CONTRACEPTION

Birth rates declining in Third World countries but family planning money still, needed

The United Nations population fund (UNFPA) has issued a report about the current state of family planning worldwide. Family size is declining worldwide but the demand for contraception is much greater than the supply. To meet UNFPAs goal of reducing the number of children a woman has from 3.8 to 3.3 by the year 2000, spending on family planning must double. Part of the campaign is aimed at the United States, where funding for UNFPA was cut off because they were accused of “abortion-related” activities.

UNFPAs director, Nafis Sadik, also “stressed the crucial link between improving the status of women and reducing birth rates,” New Scientist reports. “Women and girls must have equal value; higher status will bring increased ability to choose, and when they have the choice, women seem to exercise that choice,” she said.


India launches own contraceptive

The Indian government will soon allow the marketing of a contraceptive pill developed at the Central Drug Research Institute in Lucknow. The pill is called Centchroman and is not based on steroid hormones like all other contraceptive pills. Centchroman does not disturb the normal functioning of the hormone-producing organs such as the pituitary in the brain and the ovaries. It seems to block estrogen receptors in the uterus so that estrogen can not act on the uterus wall to prepare it for a fertilized egg.

The only side effect seen so far is a slightly longer menstrual cycle in 8% of the women. Centchroman has a failure rate that is higher than other pills but lower than the condom’s.


ABORTION

Woman’s death linked to abortion pill

A 31-year-old woman ending her 13th pregnancy died after treatment with a combination of RU 486, the abortion pill, and the prostaglandin sulprostone. The woman, a heavy smoker, died of heart failure and is the first known death from this treatment. Over 100,000 women have now had abortions using RU 486, the majority of them in France. These figures can be compared with figures for legal abortions in England for 1989, where 183,974 abortions resulted in one death. When given together with pro-staglandins, RU 486 is 95% effective in causing an abortion before the ninth week of pregnancy.
Doctors suspect that the prostaglandins might have caused the woman’s death. Prostaglandins are known to cause muscle contractions and to lower blood pressure. Sulprostone is given by injection which releases it very quickly into the body, which can, in rare cases, lead to a sudden drop in blood pressure and possible heart failure.

Other countries are using prostaglandins given as vaginal suppositories and recently, an oral form has been tested that seems to be much milder, leading to less cramping during the abortion. The oral form would make it possible for the woman to take it at home instead of under the close medical supervision required today. But researchers now are afraid that antiabortion groups will use the death to frustrate plans for wider use of RU 486.


RU 486 now available for research purposes

Previously, access to RU 486, the so-called “abortion pill,” has been restricted especially in the United States. Antiabortion groups have threatened to boycott other Roussel-Uclaf products if RU 486 was allowed into the country. But RU 486 has shown promise in treating Cushing’s syndrome and breast cancer and researchers want to pursue this research. The U.S. Food and Drug Administration has now loosened the restrictions and researchers now have access to the drug.

The New Hampshire state legislature passed a resolution in May on its willingness to host clinical trials of RU 486 for abortions. California’s state assembly is planning to do the same. These are the latest attempts to encourage Roussel-Uclaf to enter the U.S. market.

In Great Britain, RU 486 has received a licence and will soon be on the market. It is known as Mifegyne and will be tightly controlled to prevent a black market. Private abortion clinics will offer RU 486 abortions for the same price as surgical ones.


FETAL RESEARCH

Ban on fetal tissue research debated by U.S. Congress

Fetal tissue research using public funds has been banned for many years after the Reagan administration disbanded the ethics committee that was required to approve research proposals. The Bush administration has continued the ban but Congress is pushing to overturn it.

The House of Representatives has held hearings on the topic highlighting the use of fetal tissues in transplants. In July, the House voted to overturn the ban but they fell just short of a two-thirds majority which is needed to override President Bush’s certain veto. The bill now goes to the Senate for approval.


Fetal tissue researchers pressuring for abortion modifications

Dorle Vawter of the Center for Bioethics at the University of Minnesota states that doctors and researchers wanting fetal tissues from abortions are pressuring for changes in
abortion procedures. They are “persuading clinics to adopt abortion procedures that jeopardise the health and privacy of women having abortions,” New Scientist reports.

Vawter has been studying how researchers and doctors obtained fetal tissue over the past two years. A normal suction abortion makes it difficult to find the desired tissues in the fetal remains. Brain tissue is needed from fetuses 7 to 11 weeks old.

Some clinics have gone over to using less suction and have slowed down the abortion process so as to obtain less damaged fetuses. “In the U.S., women are supposed to sign a form allowing tissue from their fetuses to be used in research,” New Scientist states. But the “forms say that abortion procedures will not be modified.”

Doctors usually want other information as well such as the woman’s health records and additional blood tests. According to Vawter, “women should be better informed about how the tissue will be used and should be told that researchers who receive the tissue will also have access to their blood samples and health charts. They should also be told that there is currently no shortage of fetal tissue for transplants.”


INFERTILITY

Eggs may signal sperm to swim to them

A new study suggests that mature eggs may release a chemical signal that causes sperm to swim towards them. Researchers collected eggs and the follicular fluid around the eggs from women undergoing in vitro fertilization at Sheba Medical Center in Israel. The women had received hormonal drugs to cause them to produce many eggs at once.

The follicular fluid from each egg was tested for its ability to attract sperm. The fluid from eggs that were later successfully fertilized was found to attract the most sperm. These results have led the researchers to speculate that some types of infertility may be due to defective egg-sperm communication. The chemical responsible for attracting sperm is unknown. Purifying it would require large amounts of follicular fluid.


IN VITRO FERTILIZATION

Interim Licensing Authority critical of new watchdog’s plans

The Interim Licensing Authority (ILA) in Great Britain is critical of the plans of the permanent group to take over its work, the Human Fertilisation and Embryo Authority (HFEA). In its sixth and final report, the ILA points out loopholes in the HFEA’s proposals such as a possible inability to police in vitro fertilization (IVF) carried out at small clinics. Small clinics have low success rates and lack the expertise of larger clinics and hospitals the ILA states.

Rising numbers of multiple births are due to lack of compliance to a 1987 ILA guideline that no more than three embryos be replaced in a woman’s uterus. Yet in 10% of transfers in IVF and 60% of transfers in gamete intrafallopian transfer (GIFT), four or more embryos have been replaced. Several clinics only transfer two embryos with no reduction in success rates and the ILA hopes the HFEA will force other clinics over to a maximum of two embryos per transfer.

The ILA is especially critical of the HFEA’s refusal to regulate GIFT centers, making it impossible to restrict their transferring as many embryos as they wish. “GIFT is totally out of control,” states Mary Donaldson, chair
of ILA. “Many centres will be encouraged to use GIFT because there will be no controls.” The ILA is also critical because of HFEA’s plan to get rid of the independent ethics committees that oversee clinical and research aspects of IVF. “The HFEA says that only research on embryos presents ethical dilemmas,” Gail Vines of New Scientist writes.

In an editorial in New Scientist, Sammy Lee of the Northampton Fertility Service agrees with the major points brought up in the ILA report. He adds several other criticisms of the HFEA’s plans such as “the clause in the HFEA’s code of practice regarding the welfare of the future child. This clause requires every clinic to consider the likely family environment of the unborn – indeed, even the unconceived – child before deciding on whether to proceed with treatment.” This would allow clinics the right to evaluate patients, which some are worried will lead to discrimination.

“The issue is further complicated when one considers the question of who is qualified to carry out such assessments,” Sammy Lee continues.


Victorian Infertility (Medical Procedures) Act under review

The Victorian Standing Review and Advisory Committee on Infertility (SRACI) has been reviewing the Victorian Infertility (Medical Procedures) Act 1984, which is the legislation regulating reproductive technology programs and human embryo research in the state of Victoria, Australia. The review was prompted because of community concern about developments in embryo research and ambiguities in the legislation.

For example, there is no definition of embryo under the act, and there is a division of legal opinion as to whether experimentation is permitted on embryos older than 22 hours. In a supposed “leak” to The Age newspaper, it was reported that the SRACI would approve experimentation on embryos up to 14 days.

FINRAGE (Australia) presented a comprehensive submission to the SRACI in which it pointed out that the act already permits destructive experimentation on spare embryos which are older than 22 hours. Other aspects of the SRACI’s review include time limits on the storage of frozen embryos, criteria for people allowed to participate in reproductive technology programs, a central register for the recording of information about gamete donors, and membership of the SRACI.


Human egg freezing “perfected” in Australia

Researchers at the Royal Women’s Hospital in Melbourne claim to have “perfected” techniques to successfully freeze and thaw mature human ova. Mr. Ian Johnston, a researcher in infertility at the Royal Women’s Hospital said that research on freezing methods had been carried out after the past three years and the latest tests indicated that the eggs were “surviving well”. Mr. Johnston said many researchers had been hesitant about freezing mature eggs because of the damage that is caused to the egg’s chromosomes in the freezing and thawing process.

The researchers now want to fertilize such freeze-thawed eggs and carry out chromosomal analysis on the subsequent embryos. They have applied to the Standing
Review and Advisory Committee on Infertility in the state of Victoria to carry out tests on embryos older than 22 hours which would result in the destruction of such embryos.

At present the Victorian Infertility (Medical Procedures) Act requires approval for experiments which would involve destruction of embryos created specifically for the purposes of experimentation. Such embryos are allowed to develop up to but not beyond the point of syngamy (approximately 22 hours) under the statute. However, the same restrictions do not apply to “spare” embryos, i.e., those which are not implanted back to a woman’s body during an IVF cycle.

Mr. Johnston said that “We now have the technique which appears to be able to allow us to freeze and thaw mature eggs. The next step is to fertilize the egg . . . to see if sperm penetration is a success.”

Professor Carl Wood claimed that women have approached him to enquire about the possibility of egg freezing so that they could defer having their children while they concentrated on their careers. Wood said that if women had their eggs collected and frozen when they were young, it would enable them to give birth later in life (by embryo transfer) without the fear of having a child with genetic abnormalities, such as Down’s syndrome.

Dr. John McBain, an IVF gynaecologist said that women who faced becoming “sterile by reaching menopause, or as a result of medical treatment,” may soon be able to have their eggs stored. The researchers claim that freezing of eggs would remove the ethical problems associated with the storage of frozen embryos.


SURROGACY

France outlaws surrogacy


GENETIC ENGINEERING

Human genome ethics treaty discussed

The National Institutes of Health (NIH) in the United States sponsored a conference in June on the ethical and social issues that arise from the human genome project. The conference gathered ethicists and policymakers from around the world to discuss the need for an international genome ethics treaty. Consensus was not reached, however, as different countries have different approaches to ethical problems so the conference could only recommend international task groups to continue discussing the issues.

The Federal Republic of Germany, for example, allows embryo screening for genetic defects only for severe sex-linked disorders and has banned human germ-line gene therapy. James Watson, head of NIH’s genome project, “said he could not see how a developed nation can continue being ‘backward,’ denying pre-implantation genetic screening for couples at risk of having children with genetic diseases, simply ‘by invoking the name of Hitler,’” Peter Aldhous of Nature reports. But the German representatives believe that their laws will be the model for the rest of the world.

In an editorial about the conference, Nature takes up two of the most pressing ethical issues of the human genome project. “First, there is the business of the use of personal genetic information to calculate people’s risk of calamity later in life. Second, there is the eugenic inclination stemming from people’s
wishes that their descendants should be genetically as well-endowed as possible.” In answer to these issues, *Nature* thinks that arguments to restrict insurance companies ability to exploit genetic information and prevent people from seeking eugenic improvement are unsustainable.

“A rule that insurance companies should not seek genetic information about potential policy-holders would probably be unenforceable, would be unjust to those free from defect and would probably be unconstitutional in most advanced countries.

“The eugenic issue, to which the present practice of amniocentesis followed (sometimes) by abortion is a crude approach, is similarly unstoppable in the long run. . . . And can even the manipulation of the human genome be prevented in the long run, whatever national legislation may say about today and tomorrow?”


**Who will coordinate the human genome’s ethics research?**

At a human genome workshop in London in August, Baroness Mary Warnock, told geneticists “not to patronise lay people about the ethics of research into the human genome,” Phyllida Brown of New Scientist reports. “Instead, they must help to encourage education and open debate if they want to be allowed to continue useful research.” Both the Human Genome Project in the United States and the European Commission have set aside research funds for studying the ethical and social consequences of the project. So far no one is taking responsibility for coordinating this research, but there is growing pressure on HUGO, the international human genome organization to take on this role. The head of HUGO, Walter Bod-mer, thinks it is very likely that HUGO will try to coordinate the international debate on the ethical aspects of the human genome project.


**Human Genome Project discusses database strategy**

The human genome workshop in London pulled together researchers from around the world to update the human genome database and to discuss their research. It also provided an opportunity to discuss strategy for mapping genes.

The database contains sequences, landmarks, and identified genes and their locations on the chromosomes, and the rationale for the database is that researchers freely share their data by putting it in the database. But there are nagging worries that this may not be the case in the future. Researchers wanting to outcompete their rivals or obtain patents may hold back their data. This is especially true as researchers turn from the monotonous job of sequencing the genome to the much more interesting and financially rewarding job of finding disease genes.

Another problem facing the database is the sheer amount of data that will be coming in as gene mapping picks up speed. As data has come in, it has been screened and checked for errors before being put in the database. This will lead to increasing delays in the future,
unless the screening step is removed. But that will allow errors to creep into the data. One suggestion is to create intermediate databases that will be used as clearinghouses for unchecked data.


Human genome researchers waste money on patent applications

“American researchers taking part in the international project to map the human genome are squandering hundreds of thousands of dollars in futile attempts to patent sequences of human genetic material,” New Scientist reports. “European partners in the project are angry at what they see as a waste of money and are seeking urgent discussions through the Human Genome Organisation (HUGO) . . . to avoid a transatlantic split in the programme.”

Researchers in the United States file patent applications on 1000 partial genetic sequences monthly at a cost of $30 (US) per application. This adds up to $30,000 (US) per month which is double the cost of the actual sequencing. Walter Bodmer, chairman of HUGO, thinks this “nonsense.” “The UK and European view is that you should press for a situation where those partial sequences are made unpatentable,” Bodmer states.

Besides costing a lot of money, these patent applications are also a waste of time. Patents are not valid unless the invention is novel and can be used industrially. Sequences of human genetic material have no apparent use and therefore are not patentable. It is only much later, after the sequence has probably been publicly available in the genome database for some time, that the use for that possible genetic sequence may become apparent. But at that point the sequence is no longer novel and a patent on it would not be worth much.


European Commission polls public about biotechnology

The European Commission sent out a questionnaire to 12,800 Europeans in the 12 EEC countries asking their opinions on biotechnology. The results show that those who know most about it also think that it is risky, or as one official put it, “The more they know, the less they like it.” A majority of those surveyed put more trust in what environmental and consumer organisations say about biotechnology than government agencies and industry. “Only half of the people questioned thought biotechnology would improve life,” Debora MacKenzie of New Scientist writes. “A tenth of all respondents, and 20% in Holland and Denmark, thought biotechnology would make things worse.”

Many were doubtful about research that would improve farm animals or use animals to produce drugs. But 95% were positive to producing microorganisms that could clean up oil spills although 58% saw such research as risky. Over 90% want government to control biotechnology research.

In response to this survey, Bernard Dixon, editor of the journal Bio/Technology’, laments the fact that scientists and others are not trying to combat “a rising tide of hostility towards biotechnology among the citizenry and politicians of Europe.” This inactivity, Dixon says, “leaves the arena wide open for occupation by lobbies and activists whose role is to curb scientific and technological innovations or indeed arrest them altogether.”
And in an editorial. New Scientist sees the positive side of the survey. The fact that responses from Denmark and Germany showed that these countries are best informed about biotechnology at the same time that opposition to the technology is strongest in these countries “reveals important nuances and a level of sophistication in public debate that undermine crude models of social behaviour.” These results “should not be immediately labelled as neo-Luddite opposition.” Even scientists, who are trained to question facts, should be sceptical to any new technology. In fact, “countries in which disciplined scepticism is allowed to thrive often produce not only a strong scientific community, but also an active debate over both the positive and negative contributions of science to society.”


Engineered food found unappetizing in the Netherlands

“Most people are unwilling to accept food that is produced by biotechnology or genetic engineering, according to a Dutch survey of 870 people,” New Scientist reports. People were only willing to accept such food if it showed obvious benefits to the consumer or environment. Consumers feel that decisions about using these technologies in food are made without asking them or involving them in the decision-making process.


U.S. Department of Energy genome project finally gets going

The Department of Energy (DOE) originally started the Human Genome Project but was quickly out-competed by the National Institutes of Health (NIH). The DOE has been trying ever since to find its niche in the project. During the spring, David Galas, a molecular biologist, became the new associate director of health and environmental research at the DOE and immediately began to reorient the agency’s genome research.

He has improved the three genome centers at national laboratories, created better ties with NIH and allowed research expansion into areas previously considered off limits. The DOE is now set to map and partially sequence all the active genes in the human genome. Galas also discovered that the DOE has a wealth of genetic research on mice that can be directly used to speed up mapping human genes, since many genes are very similar across species.


Japan still struggling to start own human genome project

The Science and Technology Agency in Japan plans to create a DNA analysis center using funds from private industry. This is the third center to be created for working on the human genome project. The first is being set up by the Ministry of Education, Science and Culture and the second by Chiba prefecture as part of a science park. The STA is also requesting a 50% increase in research funds for Japan’s human genome project.

**HUGO opens office in Moscow**

“The Human Genome Organization (HUGO), the body set up to help coordinate the international effort to map and sequence the human genome, is opening an office in Moscow,” *Nature* reports. The office opened in July and will hopefully improve communication between researchers in different parts of the world. The human genome project in the Soviet Union is the second largest, after the United States but communication has been poor. The opening of the office combined with a satellite link will make the human genome databases accessible for Soviet researchers. HUGO also has offices in Bethesda, Maryland, in London and in Osaka, Japan.


**HUGO seeks affiliation with Johns Hopkins University**

“The Human Genome Organization (HUGO) is negotiating to affiliate its American office in Bethesda, Maryland with Johns Hopkins University, less than one hour away in Baltimore,” *Nature* reports. “Such a move would allow the office to receive grants from federal agencies, ending its reliance on charitable funding.” HUGO currently runs on a donation from the Howard Hughes Medical Institute of $1 million for a 4 year period. Besides being able to apply for federal funding, one advantage with affiliating with Johns Hopkins University is that the Human Genome Database is housed there.


**Industry finds a role in Human Genome Project**

The National Institutes of Health (NIH) genome center has granted $5-million for a 3-year period to the biotechnology company, Collaborative Research, Inc., in Massachusetts. The company plans to sequence the genomes of two mycobacteria and promises to do so for 50 cents per base using a new technique called multiplexing. This grant will test industry’s capacity to take on the routine and boring task of sequencing, something university researchers are becoming less interested in doing.


**Genetic information disappearing along with disappearing indigenous peoples**

Two researchers, population geneticist Luigi Luca Cavalli-Sforza and molecular anthropologist Allan Wilson of the University of California, Berkeley are “are calling for an urgent, last-ditch effort – involving geneticists, anthropologists, and medical researchers worldwide – to collect, analyze and preserve for future study DNA from [disappearing] populations as part of a massive survey of human genetic diversity,” *Science* reports. There are hundreds of populations of indigenous peoples who have been isolated from interbreeding with other groups and who provide “a unique glimpse into the gene pool of our ancestors who lived thousands of years ago,” *Science* continues.

The human genome project is mainly studying the genetics of Caucasians but the project will not provide information on the genetic diversity of the human population. This variation can be used to trace the historic movements of ancient groups. The project has received much support and many genome researchers think it is one of the more interesting ideas to come along within the genome project. But the project is having difficulty finding funding as it is too expensive for most of the usual scientific programs. So the researchers are looking to the Human Genome Project for help.
The major problem is getting blood samples from the hundreds of indigenous populations spread out all over the world. Some are almost totally isolated in various jungles and Cavalli-Sforza and Wilson are enlisting the help of researchers who already have access to these groups.


**More animals become subject of genome projects**

More animals are getting their own genome projects. The latest are the pig and dog. PiGMaP is the name of the pig genome project, a 3-year project that 16 European laboratories have started to create a physical and genetic map of the pig genome. Researchers at the University of California at Berkeley are planning to search out the genes that steer dog behavior.


**Japan’s rice genome project finds unusual source of funds**

Japan is planning its rice genome project but there are several problems. One is how public the data will be. Much of the research will be done by industry and they are not sure of how open they want to be. If industry only shares data on the probes it uses and not the locations of the genes, scientific publication of the results would be blocked. This in turn would put all collaborations with other countries in jeopardy.

At the same time, the rice genome project has found an unusual source for research funding. Previously, funding has been provided by the Ministry of Agriculture, Forestry and Fisheries. This has been $2.7 million per year which is considered to be too little to fund all the research necessary for the project. But the Japanese Racing Association, the regulator of horse racing has decided to help. The Association uses 25% of its returns to support a variety of projects including research.

“And the association finds itself unusually wealthy these days, thanks in great deal to the increased popularity of horse racing among Japan’s ‘office ladies’ – secretaries who have disposable income and spend their money on clothes and entertainment,” *Nature* reports. The association plans to donate $6 million during the first year which will triple the rice genome budget. The association is also supporting a horse genome project.


**Screening for cystic fibrosis nears**

The National Institutes of Health genome center has decided to provide $1 million “for pilot studies to evaluate how to deliver a DNA test that would detect carriers of the defective cystic fibrosis gene,” *Science* states. Without such pilot studies, which would include education and counseling for those receiving the test, there are worries that the test will do more harm than good. Full scale testing will eventually include tens of millions of people in North America alone.


**Notification of potential carriers of genetic defect creates ethical problem**

Researchers at France’s Institut National d’Etudes Démographique (INED), searching through five centuries of records from one
French village, discovered a pattern of blindness that they could trace back to one couple in Brittany in the 15th century. Using this information, the researchers “have traced no fewer than 30,000 living Frenchmen and Frenchwomen who are descended from that couple, and they have found more than half of all reported French cases of juvenile glaucoma have occurred in people in that direct lineage,” Science reports.

This particular form of blindness can be prevented if treated early with drugs or surgery, so the researchers wanted to inform doctors who had these people as patients so they could treat them. The researchers have been thwarted, however, by French privacy law. The law is meant to protect the privacy of French citizens and requires that they give their permission before researchers may look for this type of information.

There is concern that giving a list of names of persons with a potential genetic defect could be used by insurance companies or employers. So, for the time being, the researchers can only alert doctors to the fact that some of their patients may develop juvenile glaucoma. They consider this to be ineffective and are currently trying to get the privacy law changed.


Genetic register proposed in Australia

The National Health and Medical Research Council (NH & MRC) in Australia has made a decision to approve genetic registers. Information for a genetic register begins to be collected when a family member is referred to register staff for diagnosis, genetic counselling, predictive testing, or management of a particular genetic condition.

The NH & MRC’s guidelines for genetic registers state that the “pedigree and health status” of family members are to be recorded in so far as they are known to the family member being interviewed. More information may be obtained from members of the immediate family, more distant relatives, hospital records, and health professionals. The register would be formed by systematic gathering and cross-checking of information. The guidelines note that information is obtained by personal contact with individuals only after obtaining consent, which may be given verbally. Information about family members could be recorded, even though consent has not been obtained from them.

Nicholas Tonti-Filippini, a bioethicist with the Australian Catholic Bishops Conference is concerned that genetic data bases provide another avenue by which medicine can control and pressure individuals to accept medical management even when they are asymptomatic and quite well. Individuals who have been identified as having a genetic disease are likely to be placed under enormous moral pressure to enter programs aimed at eliminating genetic disease, such as sterilization, prenatal testing, or IVF using genetic screening of embryos. Those individuals who have been identified may also find it extremely difficult to obtain health insurance, disability cover or death superannuation benefits.

Mr. Tonti-Filippini also points out that while this is an issue for broad community concern, the guidelines have been decided by an elite group. The NH & MRC’s guidelines are not subject to veto by Parliament. The NH & MRC has the role of promoting research but it is also the body that sets ethical limitations on research. The two roles are conflicting and the result is a lack of ethical review of medical research and new procedures.

Screening for cancer susceptibility moves closer to reality

In the wake of the human genome project, genes are being discovered that indicate susceptibility to specific types of cancer. This will make it possible to screen people and predict their chances of getting such cancers, as well as making possible preventive measures. Most cancer is caused by environmental exposure to carcinogens, however, and not specific genetic defects. Researchers are trying to find genetic markers though, that may detect people who are at highest risk from such environmental exposure.

There are many ethical problems with this approach. Many of the screenable cancers are not treatable, so it is of questionable value to screen for them. Some genes for susceptibility, such as that for Li-Fraumeni syndrome, can only tell that the person with the gene will get cancer, but not which type. This makes it difficult to detect the cancer early. But many are sure that screening for cancer susceptibility genes in the future will enable doctors to prevent or treat cancer very early.


California to ban use of genetic information by insurance companies

The California state legislature is planning to pass a law that would ban the use of genetic information by health insurance companies for eight years. The law will also ban genetic information use by employers. The insurance companies “argue that genetic test results are no different from the other medical data they use in underwriting health insurance,” Nature reports. “The industry fears that if applicants for health insurance are able to withhold genetic information, those whose genetic test results reveal that they are likely to have high health care costs will seek out health insurance in greater numbers.”

But medical geneticists don’t agree. They argue that genetic information is different from other kinds of information that insurance companies use. “If tests become available to identify a wide range of genes that confer susceptibility to particular health problems, they say, the whole notion of ‘shared risk’ that underlies the insurance business will be subverted, and people whose genetic makeup indicates a higher probability of illness will find it difficult to get affordable health insurance,” Nature states.


Diabetics sue insulin suppliers

“British diabetics are preparing to sue suppliers of the genetically engineered ‘human’ insulin that keeps them alive,” Science reports. The diabetics claim that the engineered insulin makes them less sensitive to signs of low blood sugar than pig insulin did, resulting in more episodes of unconsciousness. However, medical studies don’t agree completely. Some find that 30% of patients put on human insulin have problems whereas others see no difference between patients using human and pig insulin.


Research finds more genes linked to specific diseases, conditions

There may be genes that slow down the development of AIDS. Researchers in California have found that HIV-positive men who stay healthy have a higher occurrence of certain genes in the human leucocyte antigen (HLA) system than men with AIDS. HLA genes play important roles in the body’s immune system and the specific genes may help fight off the effects of HIV, which breaks down the immune system.
Researchers at Thomas Jefferson University in Philadelphia have successfully blocked the gene that leads to a specific form of leukemia. So far they have only done experiments in cell cultures but will now try the process in mice. The researchers created a piece of single-stranded DNA which was complementary to the leukemia gene, so-called “antisense” DNA. The antisense DNA bound to the gene and stopped it from being read, thus preventing the growth of cancerous cells.

The gene linked to Marfan syndrome has been identified by researchers in the U.S. Marfan syndrome is caused by defects in a protein found in connective tissue and leads to abnormally long limbs, eyesight defects and heart disease, including a weakened aorta. The aorta is the major blood vessel leading blood from the heart.

Twenty percent of British men carry a genetic variation of the gene for the blood coagulation protein, factor VII. The variation leads to lower levels of factor VII which may, in turn, protect them from heart attacks.

“Scientists in the U.S. and Japan have isolated a gene in rats that may cause high blood pressure,” Alison Abbott of New Scientist writes. “The gene codes for a protein that acts as the receptor for angiotensin, a neuro-transmitter known to be linked to high blood pressure in humans.” The researchers are hoping to use the rat gene to develop a probe to search for the human one.

A gene that is linked to a specific and rare form of epilepsy has been found by Finnish researchers. This is the second epilepsy gene that has been found.

Cardiologists may have to learn more about the ras gene, a gene that has long been implicated in the development of certain cancers. The ras gene is now thought to be linked to a rare heart rhythm disturbance called “long QT syndrome,” after the drawn out Q and T peaks that are seen in electrocardiograms (EKG). There are therapies available but it has been difficult to identify patients with the syndrome. It can lead to ventricular fibrillation and sudden death if not treated. Finding the linkage means it will be possible to detect those with the syndrome and give them proper treatment.

The gene for familial adenomatous polyposis (FAP), an inherited form of bowel cancer has been found by scientists in the United States and Japan. The discovery will pave the way for a genetic test that can be used to identify individuals at risk of getting FAP, which is a fairly common cancer.


Screening for Down’s syndrome in Britain with new test

A new blood test for screening for Down’s syndrome could find up to 90% of affected pregnancies. In Britain, Down’s syndrome is usually screened in women over the age of 36 using amniocentesis, a method where fluid from around the fetus is removed. Fetal cells in the fluid are cultured and then the chromosomes checked for an extra chromosome 21 which indicates Down’s. This method detects only 30% of fetuses affected with Down’s.
The new method makes it possible to test all pregnant women, for a price. The test is marketed directly at women and not through the health service so they must pay for it themselves. The test involves measuring the levels of three substances in the body – human chorionic gonadotrophin, estriol, and alpha-fetoprotein – and testing a blood smear with a stain for an enzyme called urea-resistant neutrophil alkaline phosphatase. The substance levels and intensity of the stain are different for normal versus Down’s pregnancies and using all four variables increases it’s ability to properly identify those fetuses with Down’s.


Netherlands plans first gene therapy experiments in humans

Researchers in the Netherlands are planning a new form of gene therapy to treat a patient with severe combined immune deficiency (SCID) which is caused by the lack of adenosine deaminase (ADA), an enzyme. The method they will use is different from that used by researchers in the United States. The U.S. method involved removing T-cells from the patient’s blood, adding the ADA gene to the cells and then transfusing them back into the patient. The process has to be repeated every month since the T-cells die off and new ones, without the gene, take their place.

In the Netherlands experiment, they will try to put the gene into bone marrow stem cells, the cells that develop into T-cells. By putting the gene into the stem cells, all new T-cells will have the new gene, reducing the need to repeat the procedure. So far the only problem the Dutch researchers have had is in finding a patient. There are only 50 people in all of Europe who have the disease.


Four gene therapy experiments approved in United States

The National Institutes of Health’s Recombinant DNA Advisory Committee (RAC) approved four, of five proposals for new gene therapy experiments. One trial will try to treat patients with familial hypercho-lerolemia, an inherited disorder that leads to extremely high cholesterol levels in the blood.

Two trials will be performed by Steven A. Rosenberg of the National Cancer Institute to further test gene therapy cancer treatments. In both cases, he will try to add genes to the patient’s cancer cells that will hopefully make the body fight the cancers. The fourth trial involves adding a gene from the herpes virus to cancer cells. When this was done with cancer cells in culture, drugs used to fight herpes virus killed the cancer cells. All four experiments must now go to the Food and Drug Administration for final approval.


Gene therapy for muscle defect tested in mice

A surprisingly simple method of inserting genes into muscle cells was discovered a year ago. The new genes were simply injected straight into the muscle and were later found to have been picked up by the muscle cells. This method is now being tested to treat mice with the equivalent of Duchenne muscular dystrophy. The treatment leads to the production of the missing protein, dystrophin, and the effect is long-lived, lasting for several months.
However, the production is too low and the mice show no changes in the disease. The production of dystrophin needs to be at least 10-50 times what it is now to be of any use. But the method is seen as a possible future treatment for the disease.


Two new methods for treating lung diseases with gene therapy

Two new methods have been developed to treat lung diseases where gene therapy might be used. Both involve delivering the new genes directly to the lungs. One approach uses an adenovirus, a virus that naturally infects lung cells. The gene for alpha-1-antitrypsin was put into an adenovirus and then injected into the tracheas of rats. The lung cells were later found to secrete alpha-1-antitrypsin. Without this inhibitor, enzymes break down the cells in the lungs which can lead to emphysema.

Another group used tiny globules of fat called liposomes to introduce new genes into rabbit lungs. The gene tested was also that for alpha-1-antitrypsin. The liposomes can be administered as an aerosol that can be breathed in.


Special committee on germ cell gene therapy created

“A special panel of NIH’s Human Gene Therapy Subcommittee will meet for the first time this fall [1991] to discuss a possible extension of gene therapy: the insertion of genetic material into human eggs,” Science reports. “The accompanying ethical questions’ are so thorny, says immunologist Robertson Parkman of Children’s Hospital of Los Angeles, who heads the Germ-line Therapy Panel, that at the first meeting scientists will simply ‘discuss how to discuss them.’”

The panel will discuss the possible use of such gene therapy to correct genetic disorders. The problems are greater “if the Human Genome Project identifies clusters of genes that influence traits such as height or intelligence. If genetic tweaking could boost a child’s chance of a high IQ, should it be done?”


Sex of mouse reversed using genetic engineering

“When female mice embryos carrying the normal pair of X chromosomes are injected with a small fragment of Y chromosome DNA containing the Sry-gene (short for sex-determining region Y’ gene), they grow up as males with testes and male behavior,” Science reports. But not all the treated embryos turned into males and the testes in the one successful reversal were very small. There has been a long controversy about the existence of a “master gene” that codes for male development. The Sry-gene seems to be the closest thing to such a gene found so far. The researchers hasten to assure that doing similar experiments on humans would be “morally wrong and highly impractical.”


Genetically engineered pigs produce human hemoglobin

DNX, Inc., a New Jersey biotechnology firm, has created genetically engineered pigs that produce human hemoglobin. Hemoglobin is the red pigment in red blood cells that
carries oxygen in the blood. The hemoglobin was hoped to be used as a blood substitute, but so far it has not shown much promise. There are two major problems. The first is that hemoglobin binds oxygen very tightly, and when outside of red blood cells, it doesn’t give the oxygen up to the tissues that need it. The other problem is that hemoglobin is made of four similar protein chains, and outside of the red blood cell it falls into two halves that are rapidly removed from the blood.


Drugs from goat, sheep, and cow’s milk

Researchers created transgenic mice that contained specific human proteins in their milk. Development is now geared toward repeating this in larger animals where milk yields are higher. The idea is to create transgenic animals that have high milk yields and high concentrations of substances in the milk which can then be purified from the milk. This would be a much more efficient method than the current one of using large vats of bacteria to do the job.

A group in Edinburgh has produced five sheep carrying the human alpha-1-antitrypsin gene. The human protein is found in fairly high concentrations in the sheep’s milk. Another group has created goats that produce human tissue plasminogen activator (TPA). Cows have been transformed to produce a human milk protein in their milk. The protein can be used in infant formulas.


Genetically engineered chickens

Merck & Co. have used retroviruses to insert the gene for bovine growth hormone into fertile chicken eggs. They hope to create “super chickens” as big as turkeys.


Engineered plants in the works

Many researchers are working on various genetically engineered plants. At Scripps Clinic and Research Foundation, tobacco plants have been engineered to produce human antibodies, called “plantibodies.” They behave similarly to the human ones and are hoped to be used for diagnosis and treating disease in the future.

Other plants are being engineered to produce oils which may be able to replace those made from petroleum oil. Tomatoes and tobacco plants have been modified by putting a gene from winter flounder into them. The gene codes for an antifreeze protein that may protect the plants from freezing.

Vaccine to be tested in Chile

A genetically engineered cholera vaccine will soon be tested in Chile. The vaccine has been tested on volunteers in the United States and was very effective. The researchers who tested the vaccine were required to add a marker gene to the vaccine, since its use was defined as being an environmental release. The marker gene could be used to follow the vaccine or the gene if they were to spread. The trial in Chile will test if the vaccine is safe and effective. There are plans for other trials in Indonesia, in Lima, Peru, and San Jose, Costa Rica. If these trials go well, the vaccine will be tested on a larger scale, possibly in Indonesia, Bangladesh, or Peru.


Bovine milk hormone approved in Europe

Bovine growth hormone (BGH) produced using genetically engineered bacteria has been approved by the European Commission. Injecting BGH into cows increases their milk yields. The hormone has been controversial since it is suspected to damage the health of the cows and because the use of the hormone will change the structure of dairy farming. This in turn will mean the end of small, family dairy farms. Therefore, many groups have been calling for a boycott or ban on BGH. The Commission’s approval will allow European countries to lift the moratorium on using the hormone after December 31, 1991.


Biological pesticides being field tested

Pioneer Hi-Bred International, Inc. of Johnston, Iowa, is using the bacterium Bacillus thuringiensis (Bt) as a pesticide instead of the usual chemicals. Bt is toxic to certain insects but is not harmful for humans. Other researchers are putting the gene for the Bt toxin into other bacteria that are more long-lived or which have wider ranges of tolerance. In one case, the researchers put the gene into another bacteria and then killed the bacteria before applying them to the plants. This was the first field test of a genetically engineered biological pesticide approved by the U.S. Environmental Protection Agency.

In some cases, the Bt toxin gene is being put into the plants themselves, creating transgenic crops that produce their own pesticides. However, there are criticisms of the widespread use of Bt toxin. The use of Bt toxin, like previous use of chemicals will lead to the development of resistant insects. And this is now appearing to be the case.

Other researchers are using insect viruses as potential pesticides. Or combinations of viruses and venom from mites. Genes for mite and scorpion venoms have been placed in baculoviruses that normally kill insects very slowly. With the new genes in the virus, it kills insects much more quickly.


Different European directives on modified organisms conflict

“Europe’s agriculture ministers have approved a directive regulating the sale of pesticides that conflicts with procedures drawn up by environment ministers last year,” New Scientist states. “The clash is over the release
of genetically modified organisms (GMOs) into the environment. Under the new directive, the release of organisms designed as pesticides—bacteria that secrete insecticide, for example—would be controlled by a committee of agricultural experts in Brussels, rather than by environmental authorities.

The environmental directive requires a risk assessment of such releases but the new directive has no rules for risk assessment and is seen as supporting agribusiness.

The European Commission has also written a policy document promoting the biotechnology industry which contradicts directives already adopted by the European Economic Community (EEC). The policy document was signed by the commissioners of industry, agriculture and research but not the environment commissioner. The policy document calls for regulating products of biotechnology under existing laws “without extra environmental approvals designed to monitor genetically modified organisms,” New Scientist reports.

Other directives that deal with biotechnology are also being prepared, such as for “novel foods” and patenting questions. And there are many potential conflicts. Such as yogurt with genetically modified Lactobacillus— is it regulated as a novel food or should it go through the procedure for deliberate release into the environment, or both? Industry is worried that there will be a patchwork of regulations that will be difficult to orient through when all the directives are in place. “When industry was afraid it was going to be banned,” one official stated, “it came to us and said, ‘Please pass a law to stop them from banning things.’ Now that there’s no danger of that, they are saying we don’t really need the laws at all,” Science reports.


Aquatic microbes swap DNA more often than expected

“Fresh doubts have been cast on the safety of releasing genetically engineered organisms into the environment, following the discovery by biologists in the US that microbes living in lakes, rivers and seas are capable of swapping much more genetic material than expected,” New Scientist states. “The fear is that the DNA introduced into a microbe could migrate into other populations of microorganisms.”

Bacteria in water are often attacked by viruses known as bacteriophages. The bacteriophages can pick up DNA from one bacteria and carry it to others. This happens even when the bacteria are in very low concentrations, something that was not thought possible.


Genetically engineered fish field tested

Carp have been genetically modified to grow faster. They are being field tested in specially built ponds in Baltimore, Maryland. To satisfy the Environmental Protection Agency, the ponds are surrounded by fences, TV cameras keep the area under surveillance and the ponds are covered with a fine screen to keep animals from trying to get at them. Genetically engineered fish could be a big market considering that fish farming is now providing 15% of the fish consumed in the world.

Fish are also being engineered to be cold resistant. Halibut and Atlantic salmon have been engineered with a gene from winter flounder which produces an antifreeze protein. The salmon seem to tolerate the colder water better than normal salmon.
But there are currently no regulations on genetically engineered fish in the United States or Canada. And it is a well known fact that fish escape from fish farms. No one knows what the ecological risks are if genetically engineered salmon escape into the wild.


**White House tries to deregulate genetic engineering**

“The White House proposed a new policy for deregulating the biotechnology industry . . . and immediately ran into a storm of criticism,” *New Scientist* reports. “Environmentalists say that it would remove all controls on genetically engineered organisms, ignoring their special risks.” Industry wasn’t too pleased by the policy either. The White House Council on Competitiveness does not want genetically modified organisms regulated unless they pose “unreasonable” risks.


**Biotechnology companies. Western researchers to pay for Third World seeds**

Western researchers have continuously used seed varieties from Third World countries in their own plant breeding. Most crops originally come from countries around the equator and the genetic diversity within these crops is maintained in the local varieties still raised by farmers in these countries.

But the work of selecting and breeding these local varieties is not acknowledged by Western researchers when they collect the seeds for their own use. And the new hybrid varieties that Western countries then sell back to these countries are rapidly replacing the old varieties, leading to a rapid decline in the genetic diversity of these plants. The decline is so rapid that conservation steps need to be taken before the varieties are gone forever. Gene banks were once thought to be the solution, but many seeds don’t keep. They have to be planted each year to preserve them.

A current proposal is to pay Third World countries for their contribution while allowing Western countries access to their genetic resources. Some of the money would go to local farmers to plant the old varieties instead of the new hybrids coming from the West. “The issue is not equity, but joint payment for conservation,” a Dutch scientist stated. “The Dutch make a lot of money on their seed potato industry, but they rely on genes from Peru. We can’t assume that the Peruvians will do all our conservation for us.”


**Criminal’s DNA fingerprints put into computer database**

“Law enforcement agencies in the US are starting to collect DNA samples from convicted criminals,” *New Scientist* states. “Their aim is to keep such ‘genetic profiles’ on file, just as they keep fingerprints. The DNA fingerprints will be used to solve future crimes. Thirteen states now allow police to take DNA fingerprints of convicts. The developments have resulted in larger databanks than those at research institutions. Ethicists and others are voicing concern over the developments and fear that the police will collect data from larger and larger groups of people.

The U.S. Congress is proposing legislation that would regulate the use of DNA fingerprints in criminal cases. The bill would create an advisory panel to the FBI that would
create standards and periodically test laboratories doing genetic fingerprinting.


**No clear rules on mailing modified organisms**

Although deliberate release of genetically modified organisms (GMOs) is strictly regulated in many countries, sending them by mail is not. The United Nations Committee of Experts on the Transport of Dangerous Goods is currently working on guidelines for the transport of GMOs. In the United States, GMOs are packaged according to the properties of the host organism. Transport rules were not included in either of the European Commission directives dealing with GMOs, but they are looking into the problem. Britain’s Health and Safety Executive’s Advisory Committee on Genetic Manipulation is currently writing guidelines for transporting GMOs.

There are some rules about sending non-modified organisms such as highly pathogenic bacteria by mail. Those that are most dangerous (Class 4 organisms) may not be sent by mail. Three other categories (Classes 1 to 3) may be sent by mail but have to be packaged in leakproof containers and packed in absorbent material in case there is a leak. The box must then be put in a leakproof metal or plastic container.


**Jumping genes in fruit flies**

Sometime around 1950, fruit flies (*Drosophila melanogaster*) picked up movable DNA segments called P elements from another species. Except for microorganisms, it was not thought possible for genes to be transferred from one species to another. The P elements have since spread to all fruit fly populations. So the question is, where did they come from?

Researchers in Arizona believe that the P elements were transferred from another *Drosophila* species, *D. willistoni* by a tiny, parasitic mite that infests both species. This has implications for studies in evolution as well as for risk assessments of genetically modified organisms. If such lateral transfer of DNA is a common event in insects, then it could imply that new genes inserted in insects could be transferred to other insect species, which could lead to undesired effects.


**Mouse patent to be decided soon in Europe**

A genetically engineered mouse that gets cancer and which was designed for testing anticancer drugs was patented several years ago in the United States. The so-called “oncomouse” was the first animal to ever be patented. A patent application was also filed in Europe but has been the subject of much debate.

The European Patent Convention expressly forbids the patenting of plant and animal varieties. But in October 1991, the European Parliament legal affairs committee will probably approve a draft directive that would allow the patenting of “biotechnological inventions” such as the oncomouse.

There is much resistance to the idea of patenting live organisms. Allowing patents will lead to decreased genetic diversity, increase animal suffering and allow monopolies to own living things. And Third World countries argue that the genes that will be engineered into new plants and animals will have been “stolen” from their own natural resources.

United States to change patent laws

“Two bills have been introduced into Congress that are intended to reform U.S. patent and trade law and protect the U.S. biotechnology industry against unfair foreign competition,” Nature writes. The new legislation would make U.S. patent law more like that of Europe and Japan. Old patent law is very restrictive about awarding patents to biotechnology inventions using process patent protection. A patent can only be given to something that is “novel” or not an obvious development with existing knowledge and techniques. Biotechnology, in essence, has a problem because it is not producing anything new.


Biotechnology deals

American Home Products has bought 60% of Genetics Institute of Massachusetts for $666 million. And Chiron, the California biotechnology company that started as a spin-off of Cetus, has now bought Cetus for $660 million. The two companies will merge after Cetus sells its polymerase chain reaction (PCR) business to Hoffman-LaRoche. Cetus won the patent rights to PCR earlier this year. Hoffman-LaRoche is paying $300 million for PCR which it intends to develop for diagnostic tests.