NEWS ON DEVELOPMENTS
CURRENT DEVELOPMENTS AND ISSUES: A SUMMARY

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CONTRACEPTION

Contraceptive ring tested in Great Britain

A vaginal ring made of soft plastic and releasing small amounts of the hormone progestogen has been tested on over 1,500 women worldwide. The ring, called Femring, is now being tested in clinical trials at 60 health centers in Great Britain. The ring has been developed by the World Health Organization together with Roussel Laboratories, a pharmaceuticals company and they are now awaiting approval of Femring by the Department of Health.

Femring is easily inserted by the woman herself, can be left in place up to 3 months and has a 3.5% pregnancy rate, which is comparable to that of combined estrogen-progestogen birth control pills. A major side effect of Femring is that it can cause extra bleeding.

1990. Contraceptive ring goes on trial in UK. *New Scientist.* September 29: 21.

Biodegradable contraceptive implant being developed

"Trials of a contraceptive implant which degrades in the body will begin within the next two years in the US," *New Scientist* reports. Once inserted, the implant, called Capronor releases progestogen for about 1 year. The capsule then breaks down and is excreted.

Capronor is small enough to be implanted by injecting it into a woman's arm with a needle. The implant is being developed by researchers at Research Triangle Institute in North Carolina.

Norplant, a contraceptive implant that is effective for up to 5 years, is now licensed within the United States. Norplant must be removed surgically.

PHYLLIDA BROWN. 1991. Shot in the arm for contraception. *New Scientist.* January 12: 35.

Male contraceptive effective in trials

Men injected weekly with the hormone testosterone enanthate stopped producing sperm. In a study supported by the World Health Organization, 119 men received the injections as their only form of contraception for 12 months. Only one woman became pregnant, making the male contraceptive much more effective than female contraceptive pills and condoms. Weekly injections are not practical so researchers are working on methods that would require only three injections per year.

PETER ALDHOUS. 1990. Equality for the sexes? *Nature* 347: 701; FRANK LESSER. 1990. Hormone jab may herald male contraceptive. *New Scientist.* November 3: 24.

ABORTION

RU486 experiments blocked in United States

The French drug company, Roussel-Uclaf, is refusing to supply United States researchers with RU 486, the so-called abortion pill. The company cites the strong anti-abortion climate in the United States as the reason. Anti-abortion groups threatened to boycott the company's other products if they marketed RU 486 in the United States.

Among other things, researchers want to study the drug's effects on breast cancer. RU 486 has also been found to be helpful for patients suffering from Cushing's syndrome, where the drug blocks the effects of an over-production of cortisol. But no one in the United States has been given permission to use RU 486

in new research projects since June 1989. The United States Food and Drug Administration (FDA) has banned the import of RU 486 as well.

However, FDA officials have insisted they only wanted to stop the private use of the drug, not clinical research and now realize that banning the drug for researchers has been a mistake. The FDA states that it will consider giving permission to import RU 486 to researchers who submit proposals for clinical trials, provided that FDA's scientific committee decides that the research is important.

DAN CHARLES. 1990. American pressure thwarts studies on "abortion pill." *New Scientist.* December 1: 25; PHYLLIDA BROWN. 1990. Abortion pill may help fight breast cancer. *New Scientist.* November 3: 21; CHRISTOPHER ANDERSON and PETER COLES. 1990 Drug debate expands. *Nature* 348: 382.

Right to abortion divides Germanies

The unification of the two German states was threatened by different government policies on abortion. In East Germany (German Democratic Republic), women have had the right to abortion on demand. In West Germany (Federal Republic of Germany), abortion is considered a criminal offence unless a woman can convince two reviewers that there are social or medical reasons for an abortion.

Politicians in West Germany were afraid that women would travel to East Germany to get abortions. And forcing the West German abortion law on East Germany was politically impossible. Women demonstrated in the streets and threatened the coming unification. So to solve the problem, a compromise was reached.

For the next 2 years, the former East German states will be allowed to keep their abortion on demand law, and the West German states will keep their more punitive law. A new Bundestag will then make the final decision for the entire country. No West German women will be prosecuted if they obtain abortions in the East.

RICHARD SIETMANN. 1990. Abortion divides uniting Germanies. *Science* 249: 1100.

INFERTILITY TREATMENT

British study of multiple births after infertility treatments

A research report published in Great Britain (*Three, Four or More: A Study of Triplets and Higher Order Births,* HMSO) presents the first comprehensive data on multiple births after infertility treatment. There has been a large rise in the number of higher order births largely because of the use of fertility drugs, in vitro fertilization (IVF) and gamete intrafallopian transfer (GIFT). The study covers the period between 1979 and 1985.

Triplets and quadruplets have higher mortality rates because they are often born premature. Women having triplets and quadruplets have higher rates of complications, up to half of the pregnancies in the case of quadruplets. Many of the babies end up in intensive care for a period of time after birth and in most cases, the parents are not prepared to cope with so many babies at once when they return home.

Parents need help with child care, feeding, and time off from the babies. "Comments from parents in the national study also give rise to concern about the information they received when they sought medical assistance to establish a pregnancy," *New Scientist* reports. "Typically, women who were treated with fertility drugs remembered being made aware of the possibility of twins—but nothing more." Some clinics try to encourage women to see triplets or quadruplets as a positive result of the treatments.

FRANCES PRICE. 1990. Too much of a good thing. *New Scientist.* August 18: 29–30.

GIFT may fall outside British licensing authority's jurisdiction

There has been a rapid increase in the number of triplets and quadruplets born in Britain after infertility treatments. Because of this, the new Human Fertilisation and Embryology Authority (HFEA) is recommending that no more than three embryos be transferred to a woman at one time.

The HFEA regulates research and medical practice that uses human embryos and licenses in vitro fertilisation clinics. But due to a loophole in the new law governing infertility treatments, the practice of GIFT (gamete intrafallopian transfer) is not covered by the HFEA.

Because of this the HFEA cannot force GIFT clinics to counsel couples about the risks of multiple births. These clinics are not required to send in data for the national IVF register, which means that the HFEA may not be able to monitor the number of multiple births that occur due to GIFT. Although many clinics that provide GIFT are IVF clinics and therefore regulated by HFEA, there are a number of clinics that only do GIFT, and this is giving rise to some concern.

GAIL VINES. 1991. Loophole in code to restrict multiple births. *New Scientist.* March 30: 7.

SURROGACY

Surrogacy proposals rejected in Australia: national bioethics committee disbanded

A joint meeting of Australian Health and Social Welfare Ministers in March 1991 unanimously rejected the controversial proposals for the legalization of surrogacy in Australia, put forward in a report issued by the National Bioethics Consultative Committee (NBCC; Heath, *The Age,* March 26, 1991).

The NBCC was set up by the Australian federal government in 1988 to advise the government on issues such as surrogacy, in vitro fertilization, genetic engineering, and euthanasia. The Committee issued a draft report on surrogacy in 1989, which discussed surrogacy as a way of alleviating infertility for childless couples. It also proposed that state-run agencies be set up to regulate the practice. After receiving public submissions, more than half of which disagreed with allowing regulated surrogacy, a final report was issued in April 1990, further endorsing legalized surrogacy. Two members of the NBCC, Heather Dietrich and Sister Regis Dunne, dissented from the report.

At the joint meeting of health and social welfare ministers, not one minister spoke in favour of surrogacy. The federal health minister, Mr. Brian Howe called for a unified national approach that would outlaw surrogacy. Kay Setches, the Victoria community services minister, strongly supported this call, and said that there were potential overtones of slavery in surrogacy.

Consequently, Howe dissolved the NBCC, and this was widely seen as a response to the overwhelming defeat of the legalized surrogacy proposals (West, The Age, April 11, 1991a). A new committee will be set up within the National Health and Medical Research Council (NH & MRC) to advise the government on bioethical issues. It is believed that some of the previous NBCC members will take up positions on the new committee. Critics have expressed concern that policy decisions on issues such as reproductive technologies will now be shifted back into a medical framework. Nicholas Tonti-Filippini, a medical ethicist, said that the NBCC was dominated by "an interest group that was proexperimentation, anti-church, and anti-feminist," and that the old dominant group should not be carried over onto the new committee (West, The Age, April 11, 1991b).

SALLY HEATH. 1991. Surrogacy to be outlawed as health ministers unite. *The Age (Melbourne).* March 26: 3; ROSEMARY WEST. 1991a. Howe disbands bioethical committee. *The Age (Melbourne).* April 11:3; ROSEMARY WEST. 1991b. IVF birth: a question of ethics. *The Age (Melbourne).* April 11: 13.

Breaches of Victoria infertility (medical procedures) act

The Health Department in Victoria, Australia has issued warnings to the Epworth Hospital (Melbourne) and the *Sunday Herald-Sun* (Melbourne) following the publication of requests for an anonymous egg donor and a surrogate mother (Lopez, *The Age,* May 24, 1991). These items have renewed concerns about the credibility of Victoria's Infertility (Medical Procedures) Act 1984, and how it is enforced.

On April 28, 1991, the *Sunday Herald-Sun* published a story about a woman from Canberra, in the Australian Capital Territory, who was seeking a surrogate mother to bear a child for her. The *Herald-Sun* reprinted part of her advertisement, including a post office box number. The advertisement had originally appeared in an interstate newspaper. According to a reporter from *The Age* newspaper, the *Sunday Herald-Sun* refused to comment on its story.

The Victoria Infertility (Medical Procedures) Act clearly prohibits statements, advertisements, or other documents that are intended or likely to induce a person to engage in a surrogacy arrangement. The maximum penalty is a $5,000 fine or 2 years' imprisonment. Since its inception in 1984, there have been no prosecutions under the Victoria Infertility Act.

Christine Ewing, *FINRRAGE (Australia)* coordinator, drew these two advertisements to the attention of a reporter from *The Age* newspaper. Ewing said that the Health Department's reaction to the two items was crucial in determining the effectiveness of the legislation.

"Is it going to be dealt with? Is there going to be a prosecution under the act? This may be the first test to see if the act is really worth the paper it's written on," Ewing said. "There's absolutely no question that an advertisement for a surrogate mother is illegal in Victoria . . . . (Letter-writing is) letting people off the hook."

The chief medical officer of the Health Department, Dr. Rob Simpson, is responsible for administering the act. A spokeswoman for Simpson said the department wrote to the *Herald-Sun* newspaper on May 9 to point out that it had breached the act. The spokeswoman said that Simpson did not know the procedures for prosecutions, how and by whom charges would be laid, and where the case would be heard. She suggested that *The Age* reporter contact a lawyer to find out. No further action has been recommended by the Health Department.

On May 1, *The Age* published an advertisement for an egg donor that assured the donation could be anonymous, "if preferred." Under the Victorian Infertility Act, gamete donations must be recorded, that is, donations cannot be anonymous. The deputy advertising manager of *The Age* said that in the normal course the company was careful not to publish advertisements that breached the law or appeared to be unethical. Exactly what happened in this case was unclear.

The department is awaiting a reply from the Infertility Medical Centre at Epworth Hospital concerning the Infertility Medical Centre's egg donor advertisement. Although a private clinic, the centre operates under the Epworth Hospital's code of ethics. The clinic was told its assurance of anonymity may have breached the act.

The act requires the names of sperm and egg donors and children to be registered with the Health Department. Infertility Medical Centre's manager, Catriona King, said the advertisement's

reference to anonymity simply meant that the donor could request that her identity be withheld from the recipient couple. She said the donor's identity would still be given to the Health Department.

However, the register of gamete donations at the Health Department exists in name only. The department has had 7 years to set the register in motion; it remains blank.

"What that essentially means is that children born as a result of donor gametes can't trace their genetic origins," Ewing stated. "It just seems like the hospitals have not been pushed to submit those records to the central register. It can certainly be seen as not good enough, because under the act the register should be maintained."

The Health Department said it is not insisting that hospitals comply with this requirement because of ambiguities in the Victorian legislation. Under the act, there is no distinction between donor and nondonor gametes, which means hospitals wanting to comply with the act could have to supply "reams and reams" of information.

ELISABETH LOPEZ. 1991. Sperm, egg register exist in name only. *The Age* (Melbourne), May 24: 12.

SEX DETERMINATION

Patent fight over controlling sex

The United States Department of Commerce and a small company called Cytogam have both filed patents for almost identical methods for controlling the sex of mammalian offspring at conception. Sex is determined by two chromosomes, the X and the Y chromosomes. Women have two X chromosomes and men have an X and a Y chromosome.

The method takes advantage of the fact that the X chromosome contains a bit more DNA than the Y chromosome, thus making sperm with one or the other chromosome weigh a bit more. Sperm is incubated with a fluorescent dye that binds to DNA only and that is nontoxic to the sperm.

Sperm containing the X chromosome will contain more dye and will shine brighter than sperm with the Y chromosome when irradiated with a laser. Using a flow cytometer, an instrument that can sort single cells, each sperm is passed through a laser beam and those that are brighter are sorted into a separate container using an electrostatic charge.

One possible use for the method would be to separate sperm for use in artificial insemination where the sex of the child could be decided beforehand. "Sex-associated" proteins have been found on the two sperm types as well, which has allowed the production of monoclonal antibodies against X or Y sperm. The antibodies disable one or the other sperm type, a method that also can be used to produce offspring of the desired sex. The antibodies can also be used to immunise a woman against one or the other sperm type, meaning she can receive injections that will determine the sex of her child. These applications raise difficult legal and ethical questions.

BARRY FOX and CHRISTOPHER JOYCE. 1990. Americans compete for control over sex. *New Scientist.* January 12: 23.

FETAL TISSUE RESEARCH

Fetal tissue research ban challenged

The United States Department of Health and Human Services has banned federal funds for research using fetal tissue for transplantation. The Office of Technology Assessment (OTA) has published a report (*Neural Grafting: Repairing the Brain and Spinal Cord,* OTA-BA-462, September 1990) that is a subtle case for overturning the ban. Representative Henry Waxman has also introduced legislation that would overturn the ban on use of federal funds for such research. And the Parkinson's Disease Foundation is considering suing the United States government because of the ban.

In the midst of this situation, two medical organizations have decided to create a national advisory board on ethical guidelines in reproductive and fetal tissue research. The National Advisory Board on Ethics in Reproduction will be set up by the American College of Obstetricians and Gynecologists (ACOG) and the American Fertility Society (AFS) and will consist of 15 members including lawyers, ethicists, theologians, scientists, and the lay public. The ethics board will have no legal authority and can only provide assistance to privately funded research.

DAVID HAMILTON. 1990. OTA quietly backs fetal tissue work. *Science* 250: 201; A new fight over fetal tissue? *Science* 249: 983; DIANE GERSHON. 1990. Move to overturn ban. *Nature* 346: 598; DIANE GERSHON. 1990. Will ban provoke challenge? *Nature* 347: 4; DIANE GERSHON. 1991. New panel for ethical issues. *Nature* 349: 184; Private initiative on fetal research. *Science* 251: 275.

Fetal tissue research allowed in France

A ban on the use of fetal tissue for transplantation purposes has been overturned by a French national ethics committee. This means that doctors at Henri-Mondor hospital south of Paris will attempt to graft fetal brain tissue into the brains of patients with Parkinson's disease. Similar experiments in Sweden have shown some success and this seems to have influenced the ethics committee's decision.

PETER COLES. 1990. French fetal cell transplant operations. *Nature* 348: 667.

EMBRYO RESEARCH

Federal Republic of Germany restricts embryo research

As of January 1, 1991, legislation has taken effect in Germany that makes research on human embryos illegal. Embryos may only be created for implantation in a woman's uterus by in vitro fertilization (IVF) methods. Only three embryos may be implanted and the creation of surplus embryos is not allowed.

The law also bans cloning of human beings, the creation of human-animal chimeras and genetic manipulation of germ line cells. The law does allow for preimplantation diagnosis in order to check the sex of the embryo in the case of sex-linked genetic diseases such as muscular dystrophy.

This has led to protests by the Green Party who criticize this part of the law for being eugenic. In an interview in *Nature,* Marie-Luise Schmidt of the Green Party states, "People who were born with muscular dystrophy are apparently meant to find themselves in this law as the objects of a . . . negative selection that defines them as worthy as extermination."

STEVEN DICKMAN. 1990. Germany turns clock back. *Nature* 348: 8; 1990. Germany restricts embryo research. *New Scientist.* November 3: 21.

Father's exposure to toxic substances can affect fetus

"Fathers exposed to toxic substances are probably just as likely to be the cause of defects in their children as mothers," *New Scientist* reports. "Yet it is women who are told to stop drinking and smoking and to look after their health when they are pregnant. And it is women who find that they are banned from jobs where they are exposed to harmful chemicals or radiation."

For example, a wide spectrum of problems may be caused by the father's exposure to drugs, toxins in the workplace, radiation, and alcohol. These include stillbirths, miscarriage, growth retardation, childhood leukemia, and brain tumors. Researchers have shown that the offspring of male mice treated with morphine before mating have reduced learning ability. This raises the important question of why women are the center of so much attention when most of the work force is male.

1991. Why men should also think of the baby. *New Scientist.* March 2: 16.

GENETIC ENGINEERING

Prenatal diagnosis using simple blood test now possible

Fetal cells are known to be present in the mother's blood. This was used by researchers at Flinders University in Adelaide, Australia, to determine fetal sex in 12 pregnant women. The blood samples were taken during the first 8 weeks of pregnancy.

The fetal cells were isolated from the blood using monoclonal antibodies attached to magnetic beads. The cells could then be used to multiply the DNA using the polymerase chain reaction (PCR). The fetal DNA was then tested for the presence of the Y chromosome, which is only present in males.

The women also underwent chorion villi biopsy to confirm the blood test results. The blood test was correct in 11 of the 12 cases. The researchers expect that this method of prenatal diagnosis will soon be used routinely to test fetuses for a number of genetic diseases including Down's syndrome and cystic fibrosis. The method is being patented and plans are well underway for marketing the test.

FRANK LESSER and IAN ANDERSON. 1990. "Safe" test may spot fetal abnormalities. *New Scientist.* August 11: 32.

Genetic screening - in whose interest?

Three percent of the budget for the Human Genome Project, a project to map the human genome, will go to studying the ethical, legal, and social consequences of this knowledge on people's lives. One of the major areas of worry is genetic screening for disease and for predisposition to disease.

The recent discovery of the cystic fibrosis gene set off an immediate cry to screen the entire United States population. But many warned against such widespread screening asking such questions as Why screen when no treatment exists? How do you counsel carriers or pregnant women with an affected fetus, especially when the number of genetic counsellors is limited?

But the planners of the Human Genome Project have decided to go ahead with a pilot project for general screening for cystic fibrosis. One of the major problems is cost. The test costs as much as $300 (US.), which usually has to be paid for by the patient.

In countries with national health programs, screening is more widespread and the cost much lower, about $2 (U.S.) per test. The hope is that mass screening in the United States will also reduce the cost of the test, but it also means the number of laboratories and genetic counsellors must increase.

Many worry that the advent of genetic screening may be used by employers and insurance companies to decide whom to employ or insure. Companies want to protect themselves from lawsuits brought by employees who claim they were injured or made sick by their job, which makes screening for susceptibility to chemicals a real possibility.

Insurance companies are interested in reducing their risks of insuring someone who may die earlier or become disabled. Genetic screening would be one method of weeding out those people who are at higher risk. In the United States, private health insurers pay for some prenatal genetic tests, but some require that the fetus be aborted if it will develop a serious genetic disease, to save future health costs.

Members of the Committee for Responsible Genetics in Boston, Massachusetts, are worried that genetic screening may lead to "a creeping stratification of the population into genetic ghettos," *New Scientist* reports. Cases of genetic discrimination have already occurred and are being compiled by Paul Billings of New England Deaconess Hospital in Boston.

In several cases, people with minor genetic disabilities have been denied insurance. A man found to be a carrier of a genetic disease was refused a job. These examples illustrate how wide the public's misunderstanding of genetic disease and disability is.

CHRISTOPHER JOYCE. 1990. Your genome in their hands. *New Scientist.* August 11: 52–55; CHRISTOPHER ANDERSON. 1990. Genome project to tackle mass screening. *Nature* 348: 569.

Law introduced in United States to protect from genetic discrimination

Representative John Conyers (Democrat, Michigan) has introduced legislation that would prohibit discrimination based on an individual's genetic screening results. The Human Genome Privacy Act would cover employment, insurance, and education and would forbid the "release of genetic information without the individual's written consent," *Science* reports.

SUSAN KATZ MILLER. 1990. Genetic privacy makes strange bedfellows. *Science* 249: 1368; KEVIN DAVIES and DIANE GERSHON. 1990. Law to keep labels off genes. *Nature* 347: 221; 1990. Congress to consider genetic privacy law. *New Scientist.* September 22: 25.

Genetic screening not as attractive as previously considered

A report published by the United States Office of Technology Assessment (OTA) states that "little or no growth" of genetic screening in the workplace has taken place during the past 7 years. The report *(Genetic Monitoring and Screening in the Workplace)* states that because of the sensitive ethical dilemmas and new laws that would protect from discrimination, companies have not been very enthusiastic about such programs. Only 12 of 300 so called "Fortune 500" companies have genetic screening programs.

In the Federal Republic of Germany, the unions want a ban on using genetic screening for employment or insurance purposes. They also want it made illegal for employers to force workers to undergo genetic tests. If an individual personally wants a test done, then the results must be kept confidential.

1990. Employers shun genetic screening. *Science* 250: 752; 1990. Screening ban. *New Scientist.* August 4: 27.

Developments in Japan

Japanese scientists have been lobbying to launch their own part of the Human Genome Project, but the government has not been generous. Only a small amount of money has been set aside to start a center for human genome analysis. Genome research grants will also be increased. But it is much less than was hoped for.

This has led Chiba prefecture, located on the opposite side of Tokyo Bay from Tokyo, to begin planning a DNA research institute. The institute will be part of a science park that is set to open in 1993. The institute will work on sequencing genes and will probably function as a sequencing service to academic researchers.

Sequencing is essential to the human genome project but is considered to be boring drudge work by scientists. The institute is being supported by Nippon Steel Corporation, Kawasaki Steel Corporation, Tokyo Electric Power Company, Tokyo Gas Company, Hitachi, Mitsui Toatsu Chemicals, and several banks.

DAVID SWINBANKS. 1991. Japan's project stalls. *Nature* 349: 360; DAVID SWINBANKS. 1991. DNA research institute to open in Japan. *Nature* 349: 640.

Centers for human genome grants chosen

The centers that will receive large, long-term research grants from the Human Genome Project have now been chosen. Groups at the University of Michigan, Massachusetts Institute of Technology, University of California at San Francisco, and Washington University will receive

money. Most of these groups are working on genetic and physical genome mapping.

The National Institutes of Health also managed to find money for two other centers, one at the Salk Institute and one at Stanford University. The idea of funding centers instead of individual research grants has caused some controversy within the scientific community. Many biologists believe that such centralized funding produces mediocre results, but James Watson, head of the Genome Project, believes it will be an incentive for groups already working on genome mapping to get the job done.

LESLIE ROBERTS. 1990. Genome center grants chosen. *Science* 249: 1497.

Editorial blasts human genome project

Martin Rechsteiner, professor of biochemistry at the University of Utah has written an editorial in *New Scientist* that is very critical of the human genome project. "Few scientific proposals have been greeted with as much media attention as the human genome project. . . . But critics of the project, like myself, have had difficulty getting their views printed even in traditional scientific weeklies," Rechsteiner writes. "My principal criticism is that the project is a costly, inappropriate and unwise allocation of precious research funds." At a time when research funding is declining, "we see a proposal to distribute previously unheard of amounts of money to a handful of scientists."

Rechsteiner is also critical of the strategy being employed. "I believe it is poor medical strategy to obtain more and more sequences when we really need to discover how the proteins malfunction," he states. "However, another critical resource is also threatened – the next generation of scientists. The genome project is in many ways an engineering project. Turning the crank on sequence determination until all 3 billion base pairs have been identified and verified is basically repetitive, technical work that will not engage the imagination of our brightest prospective researchers."

MARTIN RECHSTEINER. 1990. The folly of the human genome project. *New Scientist.* September 15: 20.

Human mitochondria/ genome implicated in some genetic disorders

When talking about the human genome, researchers usually are referring to all the genes found on the chromosomes in human cell nuclei. But a small amount of the human genome is also found in the mitochondria, the small organelles that produce energy in each cell. It is now clear that mutations in mitochondrial DNA are linked to at least three rare diseases, Kearns-Sayre syndrome, chronic external ophthalmoplegia and myoclonic epilepsy with ragged red fibers.

JOSEPH PALCA. 1990. The other human genome. *Science* 249: 1104–1105.

Head of Department of Energy's Genome project removed

Charlie Cantor, head of the United States Department of Energy's genome project at Lawrence Berkeley Laboratory has been removed from his post. Officially he has received a promotion, but the real reason seems to be his inability to get the project rolling. Cantor was seldom at the laboratory to direct research, but was out globe-trotting most of the time. Leroy Hood of the California Institute of Technology has been offered Cantor's job.

PAUL SELVIN. 1990. Charlie Cantor gets kicked upstairs. *Science* 249: 1238–1239; LESLIE ROBERTS. 1990. Hood seems likely to head Berkeley genome center. *Science* 250: 757.

New methods being developed for human genome project

A new machine is being developed at the University of Wisconsin that may be able to sequence genetic material 25 times faster than today's machines. The usual

method is to break down the DNA into fragments that are then labelled with fluorescent markers. The fragments are separated by placing them on a gel with an electrical current that makes them move in the gel at different rates depending on their size. A laser then reads the bands in the gel and a computer calculates the original sequence.

The new method puts the gel in quartz capillary tubes, which can have a much higher electrical current applied to them than the gel by itself. This makes for faster sequencing and the method will probably be cheaper as well.

JONATHAN BEARD. 1990. Gene machine could speed up human genome project. *New Scientist.* October 27: 27.

Human genome database set up

Over 140 geneticists met at the University of Oxford in England to test a database for the human genome project. The database has been restructured and is online internationally. The data base contains information on genetic linkage, polymorphism, and genetic probes, and eventually will contain information on the 100,000 genes in the human genome.

PHYLLIDA BROWN. 1990. Genome mappers test their system. *New Scientist.* September 8: 30; PETER ALDHOUS. 1990. Database goes on-line. *Nature* 347: 9; SUSAN WATTS. 1990. Making sense of the genome's secrets. *New Scientist.* August 4: 37–41.

Genetic fingerprinting wins approval in United States

The United States Office of Technology Assessment (OTA) has published a report *(Genetic Witness: Forensic Uses of DNA Tests,* OTA–BA–438, Washington, DC, July 1990) that states DNA fingerprints are "reliable and valid when properly performed and analysed by skilled personnel."

The validity of the test itself has not been disputed. It is the way the test is performed and interpreted that has caused problems. The report does not attempt to answer the question of how to interpret DNA fingerprints.

Meanwhile, Cellmark Diagnostics, one of the leading DNA fingerprint laboratories, is offering to doublecheck other laboratories' work in order to fight the criticism that has come against the technique. Cellmark is the first company to receive a quality standard.

Results from a 10-lab study in Europe to test consistency in producing DNA profiles have also come in. All 10 labs received the same DNA samples and used the same restriction enzymes and probes, but the results showed considerable variation between labs.

A second round of tests will begin to determine those features of the method that will make the method comparable. This is necessary so that police in different countries can use fingerprints produced by different laboratories in international criminal cases.

ALUN ANDERSON. 1990. Forensic tests proved innocent. *Nature* 346: 499; SUSAN WATTS. 1990. DNA fingerprinters aim to counter critics. *New Scientist.* August 11: 20.

Gene therapy experiments approved in the United States

Two gene therapy experiments have received approval in the United States. In September (1990), a 4-year-old girl was the first patient ever to undergo gene therapy meant to cure her. The girl received a transfusion of her own white blood cells that had been genetically altered to cure adenosine deaminase deficiency (ADA), a disease that causes the immune system to malfunction.

The other experiment involves genetically altering blood cells that naturally seek out cancer cells by adding a gene for an anticancer drug. These cells would then become very specific anticancer agents. The researchers carrying out this experiment have previously tested genetically altered anti-

cancer cells that had a marker only in order to track them in the patient's body.

In February (1991), two patients who were terminally ill with malignant melanoma, a severe form of skin cancer, were the first to receive the anticancer gene therapy. More gene therapy proposals are underway.

DIANE GERSHON. 1990. First experiment approved. *Nature* 346: 402; DIANE GERSHON. 1990. Anticancer trial's surprise approval. *Nature* 346: 497; CHRISTOPHER JOYCE. 1990. US approves trials with gene therapy. *New Scientist.* August 11: 19; BARBARA J. CULLITON. 1990. Gene therapy: Into the home stretch. *Science* 249: 974–976; CHRISTOPHER JOYCE. 1990. Four-year-old is first gene therapy patient. *New Scientist.* September 22: 25; BARBARA J. CULLITON. 1990. Gene therapy begins. *Science* 249: 1372; D. J. WEATHERALL. 1991. Gene therapy in perspective. *Nature* 349: 275–276; DIANE GERSHON. 1991. Cancer trial starts. *Nature* 349: 445.

First European gene therapy experiment planned

Italian researchers are hoping to receive permission for the first European gene therapy experiment. Claudio Bordignon at the Instituto Scientifico San Raffaele in Milan indicates that there are groups in the Nether-lands and France getting ready to perform gene therapy experiments as well.

Bordignon has worked together with researchers in the United States who received approval from United States agencies and subsequently started gene therapy experiments to treat for adenosine deaminase deficiency (ADA).

Bordignon plans similar experiments in Italy. Unlike the procedure in the United States, he only needs approval from the hospital. The decision will be based on whether his approval meets medical and ethical standards.

The experiment has created a controversy in Italy as there are fears that researchers from other countries may try to do their experiments in Italy. Members of Parliament have called for a moratorium on gene therapy experiments but the Health Minister, Francesco de Lorenzo, is satisfied with letting the hospitals make the decision.

STEVEN DICKMAN. 1990. First European experiment. *Nature* 348: 378.

Cystic fibrosis may be candidate for gene therapy

Researchers in the United States have managed to correct the genetic defect that causes cystic fibrosis in cells cultured in the lab. The genetically modified cells functioned properly and researchers are now hoping that they may one day be able to use gene therapy to treat cystic fibrosis patients.

Cystic fibrosis is a lung disease in which special channels in cell membranes are plugged. This causes a build-up of mucous in the lungs. In order to begin gene therapy experiments, an animal model must first be produced so that researchers can test whether or not gene therapy works. It will be many years before similar experiments can be performed on humans.

In the interim, one suggestion is to produce an aerosol with the normal gene in a solution that could then be inhaled. The solution would ferry the gene into the airway cells and temporarily relieve the cystic fibrosis problems. But these cells die off and are replaced by new ones, so the treatment would have to be repeated at regular intervals.

LESLIE ROBERTS. 1990. Cystic fibrosis corrected in lab. *Science* 249: 1503; CHRISTOPHER JOYCE. 1990. Quick fix found for cystic fibrosis gene. *New Scientist.* September 29: 15.

More genes linked to specific diseases

"A defective gene may be responsible for up to 30 per cent of cases of osteoarthritis, according to scientists in the

US," *New Scientist* reports. "The gene codes for collagen, a type of tissue which holds together cartilage at a joint. Defective collagen is thought to weaken the cartilage, whose job is to cushion the bone."

Not all the collagen that is produced in these patients is defective. But enough is defective that after middle age, the healthy collagen is worn down and the bones begin to grind against each other, causing osteoarthritis. A genetic test can be used on children and if they are at risk, they can be advised to change their diet or career to reduce their risk of contracting the disease.

Li-Fraumeni syndrome is a rare genetic disorder that makes certain people susceptible to several types of cancer at a relatively young age. Researchers in the United States have discovered that the syndrome is caused by a genetic defect in a tumor-suppressor gene, a gene that normally stops cancerous growths.

The discovery makes possible genetic tests so those at risk can be identified and then watched carefully so any cancers can be diagnosed early. However, the discovery raises social and ethical questions. Some researchers feel that, in addition to close medical monitoring, these patients should receive counselling to deal with the uncertainty of their futures. There is also some concern that these patients may be discriminated against by insurance companies and employers.

A form of Alzheimer's disease in younger people has previously been linked to a genetic defect on chromosome 21. Researchers in Great Britain have determined that the gene mutation in this case causes a protein, amyloid precursor protein (APP), to break up into smaller fragments that then accumulate in the brain. Abnormal amounts of a particular APP fragment are found in the brains of Alzheimer's patients.

1990. Gene could cause osteoarthritis. *New Scientist.* September 15: 30; JEAN MARX. 1990. Genetic defect identified in rare cancer syndrome. *Science* 249: 1209; KEVIN DAVIES. 1991. Altered gene that can lead to Alzheimer's disease. *New Scientist.* February 23: 25.

No proof for "alcoholism" gene

In April of 1990, United States researchers stated that they had found a gene linked to severe cases of alcoholism. But other researchers have been unable to confirm this link. Instead, "some scientists are beginning to suspect that there may be no genes for alcoholism per se, but rather for a general susceptibility to compulsive behaviors whose specific expression is shaped by environmental and temperamental factors," *Science* reports.

To try to determine if this is true, the National Institute on Alcohol Abuse and Alcoholism (NIAAA) has started a large-scale study on the genetics of alcoholism. The study will include "everything from psychological tests to DNA probes," *Science* states, and will cover 600 alcoholics and several thousand family members.

CONSTANCE HOLDEN. 1991. Probing the complex genetics of alcoholism. *Science* 251: 163–162.

Genes that protect against malaria discovered

Two sets of genes have been discovered that seem to protect against severe cases of malaria. The genes were discovered by researchers in Great Britain and Gambia and belong to a large and complex family of genes called human leucocyte antigen (HLA) genes. These genes take part in the body's defense against infection.

Researchers have theorized that "different HLA genes must protect people against different infectious diseases, so natural selection has resulted in the large variety of genes," *New Scientist* reports. These results are the first real proof that this theory may be true.

What the researchers found was that children with severe forms of malaria rarely had a particular sequence of two sets of HLA genes. Healthy children had

both sets of genes. The sets of genes are fairly common in people living in parts of Africa, where malaria is common, and are very rare in Europeans.

PHYLLIDA BROWN. 1991. The genes that protect against malaria. *New Scientist.* February 23: 26.

Release information to be accessible in Great Britain

After being pressured by environmental groups and the House of Lords, the British government has backed down on its previous decision, and will make information on releases of genetically modified organisms accessible to the public. A clause will be added to the Environmental Protection Bill that will propose a public register containing the applications for release, other information and the advice given by the Advisory Committee on Releases to the Environment.

PETER ALDHOUS. 1990. Glasnost for UK release information. *Nature* 347: 503.

Moth study to provide model for releases

The Mediterranean firethorn leaf-miner moth has invaded the county of Essex in Great Britain. The invasion provides a chance to study how insects spread, so the Department of the Environment is funding a 3-year project to monitor the moth's invasion.

It is hoped that the data will provide more information that can help predict what might happen with a future release of genetically modified insects into the environment. The researchers will monitor the insect spread with a small research team as well as by recruiting local natural history groups, biology students and conservation groups via leaf-lets. The results from the research group will be compared to those of the volunteer groups.

One fear is that the results will show that a small research group may give a distorted picture of the situation.

PETER ALHOUS. 1990. Moths provide a model. *Nature* 347: 115; 1990. Model moth for insect engineers. *New Scientist.* September 1: 16.

How should we best assess risks of environmental releases?

Internationally speaking, there seem to be two main lines of thought on how to assess the risks of and how to regulate genetically engineered organisms.

One line puts the emphasis on the *product,* the organism and the environment into which it will be introduced, with less emphasis on the methods used to make the organism. The other line is based more on the *process* used to make the organism.

The first line would judge not only genetically engineered organisms but organisms created by other genetic modification methods using existing regulations. This can be used in two completely different ways. A risk assessment can be made on all environmental releases, including organisms created by traditional breeding practices (such as crop plants). Or the risk assessment of the genetically engineered organisms can be based on what is already known about similar nonmodified organisms.

The line based on process is much more specific. It assumes that only genetically engineered organisms need risk assessment; however, different countries and agencies often use different definitions of what genetically engineered means.

Different agencies and countries are currently setting up regulatory frameworks and laws based on one or the other of these lines, which is already creating conflicts. In the United States, the Food and Drug Administration (FDA) and the National Institutes of Health (NIH) have pushed for the product-based line with the emphasis on judging the modified organisms based on what is known about unmodified organisms.

On the other hand, the United States

Environmental Protection Agency (EPA) and the Department of Agriculture are following the second, process-based line. The European Economic Community (EEC) has also adopted process-based regulations.

The major proponents of the product-based line have written an editorial in the journal *Science*. They complain that release experiments "have been subjected to extreme regulatory scrutiny and lengthy delays solely because recombinant DNA techniques were employed in the manipulation of the organism."

They are worried that researchers are avoiding areas of research in which field tests would be necessary and that companies are losing investors if they have products requiring field tests.

They propose a "risk-based oversight" of field tests based on a three-level system of risk assessment. The first level determines the need for concern based on knowledge of the unmodified parent organism. The second level determines the need for safety concern based on the site and conditions of release. This identifies the type of confinement that should be used in the field test.

The third level then looks at the genetically modified organism to determine if the modification changes the need for safety concern and therefore changes what confinement practices should be used.

Recently, the *Report on National Biotechnology Policy* was released by the United States president's Council on Competitiveness. The report claims that federal regulators "must reduce the burden of regulations that hamper companies trying to bring products to market," *Nature* reports. The council opposes all efforts to regulate biotechnology with new legislation.

Margaret Mellon of the National Wildlife Federation sees the report as the Bush administration's "unwillingness to regulate the technology."

HENRY I. MILLER, ROBERT H. BURRIS, ANNE K. VIDAVER and NELSON A. WIVEL. 1990. Risk-based oversight of experiments in the environment. *Science* 250: 490–491; DIANE GERSHON. 1991. Staying in competition. *Nature* 349: 729.

Modified bacteria in effluents leads to factory closure

The biotechnology company PROWIKO of Schönebeck bei Magdeburg has been shut down by the National Genetics Commission in the former German Democratic Republic (East Germany). The shutdown came after it became clear that there is a continuous trickle of genetically modified bacteria in effluent water from the factory, leading to release of the bacteria into the environment.

The bacteria are genetically modified to produce alpha-amylase. They are not considered to be harmful but the Commission wants the factory to conform to stricter standards and filter out the bacteria. This is currently not required by the Organization of Economic Cooperation and Development (OECD) guidelines for good industrial large-scale practice (GILSP).

STEVEN DICKMAN. 1990. East Germany says no. *Nature* 346: 502.

Modified petunia confuses scientists

Scientists planted thousands of genetically engineered petunias in a large-scale environmental release in Cologne, Federal Republic of Germany, during the summer of 1990. The experiment was meant to study "jumping genes," which are genes that can move within the DNA, leading to changes in certain visible characteristics.

The petunias were engineered to have a red color, but if a gene "jumped," the petunia would be white. During the field test, most of the petunias were red, as was expected, with a few white ones. But the white petunias were more frequent than predicted.

During a heatwave, all the petunias turned white, which is a normal occurrence when petunias are exposed to high temperatures, but they did not revert

back to the original numbers of red and white flowers as they should after the heatwave. More white flowers were produced.

And so far the researchers haven't found a "jumping gene" in any of the white petunias. Environmental groups say that this proves that scientists can't predict what will happen during releases and therefore can't really predict the risks involved.

DEBORA MACKENZIE. 1990. Jumping genes confound German scientists. *New Scientist.* December 15: 18.

British release program studies ecological consequences of modified plants

The ecological behavior of genetically modified oil seed rape (canola) has been studied in the British research program Planned Release of Selected and Modified Organisms (PROSAMO).

The oil seed rape plants were field tested at three sites with different climates and the seeds were sown next to unmodified plants in four different habitats: wet, dry, sunny, and shady. Some plants were given full protection (pesticides, fences, weeding) while others were not protected.

The results showed that none of the rape seed in the unprotected areas reproduced, meaning they cannot compete with weeds whether modified or not. In the protected plots, the rape seed thrived and reproduced.

One worry is that oil seed rape is genetically related to certain weeds with which it could hybridize. This would increase the risk of a genetic modification being spread to other plants.

So far, the researchers have found that oil seed rape does hybridize with some of its weedy relatives, but that the hybrids are sterile. Plant Genetics Systems (PGS), the biotechnology company that developed the genetically modified rape seed is hoping that this research will eventually lead to changes in policies for regulating these products.

JEREMY CHERFAS. 1991. Transgenic crops get a test in the wild. *Science* 251: 878.

Genetically engineered rabies vaccine tested in the United States

After several years of attempts to receive permission for a field test, the Wistar Institute has finally been able to test its genetically engineered rabies vaccine on raccoons. The vaccine was mixed in fish bait and placed out on Parramore Island, off the coast of Virginia.

The vaccine has already been field tested in Canada, Belgium, and France. Blood tests will be made on the raccoons to see if they have been protected by the vaccine.

The test received approval from the United States Department of Agriculture (USDA) in 1989, but officials in South Carolina, where the test originally was meant to take place, said no. The project then moved the test proposal to Parramore Island, which is owned by the Nature Conservancy.

After a year of negotiations with the Nature Conservancy, Wistar finally got the go-ahead. According to Jane Rissler of the National Wildlife Federation, "it was only when the Nature Conservancy became involved that 'the protocol finally came up to the science and safety standards that the USDA should have imposed,'" *Nature* reports.

DIANE GERSHON. 1990. Better late than never for start of tests. *Nature* 346: 785; 1990. Raccoons invited to lunch on rabies vaccine. *New Scientist.* September 1: 12; 1990. Recombinant vaccine finally gets a chance. *Science* 249: 982.

Plant biotechnology developments

"Researchers at DeKalb Plant Genetics in Groton [Connecticut] have produced fertile corn transformed with a foreign gene that makes the plants resistant to the herbicide bialphos," *Science* reports. This is the first time transgenic corn has been produced.

Researchers from the United Kingdom, China, and Australia have succeeded in inducing nitrogen-fixing bacteria to form nodules in the roots of rice, wheat, and oil seed rape. Normally, these bacteria only form nodules on the roots of legumes such as soya beans. So far, the researchers have not been able to show that the nodules fix nitrogen, but they hope that further modifications will lead to crops that can produce their own fertilizer.

The California biotechnology company Escagenetics has succeeded in producing vanilla in commercial quantities from vanilla plant cells grown in culture. Only 5% of commercial vanilla comes from the vanilla bean. The rest is made synthetically. The market for vanilla is thought to be $200 million (U.S.). The company is also planning to apply the method to producing drugs.

Researchers at the University of California at Davis and the biotechnology firm Calgene have succeeded in creating transgenic grapevine. They hope to place genes for pest and disease resistance into grapevine in the future. In the experiment, they placed marker genes in cabernet sauvignon and chardonnay grapevine.

Making genetically modified grapevine may cause problems in Europe however, as there are strict rules as to what constitutes wine — "a natural product of fresh grapes." Wine from "tinkered with" wine grapes would not be classified as wine. And transgenic grapevines will not be accepted easily in a system that requires the use of traditional cultivars by law.

ANNE SIMON MOFFAT. 1990. Corn transformed. *Science* 249: 630; SUSAN WATTS. 1990. Gene-spliced corn heralds customized crops. *New Scientist.* September 1: 27; ANNE SIMON MOFFAT. 1990. Nitrogen-fixing bacteria find new partners. *Science* 250: 910–912; COLLEEN SHANNON. 1991. Growing vanilla down on the factory farm. *New Scientist.* January 5: 24; ANDY COGHLAN. 1990. Splice of life for ailing vineyards. *New Scientist.* December 22/29: 15.

Biological diversity convention breaks down

"A global convention to conserve biological diversity could fall apart if developing and industrialised countries cannot settle a dispute over who should have access to biotechnology," *New Scientist* reports. "The future of the convention was thrown into doubt when developing countries, led by Brazil, India and China, demanded that the convention must allow them access to expertise in biotechnology that would enable them to exploit their biological resources."

Others at the conference were irritated that technology transfer became the focus, pointing out that the conference was on biodiversity, not biotechnology. The conference illustrates the growing conflict between developed and developing countries over control of world genetic resources.

OMAR SATTAUR. 1990. Convention breaks down over protecting gene pool. *New Scientist.* December 15: 12.

Next step for mouse patient in Europe

An appeals board at the European Patent Office (EPO) has instructed patent examiners to reconsider a previous decision that a genetically modified mouse can't be patented. However, the board has indicated that the patent may be refused if it goes against "public morality."

The "onco-mouse" has been previously patented in the United States. But Europe has not been as enthusiastic over the idea of patenting life forms. The European Patent Convention strictly rules out patenting "animal and plant varieties." However, the EPO has allowed a single plant to be patented because a single plant was not a plant variety, which is definedas "a multiplicity of plants which are largely the same in their characteristics."

Such legal loopholes are making it clear that lawyers, not scientists, are becoming the key interpreters of what plant and animal varieties are and what can and cannot be patented.

The European Commission is proposing in a new directive that all genetically engineered plants and animals should be patentable. The European Parliament is being lobbied intensively by the biotechnology industry to accept the proposal. Industry sees the lucrative market that patented plants and animals will bring. Environmental, farm, consumer, legal, and religious groups are campaigning against the proposal.

In Australia, the government has proposed a new bill that would make it possible to patent life forms, but not human beings. "The patenting of living things will be solely at the discretion of the Patents Office staff without reference to parliament, bioethics committees, the public or the constitution," Tania Ewing of *Nature* reports.

STEVEN DICKMAN. 1990. Mouse patent a step closer. *Nature* 347: 606; 1990. Europe changes tack on transgenic animals. *New Scientist.* October 20: 13; MARGARET LLEWELYN. 1990. Animal patents: Lawyers call the tune. *New Scientist.* December 1: 18; SUSAN WATTS. 1991. A matter of life and patents. *New Scientist.* January 12: 56–61; TANIA EWING. 1990. Australian law finds balance. *Nature* 347: 320.

Cetus Corporation wins patent on PCR technique

Cetus Corporation developed a revolutionary technique called the polymerase chain reaction (PCR), that can produce billions of copies of DNA in a very short time. The method has become a standard in all molecular biology work and the market for the technique is enormous.

Cetus patented the method but the patent was challenged by DuPont. DuPont has been producing kits using PCR that Cetus charges violate its patent. DuPont stated that a previous researcher had discovered the method and published it so that the method was in the public domain and therefore not patent-able. But the courts have upheld Cetus' patent rights and Cetus now plans to sue DuPont for infringing its patent.

MARCIA BARINAGA. 1991. Biotech nightmare: Does Cetus own PCR? *Science* 251: 741; MARCIA BARINAGA. 1991. And the winner: Cetus does own PCR. *Science* 251: 1174; ELIZABETH SCHAEFER. 1991. Cetus retains PCR patents. *Nature* 350: 6.

Amgen wins against Genetics Institute over EPO patent rights

Amgen and Genetics Institute have been in a long and bitter patent conflict over who has the rights to erythropoietin (EPO) manufacture and sale in the United States. A United States court has decided in Amgen's favor, invalidating Genetics Institute's patent. This guarantees a monopoly for EPO for Amgen. Genetics Institute has previously sold EPO in the United States via its license with Chugai Pharmaceutical Company from Japan.

DIANE GERSHON. 1991. Amgen scores a knockout. *Nature* 350: 99.

Cetus doesn't receive approval for new product

The United States Food and Drug Administration (FDA) has decided not to approve Cetus Corporation's new drug, interleukin-2 (IL-2). IL-2 is being clinically tested for an untreatable form of kidney cancer and has shown promise.

But Cetus made the mistake of presenting new material at the last minute to support its claims, leading the FDA to ask for more time to evaluate the drug's risks and benefits. The FDA also asked for the material to be presented in a better form for risk assessment. The decision sent Cetus stock prices plummeting.

In response to the decision, Cetus president Robert Fildes was forced to resign and 100 workers were laid off. Cetus may be forced to sell off parts of the company as it was counting on the IL–2 approval to bring in badly needed revenues.

BARBARA J. CULLITON. 1990. Cetus's costly stumble on IL–2. *Science* 250: 20; ELIZABETH SCHAEFER. 1990. The long and winding road. *Nature* 346: 501; ELIZABETH SCHAEFER. 1990. Cetus forced into staff cuts. *Nature* 346: 691.

Naked DNA may be cancer risk

"Fresh evidence has emerged that laboratory workers who handle DNA without taking precautions may be at risk of cancer," *New Scientist* reports. The British government has thus decided to tighten its safety guidelines for such work.

Researchers have found that certain sequences of naked human DNA from cancer cells can cause skin tumors in mice when applied to broken skin. The additions to the guidelines include how to clean up after a DNA spill and advise workers with broken skin to receive medical advice before working with cancer genes.

PHYLLIDA BROWN. 1990. Naked DNA raises cancer fears for researchers. *New Scientist.* October 6: 17.

Link between drug and fatal blood disorder in United States

An outbreak of eosinophilia-myalgia syndrome (EMS) has been linked to batches of L-tryptophan manufactured in early 1989 by Showa Denko in Japan. The product is produced by genetically engineered bacteria and is taken for insomnia, depression, and premenstrual tension. So far 27 people have died and 1,535 others are affected.

The company made two production changes in early 1989: They modified their purification system and they introduced a new genetically engineered strain of the bacteria into the process.

The outbreak has caused a widespread outcry and the Foundation for Economic Trends, a public interest group, has filed a petition with the United States Food and Drug Administration (FDA) calling for a risk assessment of the dangers of recombinant DNA technology, including full disclosure of all findings in the L-tryptophan case.

Margaret Mellon of the National Wildlife Federation states that this is a good example of the conflicting roles the FDA plays as both promoter and regulator of biotechnology. The FDA apparently was aware of the link between EMS and L-tryptophan for several months before the results were published. But FDA officials were hoping to keep the link quiet until they were sure that genetic engineering played a role.

Researchers think that the new strain of bacteria may have inadvertently produced L-tryptophan dimers leading to a doubled concentration of the substance in the product. Rats fed with the Showa Denko product develop symptoms linked to EMS. Researchers are now trying, to determine exactly what in the L-tryptophan product is the cause of the symptoms, the tryptophan, the dimer, or other contaminants.

DIANE GERSHON. 1990. Tryptophan under suspicion. *Nature* 346: 737; LESLIE ROBERTS. 1990. L-tryptophan puzzle takes new twist. *Science* 249: 988; PHILIP RAPHALS. 1990. Does medical mystery threaten biotech? *Science* 250: 619; MARGARET MELLON. 1990. Biotechnology, human disease, and the FDA. *Science* 250: 359.

Bovine growth hormone controversy continues

The British government has decided to refuse a license for bovine growth hormone (BST), which increases milk production in cows. This puts Great Britain on a collision course with the European Commission, which is currently reviewing its own position on the hormone.

In the United States, the state of Wisconsin has banned the use of the hormone mainly to protect family farms. Studies have shown that widespread use of BST would increase milk yields and would cause small farms to go under in the economic competition.

In a surprise move, the United States Food and Drug Administration (FDA) published "data on the safety of a drug before it has been approved for use," Ann Gibbons of *Science* reports. The FDA concludes that BST poses no health risks to consumers.

"Critics charge that publishing the article makes the agency a backer of the drug rather than a neutral evaluator," *Science* continues. It places the FDA in the role of advocate for a drug that has yet to be approved. Critics also claim that the FDA has refused to release data showing ill effects of BST on cows.

To further complicate matters, the National Institutes of Health (NIH) asked 13 experts to go through all the data on the BST to determine its safety. The panel of experts concluded that BST poses no threat to humans even if it were to be transferred to the milk.

But the group stated that it had not received data on BST's effects on cows. This data is held by the FDA. Samuel Epstein, professor of occupational medicine and one of the major critics of BST stated that this data damned the hormone.

Several scientists also told the panel that they had been intimidated by drug companies and the FDA in attempts to manipulate animal health data on BST. One scientist from Virginia Tech [Virginia Polytechnic Institute] stated that letters had been sent to the dean of his institute stating that he "should not be allowed to speak on BST or that the company would not give money to Virginia Tech," Diane Gershon of *Nature* writes.

Milk produced by cows being tested with BST is currently going into the general milk supply in the United States.

1990. Thumbs down for milk hormone. *New Scientist.* August 4: 25; WILLIAM LESSER. 1990. Technology and the family farm. *Nature* 347: 11–12. ANN GIBBONS. 1990. FDA publishes bovine growth hormone data. *Science* 249: 852-853; DIANE GERSHON. 1990. BST gets clean bill of health. *Nature* 348: 574; CHRISTOPHER JOYCE. 1990. Scientific support for "milk" hormone rekindles controversy. *New Scientist.* December 15: 11.

DOCUMENT
INTRODUCTION TO "THE NEW REPRODUCTIVE TECHNOLOGIES: A TECHNOLOGICAL HANDMAID'S TALE"

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REPORT ON THE CANADIAN ROYAL COMMISSION EXAMINING NEW REPRODUCTIVE TECHNOLOGIES

In Canada, a Royal Commission is underway that has a broad mandate to investigate is sues surrounding new reproductive technologies (NRTs) and their implications for Canadian society. A Royal Commission is a government-funded study group that travels the country hearing from individuals and groups in order to examine an issue and file a report making recommendations to any level of government concerning issues raised in the study. Canada is without legislation concerning NRTs and, consequently, the report could recommend legislation where applicable as well as recommend areas that need further research, funding, or attention.

The Royal Commission on New Reproductive Technologies was lobbied for by many groups including feminists, medical and legal groups, infertile couples, and researchers. The Commission has an incredibly broad mandate to hear submissions on the social, ethical, health, research, legal, and economic implications of NRTs. In addition, the Commission is mandated to examine the implications for women's health care–in particular, the causes, treatment, and prevention of the male and female infertility, sterilization procedures, artificial insemination, in vitro fertilization (IVF), embryo transfer, prenatal screening, genetic manipulation and therapeutic interventions to correct genetic anomalies, sex-selection techniques, embryo experimentation, and fetal tissue transplants. The Commission is also looking into the social and legal arrangements of NRTs, including surrogacy, judicial interventions in gestation and birth, and the "ownership" of ova, sperm, embryos, and fetal tissue. The Commission will investigate the status and rights of individuals using or contributing to NRT as well as access to procedures, "rights" of parenthood, informed consent, status of gamete donors, confidentiality, and the impact of all of these services on all parties, particularly children. Last, the Commission will examine the economic aspects of NRTs, as well as the commercial marketing of ova, sperm, and embryos, the application of patent laws and the funding of research and procedures, including infertility treatment.

The Commission was established in October of 1989 and began holding public hearings in September of 1990. During the phase of public hearings, more than 550 people presented submissions. A unique facet of the Royal Commissions is that any concerned individual may make a submission to the Commission. While most submissions are from organized lobby groups, the Commission structure allows individuals to impact the research of the Commission and the final report. Among the groups that presented were groups involved with or advocating for community health, women, medical groups, academics, researchers, religious, legal and ethical scholars, labour and Aboriginal groups, immigrant and visible minority groups, and many individuals.

The Commission has now finished public hearings and is awaiting the final written submissions from those groups due in April of 1991. Currently, commissioners are meeting in private sessions with individuals or couples who wish to share their experiences with NRT in a private rather than public capacity. Individuals or groups may also submit briefs without appearing before the Commission or call a toll-free telephone line for information on the Commission.

The Commission is requesting an extension of time to gather information and write its report because of the overwhelming number of responses from across the country. The Commission has heard a variety of different perspectives from a broad range of groups and individuals. One theme that has been stressed in many submissions is the aspect of prevention of infertility through the treatment of sexually transmitted diseases or workplace and environmental hazards. Most methods of infertility treatment are recognized as both expensive and invasive treatment methods.

The Canadian health care model offers limited access to individuals regarding education and information. Medical professionals have a privileged access to information that may or may not be offered to women as part of the decision-making process involved in choosing NRTs. In this context, many women's groups have expressed concern about the lack of information, the lack accurate statistics on success and failure rates, and the lack of choices offered to women involved in infertility treatment. In addition, groups representing women in northern communities where medical professionals and facilities are often lacking have expressed concern that basic health care is a greater priority than NRTs.

Of the many perspectives offered by groups and individuals to the Commission, the feminist criticisms of NRTs have been very prevalent in submissions. Many of the criticisms of the technologies are rooted in an understanding of the current societal context of the status of Canadian women in our society. NRTs are accused of offering male-controlled medical and pharmaceutical industries entirely new ways of exploiting and oppressing women. The priorities in spending (on both research and treatment) enormous amounts of money on risky and often unsuccessful infertility treatments do not represent a commitment to improving all women's reproductive health care. NRTs also offer the possibility of the commercialization of human body parts, in this case mostly women's bodies, which may further erode the choices available to poor and marginalized women in Canada.

Many feminists have identified reproductive technology that can be of benefit to individual women but does not risk collective harm to women or to the status of women in Canadian society. Techniques such as tubal reconstruction or nonmedical artificial insemination have been viewed by some feminists as uses of reproductive technologies that are not harmful. The continued medicalization of reproductive health can be viewed in terms of narrowing women's reproductive choices by placing more control of women in the medical profession. Ideologically, the technologies view the woman and the fetus, or potential fetus, as entirely separate entities or entities in conflict with each other. Also ideologically, the techniques are accused of reinforcing the social pressures for all women to have their own biologically linked children. Finally, women are continually being used in the development and implementation of NRTs as experimental subjects, often without regard for the short- or long-term risks involved.

At the centre of some feminist analysis of reproductive technologies in Canada is a distinction between individual and group benefits of technologies and how such technologies can be used to benefit all Canadian women, rather than just a privileged few. Most feminists have argued that regardless of which technologies are permitted, they must be available to all women regardless of discrimination in terms of income, marital status, sexual orientation, race, or disability. Many feminists also advocate that our societal resources be primarily directed at prevention of infertility as well as poverty

malnutrition, pollution, stress, and substance abuse to improve the reproductive and general health status of Canadian women.

Finally, feminists have insisted on a democratization of knowledge on NRTs. The Royal Commission is viewed as a positive first step in the process of widespread education and dialogue surrounding the complex issues raised by NRTs. It is hoped that through the Commission there will be an ongoing consultation with women, both individually and collectively, through feminist organizations. The Commission will, it is hoped, recommend the establishment of a monitoring body to keep track of research or the practices of NRTs in Canada. While recommendations from Royal Commissions are not binding on any level of government, women's groups will keep pressure on both the Commission and the Government for continued involvement in the debate and legislation of NRTs in Canada.

For more information on NRTs in a Canadian context contact:

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