1987. DNA fingerprint ruling. *Nature* **330**: 197.

DNA fingerprinting to be used by British immigration authorities

"Immigration authorities in Britain are considering the introduction of the DNA fingerprinting test ... as a routine procedure to establish paternity, depending on the results of a trial now in progress," Kathy Johnston reports in *Nature*, "But immigrants' associations are concerned at the social implications if the test becomes compulsory. ..."

"Immigration authorities are carrying out a trial of the genetic technique on 35 families from Bangladesh and Pakistan ... Immigrants' representatives are worried about the possibility that the technique may become routine procedure. In addition to questions about civil liberties, the representatives say there are also serious social implications for marriages in the highly conservative Asian societies if the fingerprinting proves non-paternity."

KATHY JOHNSTON. 1987. UK immigration authorities may use DNA fingerprinting. *Nature* **329:** 5.

DNA fingerprinting spreads to the United States

"British technology for 'fingerprinting' individuals by their DNA has arrived in America." New Scientist reports. "Cellmark Diagnostics, a subsidiary of Imperial Chemicals Industries (ICI) ... offered police departments, courts, and immigration officials in the US the services of DNA fingerprinting. ... An committee the advisorv to US government's National Crime Information Center" has suggested "that the centre's computers carry genetic information on convicted criminals" based on the fingerprinting test.

1987. DNA fingerprinting crosses Atlantic. *New Scientist* September 24: 20.

New laboratory involved in Human Genome Project

Lawrence Berkeley Laboratory has been chosen by the Department of Energy (DOE) as one of two centers for human genetic studies. *Nature* reports that this is somewhat of a surprise since it was assumed that Lawrence Livermore National Laboratory would be involved because of its work on chromosome sorting. Lawrence Berkeley Laboratory has the computer facilities required for producing a physical map of the human genome.

MARCIA BARINAGA AND JOSEPH PALCA. 1987. New lease of life for Lawrence Berkeley Laboratory. *Nature* **330:** 9.

New techniques needed for mapping human genome

Scientists' enthusiasm for mapping the human genome (all human genes) is far ahead of their ability to accomplish the task. New techniques and new machines are needed for the project. According to *New Scientist*, the U.S. Department of Energy (DOE) "believes that the US is in a three–way race with Japan and Europe" over mapping the human genome.

To help, automatic sequencers have been developed and an American company now offers such a machine. Two more companies are developing sequencing machines.

Walter Gilbert, the man who upset the research community with his plans to copyright the human genome, has developed a new technique for sequencing that he calls multiplex sequencing. But he refuses to discuss details of the method.

Science reports that Japan is spending U.S. \$1 million per year on developing sequencing techniques.

Powerful new tools in race to identify genomes. 1987. *New Scientist* October 15: 36; LESLIE ROBERTS. 1987. New sequencers to take on the genome. *Science* **238:** 271–273.

What will sequencing the human genome cost?

Ever since the idea of sequencing the human genome got off the ground, the cost of the project has caused the most concern. Initially it was estimated to cost \$3 billion and fears were expressed that this project could only be funded if other researcher projects had their funding reduced.

In a recent meeting in the United States, some of the major researchers

involved in the project discussed both funding and research strategy. According to *Science*, they "compiled a menu of sorts for Congress on what components the project will likely include and how much each might cost: the genetic map, a guide to the loci of known genes; the physical map, a complete ordered set of DNA fragments; and the sequence itself – the exact chemical order of the three billion ... base pairs that make up the genome."

All three projects are underway and it is the cost of each that is debatable. For instance, the price of sequencing the genome may go down as the system is automated, but there is a relatively high error rate which may mean the genome must be sequenced up to 10 times to ensure accuracy.

When all the costs are added up, it looks as if the original \$3 billion estimate "might not be that far off," *Science* comments.

Nature reports: "If Senator Pete Domenici has his way, US law will require that the human genome be mapped and sequenced as rapidly as possible... A primary goal of Domenici's bill is to improve US economic competitiveness." He has especially asked experts to answer questions "on what specific benefits sequencing the human genome would have for US competitiveness in high technology."

LESLIE ROBERTS. 1987. Human genome: Questions of cost. *Science* 237: 1411–1412; JOSEPH PALCA and CAROL EZZELL. 1987. US Congress adds its voice to the genome–sequencing chorus. *Nature* 329: 280.

Genome map causes controversy

In mid-October 1987, researchers at Collaborative Research, Inc. announced that they had made "the world's first genetic linkage map of the entire human genome," according to *Nature*.

This map, *New Scientist* reports, "is a rough chart of molecular signposts along the 23 pairs of human chromosomes." The

map is made up of 403 markers that can then be used to locate important genes. The probes are being patented as Collaborative Research is interested in developing diagnostic tests for genetic diseases.

But the development of the map has not been without controversy. *Science* reports that many scientists are critical over "how complete the map is, whether publication is premature, and how much credit the company can rightfully claim."

At the heart of the matter is a longterm conflict between two research groups. Raymond White of the Howard Hughes Medical Institute and Helen Donis-Keller of Collaborative Research started a cooperative project to map the cystic fibrosis gene.

A disagreement led the two to end their cooperation and start rival research groups that have been competing in the research for markers along the chromosomes.

Many criticize Collaborative Research's Donis–Keller for announcing the map in order to win publicity for her company. Donis–Keller's rival, White, doesn't think that what she and her group have done should be called a map yet.

Many point out that a fourth of the probes used by Collaborative Research were previously developed by White who had then made them available to other researchers via Centre d'Etude du Polymorphisme Humain in France.

Many feel that the broader research community has contributed to the progress Collaborative Research has made.

Raymond White is working on a more thorough map that has many more markers than Helen Donis-Keller's map, *Science* reports.

MARCIA BARINAGA. 1987. Critics denounce first genome map as premature. *Nature* **329:** 571; CHRISTOPHER JOYCE. 1987. Mapped genome moves a step nearer. *New Scientist* October 15: 24; LESLIE ROBERTS. 1987. Flap arises over genetic map. *Science* **238:** 750–752.

Common European biotechnology guidelines?

European countries have been dealing with the regulation of biotechnology separately leading to widely varying policies. But, writes David Dickson in *Science*, "the development of acceptable safety guidelines for releasing genetically altered microorganisms into the environment is currently the biggest outstanding issue in the regulation of biotechnology."

The different policies developed by different countries in relation to environmental release are seen as a threat to Europe's competitiveness.

European countries now fall into three categories on the regulation of the deliberate release of genetically engineered organisms into the environment, Dickson continues.

"The first are the 'yes, but' countries – those that have said they approve of such practices in principle, but have designed a carefully controlled approval process in which each project is assessed by a range of government agencies before being given the go-ahead."

Britain and France have this type of policy and the Netherlands is setting up a similar one.

A second group of countries has chosen the "no, but" policy, Dickson writes.

"Here the philosophy is to impose a general ban on all deliberate release experiments, on the grounds that more information is needed on the likely hazards."

Denmark and the Federal Republic of Germany have adopted this policy.

The seven other countries in the European Economic Community (EEC) have developed no policies yet. This situation is being used by the United States' Advanced Genetic Sciences, Inc. to test its "ice–minus" bacteria in Italy where there are no regulations.

The EEC is developing its own guidelines on the environmental release of engineered organisms that it then wants all member countries to adopt. This would require that countries that have different policies would have to change them to bring them into accord with the EECs new rules.

The EEC regulations would allow environmental release after a thorough evaluation "by what are referred to as the 'competent national authorities' (such as Britain's advisory committee) using a commonly agreed upon set of procedures."

Small experimental releases would only require that the commission be notified.

One controversial point in the proposed regulations would require that an application for a large-scale release would be circulated to all the member states. They would have 60 days to file an objection. Many biotechnology companies are upset by this as it would allow another country to veto such a release.

Another issue is whether or not other countries would be allowed to have more stringent regulations than EECs. This could force Denmark to lift its ban on environmental release.

DAVID DICKSON. 1987. Europe splits over gene regulation. *Science* **238**: 18–19.

Director in charge of U.S. biotech regulation linked to biotech firm

David Kingsbury, an assistant director at the National Science Foundation in the United States, is currently under investigation for his ties to a British biotechnology company, according to both *New Scientist* and *Science*.

In 1985, Kingsbury was elected chairman of the Biotechnology Science Coordinating Committee which oversees federal biotechnology regulations. In 1986, Kingsbury signed a paper reelecting himself as a member of the board of directors of IGB, Inc., a medical diagnostics research company and a part of Porton International PLC, Mark Crawford of *Science* states.

New Scientist writes that critics of the way biotechnology is being regulated in the United States said that many of the

scientists on key government committees were also consultants to the biotechnology industry.

Government officials are not allowed to be directors or to hold shares in companies that they are trying to regulate.

IAN ANDERSON and STEVE CONNOR. 1987. US questions gene regulator's links with Porton. *New Scientist* October 22: 24. *Mark Crawford*. 1987. Document links NSF official to biotech firm. *Science* 238: 742.

Critics protest India – United States pact on vaccine testing

"A cooperative Indo-US vaccine development program has been the subject of a sharp exchange of criticism in the Indian press and rebuttal by the Indian government," *Science's* John Walsh reports. "A main contention of the critics, denied by the government, is that U.S. drug companies intend to use the agreement to make India a testing ground for bioengineered vaccines, thereby bypassing stringent U.S. regulations on vaccine field trials on humans."

The United States plans to spend \$7.6 million on the project over the next five years and India will contribute \$2 million.

Critics were concerned about a research center for epidemiology that could be used by biological warfare researchers and also about weak safeguards for introducing engineered organisms into the environment, according to Walsh.

The government issued a statement that "no vaccine developed elsewhere will be tested in India unless it has been cleared for testing in the country in which it was developed."

The project is still being negotiated and two issues have still to be worked out: "protection of subjects in field trials of vaccines and provisions on patents, copyrights, and other intellectual property," writes Walsh.

K. S. Jayaraman writes in *Nature:* "Apart from the ethics of using Indians for trying out new vaccines, questions have

been raised about the desirability of giving the US access to militarily sensitive data on epidemiology and immunity profiles of the population."

The Indian researchers note that information on a population's immunity "can be of strategic importance.' The absence in India of yellow fever, or of a single case of overt AIDS may be due to a immunocompetence peculiar [natural immunity] of the Indian population; those knowledgeable about developments in biological warfare resent any collaboration that may enable outsiders to study the immunological 'herd structure' that apparently provides a natural barrier against certain infections."

Indian researchers want to be sure that "the project is under Indian control and that there is no military implication," Jayaraman writes.

JOHN WALSH. 1987. Indo-US vaccine pact disputed. *Science* **238**: 19; K. S. JAYARAMAN. 1987. Indian turmoil over planned US tests of new vaccines. *Nature* **329**: 94.

Is personality in our genes?

An article in *Science* addresses the issue of personality and inheritance. Using studies of identical and fraternal twins reared together or apart, researchers have tried for years to determine how much of people's behavior is genetic and how much is caused by environmental factors. This has created the field of behavioral genetics.

Behavioral genetics "involves attempts to quantify the relative genetic and contributions environmental the to behavioral differences between individuals through use of the questionnaires and objective tests," writes Constance Holden in Science.

According to J. Philippe Ruston of the University of Western Ontario, the following traits are largely genetic: "activity level, alcoholism, anxiety. criminality, dominance, extraversion, intelligence, locus of control [personal autonomy], manic-depressive psychosis, political attitudes, schizophrenia, sexuality, sociability. values. and vocational interests."

Personality is a relatively new frontier. But several researchers believe that many personality traits are also genetic. These results are controversial and are based on studies of relatively few groups of twins.

There is also criticism of the methodologies used since it is very difficult to find twins who, even though raised apart, have had little or no contact with one another.

Leon Kamin, psychologist at Princeton, accuses researchers in behavioral genetics of biological determinism.

CONSTANCE HOLDEN. 1987. The genetics of personality. *Science* **237**: 590–601.