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NEWS ON DEVELOPMENTS
CURRENT DEVELOPMENTS AND ISSUES: A SUMMARY

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MATERNAL MORTALITY

Giving birth kills half a million women each year

Worldwide, over half a million women die during pregnancy and childbirth each year. Ninety-nine percent of these deaths occur in the Third World.

Maternal mortality in Third World countries is the main cause of death of 25 % of all women of childbearing age, as compared to less than 1 % for the USA. Seventy-five percent of these deaths are caused by hemorrhage, infection, toxemia, obstructed labor, and unskilled abortion.

A major problem is the lack of access to health care, especially in emergencies. Poor women are faced with nonaccess because they cannot pay the costs of health care.

In many places, hospitals are understaffed, overworked, are lacking beds and basic medicines and much of the other equipment needed to treat those who do come to them. "Hidden within this general picture of underdevelopment and overstretched services is another potent factor in maternal death: sex discrimination," Sue Armstrong of *New Scientist* reports.

"It is no coincidence that the highest rates of maternal mortality are found in societies where the status of women is lowest. Yet sex discrimination as a contributory cause has been largely ignored: poverty is mistakenly assumed to put everyone — men, women and children — at equal disadvantage in health terms."

Risks of complications during pregnancy rise dramatically after the first three children. For example, a study in Portugal has shown that maternal mortality was three times higher in women giving birth for the fifth time than in women giving birth for the second time.

In many cultures, large families are a necessity for survival. But a World Fertility Survey has shown that the majority of women do not want to have so many children, but they do not have access to contraception. "The highest proportion of women not using contraceptives were women with little education," *New Scientist* states. "Studies show that women with seven or more years schooling are three times more likely than their unschooled sisters to use effective contraception."

Unwanted pregnancy is also responsible for 40 to 60 million women seeking abortion every year. For the majority, only backstreet operations are available, with a high mortality rate.

"Abortion causes more deaths among women of childbearing age in Latin America than any other single cause, and is cited as a major factor, if not the dominant one, in reports of maternal death from all corners of the world," *New Scientist* reports.

Another cause of complications in pregnancy and childbirth is that girl children in general receive less food, health care, and education than their brothers. In many cultures, girls are breast fed for shorter periods of time. This leads to stunted growth, malnutrition, and higher risk when they do get pregnant. And for many girls, this type of sex discrimination leads to their early death.

"On the Indian subcontinent, sex discrimination is so pervasive that every sixth death of a female

infant is due to neglect," writes Sue Armstrong. What do health care professionals see as a possible solution? Education to raise women's low social status, measures to raise women's living standards and the provision of good quality maternity care for dealing with the complications that do arise during pregnancy and birth.

SUE ARMSTRONG. March 31, 1990. Labor of death. *New Scientist*: 50–55.

BIRTH CONTROL

Norplant approved for use in United States

In mid-December 1990, the U.S. Food and Drug Administration granted approval to Norplant, a long-lasting contraceptive that is implanted under the skin in six matchstick-like flexible tubes. Already available in 16 other countries, Norplant's long-term safety has not yet been fully studied.

Norplant works by slowly releasing progestin, which along with estrogen is the active ingredient in most birth control pills. The six silicone tubes, which are implanted under the skin in the upper arm, can prevent pregnancy for up to five years. In clinical trials, it showed a failure rate of one-tenth to one-twentieth of birth control pills, which have a 3% failure rate.

Known side effects include irregular menstrual bleeding and oddly timed periods, sometimes as much as 7 weeks apart, often with heavier bleeding.

Although some see the five-year life of Norplant as a distinct advantage, critics are concerned that it can be used as a method of forced contraception. Once implanted, the tubes must be removed by a physician.

Isabel Sawhill, an economist at the Washington-based Urban Institute recently published a paper suggesting that all teenage women will be persuaded to use Norplant at puberty. "The decision to have a child would become a conscious choice," Sawhill wrote, "decoupled from the dictates of biology, hormones or peer pressure."

Although Sawhill did not suggest the use of Norplant be made mandatory, others believe recent decisions involving procreative liberty point in that direction.

Arthur Caplan, director of the Centre for Biomedical Ethics at the University of Minnesota, says, "There are judges out there who will try to use Norplant."

Norplant was developed by the Population Council and Wyeth-Arest Laboratories, a division of American Home Products Corp. of Philadelphia, Pennsylvania.

ANDREW PURVIS. December 24, 1990. A pill that gets under your skin. *Time Magazine.*

California judge orders woman to have contraceptive implanted

California judge Howard Broadman of Tulare County Superior Court ordered a convicted child abuser to have the contraceptive Norplant implanted in her arm as a condition of her probation. The woman, 27-year-old Darlene Johnson, who has four children and is currently pregnant, was convicted last year to several counts of felony child abuse for beating two of her children with a belt and an electrical cord. She will complete a jail sentence in April.

Judge Broadman, who acknowledged his ruling would undoubtedly be appealed by a higher court, said that he believed his ruling constitutionally supportable because the state had an interest in protecting children.

A memorandum the judge wrote in support of his ruling stated that Ms. Johnson "has shown herself incapable of caring for children." He referred not just to her present conviction, but to six previous convictions involving mainly theft and writing bad checks.

"In the present case," Judge Broadman wrote, "she has been convicted of brutally beating her children. It is in the defendant's best interests and certainly in an unconceived child's interest that she not have any more children until she is mentally and emotionally prepared to do so."

Johnson was ordered to attend parenting classes and receive counseling.

Johnson's lawyer, Charles Rothbaum, compared the order to a plot from a science fiction film. Rothbaum noted that Johnson has heart murmurs, high blood pressure, and diabetes, all of which made the use of Nor-plant unsuitable.

The judge said that he would rescind his order if doctors certified Norplant would present a risk to her health.

Rothbaum countered that although he was prepared to gather evidence to support the medical

claims, his greater concern was whether governments had a right to intervene in this way.

MICHAL LEV. January 11, 1991. Judge firm on forced contraception. *New York Times.*

Birth control using a modern form of the rhythm method

The rhythm method of birth control relies on monitoring changes in body temperature to chart when ovulation occurs, the period during the menstrual cycle when a woman can get pregnant. The major drawback of this method is that it is not very effective.

It requires taking one's temperature every day and long periods of abstaining from sexual intercourse. The only way to reduce the need for temperature monitoring and long periods of abstinence is to know more accurately the actual hormone levels in the body that control ovulation.

It is now possible, with the use of monoclonal antibody techniques, to measure the breakdown products of progestrone, the female sex hormone that increases after ovulation. Estrogen has proven to be more difficult to measure but simple tests will soon be available.

A possible future development would be a kit with two "dip sticks", one for each hormone. A woman could test a few drops of urine to determine what stage in the menstrual cycle she is in and thus whether or not she is in her fertile period.

CARL DJERASSI. 1990. Fertility awareness: jet-age rhythm method? *Science.* 248: 1061–1062.

New contraceptive shocks sperm

"A contraceptive which works by electrocuting sperm is being developed in the US," *New Scientist* reports. The device is a tiny version of a heart pacemaker which is placed in the woman's cervix.

The lithium iodide battery produces a current of 50 microamps which is then conducted across the cervix via mucus. The current stops the sperm within a few minutes. The researchers at Women's Medical Pavilion in New York are testing the pacemaker in baboons and believe the current it produces will keep sperm from entering the cervix. So far it has shown to be 100% effective in stopping sperm.

SUSAN HULME. May 12, 1990. The little shock that's too much for a sperm. *New Scientist*: 35.

ABORTION

Research on abortion suppressed during Reagan administration

"Leading health official of the former US president, Ronald Reagan, suppressed research on abortion because they opposed the procedure," *New Scientist* reports. The charges, made by a congressional committee, were specially aimed at the former surgeon general, C. Everett Koop, and officials at the Centers for Disease Control (CDC).

"According to the committee, Koop refused to publish a study of the physical and psychological effects on women of abortion because the study found no evidence that the procedure harms women," *New Scientist* continues. A scientist at the CDC doing research on abortion had his research results censored, and another scientist was demoted on orders from the White House because they thought his research appeared to support abortion.

In 1987, the White House commissioned a study on abortion that was to focus on the aftereffects. Koop consulted with 27 professional and scientific groups and then wrote a report stating that, "while no evidence existed of adverse physical effects, there was inadequate evidence to draw any conclusions about psychological damage," *New Scientist* states. Koop then decided against publishing the report and instead wrote a vaguely formulated letter to Reagan saying that the scientific evidence of physical or psychological aftereffects was inconclusive. This letter has been used by antiabortion groups to lobby against abortion.

"Representative Theodore Weiss, a Democrat from New York who oversaw the congressional investigation, says that the White House wanted Koop to produce a study that would condemn abortion. When the report failed to provide the evidence, says Weiss, Tie therefore decided not to issue a report, but instead to write a letter to the president which would be sufficiently vague as to avoid supporting the pro-choice position that abortion is safe for women,'" *New Scientist* reports.

CHRISTOPHER JOYCE. December 16, 1989.

Reagan's official 'suppressed' research on abortion. *New Scientist*: 14.

Attack on abortion pill

An international group of medical doctors wants the abortion pill, RU 486, withdrawn from use for medical reasons.

"A 'committee of inquiry' into the drug was set up in Rome . . . at a congress of doctors opposed to abortion and contraception," *New Scientist* reports. The group's claims are based on published literature and not on any research they have done.

Roussel Uclaf, the producer of RU 486 called their report "an amazing piece of intellectual dishonesty," *Nature* states. RU 486 is currently used only in France and is given together with prostaglandins to induce early abortions.

The drug can cause heavy bleeding, in some cases requiring blood transfusions. But only a few women have suffered from serious side effects after more than 40,000 abortions with RU 486.

SYLVIA HUGHES. May 5, 1990. Anti-abortionists renew attack on French pill. *New Scientist*: 21; PETER COLES. 1990. RU486 under attack. *Nature.* 345: 7.

RU 486 may be marketed in other countries in the future

The company Roussel Uclaf makes RU 486, the French abortion pill. The company is owned by Hoechst and has previously been prevented from marketing the drug outside of France because of Hoechst president Wolfgang Hilger's opposition to abortion.

But Roussel Uclaf is now being allowed to pursue product licences in other countries where abortion is not so controversial. These include Scandinavia and Britain.

Britain is the first country where Roussel Uclaf will probably market RU 486. Patients will be required to sign a consent form and the drug will only be administered by licensed abortion clinics. Roussel Uclaf also wants clinics to strictly obey the treatment protocol, which includes prostaglandins to ensure complete expulsion of the embryo.

In the United States, the state of California has announced plans to allow a clinical trial of RU 486. But Roussel Uclaf may decide to withhold the drug because of that vociferous antiabortion movement in the United States.

A 1987 California state law which was introduced to speed tests of AIDS drugs could be used to help RU 486 by-pass approval by the Federal Drug Administration.

Money for the trial has been promised by California's Attorney General John Van de Kamp and researchers at the University of California Medical School are preparing a protocol for the clinical trials. These moves are hoped to make Roussel Uclaf more receptive to applying for clinical trials. However representatives of Roussel Uclaf have stated they do not intend to apply for trials in the US in the foreseeable future.

New Scientist. December 16, 1989. Rethink on abortion pill. p. 15; *New Scientist.* July 21, 1990. Abortion pill in prospect for Britain, p. 20; DAVID CONCAR. 1990. Backdoor trial for US? *Nature.* 344: 696.

EMBRYO RESEARCH

Embryo research bill winds its way through British Parliament

The debate on whether to ban embryo research or allow it up to 14 days after fertilization began in mid-December 1989 and the final vote came in mid-year 1990. Members of Parliament were allowed to vote their conscience instead of following any party line.

A number of different interest groups were involved in lobbying for the two different versions and the British science journals *Nature* and *New Scientist* joined the fray, carrying numerous editorials in favor of embryo research. The arguments for research centered mainly on the possibilities of carrying out preimplantation diagnosis to detect genetic defects in embryos and helping infertile couples by improving in vitro fertilization.

The bill first wound its way through the House of Lords and then the House of Commons. The version of the bill allowing embryo research up to 14 days was approved by the majority in both houses.

As part of the legislative process numerous amendments were tacked onto the bill at various states. The amendment that would have banned producing embryos purely for research purposes was defeated. The government tried to change the limit for abortion from 28 weeks to 24 weeks but this was also defeated.

A Statutory Licensing Authority (SLA) was created to replace the voluntary authority that has tried to monitor IVF clinics in Britain. The SLA will be given the authority to licence IVF clinics as well as clinics carrying out GIFT (gamete intrafallopian transfer) which fell outside the voluntary authority's jurisdiction.

An extra clause in the bill will give a child born by IVF the right to sue doctors and scientists if it is born with a disability resulting from their negligence.

New Scientist. December 2, 1989. Health secretary to vote for embryo research, p. 27; *New Scientist.* December 2, 1989. Embryonic journey, p. 24; DAVID DICKSON. December 16, 1989. Lords speak out on embryo research. *New Scientist*: 13; JEREMY CHERFAS. 1989. Britain's Lords debate embryo research. *Science.* 246: 1554–1555; MARILYN MONK. January 6, 1990. Embryo research and genetic disease. *New Scientist*: 56–59; ANDY COGHLAN. February 17, 1990. Peersset the tone for Commons debate on embryo research. *New Scientist*: 19; 1990. Embryos win rights. *Nature.* 343: 577–578; *New Scientist.* March 17,1990. Lords' vote saves supply of research embryos, p. 22; GAIL VINES. March 31, 1990. Doctors warn of loophole in Embryo Bill. *New Scientist*, p. 21; CONSTANCE HOLDEN. 1990. Lords approve embryo research. *Science.* 247: 918; *Nature.* 1990. Abortion from a hat. 344: 476; *Nature.* 1990. Embryo research. 344: 690; PETER AL-DOUS. 1990. Pressure stepped up on embryo research. *Nature.* 344: 691; ANDY COGHLAN. April 28, 1990. Parliament gives overwhelming approval to embryo research. *New Scientist*: 29; GAIL VINES. May 19, 1990. Doctors' dilemma over GIFT and the government's bill. *New Scientist*: 23; GAIL VINES. May 26, 1990. Embryo Bill faces rocky ride in Commons. *New Scientist*: 18; PETER ALDHOUS. 1990. Still some life in the 'pro-lifers'. *Nature.* 345: 565; GAIL VINES. June 30, 1990. Amended Embryo Bill faces last hurdle. *New Scientist*: 34.

Embryo research proposed in Canada

"A top legal commission in Canada has recommended that research on embryos be permitted up to 14 days," *New Scientist* reports.

The recommendation on embryo research is part of a larger report on research on humans prepared by the Law Reform Commission of Canada. The report states that "conditions under which embryos could be used in research for 'non-therapeutic experimentation,'" *New Scientist* states. "Non-therapeutic experimentation" is defined as "research conducted solely for the advancement of knowledge."

"The report says that it is appropriate to legislate for a 14-day limit 'if only to ensure that research done in Canada will be as respected as that done in the rest of the world,'" *New Scientist* continues. "But not everyone is happy with this argument. 'Certainly it's the first time I've heard that it's OK to experiment on a human entity so that your research is "respected" in the rest of the world,' says Margaret Somerville, director of the McGill University Centre for Medicine, Ethics and Law in Montreal."

"The creation of embryos specifically for scientific experimentation should be strictly prohibited, the document declares. Likewise, certain experimental procedures, including cloning and the crossing of human and animal gametes, should be outlawed. Another recommendation is that reimplantation of experimentally altered fetuses should be illegal."

LEIGH DAYTON. January 6, 1990. Canada's lawyers push for 14-day limit on embryo research. *New Scientist*: 27.

France prepares embryo research bill

Embryo research up to 14 days after fertilization has been proposed in France within the framework of a comprehensive human biotechnology bill called the Life Sciences and Human Rights Bill. The embryo research part of the bill has sparked a controversial debate that has revealed a lack of unity in scientific and political circles.

The bill was hoped to have been passed during the bicentenary of the French Revolution in 1989 but may never make it into the law books. The bill would allow embryo research up to seven days with the couple's approval and this could be extended to 14 days if permission was granted from the National Ethics Committee. Frozen embryos could be stored for up to 5 years. The bill covers infertility treatment, prenatal diagnosis, genetic fingerprinting and would make surrogacy illegal.

Opponents of embryo research include scientists who are concerned about the potential danger of

eugenics they see behind research in artificial fertilization and embryology techniques. Others fear that if legislation is too restrictive, it will encourage embryo traffic from Third World countries.

SYLVIA HUGHES. January 20, 1990. French fall out over embryo ethics. *New Scientist*: 24.

IN VITRO FERTILIZATION

Criticism of IVF research ban in US

"A key congressional committee in Washington has sharply criticised the US government's 10-year-old ban on the use of federal funds for research on in vitro fertilisation and has recommended that the ban be lifted," *New Scientist* reports.

Scientists argue that such research is necessary to improve IVF success rates and to help infertile couples who "are spending their life savings on treatment that doesn't work," said Ted Weiss, chairman of the committee. IVF research is currently carried out only in privately funded clinics. The Ethics Advisory Board (EAB) within the Department of Health and Human Services approved of IVF research but was disbanded in 1980. This meant that proposals for such research could not be approved any longer. The ban has led to an exodus of government scientists to private IVF companies.

The committee considered it to be an "embarrassment" that the government has ignored the Department of Health and Human Services regulations that require it to set up the EAB. The Secretary for Health was also urged to "implement the board's recommendation, made in 1979 before its charter was allowed to expire, to exempt research on embryos less than 14 days old from the need to be reviewed by the EAB," *Nature* states.

CHRISTOPHER JOYCE. December 9, 1989. US government urged to spend money on embryo research. *New Scientist*: 17; CHRISTINE MCGOURTY. 1989. Reformation of advisory board urged. *Nature.* 342: 606.

Test-tube methods used for rare animals

The National Zoo in Washington, DC, now has a test-tube Siberian tiger. Siberian tigers are endangered species and only 200 are left in the wild. The zoo has invested 2 million dollars in in vitro fertilization technology in order to preserve endangered species.

Other zoos are following suit using more common related species as surrogate mothers for rarer species. Zebras have been born by horse mares and bongo calves have been born by eland. Researchers are now testing embryo transfer in wild surrogates as well.

In South Africa, embryos from the endangered sable have been transferred to wild gemsbok. Stress factors have limited the success of the method but it has worked in a few cases. This method could be used to implant embryos from the severely endangered black rhino into white rhino surrogate mothers.

SHIGEKO SEGAWA. 1990. Tigret spells hope for endangered species. *Nature.* 346: 5; SUE ARMSTRONG. July 21, 1990. Embryo transplants could save rare animals. *New Scientist*: 27.

Clinic advertises for eggs

"An infertility clinic in Cambridge [England] has achieved the distinction of being the first to advertise in print for women to donate eggs to infertile couples," *New Scientist* reports.

"An advertisement in the latest issue of *Centrepiece* published by the University Centre in Cambridge, seeks women who are 'fit, fertile, and under forty.'" The ad, placed by the Grange Infertility Centre, also seeks male sperm donors. Donors are paid for lost wages and expenses.

New Scientist. April 21, 1990. Eggs wanted, p. 26.

Study of IVF children in Great Britain

"Children conceived by in vitro fertilization (IVF) seem no more likely to suffer congenital abnormalities than the general population," *Nature* reports.

The British Medical Research Council has surveyed 1,267 IVF and gamete intrafallopian transfer (GIFT) pregnancies during 1978 to 1987. The pregnancies resulted in 1,581 live and stillbirths.

The infant mortality and stillbirth rates were twice the average in other births in Great Britain. The reason given was the large number of multiple births that occur with IVF and GIFT.

PETER ALDHOUS. 1990. Children 'normal'. *Nature.* 345: 283.

New medicare benefits to IVF and GIFT procedures in Australia

It was announced in the Australian Federal Budget in August 1990 that new comprehensive Medicare benefits will be provided for reproductive technologies such as IVF, GIFT (gamete intrafallopian transfer) and similar procedures.

A news release from the Federal Minister for Community Services and Health, Mr. Brian Howe, said "Under the new arrangements, different kinds of treatment cycles will be covered by Medicare items. Each of these items will include a number of services required during the treatment cycle, for example, pathology and ultrasound. Benefits will also be provided for embryology services and treatment counselling, which were not previously covered."

Benefits for treatment cycles involving hormone stimulation and monitoring will be limited to six times during a patient's lifetime. Mr. Howe said, "This takes into account evidence that about 90 per cent of women who become pregnant through IVF do so in four cycles or less. Couples won't be prevented from having more treatment involving hormone stimulation, but they won't get a rebate after six cycles."

There would be no such limitations on other new items such as IVF and GIFT cycles which do not involve hormone stimulation or those involving frozen embryo transfers. The new arrangements follow a two year review of IVF technologies by the Department of Community Services and Health, including extensive consultations with consumer groups and providers.

"This initiative is a response to the desire of infertile couples to bear and raise their own child with the assistance of these technologies. They also acknowledge that while these technologies are still developing, they are no longer purely experimental but are accepted medical procedures for the alleviation of infertility," Mr. Howe said. The Commonwealth government will spend 6 million Australian dollars in the next full year on the new benefits.

Note: Community Services and Health issued a report in 1988, *IVF Funding in Australia*, which estimated the average live birth rate at 8.8% per treatment cycle. The unproblematic birth rate was put at 4.8%. In that report, it was suggested that IVF was an experimental procedure which should not necessarily receive Medicare rebates, and that the whole question of success rates in relation to IVF was confused and obscure.

For example, pregnancy rates do not mean birth rates. Concern was also expressed about the lack of information about the long-term safety of some of the drugs and hormones used in IVF. The 1990 Federal Budget announcement appears to reflect a change in government policy, since it now said that IVF is an accepted part of infertility treatment.

Success rates are still modest to say the least. In the latest National Perinatal Statistics Unit analysis of IVF and GIFT pregnancies in Australia and New Zealand for 1988, the average live birth rate for IVF was 9.4 per 100 cycles. This indicates no change in the overall success rates. Also the announcement that $6 million would be spent in the next full year appears to be somewhat misleading. In the 1988 report from Community Services and Health, the total cost of IVF in 1987 was estimated at $30 million, and the subtotal cost of this to governments was $17 million. It must be assumed that the $6 million is an extra sum, possibly making the amount spent on IVF in the next full year through Medicare around $25 million (given that the 1987 figure would have risen).

Minister for Community Services and Health, 1990. News release: Medicare changes to benefit IVF patients. August 21; GAIL BATMAN. 1988. Commonwealth perspectives on IVF funding. Department of Community Services and Health. Canberra.

1989 results from the United States IVF-ET registry reported

The fourth annual report of the US registry of IVF and related practices was reported on in the January issue of *Fertility and Sterility.* The report summarizes IVF, GIFT, embryo transfer, ZIFT, frozen embryos and donated oocytes in 163 U.S. clinics for 1989.

In that year the reporting clinics initiated 24,183 stimulation cycles in 17,970 women. Eighty-four percent of cycles resulted in retrieval of oocytes. Of the 163 reporting clinics, 98% (159 clinics) had at least 1 live delivery.

There were 4,598 clinical pregnancies and 3,472 live deliveries of 4,736 babies. This included 881 sets of twins, 182 triplets, and 16 quadruplets. Multiple birth figures include stillborn births. There were 20 heterotopic pregnancies; 11 from IVF, 6 from GIFT and 3 combination IVF/GIFT procedures. The heterotopic pregnancies resulted in 12 live deliveries, 7 miscarriages, and 1 therapeutic abortion.

There were 2,876 IVF babies out of the total births reported; 24% were multiple deliveries. These included 550 twins, 107 triplets, and 10 quadruplets. Fifty-four percent of IVF clinics reported transferring an average of 3.5 embryos per procedure.

GIFT was done in 133 of reporting clinics. The 1,202 GIFT babies included 223 sets of twins, 63 triplets, and 4 quadruplets.

GIFT in combination with IVF was performed at 79 clinics. One hundred forty five babies were reported, including 25 sets of twins and 1 triplet. ZIFT, TET, and TPET accounted for 206 babies, including 35 twins, 8 triplets, and 2 quadruplets.

Of the thousands of reported cycles, only 52 natural cycles were reported. Ten percent (5) resulted in pregnancies delivered to term.

There were 1,448 cancelled cycles; defined as a cycle that does not result in egg retrieval. But of these cancelled cycles, 34% (344) went on to intrauterine or intracervical insemination and 8% (29) resulted in conception.

Not surprisingly, the highest pregnancy rates for IVF were reported in women with unexplained infertility.

In 1989, IVF clinics report 18,211 stimulation cycles of which 85% (15,392) resulted in egg retrievals. Eighty-seven percent of retrievals were by ultrasound, 8% by laparoscopy, 4% a combination of both, and 0.1% by laparotomy.

There were 2,124 frozen embryo transfer cycles reported in 110 clinics. The delivery rate of 8% produced 195 babies, including 23 twins. A total of 23,468 frozen embryos, obtained from IVF, was reported.

Thirty-four chromosomal abnormalities were reported and 28 different congenital malformations in 25 pregnancy outcomes.

Forty-eight of the clinics reported performing IVF with donated oocytes in 1989. There were 328 patients who underwent 377 donor transfers. Of these, 109 resulted in a pregnancy, and 81 live deliveries were reported. This included 25 twins and 3 triplets.

The registry reports that it appears that stimulation cycles are levelling off. Although there was an increase of 21% in the number of clinics reporting to the registry over the previous year, there was only a 7 % increase in stimulation cycles.

Fertility and Sterility. January 1991.

Transplanted eggs grow into functional ovaries

Researchers at the University Medical School in Edinburgh transplanted immature eggs into sterile mice and found that the eggs developed into a complete and functional ovary.

The immature eggs were removed from the ovaries of week-old mice. The method works both in mice made sterile by irradiation or where the ovaries are absent.

Scientists now are interested in finding out if the method works in women. The method could give women going through premature menopause or who have no ovaries a chance to have children after such a transplant. Or children going through cancer treatment could have the ovaries removed and the immature eggs could be stored frozen and transplanted back at adulthood.

"The best source for human follicles would be the prenatal ovary," states Roger Gosden, the scientist who discovered the method. Aborted fetuses would be one possible source but follicles do not develop until half-way through the pregnancy, a time when fewer abortions are done.

GAIL VINES. February 10, 1990. Transplanted eggs can create ovaries. *New Scientist*: 30.

First clinical trials of pre-implantation diagnosis held

Researchers at Hammersmith Hospital in England are now carrying out the first clinical trials of genetic screening of embryos, also known as preimplantation diagnosis.

Previous research in their labs has shown that it is possible to remove one cell from an eight-cell human embryo created by IVF without damaging the embryo. DNA from the removed cell has then been amplified using the polymerase chain reaction (a method that can rapidly create millions of copies of small amounts of DNA) and tested for genetic defects.

The clinical trial involves replacing the screened embryos back into the mother. The trial involves screening for sex-linked genetic diseases that are passed on to boys only so the embryos are screened for a genetic sequence on the Y-chromosome, which is only found in male embryos. Only female embryos are replaced in the mother.

Five couples have been treated. Two women became pregnant, both with twin girls. This was confirmed by carrying out chorion villi biopsy at 10 weeks of pregnancy.

The researchers are well aware of the ethical problems with sex determination. They do not think it ethical to use the method of embryo screening only to choose the sex of the baby. They hope that the newly formed Statutory Licensing Authority will be able to regulate this.

GAIL VINES. April 7, 1990. Test-tube embryos 'can survive' genetic screening. *New Scientist*: 30.
ALAN HANDYSIDE. April 21, 1990. Sex and the single cell. *New Scientist*: 34–35.

SURROGACY

Australian national bioethics consultative committee releases final report on surrogacy

The Australian National Bioethics Consultative Committee (NBCC) released its final report on surrogacy in June, 1990 (Surrogacy Report #1). The draft report or discussion paper was issued in September 1989 and was then open to submissions from the public. The recommendations of the final report are essentially the same as those put forward in the draft report: that surrogacy should not be prohibited and that its practice should be controlled by uniform legislation.

The NBCC discussed surrogacy as a legitimate means of alleviating infertility, and based its discussion on the principle of qualified personal autonomy, that any person should be free to make their own life decisions as long as it does not involve harm to others. Therefore a "surrogate" mother has the right to freely make decisions about the use of her own body. Couples have the right to seek a child through a surrogacy arrangement as long as "surrogate" mothers and children born through surrogacy arrangements are not used merely for the ends or purposes of others.

The final report had strong dissenting statements from two of the 13-member NBCC. Sister Regis Dunne, director of the Provincial Bioethics Centre for the Queensland Catholic Dioceses, said that she was unable to endorse the report. She opposed the treatment of women and children as commodities in surrogacy arrangements, the impact of legalized surrogacy arrangements on public policy, and the application of the principle of personal autonomy.

The principle she wrote "pays small regard to common interest, is unevenly applied to the woman who bears the child and mainly supports the case of the commissioning couple."

She also pointed out that there was no reason why IVF-assisted surrogacy arrangements would have a higher success rate than the current overall success rate of 10%. "If surrogacy is acknowledged, tolerated and legally established in Australia, we provide yet another means of exploiting the poor," she said.

She perceives "surrogacy as a further movement towards the commodification of life and towards treating people, and parts of people — organs, semen, eggs, embryos — as commodities in a consumer society."

The second dissenter, Ms. Heather Dietrich, a lecturer and researcher at the University of Technology in Sydney, said that surrogacy risked reducing women to extension instruments of a medical process and "surrogates" were expected to deny themselves, and the child they bore. "Knowing you were conceived deliberately to be given away could be . . . a painful reality for the child born," Ms. Dietrich said.

The surrogate mother could not know before she conceived and bore a child how she would feel about relinquishing it. Ms. Dietrich also commented that the pain of infertility should not be dismissed. "All of us would probably be tempted (to consider surrogacy) if we couldn't have a child. You'd want to close your eyes a bit. The aim should be not to criticize these people who are tempted but to criticize the doctors and public policy that should have a broader perspective," Ms. Dietrich stated.

Of the 142 public submissions received to the draft report, 58% disagreed with the preferred option of the NBCC that surrogacy be allowed but controlled. Only one submission supported uncontrolled surrogacy according to the *Sunday Age*.

However, this sway of community opinion did not influence the NBCC in its final deliberations. The NBCC was also divided between options 3 and 4 listed in the final report, which are ethically diametrically opposed. Option 3 said that there was nothing inherently immoral or antisocial in surrogacy arrangements, whereas option 4 said that surrogacy is undesirable in that there is real risk that harm will be caused as a result of such arrangements.

In fact the NBCC only reached consensus on appropriate and necessary uniform legislation, not on the social desirability of surrogacy. There have been nine other reports on surrogacy published thus far in Australia. None except the NBCC's report has encouraged surrogacy. A second discussion paper on the implementation of the recommendations of Surrogacy Report No. 1 was released in November 1990.

Surrogacy Report No. 1. 1990. Australian National Bioethics Consultative Committee; *The Sunday Age* (Melbourne). June 24, 1990.

Lobby by IVF doctor to approve IVF/ surrogacy in Victoria, Australia

Melbourne IVF doctor Professor John Leeton has presented a submission to the Victorian Standing Review and Advisory Committee on Infertility (SRACI) to approve IVF/surrogacy arrangements for seven women who want to bear children for their sisters or best friends. He claims that his submission hinges on the lack of any definition of infertility in the Victorian (Medical Procedures) Infertility Act of 1984.

If potential "surrogate" mothers can be defined as infertile, then they would be eligible to participate in the IVF procedure. Most of the seven women say they are prepared to undergo voluntary sterilization if it would help their sister or friend to have a child.

Professor Leeton claims that the risk of the birth mother bonding to the child would be minimised in cases of IVF/surrogacy arrangements where the pregnant woman is carrying a child that is genetically unrelated to her. Leeton advocates that the existing Victorian legislation be changed "to allow infertile couples the only chance of conceiving their own child."

Sunday Herald Melbourne. June 17, 1990; *Sunday Age* Melbourne. July 1, 1990.

SEX DETERMINATION

Sex of fetus determined by blood test

Blood from a pregnant woman contains cells from the fetus that have entered her bloodstream via the placenta. These cells can be tested using genetic screening methods.

The first experiments took advantage of a genetic screening method that can identify male fetuses based on genetic sequences of the Y chromosome, which is only found in males. The researchers used the test on 19 pregnant women and succeeded in identifying the genetic sequence in the 12 women who were pregnant with male fetuses. They found no such sequence in the 7 with female fetuses.

The researchers see the test as a method for determining the sex of the fetus in families that are affected by sex-linked genetic diseases such as hemophilia. In the future the test could be made more sensitive and thus be used to identify specific genetic diseases in fetuses. A blood test would be less invasive and would not put the woman or fetus at risk as is the case with other prenatal diagnosis methods.

New Scientist. December 16, 1989. Simple blood test reveals sex of fetus, p. 20.

Portable kit for sexing animal embryos available in Australia

"Scientists in Australia have developed a portable kit to sex animal embryos and split them to double their numbers-in a three-hour procedure that can take place on the farm," *New Scientist* reports. The method has shown to be very accurate and is being used to select seven-day-old embryos for embryo transfer to surrogate mothers.

Cows are first superovulated with hormones and then inseminated. The embryos are flushed out of the uterus and several cells from each embryo are removed. A segment of DNA is amplified using the polymerase chain reaction which can make millions of copies in a few hours. The DNA is then tested for the presence of sequences from the Y chromosome which is only found in males. The entire test can be done in one test-tube.

LIZ GLASGOW. December 9, 1989. Kit for sexing embryos sets to work down on the farm. *New Scientist*: 31.

Sex selection continues in India

"Legislative attempts to prevent the selective abortion of female fetuses in India's western state of Maharastra have failed according to an Indian pressure group, the Forum against Sex Determination and Sex Preselection," *Nature* reports. "In 1988, Maharastra enacted India's strictest legislation on the issue, banning the use of amniocentesis for fetal sex determination. But the political will needed to implement the act has failed to materialize and nationwide legislation on the misuse of medical techniques in sex-selective abortion is still lacking."

RADHAKRISHNA RAO. 1990. Sex selection continues in Maharastra. *Nature.* 343: 497.

Amniocentesis may cause ear problems in children

A study by researchers at the Hospital for Sick Children in Toronto, Canada, has found that the children of women who underwent amniocentesis during pregnancy were more likely to get ear infections. The researchers tested the children's hearing and found subtle differences in the way the ear responded to sound which seemed to be linked to changes in the stiffness of the eardrum.

They believe the changes occur because the pressure across the eardrum is disrupted when fluid is removed from the uterus.

JEREMY WEBB. April 21, 1990. Does amniocentesis have a long-term affect on children? *New Scientist*: 28.

FETAL TRANSPLANTS

Fetal nerve cell transplants relieve Parkinson's disease

Researchers at the University of Lund, Sweden, have succeeded in improving the condition of a patient with Parkinson's disease by transplanting human fetal nerve cells into his brain. It is the first verified case where such a transplant has worked. The nerve cells were obtained from eight- to nine-week-old aborted fetusus.

JEAN MARX. 1990. Fetal nerve grafts show promise in Parkinson's. *Science.* 247: 529; JENNIFER ALTMAN. February 17, 1990. First success for fetal transplants in Parkinson's disease. *New Scientist*: 31.

Baby born for bone marrow

A woman in California has acknowledged that she and her husband deliberately conceived a baby to serve as a potential bone marrow donor for their 17-year-old daughter. The daughter suffers from leukemia.

This has caused a "fierce debate in the medical community over the ethical implications," *New Scientist* reports. "Already some doctors have refused to provide genetic screening to parents who admit that they are looking for particular characteristics in their children and have made it clear that they are prepared to abort fetusus lacking these characteristics."

New Scientist. February 24, 1990. Bone marrow baby. p. 26.

GENETIC ENGINEERING

HUGO gets a new president

The Human Genome Organization (HUGO) has elected Walter Bodmer, director of research at the Imperial Cancer Research Fund in Britain, to be its new president. HUGO has also been recognized as a charitable foundation in Europe and the US which means it can accept donations. The Howard Hughes Medical Institute has decided to invest one million U.S. dollars in HUGO over a four-year period. The Wellcome Trust is also expected to donate the same amount.

HUGO scientists do not accept James Watson's threats of withholding data from countries that don't support the organization. They want all data to be freely available to all scientists.

CHRISTINE MCGOURTY. 1989. A new direction for HUGO. *Nature.* 342: 724; G. CHRISTOPHER ANDERSON. 1990. Howard Hughes gets HUGO off the ground. *Nature.* 345: 100; *New Scientist.* February 17, 1990. Wellcome to back genome project, p. 21; 1989. *Science.* HUGO: Genome data open to scientists. 246: 1565.

HUGO news in brief

"The National Institutes of Health is having a hard time coming up with conflict-free scientists to review the flood of applications for its new genome research center grants," Constance Holden of *Science* writes. The research community is very small and almost everyone involved in genetic mapping research has applied for research center

grants. NIH is trying to find reviewers "who are well versed in the genome project but not actively involved in it."

The Japanese government has decided not to contribute money to HUGO. James Watson, the director of the U.S. human genome project, has previously threatened to withhold data from Japanese scientists if Japan doesn't contribute to the project.

Researchers from 35 countries met in Paris in late January 1990 to discuss international cooperation within the human genome project. James Watson announced that an all out research effort to sequence the human genome would not begin for at least 5 years. This will give researchers time to develop methods needed to bring down the cost of sequencing. Watson has also softened his statements about withholding data from noncontributing countries. Watson now suggests that scientists sit on their data until it has been "fully interpreted", which could mean up to six months. In the United States, 3 % of the NIH budget for the genome project will be used to study the social consequences and ethical implications of the project.

The principle of scientific sharing of data is under pressure and may become a problem with the human genome project. Because many researchers are tied to commercial firms or universities that are interested in making profits on scientific discoveries made by their staffs, they are hindered or feel less inclined to share their data with colleagues. Several leaders in genetic engineering research say they feel there is a declining ethic towards academic openness. There is a tendency for some scientists to publish their data but to withhold critical information that might jeopardize a patent claim.

Other scientists have been using peer pressure and informal sanctions to force colleagues to share their data. As an example, Scripps Clinic of La Jolla developed a new method for producing antibodies using *E. coli.* Scripps insists that they are willing to share their discovery but only on certain conditions. These include not sharing the material with anyone else, notifying Scripps before publishing any data and giving Scripps first rights to any improvements on the method. Many scientists were angry with the conditions but signed to get the material. Paul Berg at the University of Berkeley took a different stance. "I said 'bullshit,' we've sent you all of our material; send us yours." Berg was sent the material without having to sign. Several journals and government grant givers are now drawing up guidelines requiring the free dissemination of raw data for publication or funding.

The first goal of the human genome project is a genetic map. The idea behind a genetic map is to identify landmarks along the chromosomes. The closer and more numerous the landmarks the better the resolution of the map. Landmarks can then be used to hunt for and map particular genes. Partial genetic maps have been used to identify genes for cystic fibrosis and Huntington's chorea. But although this is the first goal, very little has been done to achieve it. Scientists have been disappointed in the lack of support they have received. A genetic map is boring, routine work, not innovative research and therefore has not received proper funding. But it is a necessary step. Blame for the slow progress has also been aimed at the researchers themselves for putting their efforts into searching for disease genes, which brings both prestige and possible patents.

The complaints led the NIH Center for Human Genome Research to call a meeting of all involved in the genetic map. The scientists managed to come up with a plan for the mapping project and different research groups have agreed to work on mapping specific chromosomes.

CONSTANCE HOLDEN. 1990. NIH left peerless for genome centers. *Science.* 247: 1182; MICHAEL CROSS. January 6, 1990. Japan drags its feet on project to map the human genome. *New Scientist*: 25; DAVID SWIN-BANKS. 1990. No special treatment for HUGO. *Nature.* 343: 195; SYLVIA HUGHES. February 10, 1990. Five-year wait predicted for genome project. *New Scientist*: 23; *New Scientist.* February 24, 1990. Genome scientists map out details of five-year plan. p. 22; PETER COLES. 1990. Keeping them guessing. *Nature.* 343: 579; ELIOT MARSHALL. 1990. Data sharing: a declining ethic? *Science.* 248: 952–957; LESLIE ROBERTS. 1990. Whatever happened to the genetic map? *Science.* 247: 281–282; LESLIE ROBERTS. 1990. The genetic map is back on track after delays. *Science.* 248: 805.

Much ado about human genome project

James Watson, leader of the human genome

project, has written that the human genome project has greater significance for humans than sending a man to the moon. "A more important set of instruction books will never be found by human beings," Watson writes. "When finally interpreted, the genetic messages encoded within our DNA molecules will provide the ultimate answers to the chemical underpinnings of human existence."

New Scientist has begun a series of articles on the project, trying to determine what Great Britain's role will be in the project. "Involvement with the genome project is important for Britain," John Galloway writes. "Whoever gets the human genome data first will decide what will happen to them, and will be in an unassailable position to dictate terms over its commercial, including its medical, exploitation."

The Human Genome Mapping Project Resource Centre has recently been established at Northwick Park Hospital at Harrow in Middlesex, England. The center's strategy is to "go after the human genes that appear medically or commercially important, to sequence them and map their position within the genome," Galloway writes.

JAMES D. WATSON. 1990. The Human Genome Project: past, present and future. *Science.* 248: 44–49; ROGER LEWIN. July 21, 1990. In the beginning was the genome. *New Scientist*: 34–38; JOHN GALLOWAY. July 28, 1990. Britain and the human genome. *New Scientist*: 41–46.

Opposition to genome project grows

A growing number of scientists are protesting against the human genome project. They accuse the project of being bad science, diverting funds from other biological research and that it has grown too big, too fast.

Two letter-writing campaigns have resulted in at least 60 letters being sent to NIH and the White House urging a stop to the genome project. A letter written by a number of microbiologists and molecular geneticists has also been published in *Science.*

The conflict arises partly from the perception that the genome budget has grown while other research funding is being cut. The genome project has received generous funding and funding increases have come easily.

But, in July 1990, the House of Representatives Appropriations Committee decided to cut the genome project's budget request from 108 million U.S. dollars to 66 million dollars. This may be a signal that politicians are being swayed by the arguments made by the protesters or may be a signal that Congress has less confidence in the project than earlier.

LESLIE ROBERTS. 1990. Genome backlash going full force. *Science.* 248: 804; BERNARD D. DAVIS and colleagues. 1990. The human genome and other initiatives. *Science.* 249: 342–343; LESLIE ROBERTS. 1990. Tough times ahead for the genome project. *Science.* 248: 1600–1601; G. CHRISTOPHER ANDERSON. 1990. The honeymoon is over. *Nature.* 346: 309.

Plant genome agencies band together

"The four major US government agencies involved in mapping and sequencing of plant genomes agreed . . . to join forces and create a single project, focusing on *Arabidopsis thaliana*, in order to avoid the kind of inter-agency rivalries that marred the beginnings of the Human Genmome Project," *Nature* reports. The agencies involved are the National Science Foundation, which will coordinate the work, the National Institutes of Health, the Department of Energy and the Department of Agriculture.

The plant genome project will concentrate on existing laboratories, instead of building up special centers like the Human Genome Project.

G. CHRISTOPHER ANDERSON. 1990. Green scheme avoids quarrels. *Nature.* 345: 654.

Researchers hope for funding for animal genome projects

Animal researchers are hoping to cash in on some of the money in the human genome project. They are hoping to find the genes that control fat deposition so they can produce leaner cattle for the U.S. market.

Disease resistance, higher milk yields in cows, and larger litters in pigs are other goals. Genetic maps of the more important domestic animals are needed first and since many domestic animals are not very different genetically from people, the researchers hope they will benefit from funding within the human project.

LESLIE ROBERTS. 1990. An animal genome project? *Science.* 248: 550–552.

New DNA fingerprinting fiasco in the courts

A court case in Portland, Maine, has again called into question the reliability of DNA fingerprinting as evidence. A 5-year-old girl was sexually assaulted and blood from a man fitting the description of the attacker was tested to see if his DNA matched that of DNA from semen from the victim. The tests were sent to Lifecodes Inc. Lifecodes stated that the blood and semen DNA did not match.

A second man, not fitting the description, was also tested and his DNA did match according to Lifecodes.

However, the two fingerprints could not be superimposed on each other because of band shifting, where the bands have moved at different speeds on a gel. Band shifting is something that is rather common in DNA fingerprinting but there are ways of controlling for it using a probe in both prints for DNA found in everyone. This probe gives a correction factor that can then be used to compare two fingerprints.

Lifecodes used a probe that they claimed gave them a match. But by some mistake, Lifecodes had sent the defense a paper that showed they had tested a second such marker that gave a correction factor that would mean the two prints did not match.

"It *appeared* from what had happened that Lifecodes had done the most unscientific thing imaginable, which was they had hidden data, not disclosed data that did not agree with their conclusion," *Nature* reports. This is the second such blunder that Lifecodes has made where lack of scientific rigor has led to the evidence not being usable.

ALUN ANDERSON. 1989. DNA fingerprinting on trial. *Nature.* 342: 844; COLIN NORMAN. 1989. Maine case deals blow to DNA fingerprinting. *Science.* 246: 1556–1558.

Current status of DNA fingerprinting

Many think that DNA fingerprinting was rushed too quickly into U.S. courts. At first no one questioned their validity as evidence. But in 1989, some scientists began to question how reliable and accurate the tests were since there were no national standards for guaranteeing the quality of the results.

In several court cases, DNA fingerprints have not been used because the tests have not been done properly. Several problems have shown up with the tests. Contamination from bacteria, dirt, and chemicals is one problem. Careless laboratory practice may result in unreliable results.

How then are law enforcement agencies to know if the results are reliable or not?

In one test, three commercial laboratories were sent 50 unknown blood and semen samples. Two of them had false positives stating matches of blood and semen that actually came from two different people. The third laboratory had no false positives but couldn't decide with 14 of the samples. When they reanalyzed the samples they failed to identify the samples that had mixed material from two individuals. These results have not been very reassuring.

Other criticism comes from scientists who question the statistics being used to calculate how often two different people's DNA prints match by chance. Most of the information available is based on DNA prints of only several hundred individuals.

The FBI in the US estimates that the chance of two people having an identical DNA fingerprint is one in a million. But population biologists state that that is only true in populations that find partners at random. That is not true for many human populations which means the genetic similarity in some groups will be much greater. This will mean that there is a higher risk of having two prints from different people match up.

Until the numbers are better, most involved think DNA fingerprinting should be used mainly for determining nonmatches, exonerating suspects. It will take a while before the technique is good enough to identify suspects.

WILLIAM C. THOMPSON and SIMON FORD. March 31, 1990. Is DNA fingerprinting ready for the courts? *New Scientist*: 38–43; CHRISTOPHER JOYCE. July 21, 1990. High profile: DNA in court again. *New Scientist*: 24–25.

Increased cancer risk at Pasteur Institute

An epidemiological study of workers at the Pasteur Institute indicates that certain types of rare cancer are more frequent than would be predicted. The cancer types include certain types of bone, pancreas, and brain cancer. Other cancer types were lower than in the general public.

Inquiries started when several researchers

working with recombinant DNA techniques on the same floor contracted rare bone cancers. The study shows that women are at higher risk for pancreas cancer. This may be due in part because women are more likely to be employed as technicians and this job category is more apt to be exposed to carcinogens. Similar results have been found for chemists in the United States and Sweden.

PETER COLES. 1990. Cancer risk indicated. *Nature.* 343: 583; DEBORA MACKENZIE. February 17, 1990. French research centre admits cancer risk. *New Scientist*: 18.

Unusual collaboration in search for Huntington's gene

Jim Gusella of MIT managed to narrow the search for the Huntington's chorea gene to a small portion of chromosome 4 in 1983. The foundation that had funded his research then proposed that Gusella and his competitors band together to join forces in the search, a controversial thing to ask a scientist. But he agreed and a collaboration between six rival research groups started.

Collaborations of this size are very unusual since this area of research is highly competitive and researchers often jealously guard their probes. There are tensions, personality clashes, arguments about when things were sent in the mail but the collaboration has worked surprisingly well.

The major actor in this research project is a large, extended Venezuelan family that seems to be the biggest concentration of Huntington's in the world. The family has 144 affected members who are alive and 1000 more are at risk. Blood samples have been taken from each member of the family and are being used to help find markers for the gene. The researchers were hoping to have the gene within a year but are now saying it may take up to 4 years. No one knows how long it would have taken without the collaboration.

LESLIE ROBERTS. 1990. Huntington's gene: so near, yet so far. *Science.* 247: 624–627.

Gene for neurofibromatosis found

Two groups have simultaneously found the gene for neurofibromatosis, a relatively common genetic disorder. The disease is found in 1 out of every 4000 babies of all ethnic groups and causes café au lait spots and benign tumors called neurofibromas on the skin. In some cases these are malignant. The disorder also can cause learning disabilities and neurological symptoms.

The two research groups had previously collaborated with each other but broke up in mid-1989 because of different research styles and went their separate ways. This lead to each of them trying to beat the other in a frantic rush to find the gene and publish the results.

Francis Collins of the University of Michigan submitted a paper to *Science* and Ray White of the University of Utah submitted his paper two weeks later to *Cell*. *Cell* published the paper in a record 17 days and White would have beaten Collins, but *Science* pushed Collins' paper up so they were both published on the same day, July 13, 1990.

Both research groups were funded by the same institute which found itself in a very awkward position with the two of them trying to outscoop each other. "What makes these gene hunts so competitive," says Lap-Chee Tsui of the Hospital for Sick Children in Toronto, who has his own battle scars from his successful race for the cystic fibrosis gene, "is simple: 'It's public recognition. People don't come to you if you are second,'" *Science* reports.

Identifying the gene will now make it possible to diagnose the disorder in young children and to perform prenatal diagnosis. But there are problems since each family with the disorder has a slightly different version of the gene. This will make the test less widely applicable.

DAVID P. HAMILTON. 1990. Down to the wire for the NF gene. *Science.* 249: 236–238.

Should screening start for cystic fibrosis gene?

Geneticists and researchers in the United States are calling for widespread screening of the U.S. population for the cystic fibrosis gene. This would mean screening up to 200 million people of reproductive age to see if they were carriers, a huge task.

But others are more critical. Many caution against screening on such a large scale since the results could be used to deny health insurance for newborns where both parents know they are carriers.

The American Society for Human Genetics has also stated that they are opposed to widespread

screening. There are major questions that need to be addressed before such programs start. Who should be screened? How old should they be? Who is going to educate the public and explain what the results mean?

Most agree that there are not enough counsellors or clinical geneticists available for this at the moment. And previous screening for other diseases has mostly created confusion and frightened people.

But recent research has set a damper on screening plans. The researchers who first discovered the cystic fibrosis gene, had found a gene that explained 75 % of cystic fibrosis cases. They expected to find the genetic changes that explain the other 25% fairly quickly, thus making a reliable genetic diagnosis possible.

But the changes in the gene are much more complex than anticipated. Lap-Chee Tsui of the Hospital for Sick Children in Toronto has found at least 20 different mutations in the cystic fibrosis gene that explain only a few percent of the 25% of cases left. They recommend not carrying out screening programs since they will only be 75% accurate. This will do more harm than good they fear since many couples will still not know if they are carriers after the test.

In spite of this, Britain plans to start a pilot screening program at three centers. Based on the results from this pilot study, a national program will then be drawn up.

LESLIE ROBERTS. 1990. To test or not to test? *Science.* 247: 17–19; LESLIE ROBERTS. 1990. CF screening delayed for awhile, perhaps forever. *Science.* 247: 1296–1297; CHRISTOPHER JOYCE. February 10, 1990. Gene test for cystic fibrosis sparks off screening debate. *New Scientist*: 22; *New Scientist.* June 2, 1990. Gene screen, p. 27.

First trial of gene therapy being prepared

An application for the first clinical trial of actual gene therapy, replacing a gene responsible for a disease, is winding its way through regulatory committees. The proposal would treat children lacking a gene for adenosine deaminase (ADA), which causes severe immunodeficiency (SCID).

These children have to live in sterile bubble chambers as they lack a normal immune system and can not fight off infections. The researchers plan to insert the ADA gene into bone marrow stem cells and then replace the bone marrow into the patient. The stem cells build blood cells which would then produce ADA and hopefully cure the disease.

The proposal received first approval from the National Institutes of Health (NIH) biosafety committee. It then received approval from the NIH human gene therapy subcommittee which had previously rejected the proposal because of lack of supporting research in animals. The new proposal included results from studies with SCID mice done in Italy that support their idea.

But then it ran into trouble when the NIH Recombinant DNA Advisory Committee (RAC) discussed it. Tempers flared during the review of another gene therapy trial that has been ongoing, but where the researchers now want to expand the trial. Several scientists questioned the results of that trial.

By the time the ADA trial proposal came up everyone was very tense. Many of those on the RAC are direct competitors working in gene therapy and there were accusations that they were trying to stall the trials. But these accusations were denied and the RAC stated that they are only interested in ensuring that these proposals are the very best science available.

The proposal was revised and resubmit-ted. At the same time a treatment for ADA was approved by the Food and Drug Administration called PEG-ADA. PEG-ADA is bovine ADA attached to a polyethylene glycol molecule which is given to the patients. It has led to considerable improvement. The gene therapy trials will be carried out on patients who have first received PEG-ADA for at least 9 months, so as to study the effectiveness of this new treatment.

BARBARA J. CULLITON. 1990. Gene therapy clears first hurdle. *Science.* 248: 1287; BARBARA J. CULLITON. 1990. One step closer for gene therapy. *Science.* 248: 1182; DIANE GERSHON. 1990. Clinical trials next step. *Nature.* 344: 2; BARBARA J. CULLITON. 1990. Conflict at the RAC. *Science.* 249: 159; DIANE GERSHON. 1990. Transfer study expands. *Nature.* 344: 483; HELEN GAVAGHAN. April 7, 1990. Gene therapy: the struggle for acceptance. *New Scientist*, p. 28; DIANE GERSHON. 1990. Approval next time round? *Nature.* 345: 468.

A simpler way of doing gene therapy?

"Scientists in the US may have hit upon a simple form of gene therapy which avoids the sophisticated procedures of genetic engineering, and relies instead on crude injections of genetic material straight into an animal's muscles," *New Scientist* reports.

The researchers found that muscle cells of mice which had been injected with foreign DNA appeared to have taken up the DNA and produced foreign proteins in their blood. If the method is that simple, it would mean that patients could inject themselves once a week or once a month with the appropriate DNA to replace a substance they themselves can not produce and have previously had to inject daily.

SUSAN WATTS. April 21, 1990. Surprise success for genetic jabs. *New Scientist*: 31.

Growth hormone reverses ageing, but may cause cancer

"A genetically engineered form of growth hormone appears to reverse some of the effects of ageing, according to experiments undertaken in the US," *New Scientist* reports. "But, say researchers, the findings do not justify widespread treatment with the hormone because of the risks to health, including leukaemia."

Human growth hormone (hGH) is used mainly to treat children lacking the substance naturally and who would otherwise become dwarves. But scientists have now tested the hormone on 12 men between the ages of 61 and 81 and found that several signs of ageing were reversed after 6 months.

The link to leukaemia comes from studies of children taking the hormone, where a nine-fold increase has been seen in Japan. Other studies have not seen such an increase, but scientists warn that general use of hGF for the elderly is not justified at present.

New Scientist. July 14, 1990. 'Youth' hormone tainted by link to cancer, p. 25.

Conflict between Europe and United States over hormone to boost milk production

Europe is reluctant to approve use of bovine somatotropin (BST) in cattle to boost milk production. The hormone is produced by genetic engineering methods and when injected in cattle raises their milk production by 10 to 25 percent.

The pressure to approve its use is coming from the United States, where BST is produced by companies such as Monsanto and Eli Lilly. But protests against the hormone have been mounted by among others, European and U.S. dairy farmers, consumer groups, and Green parties. This has led 2,500 U.S. supermarkets to boycott such milk, and at least two U.S. states, Minnesota and Wisconsin, to ban the sale or use of BST.

In Europe, most countries have been trying to reduce milk production and have recently gotten rid of their surpluses. BST and increased milk production are therefore not exactly what politicians are interested in.

The European Commission is trying to assess BST based on the three pillars of drug regulation — quality, safety, and efficacy. But it is also considering a so-called "fourth hurdle" — socioeconomic reasons.

Studies have shown that BST will favor large scale dairy farms and will put small farms out of business. But for political reasons, the commission wants to keep small farms alive. So approval of BST would go against the commission's political goals, which is why the fourth hurdle is attractive to add to the assessment.

But the BST industry and the United States do not want fourth hurdles which they see as "subjective, unscientific and political."

The fourth hurdle is important, but BST may not even live up to the three pillars — quality, safety, and efficacy. The BST companies claim that it is safe and effective but researchers state that research to prove this has not been done.

Most of the research on BST is controlled by the BST companies and is therefore suspect. There are two areas of special concern: BST's effects on the animal's health and the effects of the milk on humans. Cattle treated with BST have lowered fertility, shorter life spans, and high rates of infection in the udders. There are also symptoms of stress. Stress may lead to increased production of stress hormones that then are transferred to the milk, exposing humans. Stress may also lower the cow's immunological resistance and lead to transfer of viruses to the milk. None of these possibilities has been studied.

DEBORA MACKENZIE. December 12, 1989. Can biotechnology pick up the pinta? *New Scientist*: 32–33; G. CHRISTOPHER ANDERSON. 1990. Health worries over use of milk hormone. *Nature.* 345: 280.

Animals becoming bioreactors for industry

"Animals genetically engineered to become living factories that produce useful drugs or proteins in their milk, may soon become the tools of a new industry," *New Scientist* reports. The technique is already successful in mice, where researchers have genetically engineered them to produce human growth hormone at very high levels in their milk. They are now scaling up the process in rabbits.

Others are using sheep as bioreactors but so far the amounts produced have been much less than in mice.

SUSAN WATTS. April 14, 1990. Drugs industry turns animals into 'bioreactors'. *New Scientist*: 26, ROBERT POOL. 1990. Molecular biology lies down with the lamb. *Science.* 249: 124–126.

Genetically engineered pigs sold for slaughter without approval

"Australia's leading environmental pressure group has called for legislation following accusations that 53 genetically altered pigs were transported to market and sold for human consumption without proper approval," *New Scientist* writes.

The pigs were produced within a research program at the University of Adelaide which is trying to produce 'super-pigs' that grow faster on less feed. The transport of the pigs is being called the equivalent of an unauthorized release into the environment.

Currently, guidelines for genetic engineering in Australia are voluntary but universities are required to conform to them. The incident is hoped to result in legislation that will regulate genetic engineering.

IAN ANDERSON. May 12, 1990. Genetically altered meat slips through the net. *New Scientist*: 25; TANIA EWING. 1990. Superpigs go to market. *Nature.* 345: 377.

Genentech wins patent fight with Wellcome

The California biotechnology company, Genentech, won its patent dispute with the British company Wellcome over the clot dissolving drug TPA. Wellcome later decided to abandon its research on TPA leaving the market open to Genentech. However, an Italian study has shown that another drug, streptokinase, is just as effective as TPA for dissolving blood clots.

Streptokinase is 10 times cheaper than TPA. This may change U.S. medical practice since TPA is currently the favored drug for preventing blood clots after heart attacks.

DIANE GERSHON. 1990. Streptokinase equal to TPA. *Nature.* 344: 183; DIANE GERSHON. 1990. Genentech wins round two. *Nature.* 344: 692; DIANE GERSHON. 1990. Wellcome drops TPA. *Nature.* 345: 194.

EPO patent fight continues

Two companies, Genetics Institute and Amgen, have been fighting over patents for erythropoeitin (EPO) produced by genetic engineering methods. The court ruled that both patents are partially invalid and that they both infringe on the other.

Amgen is allowed to market EPO in the United States, but Genetics Institute is not. Genetics Institute has gotten around this by licensing production of EPO to a Japanese company, Chugai, and importing it to the United States. The patent ruling states that offshore production does not infringe Amgens patent, and that Amgen's production infringes on Genetic Institute's patent.

In another ruling, the court ordered the two companies to license each other for production of EPO. Failure to comply would lead to an injunction. But Amgen later managed to get another court to stop the court order for cross-licensing.

Meanwhile the House of Representatives has introduced a bill that would close the loophole that Genetics Institute has used to produce EPO in Japan and import it to the United States.

DIANE GERSHON. 1989. Court battle ends at the start. *Nature.* 342: 846; DIANE GERSHON. 1990. Cross-licensing ordered. *Nature.* 344: 278; DIANE GERSHON. 1990. Amgen plays for time. *Nature.* 344: 800; *Science.* 1990. Biotech protection. 248: 811.

Plant patent challenged

The Youth League of the Center Party in Sweden has filed a challenge against the decision of the European Patent Office to grant a patent for a genetically engineered plant. The patent was awarded to a U.S. company, Lubrizol, for a method to insert genes for increased protein in plants and the plants produced by the method.

The Swedish group argues that the patent is in conflict with the European Patent Convention of 1973 which states that it is not possible to patent "plant or animal varieties".

SHARON KINGMAN. December 16, 1989. Plant patent faces new legal challenge. *New Scientist*: 10.

Plants engineered for male sterility

To create hybrid seed with higher yields, seed companies often cross two different strains of the same species of plant. Naturally occurring male sterile plants have been used for some plant species because male sterile plants can not self-fertilize. Thus all seed from male sterile plants is hybrid seed. But many plant corps lack naturally occurring male sterile plants.

The Belgian company, Plant Genetic Sciences (PGS), has now developed a method using genetic engineering to create male sterile plants in any plant species. They spliced a gene from tobacco which stops development of the anther, into oil-seed rape plants. The plants produce no fertile pollen.

PGS is now developing male sterile strains of cotton, lettuce and alfalfa. "Hybrids are good business for seed companies because the improvements achieved in them apply only to the first-generation offspring of unrelated parents," *New Scientist* states. "The next generation of seed loses any benefit. So a farmer who wants the hybrids must buy new seed each year."

New Scientist: February 3, 1990. Spliced plants open up the field for hybrid crops, p. 39.

Genentech bought by Hoffman-La Roche

Genentech, one of the first biotechnology companies in the world, has been bought by the multinational Swiss drug company, Hoffman-La Roche. This is the biggest deal yet forged within the biotechnology industry. Hoffman-La Roche invested 2,100 million U.S. dollars and received 60% of Genentech's stock. The buy out shocked many scientists, as Genentech has remained fiercely independent since it started, 14 years ago. Many are worried that other biotech companies will also be bought up and researchers will lose control over their research.

A few months after the merger, allegations of insider dealing were raised against the wife of Genentech's president, G. Kirk Raab. There was an unusually high volume of trading in Genentech stock just before the merger was announced in February. The investigation focuses on communications between Molly Raab and a member of her family and later trading of Genentech stock.

SUSAN WATTS. February 10, 1990. Drugs giant takes over Genentech. *New Scientist*: 23; MARCIA BARINAGA. 1990. Biotechnology on the auction block. *Science.* 247: 906–908; DIANE GERSHON. 1990. Swiss company takes a 60 percent stake in Genentech. *Nature.* 343: 495; DIANE GERSHON. 1990. Mixed reactions to merger. *Nature.* 343: 681; DIANE GERSHON. 1990. Allegation of insider dealing. *Nature.* 345: 102.

U.S. agencies fight over regulation of environmental release

Six different U.S. agencies have conflicting views on how to regulate genetically engineered organisms.

The Environmental Protection Agency (EPA), the Department of Agriculture (US-DA), and the National Science Foundation want genetically engineered organisms to come under special regulation. The Food and Drug Administration (FDA), Department of Health and Human Services (HHS) and the National Institutes of Health (NIH) want a more flexible system which looks at the organism's properties and not how it was made.

The regulatory stalling has caused several states to consider legislation to regulate the use of engineered plants and microorganisms in agriculture. This has in turn led biotechnology companies to plead with the federal government to come up with national regulation so they will not have to deal with a patchwork, state-by-state approval system.

MARK CRAWFORD. 1990. Biotech companies lobby for federal regulation. *Science.* 248: 546–547.

India decides on regulations for genetic engineering

"Safety guidelines for recombinant DNA research just released by the Department of Biotechnology seek to regulate engineering research in India more by self-control than by legal measures," *Nature* reports. "Companies in countries such as West Germany [Federal Republic of Germany] where laws are strict may even find India's relaxed approach sufficiently attractive to shift some of their genetic engineering research to India."

Excluded from the guidelines are research concerning the "genetic engineering of human embryos, use of embryos and fetuses in research and human germ-line gene therapy."

The guidelines classify research into three categories based on perceived risk. Approval is needed for research involving cloning toxin genes, producing vaccines and releasing altered organisms into the environment.

A Review Committee for Genetic Manipulation will monitor whether or not researchers follow the guidelines. Violations will result in research grants being cancelled, not a serious threat to private companies.

Releasing organisms into the environment without approval will be liable to legal action under the Environmental Protection Act, legislation that has shown little success in stopping industrial pollution because of loopholes.

K. S. JAYARAMAN. 1990. India opts for self-control. *Nature.* 343: 680.

German law proposal to be revised

A proposed law to regulate genetic engineering in the Republic of Germany has been criticized by environmentalists in public hearings for not being tough enough.

Proposals have been made that each of the *Länder* will have the authority to grant licenses within their boundaries, not the federal government, and that the Central Commission for Biological Safety (ZKBS) should change composition to include more representation from lay groups, as it is currently dominated by scientists. The biotechnology industry is supporting the law since a court decision has put a ban on the industrial use of genetic engineering until regulatory legislation is in place.

The proposal was presented to the Parliament and finally approved but not in the form discussed in the public hearings, which has angered many. The bill has reduced the input from the public in decision-making. Four safety classes have been set up.

Academic researchers at all four levels and industrial researchers at the first level only need to inform the authorities. Approval is necessary for industry at levels 2 to 4 and public debate is needed only at level 3 and 4. Most industrial production is carried out at level one, meaning they will be able to avoid public debate.

Release of altered organisms into the environment requires public debate but the public has no say in the final approval. The new law also states that besides protecting human health and the environment, that its aim is also the furtherance of genetic science and technology. Many fear this will be used to justify increased support for genetic engineering.

STEVEN DICKMAN. 1990. New law needs changes made. *Nature.* 343: 298; DEBORA MACKENZIE. April 14, 1990. West Germany's gene law weakens role of public opinion. *New Scientist.* 17.

Engineered fish to be field tested in United States

"The first outdoor experiment with a genetically engineered, transgenic fish has received tentative approval from the U.S. Department of Agriculture," *Science* reports. Carp have been engineered to contain trout growth hormone genes.

Environmentalists are questioning the safety of the tests and want an environmental impact study carried out before approval is given.

Science. 1990. Transgenic carp; pond ready? 247: 1298.

Genetically engineered yeasts

A genetically engineered bakers' yeast has been approved for use in Great Britain. The yeast has been altered with genes from the same species which has led the Advisory Committee on Novel Foods and Processes to decide that the yeast is safe

to use in food. Bread made with the yeast does not have to be marketed stating that it is a product of genetic engineering. Environmental groups are critical of the secrecy surrounding the application for approval which prevented public debate.

In France, yeasts are being engineered to improve wine. Commercial yeasts are used in wine fermentation but in some cases, wild yeasts on the skins of the grapes produce toxins that kill the commercial yeasts. This leads to millions of liters of spoiled wine. Genetic engineers are trying to develop a commercial yeast that is resistant to the wild yeast toxins. The new yeasts have been tested in small quantities of wine and wine tasters have stated that the taste of the wines is unimpaired.

PETER ALDHOUS. 1990. Modified yeast fine for food. *Nature.* 344: 186; STEPHANIE YANCHINSKI. December 16, 1989. Genetic engineering sets the wine world in a ferment. *New Scientist*: 24.

Report critical of developing herbicide resistant crops

"Research in agricultural biotechnology aimed at developing crops with genetically engineered resistance to chemical pesticides threatens to 'entrench and extend the pesticide era', according to a scathing report," *Nature* states. The report, *Biotechnology's Bitter Harvest: Herbicide-Tolerant Crops and the Threat to Sustainable Agriculture* (Biotechnology Working Group, US, March 1990), was produced by a coalition of environmental, farm, church and consumer organizations.The group is critical of research that is meant to increase agricultural dependence on chemicals such as the 10 million U.S. dollars in federal funds that have gone to research into herbicide resistance. The report is hoped to raise consciousness in the American public that the biotechnology industry is developing in the wrong direction.

SETH SHULMAN. 1990. One man's pesticide . . . *Nature.* 344: 371.

European Communities approve genetic release directives

Ministers of the Environment from member states of the European Commission have approved two directives that will regulate the environmental release of genetically engineered organisms.

The rules require an environmental risk assessment to be carried out. Proposals for release are to be submitted to the country concerned, but all community members must also be notified.

PETER ALDHOUS. 1990. New European release rules ratified. *Nature.* 344: 371.

Scientists caught conducting illegal experiments in Great Britain .

John Beringer, chair of Britain's committee for approving the release of engineered organisms has stated that academic scientists have fewer incentives for following research regulations than their industrial counterparts.

Shortly after his statement, researchers at St. Bartholomew's Hospital in London were caught conducting illegal research on bacteria. The researchers had not given the required 30 days notice before doing their experiments.

Beringer is pleased that authorities at the Health and Safety Executive have acted. He feels that academics should be prosecuted if they don't follow the rules, to demonstrate that they must comply with the regulations.

SUSAN WATTS. April 28, 1990. 'No incentives' for academics to respect gene laws. *New Scientist*: 33; *New Scientist.* June 16, 1990. Gene culprits, p. 27; PETER ALDHOUS. 1990. Regulations breached. *Nature.* 345: 652.

British government does about turn on genetic release secrecy

During the spring of 1990, the British government proposed an Environmental Protection Bill that would allow public disclosure of information on industrial pollution but would keep secret similar information on releases of genetically engineered organisms into the environment. This restriction met with considerable opposition from environmental groups and even from scientists involved in such research.

But the government made an about turn in July and will now allow public access to information on such releases. Public information is hoped to increase public scrutiny of such releases which in the long run will also increase public confidence in biotechnology products. The government will also

create an Advisory Committee on Releases to the Environment to monitor proposed releases.

SUSAN WATTS. March 17, 1990. Britain opts for secrecy on genetic engineering. *New Scientist*: 22; ROGER MILNE and SUSAN WATTS. May 5, 1990. Ministers maintain secrecy over genetic releases. *New Scientist*: 22; SUSAN WATTS and ROGER MILNE. July 14, 1990. Government rethinks stand over altered organisms. *New Scientist*: 23.