

## CURRENT DEVELOPMENTS AND ISSUES: A SUMMARY

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### IN VITRO FERTILIZATION

#### *Pregnancy created in uterus removed from woman*

An early human pregnancy has occurred in a womb removed from a woman's body and kept perfused in the laboratory. Researchers at the University of Bologna Faculty of Medicine in Italy, who conducted the experiments, say they believe it is the first report of an early human pregnancy in an in-vitro model.

The experiments were conducted by Dr. Carlo Bulletti and associates. (*Fertil. Steril.* 46:991-96, 1988). They took three uteri of women who underwent hysterectomies, perfused those uteri in the laboratory, and implanted human embryos in them. An editorial accompanying the article on the experiments in *Fertility and Sterility* observes that ethical and legal concerns would not permit this type of experimentation in the United States.

The wombs used in the experiments were obtained from women with cervical carcinoma or leiomyomas. All the women had normal menstrual cycles. Physicians obtained the embryos injected into the laboratory-maintained wombs by superovulating another group of women – women who had irreparable fallopian tube damage.

Researchers cultured the embryos in human amniotic fluid to the expanded blastocyst stage. (*Ob. Gyn News*, which reports on these experiments, does not state how the researchers obtained the amniotic fluid.

Presumably three groups of women were used in the experiments: pregnant women who provided the amniotic fluid; women undergoing hysterectomies who provided the wombs; and women with damaged fallopian tubes who provided the eggs.)

Three blastocysts were injected under the epithelium of the perfused human wombs. One embryo implanted. When researchers examined the embryo at 52 hours, they found rapid expansion, possibly accelerated by the experimental procedure. Layers of embryonic cells and a primary amniotic cavity were present. The experimenters say that trophoblastic invasion had begun.

Study of the embryo injection technique in vivo (i.e., in living women) could improve the pregnancy rate following IVF, and further IVF studies could help to elucidate the mechanisms of implantation, the researchers maintain.

*Ob. Gyn News*. 1988. Human embryo implantation achieved in perfused uterus in vitro. 23(20):7.

#### *Three babies born after two embryos implanted*

A triplet pregnancy resulted from the simultaneous implantation of two frozen-thawed embryos and one naturally generated embryo, according to Dr. Richard J. Paulson of the University of Southern California School of Medicine and his associates.

Two embryos were transferred into a 35-year-old woman with a 10-year history of

primary infertility. Five weeks later, transvaginal ultrasound revealed three gestational sacs, each with a heartbeat (*New England Journal of Medicine*. 318:1339–40, 1988).

Physicians delivered the triplets, two boys and girl, by cesarean section at 27 weeks' gestation. Though the boys shared the same placenta, their blood types differed, suggesting the trizygosity of the pregnancy.

The woman received no stimulation.

*Ob. Gyn News*. 1988. Triplets born from two-embryo implant. 23(18):32.

*Physicians seek solution to egg and sperm donor shortage*

People scheduled for ovum transfer find egg or sperm donation by a sibling significantly more acceptable than do people scheduled for artificial insemination, according to a study by Dr. Mark V. Sauer and associates at the Harbor-UCLA Medical Center.

In response to a short questionnaire, 35 couples scheduled for artificial insemination by donor sperm were significantly less likely than 35 couples scheduled for donor egg transfer to prefer a sibling to an anonymous donor and to think their spouses would prefer a sibling donor (*Fertil. Steril.* 49:721–22, 1988).

If couples found the idea acceptable, Dr. Sauer and associates say, the use of siblings as donors of eggs and sperm could make up for the shortage of suitable donors.

*Ob. Gyn News*. 1988. Couples differ in views of gamete donation by sibling. 23(18): 32.

*Human eggs can survive injection of sperm, researchers say*

Human eggs can survive the microsurgical injection of spermatozoa, Susan E. Lazendorf, Ph.D. and associates at Eastern Virginia

Medical School in the United States, state. A quarter of the injected eggs in the experiment died.

Using microsurgery, the researchers injected spermatozoa directly into the cytoplasm of 20 eggs taken from 11 women. Five of the eggs lost the injected spermatozoon. Eight of the eggs degenerated after injection. This was demonstrated by a dark, granular-appearing cytoplasm and shrinking of the cell mass.

The researchers believe that severe disruption of the ooplasm related to the injection was responsible for the death of five of the eight degenerating eggs (*Fertil. Steril.* 49: 835–42, 1988).

Successful pronuclear formation occurred following microinjection in the eggs of five women. In these women, "a successful pregnancy was also established by transfer of same-source oocytes by standard in-vitro fertilization methods," *Ob. Gyn News* reports.

*Ob. Gyn News*. 1988. Finds human oocytes can survive injection of sperm. 23(17):7.

*Expert panels rule that in vitro fertilization is ethical*

All 16 panels in eight countries which have studied the moral, ethical, and legal issues concerning the new reproductive technologies accepted in vitro fertilization as ethical in principle. So did a majority of respondents to 17 of 18 public opinion surveys. (The exception was a recent survey in Japan.)

By the end of 1986, 16 special commissions or committees had addressed issues surrounding the technologies on behalf of governments or professional societies in United States, the United Kingdom, Western Europe, Japan, Australia, and New Zealand and had issued reports, LeRoy Walters, PhD, said at the annual meeting of the American Fertility Society.

Of the 16 panels, 12 approved the freezing of embryos for later implantation, one was

undecided, one found the practice unacceptable, and the remainder had not reported separately on the practice at the time the reports were surveyed.

Thirteen of the 16 panels considered use of donor eggs acceptable. Two others raised questions about the special circumstances under which egg donation might be carried out. Only the U.S. Department of Health and Human Services ethics advisory board flatly rejected egg donation. Public opinion on egg donation was sampled only in Australia/New Zealand and the United Kingdom and the response was generally favorable, Walters added.

Ten of 16 committees accepted embryo donation without reservation. Two considered it acceptable under rare circumstances. Four opposed it.

Most panels (11 of 16) opposed surrogacy. The Department of Health and Human Services panel eliminated any possibility of acceptance because it opposes all egg or embryo transfers outside of a spousal relationship. Three of the panels accepted surrogacy without reservations and one could not decide. Prohibiting payment, thereby eliminating the commercial aspects of surrogacy, would have persuaded only one of the committees to switch from a negative to positive assessment of surrogacy, Walters said.

While results of public opinion polls on surrogacy were mixed, later polls snowed a trend toward acceptance in Australia/New Zealand, Canada and the United States. About one-third of respondents in a U.S. survey said they would consider surrogacy themselves if there appeared to be no other way they could have a child genetically related to one spouse.

*Ob. Gyn News.* 1988. Opinions among nations vary on the moral, ethical and legal issues involved in infertility therapies. 23(23): 8.

*Leuprolide enhances ovarian stimulation, IVF practitioner says*

"The addition of the gonadotropin-releasing hormone agonist, leuprolide to one of the standard protocols that are used for ovarian hyper-stimulation appears to result in significantly higher pregnancy rates than are achieved by hyperstimulation regimens that do not include the GnRH agonist, Dr. Richard P. Marrs said at the annual meeting of the American Fertility Society."

*Ob. Gyn News.* 1988. Leuprolide found to enhance ovarian stimulation. 23(23):2.

*Federal funding for IVF research in USA*

"The US Department of Health and Human Services (HHS) has taken the first steps to end an eight-year de facto moratorium on federal funding of research on human in vitro fertilization (IVF)," states *Nature's* Joseph Palca.

The Assistant Secretary of Health, Robert Windom has said that HHS is going to "reestablish its Ethics Advisory Board, a body required by department regulations to approve all research grants for IVF, but whose charter lapsed in 1980," Palca states. The National Institutes of Health (NIH) has tried to reestablish the Ethics Advisory Board but the Reagan Administration has not wanted to alienate the politically active anti-abortion lobby which is opposed to this type of research. HHS is planning to publish a new charter for the Ethics Advisory Board sometime in August. Once published, it will be released for comment during a 60-day period.

*Science* writes that this 60-day period will "delay decisions on specific proposals for months – almost certainly until the next Administration."

JOSEPH PALCA. 1988. IVF research may yet receive federal funding. *Nature* 334:185; COLIN NORMAN. 1988. IVF research moratorium to end? *Science* 241: 405–406.

*IVF must be simplified for wider application to women, IVF practitioners argue*

In vitro fertilization must be simplified because it is now practiced in at least 35 countries, including "countries where the basic supplies for IVF many times are not easy to get or where the know-how and/or parts needed for repair of equipment are unsatisfactory," two IVF practitioners wrote in an editorial in the *Journal of In Vitro Fertilization and Embryo Transfer*.

The introduction of ultrasound for egg "retrieval" was one of the most dramatic steps toward simplification, note Carlos E. Sueldo and Luis Montoro, Department of Ob. Gyn, University of California, San Francisco-Fresno, USA. Another step was the report by C. Ranoux et al. of successful human IVF using Menezo B2 in a sealed vial left in the upper vagina and held in place by a diaphragm during 48 hours.

The writers' own experiments with pooled second-trimester amniotic fluid (SAF), and third-trimester amniotic fluid (TAF), they imply, is another step in IVF simplification. After making a comparison study of the two types of amniotic fluid, they concluded that both provided more than 90% mouse embryo growth to the blastocyst stage after 72 hours in culture.

"The value of this information lies in the fact that processing amniotic fluid is much easier than the preparation of Ham's F-10, and SAF in particular has shown a remarkable consistency in the chemical composition of the samples studied," they write.

In their laboratory, Sueldo and Montoro are using an experimental protocol with pooled second-trimester amniotic fluid for human IVF instead of Menezo B2 and the results look encouraging, they write.

Simplification of the IVF process, they observe, "will make it more accessible and, also, applicable to a larger number of infertile patients worldwide.

CARLOS E. SUELDO and Luis MONTORO. 1988. In vitro fertilization: simple or complex? *Journal of In Vitro Fertilization and Embryo Transfer*. 5(1): 1-2.

*Can the ultrasonic radiation of women's eggs during IVF cause harm?*

Researchers have reported that ultrasonography of preovulatory eggs led to reduced litter size in rats. Other researchers in Ohio concluded that because of the growing popularity among physicians of ultrasound-guided follicular aspiration in human IVF, further study was warranted.

They gave ultrasonic radiation to a group of virgin Sprague-Dawley rats on the evening of proestrus after the onset of the luteinizing hormone (LH) surge. The researchers found no differences between control and experimental animals in pregnancy rate, number of corpora lutea, implantations, pups and mean pup and placenta weights at autopsy on day 22 of pregnancy. Ultrasonic radiation applied to meiotically active, preovulatory oocytes did not affect the reproductive performance of the rats, they conclude.

They note that their data do not agree with the findings of others (R. Bologne, A. Demoulin, J. P. Schaaps, J. Hustin, R. Lambotte. 1983. Influence des ultrasons sur la fecondite de la ratte. *CR Soc Biol*. 177:381; A. Demoulin, R. Bologne, J. Hustin, R. Lambotte. 1985. Is ultrasound monitoring of follicular growth harmless? *Ann NY Acad Science*. 442:146).

However, they state that their results are consistent with the clinical experience of ultrasound-guided egg aspiration for IVF. A prospective, randomized study comparing ultrasound to laparoscopy-guided egg "recovery" found no differences between them in clinical pregnancy rates.

They write: "When 39 women underwent laparoscopic retrieval on one ovary and ultrasound-guided retrieval on the other, no difference in fertilization, embryo cleavage,

and pregnancy rate was found among oocytes recovered by the two methods.”

Recent data using spermatocytes, they add, raise the possibility of specific ultrasound-sensitive stages of meiosis.

“Since our study did not separate the various stages of meiosis before the application of ultrasound, we cannot respond to that point. Future investigators may wish to apply ultrasonic radiation at various times following the LH surge to determine its safety throughout meiosis.”

STEVEN R. WILLIAMS, IRVING ROTHCHILD, DONNA WESOLOWSKI, CYNTHIA AUSTIN and LEON SPEROFF. 1988. Does exposure of preovulatory oocytes to ultrasonic radiation affect reproductive performance? *Journal of In Vitro Fertilization and Embryo Transfer*. 5(1):18–21.

*South Africans report on woman who bore triplets using her daughters' eggs*

Physicians in South Africa arranged what they call a “surrogate gestational pregnancy” using embryos obtained from the mother’s daughter and son-in-law. (The researchers refer to the mother as the surrogate gestational mother or SGM.) This was probably the first case of its kind.

Problems that had to be overcome, the physicians write, included the synchronization of the “SGM,” who showed features of early ovarian failure, and the daughter who was not having menses due to her hysterectomy. Also, the son-in-law had asthenoterato-zoospermia (reduced motility of spermatozoa in the semen).

“The SGM is a healthy 47-year-old perimenopausal para 2 gravida 2,” the researchers write.

She was having a regular 28- to 30-day menstrual cycle until a few months before the IVF attempt. At that time, she developed an irregular cycle lasting between 40 and 52 days. The daughter’s and “SGM’s” cycles were found to be totally asynchronous.

Because of this and the daughter’s absence of menses, the IVF practitioners decided to suppress ovulation in both women with the combined oral contraceptive pill. They gave the Pill to both women for two cycles. After stopping the Pill, the “SGM” had a menstrual period. Day 1 of her cycle was considered to be Day 1 of the daughter’s cycle as well.

Physicians induced ovulation with clomiphene citrate, 50 mg, on Days 5 to 9 of the “SGM’s” cycle.

They triggered ovulation with human chorionic gonadotrophin (Profasi, Serono, Script Intal Division, Propan Ethicals, Wadeville, Transvaal, South Africa) on the fifteenth day of the mother’s cycle, such that the placement of the daughter’s embryos would occur at least 48 hours after the mother’s ovulation.”

The physicians used the Royal Women’s Hospital stimulation protocol, giving 100 mg of clomiphene citrate daily on Days 3 to 7 of the daughter’s ‘cycle’, inclusive. They began administering human menopausal gonadotrophin on Day 7 through 13, inclusive, of her cycle. To trigger final maturation, they gave hCG on Day 15 of her cycle. Following a 34 hour resting phase, they performed a laparoscopy on the 24-year-old woman to obtain her eggs.

Because of the mother’s (or “SGM’s”) perimenopausal status and the presence of low serum progesterone levels, the physicians gave the mother hCG every third day.

The IVF team comment:

Due to the SGM’s perimenopausal status and irregular cycles, as well as the daughter’s absence of menses, it was decided that suppression of hypothalamic pituitary function with oral contraceptives for a minimum of two cycles would facilitate synchronization of their subsequent stimulation cycles. As timing, rather than superovulation, was required in the case of the SGM, an empirical decision

to induce ovulation using clomiphene citrate was made. This decision was further supported by the potential risk of postpill amenorrhoea, which affects certain patients using oral contraceptives. The use of 'luteal-phase support' using hCG was decided upon only when the initial low serum progesterone results were obtained post embryo transfer. Again, this decision was partially empirical, as no specific evidence exists regarding the value of its use.

The obstetric management of the 47-year-old "SGM" was complicated by the presence of a triplet pregnancy, they note.

M. C. MICHELOW, J. BERNSTEIN, M. J. JACOBSON, J. L. McLOUGHLIN, D. RUBENSTEIN, A. I. HACKING, S. PREDDY, and I. J. VAN DER WAT. 1988. Mother-daughter in vitro fertilization triplet surrogate pregnancy. *Journal of In Vitro Fertilization and Embryo Transfer*. 5(1):31-34.

*Physician gives advice for helping women playing "IVF Roulette"*

The current climate of unregulated competition among IVF/GIFT centers has made reported success rates unreliable, Dr. Paul R. Feldman, a practicing ob. gyn and clinical instructor at Georgetown University School of Medicine, Washington, D.C., writes in a commentary in *Ob. Gyn News*. This leaves the woman playing "IVF roulette," often with little or no chance of winning, he observes. The stakes are high: large sums of money (as much as \$5,000 to \$7,000 per cycle, sometimes totally \$25,000 to \$30,000), months of inconvenience and pain, time lost from work, and emotional trauma accompanying each failure.

In a critique of IVF success rate reporting, Feldman notes that when programs combine IVF and GIFT treatments, the reported success rate is ambiguous and impossible to interpret

for patients. "A program performing combined IVF/GIFT treatments on patients with patent tubes while also allowing spontaneous intercourse may report a subsequent pregnancy as a successful IVF and a successful GIFT," he wrote. "In reality, the patient may have conceived spontaneously or only from the GIFT."

Feldman noted that some IVF centers now perform GIFT at the time of diagnostic laparoscopy. Even if the newly discovered endometriosis is not treated simultaneously with laser pelviscopy, he notes, the experts believe this gives the woman one attempt at a high-tech pregnancy while she is already under anesthesia.

"But might not the patient have had a better chance of getting pregnant and be \$5,000 ahead if, instead, the endometriosis had been treated during the diagnostic laparoscopy?," Feldman asked. "Does the one attempt at GIFT entice the patient to repeat attempts at GIFT, just as the losing roulette player keeps putting down more and more \$5 bills after each spin of the wheel?"

Feldman highlights the problem of a center performing IVF/GIFT on a woman before her infertility has been thoroughly diagnosed and treated. Centers with such patients will have a higher pregnancy rate than others whose clients have first exhausted other treatments. For example, he notes, if a woman who has an undiagnosed cervical mucus problem and luteal phase defect enters an IVF/GIFT center prematurely, an excellent chance of success would be expected.

He asks:

But might not this patient have just as good if not better odds of success if her physician treats the individual problems first, and/or offers superovulation in combination with intrauterine insemination (which has recently been shown to have a superior success rate compared to GIFT for many of the same problems)?

"Is the infertility specialist, who has his own IVF/GIFT center, herding his flock of too-willing and desperate patients into the high-tech pregnancy mill too soon or without offering information on competing centers?"

Couples considering a particular IVF center, he suggests, might obtain references from former candidates who have successfully conceived and borne babies and from those who have attempted unsuccessfully.

He also suggests that physicians referring their patients to IVF centers should telephone them periodically to provide professional and emotional support. "If the process becomes too tedious and you feel the patient desperately needs a break," he writes, "give permission for them to take an 'infertility treatment vacation.'"

PAUL R. FELDMAN. October 1, 1988. The IVF roulette: helping your patients beat the odds. *Ob. Gyn News* 23(19):22.

*Buserelin suggested for women with "resistant" ovaries*

IVF practitioners in London write:

The diagnostic response toward the administration of a luteinizing hormone-releasing hormone (LH-RH) analogue in the early follicular phase has been used sequentially with conventional human menopausal gonadotropin (hMG) treatment in patients who had previously failed to develop multiple follicles in response to a combination of hMG and clomiphene citrate. Nine of fourteen patients (64%) showed an increase in the number of preovulatory follicles and five subjects reached oocyte recovery for the first time. Two patients (22%) became pregnant after in vitro fertilization and embryo transfer during the treatment cycle and had healthy babies. It is suggested that this treatment regimen may be advantageous in some patients with resistant ovaries.

Various physicians have tried to synchronize follicular development and prevent premature luteinization by suppressing pituitary function before the administration of hMG, they point out. To date, this has involved prolonged administration of Buserelin, an LH-RH analogue, as a continuous subcutaneous infusion or through a nasal spray, the authors point out.

"We now report on the potential use of Buserelin as a superagonist for only Days 1 to 3 of the menstrual cycle to stimulate pituitary function in patients who had previously responded inadequately to clomiphene citrate and hMG."

They administered Buserelin in a nasal spray to the women in their IVF program. This was a first.

VINAY SHARMA, JANET WILLIAMS, WILLIAM COLLINS, ANDREW RIDDLE, BRIDGETT MASON, and MALCOLM WHITEHEAD. 1988. The sequential use of a luteinizing hormone-releasing hormone (LH-RH) agonist and human menopausal gonadotropins to stimulate folliculogenesis in patients with resistant ovaries. *Journal of In Vitro Fertilization and Embryo Transfer*. 5(1):38-42.

*French IVF practitioners fertilize eggs using women's vaginas*

In a letter to the *Journal of In Vitro Fertilization and Embryo Transfer*, French physicians describe their new fertilization technique, which they call intravaginal culture (IVC). It involves a tube completely filled with culture medium in which they place up to five eggs immediately after pick up and spermatozoa prepared through the swim-up technique.

They then hermetically close the tube and incubate it for 44 to 50 hours in the vagina of the woman who has sought their help for infertility.

They performed "intravaginal culture" in more than 200 cycles with a pregnancy rate of 21.1%.

"This technique gave us information on the biochemical and temperature requirements of embryos in the early stages of their development," the physicians from the Clinique Universitaire de Port Royal in Paris write.

After this experiment, they decided to considerably reduce the volume of culture fluid. They began using a cryopreservation straw to hold fluid, eggs, and sperm. But due to poor results, they abandoned this technique.

Now they are trying something new: placement of the straw directly in the uterus for 18 to 22 hours. After that time, they push the contents of the straw inside the uterus without either pulling it out or examining the contents. They fertilize the remaining eggs using "the classical technique of IVF" and freeze the embryos obtained. They have tried this out on two women so far.

"If this technique turns out to be successful, we hope to be able to develop a biodegradable straw with direct placement in the uterine cavity," they conclude. "The biodegradable time should be similar to the time of fertilization of the gametes."

C. RANOUX, C. POIROT, H. FOULOT, J. B. DUBUISSON, F. X. AUBRIOT, O. CHEVALUER, and V. CARDONE. Human egg fertilization in capillary tubes. *Journal of In Vitro Fertilization and Embryo Transfer*. 5(1):49-50.

#### *Vagina used as cheap incubator in IVF*

Researchers in Montreal, Canada, and Paris, France, have developed a new method of incubating fertilized eggs, according to *New Scientist*.

The researchers place eggs and sperm in a small glass tube with a culture medium and then insert the tube into the woman's vagina. The fertilized eggs are examined after two days and then are inserted into her uterus.

"Success" rates are the same as for in vitro fertilization using regular incubators. "The researchers say that the new technique is simpler and cheaper than using an incubator and it is better for the mother. They say it lets her feel she is participating in the early stages of her baby's development."

1988. In vitro incubation. *New Scientist* 21 July: 35.

### **GIFT (GAMETE INTRAFALLOPIAN TRANSFER)**

*Women in GIFT program become pregnant on their own, without undergoing GIFT*

Two women who entered a GIFT program in Sweden ultimately did not go through the GIFT procedure, but nonetheless became pregnant on their own. The women were among 10 who were given hormonal superstimulation in preparation for GIFT at Huddinge Hospital in Stockholm.

One of the woman ovulated before egg retrieval and the husband of the second could not leave a sperm sample. Neither had GIFT, but both became pregnant. Based on these results, the Swedish doctors believe that hormonal superstimulation may be a better alternative in some cases of unexplained infertility than GIFT.

Of the eight women who did go through GIFT, three became pregnant.

Results of GIFT from 12 centers were presented at the XIth Asian and Oceanic Congress of Obstetrics and Gynecology in December 1987. The results were based on a total of 2,092 treated cycles. The pregnancy rate was 29%. Multiple births occurred in 15% of the pregnancies. No take-home baby rate was given in the report published in the Swedish medical journal *Lakartidningen*.

GIFT (gamete intrafallopian transfer) is a method related to IVF. Physicians superstimulate the woman's ovaries with hormones and remove her eggs from the



ovaries using the same procedures as are used in IVF. But instead of mixing sperm and eggs in a glass dish and letting the fertilized eggs grow in an incubator for several days, GIFT practitioners immediately place the eggs and sperm in the woman's fallopian tube.

Because GIFT does not require growing the embryo outside the body, it does not need the same resources for cell culture that IVF does. This makes it possible to carry out GIFT in smaller hospitals and clinics.

LARS NYLUND, SAM BRODY, BENGT FREDRICSON, NELS-OLOV LUNNELL, ÅKE POUSSETTE, LENNART ROSENBOR, HÅKAN SLOTT and EVA ÅKERLÖF. 1988. Vilken roll har överförande av gameter till äggledaren? *Läkartidningen* 85:2066–2067.

#### *Physician doubts GIFT'S efficacy*

The pregnancy rate among women who undergo gamete intrafallopian transfer (GIFT) appears to be no higher than the rate among clinically eligible women on the waiting list, who may wait 12–30 months for GIFT, Dr. Christo G. Zouves said at the annual meeting of the American Fertility Society.

Zouves, of the University of British Columbia Faculty of Medicine, Vancouver, reviewed the experience of 326 women who had indications for GIFT and who were accepted for the procedure between May 1985 and December 1987.

There was a pregnancy rate of nearly 20% among those on the waiting list. The 80 women on this list who eventually underwent GIFT achieved a clinical pregnancy in 12% of 109 GIFT procedures, Zouves said.

“When separated by primary diagnosis, those on the waiting list with ovulatory dysfunction or unexplained infertility had significantly higher pregnancy rates while awaiting GIFT than did comparable patients who had the procedure,” *Ob. Gyn News* reported.

*Ob. Gyn News*. 1988. Questions efficacy of GIFT compared with no therapy. 23(23): 2.

#### *Gamete Intrafallopian Transfer leads to sextuplet pregnancy, subsequently reduced*

While GIFT is being rapidly adapted as an accepted infertility treatment, “many questions are still unanswered about safety and complications,” IVF practitioners from Philadelphia, USA, write.

Because of the risk of ectopic gestation and multiple births, they had restricted their use of GIFT to women with normal tubes, no history of maternal ingestion of diethylstilbestrol (DES), and aspiration and placement of a total of only two eggs per tube. They further modified their protocols after a 29-year-old woman became pregnant with sextuplets.

With her sextuplet pregnancy, the woman was suffering from severe hyperemesis gravidarum. (This is uncontrollable nausea, persistent retching and vomiting, inability to take any food by mouth, and exhaustion due to restlessness and inability to sleep).

Because of the problems related to a sextuplet pregnancy, the physicians decided to try to reduce the pregnancy to a twin gestation. Under ultrasonic guidance, they injected potassium chloride into the cardiac region of each of four fetuses. The fetuses died. The woman's hyperemesis resolved. At 37 weeks, the woman delivered a healthy girl and boy weighing 4 lbs, 11 oz each.

“The true efficacy of the procedure [GIFT] in terms of ongoing pregnancy and complications is as yet undetermined,” the practitioners write.

Since R. H. Asch and his associates report a high rate of multiple gestation, they note, caution must be maintained, placing no more than two eggs per tube.

“Only with greater numbers can a true assessment of the instance of complications such as ectopic pregnancy or multiple gestation be made,” they conclude.

FRANCES R. BATZER, BENJAMIN GOCILA, STEPHEN L. CORSON, STUART WEBSTER and RONALD J. WAPNER. 1988. Multiple pregnancies with gamete intrafallopian transfer (GIFT): complications of a new technique. *Journal of In Vitro Fertilization and Embryo Transfer*. 5(1):35–37.

## PREVENTABLE INFANT DEATHS

*Government study questions investment in high-tech neonatology and recommends expanded midwifery role to reduce infant mortality in Austria*

Expanding technical medical care can no longer contribute to reducing infant mortality in Austria, concludes a study conducted by the Institute for Demography (Austrian Academy of Sciences) in 1986 and 1987. The study, commissioned by the Office of the Chancellor in Austria, looks critically at increased investment in intensive neonatology care. It recommends that the current physician and hospital dominated system of childbirth be reformed so that midwives play a more active role in caring for pregnant women and their infants.

“Only a structural reform can lead to a solution of the problems still existing today,” write the authors, Dr. Christian Kock, Dr. Josef Kytir, and Dr. Rainer Munz.

An abundance of physicians and medical facilities do not necessarily bring infant mortality rates down, they point out. In areas in Austria with good clinical and specialist care and a high density of physicians, infant mortality is generally higher than in rural areas with less comprehensive medical care, the researchers found.

They add: “This is true even though there are a number of factors in rural areas (high parity, low level of personal income, limited average education) which especially here should contribute to a higher level of infant mortality.”

Studies in the United States and experience with prenatal and obstetric care in the Netherlands have demonstrated that historically, infant mortality is at first reduced by the increased implementation of technical curative medicine and the intervention of physicians, but that after a certain point, these advancements in medical science no longer seem to be effective in further reducing infant mortality, the report points out.

It raises critical questions about increased investment in Austria in intensive neonatological care.

“All new efforts and technical expenditures serve an ever smaller group of all infants – those infants whose chances of recovery are least likely to be improved by medical intervention,” the report states.

Intensive neonatology does not come into play until a point where only a reversal of medical complications is possible, resulting in a disproportional relationship between expended effort and effectiveness; a fact which must be taken into consideration before intensive neonatological care is expanded further. It is imperative that health policy in Austria be based both on attempts to prevent high risk births as well as on an effectivity analysis of intensive neonatology.

The report examines the childbirth system in the Netherlands which has a long tradition of low perinatal mortality. This, they state is due to a system of care with the following components:

- good general medical and social care
- a well developed system of midwife care
- well developed prenatal care
- medical personnel remains essentially unchanged before, during, and after childbirth
- numerous alternatives for expectant women.

In the Netherlands, pregnant women are divided into low risk groups whose care is mainly provided by midwives and high risk groups cared for by physicians in hospitals. This system, the authors point out, provides a minority of mothers and children (the "high risk") with the necessary resources of medical science and technology. It also protects "the majority of mothers and children ('low-risk group') from attempts by doctors to transform a normal and natural physiological process into an operational procedure."

The study highlights an important characteristic of the Dutch system of care with its central role for midwives: "that the persons involved in the care of pregnancies remain the same before, during and after delivery. This is essential for instilling the sense of trust essential for childbirth free of complications."

Under "Proposals for a Reform," the authors state that committing midwives to a more active role in caring for pregnant women and their infants should be of primary concern. Now in Austria, physicians handle the care of almost all Austrian women during pregnancy and supervise deliveries in hospitals. Home births are rare. The importance of midwives in caring for pregnant women and infants is negligible. Seventy-five percent of Austrian midwives are only authorized to practice in hospitals where they serve as obstetric assistants.

The study proposes that the first step in reform would be to organize midwife precincts "in which a predetermined number of independent midwives would be responsible for medical and psychological prenatal care, for advice on social rights, for providing special physical exercise and training in infant care, and in general for assuring that women can take full advantage of the facilities available to them."

Cases of high risk, they write, would still have to be treated mainly by specialists and outpatient clinics.

The study also suggests instituting "family helpers" who would be available to provide

support for mothers and help the midwives for one to three weeks after delivery.

CHRISTIAN KÖCK, JOSEF KYTIR and RAINER MÜNZ. 1988. *Risiko "Säuglingstod": Plädoyer für eine Gesundheitspolitische Reform*. Franz Deuticke Verlagsgesellschaft m.b.H.. Vienna, Austria.

*Recommendations announced to decrease infant deaths in the United States*

The National Commission to Prevent Infant Mortality, created by the U.S. Congress in 1986 to investigate the causes of and recommend solutions to the United States' high infant mortality, has recommended that universal access to early maternity and pediatric care should be provided for all mothers and infants in the country.

In its report, the Commission notes that in 1985, 9.5 million women of childbearing age in the U.S. had no health insurance. More than seven million of these women had jobs or were married to workers. Five million women have private health insurance that does not cover maternity care.

Medicaid, a government program to provide medical care to low-income people, covers less than 40% of individuals in families with incomes below the federal poverty level, and only half of all children in these families. Recent legislation increasing funding, the report stated, is "not enough."

The Commission recommends that asset tests for pregnant women applying for Medicaid be eliminated and that eligibility for Medicaid for women and infants be continuous through the infant's first year of life. It also urges Medicaid coverage for all pregnant women and infants with family incomes at or below approximately \$20,000.

While this may seem expensive, Senator Lawton Chiles, chair of the Commission, noted that a premature infant can cost "hundreds of thousands of dollars in rescue and continuing treatment expenses. Yet, for as

little as \$400 worth of prenatal care, those problems might be avoided altogether. It's pay now or pay later."

Chiles said that the United States has slipped in infant survival from 15th among industrialized nations in 1968 to 19th today.

The report notes that 40,000 infants die annually before age one year in the United States, and 520,000 more will die by the year 2000 if infant mortality goes unchecked. Black babies are twice as likely to die before their first birthday as white babies.

The Commission's second major recommendation is that the well-being of mothers and infants be made a national priority.

1988, September 15. Infant mortality report termed exciting challenge for ob. gyns. *Ob. Gyn News*. 23(18):1.

*Obstetricians may need to adapt to poorer women as patients if access to prenatal care expands*

If efforts to increase poor women's access to publically funded prenatal care are successful, obstetricians may have to adapt to a less affluent, higher-risk patient population in their practice, Dr. George M. Ryan, Jr. of Memphis, a member of an Institute of Medicine committee studying the issue in the United States, said after an announcement of the committee's findings.

Under the present public health care system which reaches only 40% of pregnant women who need services, nearly a third of U.S. women pregnant during 1985 did not receive adequate prenatal care, the study found.

Business leaders, noting the economic impact of the consequences of inadequate prenatal care, are beginning to realize their vested interest in a healthy, strong work force, several members of the Committee to Study Outreach for Prenatal Care said.

"We should have universal health care" in this area of medicine, Dr. Ryan said. This goal

fits the committee's long-term objective of achieving adequate, easily accessible prenatal care for all pregnant women, he said.

*Ob. Gyn News*. 1988. Lack of prenatal care access decried. 22(23): 1.

*High miscarriage and child mortality in Cracow, Poland*

Miscarriage rates in Cracow are eight times higher than the average for all of Poland.

Cracow is one of four regions in Poland that has been designated an ecological catastrophe area by environmental authorities. Child mortality is 25 per 1000 children born in Cracow. The Polish average is 20 per 1000 births.

The high miscarriage and child mortality levels are due to high levels of pollution which come mainly from steel mills in the area. Analyses of lettuce grown in Cracow have shown lead levels 20 times those set by the World Health Organization as safe.

GÖSTA KARLSSON. 1988. Hela Polen hotas av miljökatostrof. *Dagens Nyheter* May 27: 20.

*Computer terminals increase miscarriage risk*

Previous studies have indicated that pregnant women who work at computer terminals may have an increased risk of miscarriage.

These studies have been expanded and a United States study has shown that women who work more than 20 hours per week at a computer terminal have a doubled risk of miscarriage. No increase in congenital defects was seen in this study however.

In studies in mice, electromagnetic fields led to higher rates of congenital defects but the fields were several hundred times stronger than those found around a computer terminal. Another effect of these magnetic fields on mice is that their fertility decreases.

SIGRID BOE. Risken för missfall fördubblas. *Dagens Nyheter* August 3:6.

## CONTROVERSIES OVER FEMALE SURGERY

*“Love surgeon” finally charged after conducting surgical experiments on women for 22 years to restructure their genitals*

The Ohio State Medical Board formally charged Dr. James C. Burt in December 1988 with “gross immorality” and “grossly unprofessional conduct” in surgery he performed to restructure the genitals of his female patients. The surgery, Burt maintained in a 1975 book, turned women into “horny little mice.” It often caused permanent physical damage, The Medical Board stated. Experts say the surgery was crude experimentation on hundreds of women without their consent.

Burt’s experimentation on women has long been well-known. He wrote a book about it with his wife in 1975, *Surgery of Love*, Carlton Press. (“Women are structurally inadequate for intercourse,” he wrote. “This is a pathological condition amenable to surgery.”) Feminists exposed him years ago, for example Janice Raymond in a 1979 speech at the WAP Conference on Pornography in New York City, “The Medical Creation of the Pornographic Woman”; Diana Scully in *Men Who Control Women’s Health* (Houghton Mifflin Company, Boston, 1980) and Gena Corea in *The Hidden Malpractice* (Harper and Row, New York, 1985). But despite the public exposure of his experimentation on women, no medical body took action against Burt.

Burt, who still practices in Dayton, Ohio, has 30 days to request a hearing on the charges against him.

The Ohio State Medical Board “is now looking into the role and responsibility of his [Burt’s] colleagues who, board officials say, silently watched as many of Dr. Burt’s patients suffered permanent physical damage,” Isabel Wilkerson reported in *The New York Times*.

Burt began performing the restructuring surgery in 1966 and stopped as of January

1987. In November 1988, the medical board barred Burt from performing any surgery pending its investigation, but he retains his medical license.

For 22 years, Burt reconstructed the vaginas of women in an effort to make the women climax during intercourse solely through penile stimulation. (In the appendix title of his book, he refers to this as “The Surgical Approach to Increasing Sexual Responsiveness. The Redesign and Reconstruction of the Woman.” The appendix tells physicians how they, too, can do the “love surgery.”) The operation consists of cutting back the clitoral hood, tightening the vaginal opening, lengthening the vagina and redirecting its long axis so that the clitoris is near the entrance to the vagina where it comes into direct contact with the penis. The labia minora, after reconstruction, are almost entirely inside the vagina.

Critics observe that the surgery gives women “an entirely alien set of genitals” and, in an effort to remake women’s anatomy to synchronize with the male way of achieving orgasm, subjects women to pain and to all the risks of surgery. During the operation, Burt severs the pubococcygeus muscle which gives partial support to the bladder. Sex therapist Dr. Dianne S. Fourney, associate professor of obstetrics and gynecology at the State University of New York at Stony Brook, observed that that opened up a significant risk of urinary and rectal prolapse. Other critics noted that infection and urinating difficulty are a likely consequence of the operation because the urethra is pulled into the vagina. Moreover, with the natural route of the baby’s head changed by the operation, natural childbirth often becomes difficult or impossible.

During the evolution of his “female sexual area redesign operation,” Burt wrote, various problems “aggravating both surgeon and patient and husband” developed. As a result of his earliest operative attempts, women frequently experienced pain on intercourse. At

that time, he was elevating what he calls “the perineal body” (probably the entire area of the perineum) too high and reconstructing it with too little thickness, he wrote. He was also cutting away a larger portion of the lower vagina, more hymenal ring and skin outside the ring. The tightness of skin at the vaginal entrance, now located outside the labia minora, was enough to cause persistent pain during intercourse. Frequently the skin over the “perineal body” split, forming a fissure. This was “a frequent and aggravating problem,” Burt wrote, requiring long healing periods. Once in a while, he’d have to operate on the women again to close the fissure. (Burt and Burt, 1975, p. 43, p. 263, p. 269)

Since 1966, Burt has performed his operation in all stages of its evolution, beginning with a variation on the standard episiotomy repair, on more than 4,000 women. Burt admitted in his book that he performed the “reconstructive surgery” on many women without their knowledge or consent, usually after the delivery of a child. (At some point after the early years of experimentation, he allegedly began to “redesign” women’s bodies openly, with the women’s consent.)

While acknowledging that a significant number of women “reconstructed at the time of delivery” reported no improvement in their sex lives, he claimed that most did. He discounted the placebo effect because in the early days he did not tell the women what he was doing. Burt partially attributes the improvement to the “positive psychosocial feedback to the female from her enhanced ability to satisfy more adequately her man” (Burt and Burt, 1975, p. 263).

Women in the delivery room provided “an ideal source of material” for evaluating the efficacy of the operation, he wrote. “These patients uniformly expect some type of surgical proceeding in the perineal area coincident with their delivery, namely episiotomy and repair or having ‘stitches’ with their delivery. In many hundreds of these

patients, the patient had not been informed that anything more had been done to her than delivery and episiotomy and repair or ‘Yes, you had stitches with your delivery’ (Burt and Burt, 1975, p. 271).

While the intent of his surgery was to redesign the vagina to increase sexual responsiveness, the surgery instead caused “sexual dysfunction, extensive scarring, chronic infections of the kidney, bladder and vagina and the need for corrective surgery in many patients, according to the Ohio State Medical Board,” Wilkerson reported.

Several of the women have permanent disabilities, the board said. At least one woman suffered phlebitis, blood clots, and a heart attack.

“Gynecologists have told one former patient, Cheryl Sexton, that corrective surgery will require four specialists – a urologist, a neurologist, a plastic surgeon and gynecologist-and will cost \$25,000,” Wilkerson wrote.

Janet Phillips went to Burt with complaints of cramps six years ago, Wilkerson reported. He told her she need a hysterectomy because her oviducts were “rotting.”

Wilkerson writes: “She ended up with a changed anatomy and suffers chronic infections, extreme difficulty urinating and excruciating pain if she attempts intercourse. The strain eventually destroyed her marriage, which ended in divorce five years ago, she said. Seven hours of surgery completely changed her life.”

Phillips told Wilkerson: “I feel like a freak. I can’t date. I can’t ride horses. I can’t urinate like normal women. I was sexually abused by Dr. Burt. He stole parts of my body.”

Gynecologists knew about Burt’s surgery and recognized his work when they examined women who had been to him, Wilkerson pointed out.

Joy Martin, who had to get corrective surgery after Burt delivered her son in 1974, told Wilkerson: “Doctors would say, ‘Dr.

Burt's done surgery on you, hasn't he?' or 'Have you been to see Dr. Burt?'"

She and Sexton have filed lawsuits against Burt. Thirty-five other former patients are expected to file suits shortly, according to the women's lawyer. Over the past 10 years, 12 other suits were filed against Burt but dropped when other physicians refused to testify.

Wilkerson reports: "Some doctors say they repeatedly told investigators from the Ohio State Medical Board about Dr. Burt's eccentricities, but say the board did not take action until Gov. Richard Celeste wrote the board about the case."

ISABEL WILKERSON. December 11, 1988. Charges against doctor bring ire and questions. *The New York Times*; GENA COREA. 1985. *The Hidden Malpractice: How American Medicine Mistreats Women*. Harper and Row. New York.

#### *Routine use of episiotomy not supported by data*

A nurse midwife and a physician debating episiotomy at an obstetrics update presented by the University of California, San Francisco, School of Medicine in the United States agreed that routine episiotomy is not supported by scientific data.

They did disagree on other points, however. Nurse midwife Judith T. Bishop said claims that episiotomy prevents damage to the pelvic floor that might result in urinary incontinence and sexual dysfunction have been refuted by several studies. Dr. W. Gordon Peacock maintained that those studies are "full of holes."

No good scientific data exists to show that episiotomy protects against pelvic floor damage, he said during the debate. But, he added, it is his clinical impression that it does.

More and more women, he finds, are expressing a strong desire not to undergo episiotomy. Peacock, of the university and Children's Hospital of San Francisco, has a list

of situations in which he believes episiotomy is indicated. He said he strongly believes that "the final decision as to whether to do an episiotomy or not must be left with the person accomplishing the delivery." (It is not clear from the *Ob. Gyn News* report who Peacock believes "the person accomplishing the delivery" is: the woman delivering her child or the physician or midwife catching it.)

Birth attendants perform episiotomies on two-thirds of all women giving birth in the United States and on 80–90% of women giving birth for the first time. The incidence is much lower in midwifery practices. In the Netherlands, the rate is 8%.

Neither the women who are spared episiotomy nor their babies are the worse for it, Bishop, director of Bay Area Midwifery Services at Mount Zion Hospital in San Francisco, said.

"From the woman's point of view, there is an aspect of assault to being cut as part of a thoughtlessly applied routine, Ms. Bishop said."

In a review of claimed advantages of episiotomy, Peacock noted that episiotomy may be viewed as a form of plastic surgery that preserves the appearance and sexual function of the introitus, the entrance to the vagina.

BRUCE JANCTN. 1988. Obstetrician-midwife debate on episiotomy: agree routine use is not supported by data. *Ob. Gyn News*. 23(16): 1.

#### *Cesarean section rate still rising in the United States*

The latest statistics show that the cesarean section rate is still rising in the United States, largely because of repeat cesareans, say Paul J. Placek, Ph.D. and associates at the National Center for Health Statistics.

From 1980–1986, the cesarean section rate per 100 live births increased from 16.5 to 24.1, data from the center's National Hospital Discharge Surveys show.

“Of the 1.4 million repeat cesarean sections performed from 1980 through 1985, there were no complications in about 1 million cases,” *Ob. Gyn News* reports. “Thus, a trial of labor probably could have been attempted. And perhaps 500,000 of these trials of labor could have resulted in successful vaginal deliveries. This would have saved people millions of dollars in surgical fees and would have averted a total of 1.2 million hospital days, the investigators say.”

*Ob. Gyn News*. 1988. Cesarean rate still rising, largely because of repeat operations. 23(17):15.

#### *Possible link between breast augmentation surgery and scleroderma*

In early 1988 a report in the *Journal of the American Medical Association* by Dr. Harry Spiera, a rheumatologist at Mount Sinai School of Medicine, New York, suggested a relationship between silicon augmentation mammoplasty and scleroderma (JAMA 260:236–238, 1988).

“Others have made similar observations,” *Ob. Gyn News* reports. “French physicians have coined a phrase – the Cleopatra syndrome – to describe this pathologic autoimmune response (“human adjuvant disease”) to silicone and paraffin implants and collagen injections.”

The issue is a potential growing medicolegal battleground. The number of lawsuits may rise in response to the Spiera report, Dr. Denny L. Tuffanelli said at a meeting of the Intermountain Dermatology Society. Tuffanelli is a dermatologist at the University of California, San Francisco, School of Medicine.

*Ob. Gyn News*. 1988. Predicts more lawsuits alleging harm due to breast augmentation. 23(22): 15.

#### *Gynecologists fear their surgical territory may be invaded*

Gynecology may lose parts of its specialty to other fields because of inadequate training provided gynecologists in vaginal hysterectomy and pelvic reconstructive surgery, Dr. Raymond A. Lee, said at a program presented by Columbia University College of Physicians and Surgeons, USA.

This type of surgical training has not kept pace with advances in other areas of ob/gyn, Dr. Lee, professor and chairman of the division of gynecology and gynecologic surgery, Mayo Clinic, in Rochester, Minnesota, maintained.

He said: “Unless our specialty can improve the quality of our surgical results, the urologists are going to undertake surgery of the anterior vaginal wall, the colorectal surgeons will take over the posterior areas of the vagina, and the general surgeons will do the hysterectomies.”

JOE. R. NEEL. 1988. Risk gyns. may be supplanted in surgical area is foreseen. *Ob. Gyn News*. 23(22): 1.

### ARTIFICIAL INSEMINATION

#### *Physicians do little to protect health of women artificially inseminated, U.S. government report says*

Physicians practicing artificial insemination by donor do little to protect women from infectious diseases like AIDS potentially passed through donor semen or to prevent the inheritance of genetic disorders, the United States Congress’ Office of Technology Assessment finds in its recent report on artificial insemination.

“The report shows that only 44% of 367 physicians surveyed test donors for antibodies to human immunodeficiency virus [HIV], and fewer than 30% test for syphilis, gonorrhea, hepatitis or chlamydia,” Gregory Byrne writes in *Science*. “Only 48% of physicians screen



donors for genetic disorders such as Tay-Sachs disease, sickle cell anemia or thalassemia.”

Sperm banks are in better shape. Fourteen of the fifteen sperm banks surveyed tested donors for AIDS, twelve test for infectious diseases and thirteen test for genetic diseases. Senator Albert Gore is pushing the Food and Drug Administration (FDA) to come up with regulations requiring semen to be screened for HIV.

GREGORY BYRNE. 1988. Artificial insemination report prompts call for regulation. *Science* 241: 895.

### BIRTH REGULATION

*New data finds breast cancer may be a risk of the Pill; U.S. FDA expert panel says no need for women to stop taking Pill; Breast cancer experts disagree with panel*

New evidence indicates that the use of oral contraceptives may increase the risk of breast cancer. Previous studies had found no such relationship.

“One possible explanation for the new findings is that enough time has finally passed since the introduction of the pill 28 years ago for an effect on breast cancer to become apparent,” Gina Kolata writes in *The New York Times*.

Experts told Kolata none of the new studies were conclusive.

The Pill is the second most commonly used contraceptive method in the United States, after sterilization. It was used by 13.2 million women in 1987, including 22% of married women, according to the Alan Guttmacher Institute, a research organization in New York.

Use of the Pill among married women peaked in 1973 when 36% used it. In 1982, it dropped to 20% but has climbed again in recent years.

“The new studies include one by Dr. Samuel Shapiro of the Boston University School of Medicine and his colleagues who

compared breast cancer incidence in more than 400 women who used birth control pills and more than 400 who did not,” Kolata wrote. “They found that the longer women took the pill, the greater their breast cancer risk. Women who used the pill 10 years or more had a fourfold increase in risk.”

Dr. Clifford R. Kay and associates at the RCGP Manchester Research Unit in England conducted another of the new studies. They followed 46,000 women who took or did not take the pill. Pill users were more than three times as likely to develop breast cancer from the ages of 30 to 34 as women who did not take the pill, they found. Breast cancer is rare at these ages. It is most common in women over 50.

A third study is a reanalysis of a study of about 5,600 women by the Centers for Disease Control in Atlanta that had previously reported that the Pill was not associated with an increased risk of breast cancer. Dr. Bruce Stadel of the Food and Drug Administration (FDA) and associates found in the reanalysis that women who used the pill but who did not have children, and who started menstruating before the age of 13, had an increased risk of breast cancer.

“The extent of the risk depended on how long they had used the pill,” Kolata reported. “The risk increased by 30% for pill use of 4 to 7 years, and reached 12 times the normal risk for women who used the pill 12 years or longer.”

Dr. James Schlesselman of the Uniformed Services University of the Health Sciences in Bethesda, Maryland, recently reviewed all studies on the Pill and breast cancer published after 1980 and concluded that pill use may increase breast cancer risk in women under the age of 45.

Two Scandinavian studies and a Yugoslavian study recently found that Pill use increases breast cancer, Dr. Shapiro said.

Kolata writes: “Ever since birth control pills were first marketed 28 years ago, doctors

were concerned that they might increase the risk of breast cancer because breast cancer is affected by sex hormones and the Pill incorporates sex hormones.”

The Pill consists of estrogen and progestin which, taken continuously, suppress ovulation. In the past few years, drug manufacturers have been making the Pill with far less estrogen and progestin. While experts think the new Pill is safer, they have no data on its relationship to breast cancer.

“We and others have been monitoring the Pill since the earliest days,” Shapiro told the *Times*. “But since the Pill was only introduced in the 1960s, until recently we could only monitor short-term effects in young women. But we were always concerned about latent intervals.”

Commenting on the new studies, Shapiro said: “We have a situation where we’re all totally confused. We don’t know whether we’re dealing with cause and effect or not. While I could not advise a woman about whether she should take the pill, I think she is entitled to the information that we are concerned.”

After reviewing the new studies, an advisory committee to the FDA said that no changes in the use of the Pill or in warning labels on the Pill are warranted. None of the panel members are cancer experts. In their deliberations, the panel emphasized the benefits of the Pill as a contraceptive, Kolata reported.

The panel endorsed a plan announced by the National Cancer Institute to conduct a study of 2,000 women to seek more definitive data on whether the pill does or does not increase women’s risk of breast cancer. That study would not be completed before 1993.

Four leading breast cancer experts interviewed by Kolata after the FDA panel announced its conclusion differed markedly with that conclusion. They said they believed the new data linking the Pill and breast cancer were so troubling that women who know they

are at high risk of breast cancer should be discouraged from taking the Pill. They also said they would advise all women, especially younger ones, not to take the Pill for more than two years at a time.

Dr. Marc Lippman, a breast cancer specialist who directs the Vincent Lombardi Cancer Center of Georgetown University Medical Center in Washington, told Kolata: “I don’t want to be inflammatory, but breast cancer is a disease for which 20 years or 30 years may be the time required to see the impact of long-term use. Unfortunately, that’s the time we’re getting into now. It’s worrisome. I would do what I could to encourage women to consider other forms of contraception.”

Dr. I Craig Henderson of the Dana Farber Cancer Center said he had been concerned for years that the Pill might cause breast cancer and was finding the evidence more and more convincing. He said he believed that the Pill’s possible risks have been too lightly regarded by family planning clinics.

Dr. George Blumenschein at the Arlington Cancer Center in Dallas said that in light of the new studies, he thinks women who have been taking the Pill for several years should stop until more data is available and that no teenagers should take the Pill.

Dr. C. Kent Osborne, breast cancer specialist at the University of Texas Health Science Center in San Antonio, advised that women look into satisfactory alternatives to the Pill and if they do not find them, take as low a dose pill as possible for as short a time as possible.

GINA KOLATA. January 5, 1989. New data on the Pill find breast cancer as a possible risk. *The New York Times*: 1; GINA KOLATA. January 6, 1989. F.D.A. panel finds no need for change in taking of the Pill. *The New York Times*: 1; GINA KOLATA. January 1, 1989. Cancer experts see a need for caution on use of birth pill. *The New York Times*: 1.

*Researcher suggests link between use of the Pill and HIV infection*

HIV infection may be linked with use of oral contraceptives, Dr. Frank A. Plummer found when he and his colleagues analyzed their long-term follow-up study of African prostitutes. Plummer, a University of Manitoba physician who has been studying HIV transmission in Africa for the past four years, made his announcement at an international conference on AIDS in Stockholm.

In a study of 1,000 female prostitutes in Nairobi, Kenya, the researchers followed 124 initially HIV-1 seronegative women for 30 months. Seroconversion to HIV-seropositive occurred in 83 women (67%), Plummer said.

In two separate analyses, Plummer found an independent association between oral contraceptive use and HIV infection. Of the women who seroconverted, 91% had used oral contraceptives, compared with 71 % who remained seronegative, analysis of survival data showed. The relative risk for oral contraceptive use and acquisition of HIV was 2.1 by this analysis, Plummer said.

Using step wise regression analysis, the relative risk of HIV seroconversion was 5.2 with oral contraceptive use.

Dr. Plummer said oral contraceptives are the most frequently used form of contraception in Nairobi, particularly among young women.

Commenting on the Plummer study in a plenary address at the conference, Dr. King K. Holmes of Harborview Medical Center in Seattle, Washington and a leading venereology expert, called the findings "important and of great interest," but said that the data should be interpreted with caution.

In a subsequent interview, Holmes told *Ob. Gyn News*, "I do not feel women taking the pill, either in Africa or in other countries, should change to other methods simply because of the Plummer study. "However, it is urgent that the study be repeated and the

results be duplicated ... or refuted in other settings."

When *Ob. Gyn News* asked U.S. manufacturers of oral contraceptives to comment on the Plummer study, they questioned the applicability of a study of HIV transmission in prostitutes in Africa to other populations of women, both in Africa and in western countries.

*Ob. Gyn News*. 1988. Suggests possible link between OC use, HIV infection. 23(16): 6.

*Dalkon Shield victims share \$3.5 billion compensation*

Under a court-sponsored settlement, 200,000 people claiming compensation from the U.S. makers of the Dalkon Shield, an intrauterine device (IUD) that has been linked to 18 deaths in the United States and to pelvic infection, infertility, septic abortion, and ectopic pregnancy, will share \$3.5 billion. About 3,000 Australians are among the claimants.

More than \$1 billion of this will go in legal fees, according to a report in *The Age*.

Dunhill Morgan Solicitors, acting for the Australian insurers of the IUD manufacturer, A. H. Robins, are seeking to strike out the settlement on a technicality, *The Age* reported.

One claimant, Lyn White told *The Australian* she had been fitted with her last Dalkon Shield in 1977, three years after the IUD supposedly was withdrawn from the Australian market. She had a hysterectomy in 1978. She still suffers painful bouts of pelvic inflammatory disease.

"Money could never compensate for what we went through," she said.

After selling an estimated 3.3 million Dalkon Shields between 1971 and 1974, A. H. Robins, responding to worldwide legal claims arising from the IUD, went into bankruptcy in 1985.

JACKIE ALLENDER. July 20, 1988. Dalkon Shield victims to share in \$3.5bn

compensation. *The Australian*; JENNIFER CONLEY. July 21, 1988. Dalkon claimants will continue action. *The Age*.

*Pregnancy vaccine tested on women in Australia*

"The first vaccine to immunise women against pregnancy has passed early clinical trials in Adelaide," Calvin Miller reports in *The Herald*. "The vaccine, developed by Professor Warren Jones of the Flinders Medical Centre, will prevent pregnancy for at least six months by 'tricking' a woman's immune system into producing antibodies against the embryo."

The vaccine prevents the embryo from implanting in the uterus. Jones said none of the 30 volunteers tested had shown side-effects other than a few muscle cramps.

"This trial has shown the feasibility of vaccinating against pregnancy," Jones said.

CALVIN MILLER. June 20, 1988. Vaccine 'contraception' passes trials. *The Herald*.

*Sterilization most commonly used birth control method in Brazil*

Sterilization is the most common form of birth control in Brazil according to statistics compiled by the Brazilian Geography and Statistics Institute.

The results show that 27.2% of Brazilian women who are married or cohabiting have been sterilized. In the age group 15 to 64 years, 16% have been sterilized.

The birth control pill is used by 15.2% of Brazilian women. Differences are seen between areas with good family planning information and those where lack of information prevails. Where information is available on family planning more women use the Pill than are sterilized. In areas with little information, the sterilization rate is much higher.

1988. In Brazil sterilization is preferred method of birth control. *Women's Health*

*Journal* 6-7: 5, originally from: 1987. *Planejamento Agora* November 17, Ano II, No. 120, ABEPP, Brazil.

**STERILITY**

*New tests for Chlamydia*

Chlamydia is a sexually transmitted disease that can cause sterility in women. In Sweden alone, it is estimated that 1000 to 2000 women become infertile from this disease every year.

Previous tests for Chlamydia have been expensive, time-consuming, and not always available at out-patient clinics. Several new tests have been developed based on immunological methods. Many of these are now commercially available as kits.

A major problem with these kits is that their specificity is only 80-100%. This means that as many as 20% of those tested who have Chlamydia may not be detected. Since Chlamydia does not produce symptoms in most persons who are infected, a test is needed that can detect all cases of infection. The use of two different tests for each case may solve this problem.

KENNETH PERSSON, TORVALD RIPA and DAN DANTELSSON. 1988. Snabbdiagnostik av Chlamydia-nya metoder utvärderade. *Läkartidningen* 85: 2325-2327.

*IUD causes sterility*

One of the most commonly used IUDs, the copper-7, has caused infections that led to sterility in many women. The copper-7 was pulled off the market in 1986 by its manufacturer, G. D. Searle and Co.

A record high damages suit has been awarded to a woman in the US. She received 55 million US dollars after proving that the IUD had made her sterile.

ANDERS HELLBERG. 1988. Skadestånd 55 miljoner. *Dagens Nyheter* (Stockholm) September 11.

*Condyloma virus more worrying than AIDS*

The cancer-causing virus Condyloma is spreading rapidly in Finland. According to Ervo Vesterinen of Helsinki University's Central Hospital, first stage cervical cancer has increased at an incredible rate the past 5 years because of the spread of Condyloma.

Four percent of all women who come to the gynecological clinic at the hospital have Condyloma and a third of all women having abortions are also infected. Half of all women with inflammation in the reproductive organs are infected.

The infection does not cause discomfort or cancer in men and they seem to be the principle source of spread. Using condoms would help reduce the spread of the infection, but paradoxically, fear of AIDS has not led to an increased use of them.

STEFAN LUNDBERG. 1988. Kondylom oröar mer än AIDS. *Dagens Nyheter* (Stockholm) September 13.

*Partner follow-up after fallopian tube infections can prevent sterility*

Two studies in Sweden show that women with acute infections in the fallopian tubes (salpingitis) often have partners who are infected with either Chlamydia or gonorrhea according to two articles in *Läkartidningen*. Most of the relationships studied were stable and long term.

By actively following up the women's partners in one of the studies, it was possible to get most of them to come in for tests and treatment. If this were to be done on a routine basis, it would prevent reinfection of the women. A second fallopian tube infection doubles the risk of becoming sterile.

In the second study, the women were told to encourage their partners to come for tests and treatment. In this case, only 27% of the men did so. This study was conducted before the new law classifying Chlamydia as a venereal disease came.

This new law requires that persons with Chlamydia infection must give the names of all sexual partners and these must be followed up for tests and treatment. Authors of both articles see this as the only possible way to deal with the current wave of Chlamydia infections in Sweden and the fallopian tube infections and sterility that follow for the women affected.

LARS WESTRÖM. 1988. Partneruppföljning vid akut salpingit kan förebygga infertilitet. *Läkartidningen* 85: 2936; MATS BERGSTRÖM. 1988. Svårt förmå männen att komma till kontroll. *Läkartidningen* 85: 2936–2937.

**SURROGACY**

*Outrage expressed at proposal to use dead women as human incubators*

Mr. Cain, Premier of the state of Victoria in Australia, has expressed outrage at what he called a "horror movie" proposal that brain-dead women could be used as surrogate mothers. If necessary, he said, the government would make it illegal.

Dr. Paul Gerber, a reader in medico-legal studies at the University of Queensland, had made the proposal. He did not know how much support the medical profession would give to the idea, but said it had been discussed seriously at several medical conferences among scientists and lawyers, the *Australian* reported.

Dr. Gerber said that using a brain dead woman's womb – with permission from her relatives – would be a solution to the many legal and ethical problems of commercial surrogacy, according to a report in *The Advocate*. He said he believed many relatives would give that permission.

"All it needs is a rational approach to death," he said.

Brain dead people were already being kept "alive" as sources for organ transplants, he said, "and there is no reason why a woman's

womb should not be used as well.” He pointed out that some brain dead women were already kept “alive” if they were carrying their own baby when they died.

While he understood why some people would see the practice of using dead women as surrogate mothers as ghoulish, “. . . just because a person is dead, why not use them for useful purpose rather than bury them?”

JACKIE ALLENDER and ADAM COURTENAY. June 25, 1988. Surrogacy proposed for ‘dead’ women. *Australian*, ALEX MESSINA and DAMIEN MURPHY. June 25, 1988. Cain outraged at talk of human incubators. *The Age*; *The Advocate*. June 25, 1988. Outrage over ‘dead mums’ proposal.

*IVF surrogacy in Australia extolled, condemned*

In Australia’s first IVF surrogacy case, Linda Kirkman underwent a cesarean section May 23, 1988 in delivering a child, Alice, for her sister, Maggie Kirkman, who had provided the egg. Legislation scheduled to come into effect in Victoria July 1, 1988, the Infertility (Medical Procedures) Act 1984, would make such surrogacy almost impossible in the future by preventing a fertile woman from undergoing IVF.

At 29 weeks of pregnancy, Linda was struck with placenta praevia, a potentially dangerous disorder in which the placenta can break away from the wall of the uterus. For nine weeks, the egg donor sister maintained a vigil at Linda’s bedside either in the hospital or at their parents’ Melbourne home, Julie Dillion reported in *New Idea*.

“I felt appalled that Linda had to go through all of that,” the sister, Maggie, told Dillion, “but it was something that couldn’t be predicted. She never felt any resentment towards me.”

During those nine weeks, Linda was allowed to go home only once, for five days, to visit her husband and two children, aged 5

and 3. But she told Dillion she never had any second thoughts about decision to bear the child.

“It’s actually been a big boost to my ego,” she said. “People tell me how wonderful I am!”

While the family has kept the identity of the sperm donor secret, Dillion wrote, it has been revealed that the donor is a friend of the family who gave his sperm specifically for Alice’s conception.

In a letter to *The Medical Journal of Australia*, the physician involved in this case, John Leeton of Monash University, Department of Obstetrics and Gynecology in Melbourne, objected to the outlawing of IVF surrogacy in Victoria.

“This is a tragedy as in-vitro fertilization surrogacy represents the optimal form of surrogate pregnancy, with a minimum of risks as the commissioning woman is beyond doubt infertile because she has no uterus, and is a very close relative or friend of the surrogate,” he wrote. “The latter is not donating her eggs or genes toward the subsequent child, and thus will have less risk of bonding and wishing to keep the baby, as was demonstrated by the Baby Alice birth, in stark contrast to the American Baby M case.”

“The surrogate sister [Linda] was considered to be infertile as her husband had undergone a vasectomy,” Leeton wrote.

In a column in *The Medical Journal of Australia*, Professor Carl Wood, head of the Monash IVF clinic, and Dr. Peter Singer, professor at the Centre for Human Bioethics, both in Melbourne, while not denying certain problems involved in surrogacy, defend the practice. It “can be one of the most generous, loving and humane acts that one woman can carry out for another woman,” they state.

They write:

It seems very likely that the careful arrangements which surrogacy provokes and demands may have positive benefits for

our society. It will teach us to see child-bearing from a wider perspective than that of two parents, and the selection of couples and surrogates will define better those factors which may be important in parenting and early child development. In assessing the problems of surrogacy, we must not forget that properly-arranged surrogacy will tend to exclude many of those factors which are accepted by the community in natural conception, and which may be disastrous for the child – unwanted pregnancy, poor parental health (emotional and physical) and the use of harmful drugs. The infertile couple and surrogate, with advice, will be optimizing the conditions for a successful pregnancy and birth. In this respect, such a child may have an advantage over the child who is subject to all the risks that so often are associated with unplanned natural conception.

Wood and Singer argue that women who serve as surrogates should be unpaid, except for reasonable expenses, “and only surrogates who are motivated by altruistic desire to help another couple should be selected to provide the service.” The mother would retain the right to change her mind and keep the baby under the Wood-Singer proposal.

“With experience and the application of skills to choose and match surrogates and infertile couples, the risks would be minimized,” Wood and Singer write. “We are optimistic that a skilled approach to surrogacy could become a successful means of overcoming infertility. To date, it has suffered from inadequate support and study, overexposure of the complications in the media and unfair prejudice.”

Institutional ethical committees or a voluntary licensing authority formed by the Royal Australian College of Obstetricians and Gynaecologists and the National Health and Medical Research Council could provide

additional safeguards for the practice of surrogacy, they suggest. If the government insisted, the voluntary authority could be taken over by the government and become a statutory licensing authority with more power and legal authority.

The men conclude: “We should not condemn surrogacy on the basis of the worst forms that it can take. It is time to consider surrogacy at its best.”

Interviewed in *The Age* on the Kirkman case and altruistic surrogacy in general, Dr. Robyn Rowland, a psychologist and feminist critic of reproductive technology, commented: “This has nothing to do with a feminist concept of sisterhood. The values of feminism are against using other women for your own desires in this way. This is one woman using another as incubator.”

Maggie Kirkman maintains that she is the mother of baby Alice because her egg was used in the child’s conception. To Rowland, the idea that the genetic parent is the real parent is “a very masculine concept of parenthood. Men deliver the seed and that is parenthood for them. Women deliver the children and rear them. It is an argument that takes children away from their mothers more easily. When we split motherhood into biological and social motherhood – and in this case genetic motherhood as well – we deny the reality of biological motherhood.”

She added that US surrogate businesses have been arguing for some time that it is all right to take a child away from a woman “because it’s not really hers. What’s being sold to women is that that relationship does not exist.”

Rowland told *The Age*’s Rosemary West that US surrogacy companies recruit married women into surrogacy “so there will be pressure from the husbands not to keep the kids.”

West wrote of Rowland:

She is equally critical of what she claims is the eternal self-sacrifice that women are

supposed to make and for which Linda Kirkman has been so warmly praised in the newspaper letters pages. 'What if the woman literally lays down her life, what if she dies?' Dr. Rowland says two women have already died during IVF in Western Australia.

In a second IVF surrogacy case, a woman from Victoria, Australia underwent a cesarean section in October 1988, delivering triplets for her sister. The surgery was performed after 33 weeks of pregnancy when the mother developed toxemia, a blood disorder. The children were conceived in West Australia which has no legislation directly regulating IVF or prohibiting surrogacy.

The family wants the children born in West Australia, where the "commissioning sister" lives and where they believe it will be easier to have the triplets adopted by the gamete donors, Dan McDonnell reports in *The Sun*.

The pregnant woman had three embryos implanted earlier this year at PIVET Medical Centre, private IVF clinic in Perth. The sister in Perth was born without a uterus, an abnormality, McDonnell wrote, "that would have condemned her to a life without children."

Dr. John Yovich, PIVET team head, said of the pregnant woman: "She is pleased to provide this service for her sister. She and her husband are both pleased to be doing this."

Yovich told reporter McDonnell that PIVET had several other couples at various stages of surrogate IVF treatment.

ROSEMARY WEST. June 15, 1988. Surrogate motherhood – but is it sisterhood? *The Age*, p. 21; JULIE DILLION. July 2, 1988. 'I was worried that my baby was going to die'. *New Idea*; JACKIE ALLENDER. June 17, 1988. Business booming, says four-times surrogate. *The Australian*. DAN McDONNELL. June 10, 1988. Triplets: Now, three IVF 'gifts' for sister. *The Sun*; JOHN LEETON. October 17,

1988. Untitled letter. 149; E. CARL WOOD and PETER SINGER. October 17, 1988. Whither surrogacy? 149:426–430.

*Michigan Attorney General agrees to interpret law banning surrogacy in a way that would allow surrogacy to continue*

In response to a lawsuit by the American Civil Liberties challenging a new Michigan law that would ban surrogacy, the state attorney general agreed to interpret the law in such a way as to permit surrogacy contracts. The contracts would be allowed as long as they do not require the woman to give up her maternal rights.

The American Civil Liberties Union agreed to drop its suit if the presiding judge would uphold that interpretation. Judge John H. Gillis, Jr. of the Wayne County Circuit Court ruled that the law was constitutional if interpreted that way.

Noel P. Keane, the lawyer who arranged the births of more than 200 babies through surrogacy, including that of Baby M, said the decision will not affect his business.

"I don't have to change anything," he said, "because we don't make the payment contingent on the mother giving up her parental rights. This is not baby selling; it's women providing a service, and we treat these agreements as payment for services."

Howard Simon, executive director of the Michigan American Civil Liberties Union, claimed victory: "The attorney general has given a very narrow interpretation of the law and we're delighted. The bottom line on this is that surrogacy is still permissible in Michigan."

He said the ruling would permit couples to arrange to have children through the use of surrogate mothers and permit the mothers to be paid fees.

Judge Gillis subsequently issued a ruling that held surrogacy permissible in cases where compensation was limited to "actual medical expenses as a result of the pregnancy."



After the ruling, *The New York Times* commented, two issues were apparently left unresolved: "whether surrogacy for pay is allowable in some circumstances and what kind of payments are permitted."

The compensation issue remains cloudy because State Attorney General Frank Kelly has argued that the law "does not prohibit compensation for gestation," that is, paying for agreeing to bear a baby.

The law which took effect September 1, 1988 makes arranging illegal surrogacy contracts a felony with penalties of up to five years in prison and a \$50,000 fine.

JOHN HOLUSHA. September 20, 1988. Judge upholds ban on surrogate birth contracts. *The New York Times*. TAMAR LEWIN. September 20, 1988. Surrogacy: a consensus. *The New York Times*; *The New York Times*. November 15, 1988. Judge rules on surrogacy ban.

#### *States within the United States consider legislation on surrogacy*

Legislators in more than two dozen U.S. states, acting in the wake of the controversy over surrogacy provoked by the celebrated "Baby M" case, have introduced bills that would prohibit, regulate or investigate surrogacy. According to the National Conference of State Legislatures in Denver, Colorado, more than 50 such bills were considered in 1988 by state legislators.

"In Florida, Indiana, Kentucky, Louisiana, Michigan, and Nebraska, laws have been enacted that either ban surrogacy for pay or declare surrogacy contracts void and unenforceable," Calvin Pierce reports in *Ob. Gyn News*. "In at least two states (Michigan and Florida) violators are subject to felony penalties."

Legislators are considering several surrogacy bills in New York, where a commission recommended making it illegal to pay women to serve as gestators.

To date, no state has passed a statute that explicitly recognizes surrogacy and regulates how the practice should be conducted.

Supporters of surrogacy are looking for help from a lawsuit filed by the American Civil Liberties Union challenging the constitutionality of a Michigan law that prohibits commercial surrogacy contracts. The new Michigan law makes it a felony to arrange a surrogacy contract for pay. The offence is punishable by a maximum \$50,000 fine and five years in prison.

Michigan is the home of the most active surrogacy broker in the U.S., Noel P. Keane. Keane told *Ob. Gyn News* that because of ambiguities in the new law, he could continue to run his surrogacy business in Michigan. Keane, who also runs a surrogacy business in New York, said he is keeping his options open by establishing another office in Nevada. If necessary, he told the newspaper, he will move his practice there.

"Michigan's new surrogacy law does not prevent a broker from conducting follow-up services in Michigan on a contract established out of state," Pierce observes.

The constitutional issues of the right to privacy and the right to procreate will be addressed in the lawsuit being filed by the American Civil Liberties Union, Keane told Pierce.

CALVIN PIERCE. 1988. Many states enacting, studying surrogacy laws. *Ob. Gyn News*. 23(17): 1.

#### **SEX PREDETERMINATION**

##### *Increase in physician approval of sex predetermination in the United States*

In a major change in medical attitude and practice, many physicians are either providing prenatal diagnosis for sex determination alone or are telling clients where to go to get it, Gina Kolata of *The New York Times* reports.

Very rarely is there any medical reason to determine a fetus' sex, according to Dr. Mark I. Evans, a geneticist at Wayne State University in Detroit.

The percentage of geneticists who approve of prenatal diagnosis for sex selection rose from 1% in 1973 to nearly 20% in 1988, national surveys conducted in those years indicate.

The reasons for the attitude change, geneticists told Kolata, are an increased availability of diagnostic technologies, a growing disinclination of doctors to be paternalistic, deciding for patients what is best, and an increasing tendency for patients to ask for the tests.

At the time of the first survey, prenatal diagnosis was a scarce commodity and the only method available was amniocentesis. By the time of the second survey, geneticists had begun to offer a second method, chorionic villus sampling (CVS), performed in the first trimester of pregnancy.

The 1973 survey was conducted by James R. Sorenson, a social scientist at the University of North Carolina. He mailed questionnaires to a national sample of 661 geneticists. Only 1% of the 496 who responded approved of sex determination.

The 1988 survey was conducted by Evans, John C. Fletcher, an ethicist at the University of Virginia, and Dr. Lawrence D. Platt, a geneticist at the University of Southern California in Los Angeles. In mailed questionnaires filled in by 212 geneticists, 20% approved sex determination.

While there are no national data on the number of prenatal diagnoses done for sex selection, nor on the number of women who abort pregnancies because of fetal sex, every one of more than a dozen geneticists interviewed by the *Times* said he or she regularly receives requests sex predetermination procedures.

GINA KOLATA. December 25, 1988. Fetal sex test used as step to abortion. *The New York Times*: 1.

*Many sex predetermination techniques not proven to work*

"Dietary methods, the Shettles method, and the sperm separation methods, including that of Ericsson, all claim success rates of approximately 80 percent," Dr. Sandra Ann Carson writes in *Fertility and Sterility*. "In none of these techniques have rigorous studies been conducted. No controlled studies have been reported, and follow-up is not sufficiently rigorous to offer confidence that cases are not lost to follow-up."

Carson, of the Department of Obstetrics and Gynecology at the University of Tennessee, Memphis, concludes:

Sex preselection is not for all couples. Nonetheless, sex preselection has an obvious advantage for couples at risk for X-linked diseases. A successful method would also allow couples desiring children of particular gender to limit their families and even assign birth order – an ultimate family planning. Those couples who object on moral, ethical or religious grounds need not use these techniques. In seeking to develop successful techniques, we also gain knowledge and benefits that surely outweigh any potential demographic and socioeconomic harm that these techniques pose.

SANDRA ANN CARSON. 1988. Sex selection: the ultimate in family planning. *Fertility and Sterility*. 50(1): 16–19.

## FETAL TISSUE AND ORGANS

*Guatemalan babies allegedly sold for transplantation purposes*

A Guatemalan women's group, IXQUIC, has charged that babies from Guatemala are being 'exported' to the United States to "provide organs for the children of wealthy North Americans."

According to IXQUIC, two men of Israeli nationality "bought seven Guatemalan babies

ranging in age from 11 days to 4 months with the intention of selling their organs for 75,000 US dollars a piece to families in the United States." IXQUIC also states that during 1985–1987, "the sister-in-law of ex-president General Oscar Mejia Victores was implicated in the exportation of Guatemalan children for the same purposes." As many as 166 children were 'exported', the group charges.

1988. Babies exported to provide transplant organs. *Women's Health Journal* 6–7:14, originally from 1987. IXQUIC, *Mujer en Guatemala*. Mexico, January.

*U.S. panel approves research use of fetal tissue from abortions*

An advisory committee to the National Institutes of Health has concluded that use of human fetal tissue obtained from legal abortions for research and therapy is morally acceptable. Dr. Robert E. Windom, Assistant Secretary of Health, appointed the 21-member panel last spring. At that time the government suspended federal financing of new research involving human fetal tissue until the ethical issues could be addressed.

The panel's recommendation is not binding but is expected to influence senior federal health officials substantially.

The panel said that fetal tissue is like other cadaver tissue that normally would be disposed of and can be used for research and possible treatments.

However, the committee "suggested developing guidelines that would separate any decision about having an abortion from the potential use of fetal tissue, as well as preventing commercial trafficking in such tissues," *The New York Times* reported.

"In testimony before the panel this week," the *Times* stated, "scientists said that based on animal research and limited human studies, transplants of human fetal tissue might be useful against Parkinson's disease

and other neurological disorders, diabetes and other serious diseases. Implanted fetal tissue grows rapidly and is less likely than adult tissue to be expelled by the body's immune system."

In testimony before the panel, Dr. Lars Olson, professor and chairman of the department of histology and neurobiology at the Karolinska Institute, Stockholm, one of the few researchers who has transplanted human fetal tissue, said that early results against Parkinson's disease in a few patients were modest. The transplantation of fetal neural tissue appears to have resulted in minor positive changes and no adverse effects, *Ob. Gyn News* reported. The surgery was performed just last autumn, Olson said, so it is too early to say what the long-term effects of the procedure will be.

Dr. Eugene Redmond, Jr., director of the neurobehavior laboratory at Yale University School of Medicine, New Haven, Connecticut, has performed similar experiments in monkeys who have a drug-induced syndrome that resembles Parkinson's disease. In the small experiment, some animals showed dramatic improvement.

The results suggest that the transplanted tissue survives the surgery, integrates with the host brain, produces dopamine, and may promote recovery of even severely parkinsonian animals, Redmond said.

Redmond and Olson agreed that the research on treating Parkinson's with fetal neural grafts is too promising to be halted now.

Olson told the panel: "I believe it is unethical not to try these experiments in patients."

JONATHAN ADAMS. October 15, 1988. Federal panel terms fetal tissue research ethically acceptable. *Ob. Gyn News* 23(20): 1; WARREN E. LEARY. September 17, 1988. U.S. panel backs research use of fetal tissue from abortions. *The New York Times*: 1.

## EMBRYO EXPERIMENTATION

### *Federal Republic of Germany may ban embryo research*

"In spite of heated opposition from scientific groups, the Bundestag of the Federal Republic of Germany (FRG) is expected to approve legislation [this fall] that would make it a crime to conduct research on human embryos," Don Kirk of *Science* reports. "Under a so-called embryo protection bill that is currently under consideration, the intentional in vitro fertilisation of a human egg for research purposes would be punishable by up to 5 years in prison."

Numerous scientific research organizations are opposed to the law and have been openly critical. In order to "head off the proposed legislation, both the Max Planck Society and the German Research Foundation (DFG) have suggested that a voluntary moratorium be instituted," states Kirk.

"The law would consider a fertilized human egg cell, from the point of fusion of sperm and egg nuclei, as 'deserving of legal protection'," reports Steven Dickman of *Nature*. The law would make illegal any manipulation of sex cells as well as cloning of humans.

"Also to be banned is the creation of human embryos purely for the purposes of research, even for 'high-level scientific goals' such as the improvement of in vitro fertilization (IVF) techniques or the potential use of fetal tissue or secretions for therapeutic purposes," Dickman states.

DON KIRK. 1988. West Germany moving to make IVF research a crime. *Science* 241:406; STEVEN DICKMAN. 1988. Embryo research ban causes ructions in West Germany. *Nature* 333: 791.

### *Researchers want lax rules on embryo experiments in New South Wales*

"New South Wales [Australia] has been urged to adopt less stringent regulations on in

vitro fertilization research than the controversial regulations agreed in the neighbouring state of Victoria," Charles Morgan of *Nature* writes.

The New South Wales Law Reform Commission "urges that all types of research on human embryos be permitted until 14 days after fertilization, the usual time of implantation. In Victoria, research is limited to a 22-hour period after fertilization," Morgan states.

The committee has taken such a liberal stance by accepting that embryos "need not necessarily be given the full rights accorded to people, and the realization that the poor success rate of in vitro fertilization techniques can be improved only through further experiments," Morgan reports.

CHARLES MORGAN. 1988. Liberal stance on embryo experiments. *Nature* 334: 640.

### *US panel discusses allowing fetal tissue transplants*

A special panel, the Human Fetal Tissue Transplantation Research Advisory Panel, has been created by the National Institutes of Health (NIH) to discuss "the ethical, legal and scientific issues surrounding the therapeutic use of fetal tissue from induced abortions," states Leslie Roberts in *Science*. Such experiments were banned in March 1987.

Assistant Secretary of Health Robert Windom has sent a list of questions that he wants the panel to discuss at its meeting 14–16 September, "including whether the use of fetal tissue in research will encourage women to have abortions they otherwise would not, and whether abortions will be intentionally delayed so that a second trimester fetus will be available," *Science* reports.

A few days before the meeting, an anti-abortionist White House aide tried to force through an executive order that would ban all research on fetuses, according to Barbara J. Culliton of *Science*. Currently, NIH funds 116 research projects that use human fetal tissue.

Research scientists protested and forced the White House to back down.

The panel met as planned and tentatively approved the use of fetal tissue for transplantation purposes. The panel stated that "the use of post-mortem fetal tissue for purposes of research and therapy that has been obtained from legally performed abortions is acceptable," states *Nature*.

However, such research will not be allowed to have any influence over a woman's decision to have an abortion, and no woman will be allowed to donate organs or tissue from the aborted fetus to a particular recipient, according to *Sydsvenska Dagbladet*. A final report will be presented on November 15.

LESLIE ROBERTS. 1988. Fetal panel to meet. *Science* 241: 1164; BARBARA J. CULLITON. 1988. White House wants fetal research ban. *Science* 241: 1423; JOSEPH PALCA. 1988. Fetal tissue panel labours to beat a presidential ban. *Nature* 335: 291; ANNA-LENA HAVERDAHL. 1988. Sager ja till experiment med aborterade foster. *Sydsvenska Dagbladet* (Malmö) September 18.

#### *Brainless babies program discontinued in California*

Loma Linda University Medical Center in California, USA, has discontinued its controversial program of keeping babies born without brains alive for transplantation purposes according to *Nature*.

Babies born without brains have only a brain stem and do not live more than a few days after birth. But by the time they die, their organs have deteriorated and cannot be used for transplantation. Loma Linda performs organ transplants on babies and has problems finding enough organs.

Loma Linda began a program of putting brainless babies on life support systems after birth so that when they died, their organs would not have deteriorated. But the life

support system also supported the brain stem which in turn prolonged the life of the babies.

None of the babies kept on life support were used for transplantation.

JOSEPH PALCA. 1988. Loma Linda halts controversial trial. *Nature* 335: 7.

#### *Ethical aspects of transplants from aborted fetuses discussed*

Ethical guidelines were drawn up in Sweden when researchers were on the verge of using brain cells from aborted fetuses to treat adults with Parkinsons disease.

These guidelines were revised earlier this year to include a clause stating that the woman undergoing an abortion must give explicit, informed consent before tissue from the aborted fetus may be used. Previously, all that was required was that she not say no if asked to donate "birth material."

Jan Arlebrink, doctoral student in ethics and lecturer in medical ethics at Lunds University, has written about the complex ethical issues raised by this type of research in the Swedish medical journal, *Läkartidningen*.

Informed consent requires that 4 criteria be met according to Arlebrink. The woman must be aware of what she is doing and not be under the influence of drugs or anesthesia. No violence or threat of violence should exist. She should not be promised any advantages or reward if she goes along with the treatment and should not lose anything by not accepting. She should not be in a position of disadvantage or feel she has to show gratitude toward the doctor or anyone else.

Arlebrink writes that it is the last criteria that is the most problematic. Every woman undergoing an abortion is in a position of disadvantage in relationship to the health care system.

Thus she may feel she should donate the fetus to show her thankfulness for being allowed to have an abortion.

Arlebrink points out that a major ethical criteria is that no person is to be used as the means to a goal. Using tissue from aborted fetuses is therefore unethical since the fetus is being used as the means to a goal.

Another risk is that using fetal cells for transplantation purposes can create a demand for producing fetuses for donation purposes only.

JAN ARLEBRINK. 1988. Etiska aspekter på cellbehandling av Parkinsons sjukdom. *Läkartidningen* 85: 3073–3074.

*Swedish politician accuses government of stalling on sensitive issues*

Ingrid Ronne-Björkqvist, doctor and member of the Swedish Parliament, writes in *Läkartidningen*, the Swedish medical journal, that the Swedish government lets Parliamentary decisions on sensitive ethical questions sit for years before they are addressed.

This is especially true for questions having to do with abortion, prenatal diagnosis, and IVF. Politicians often receive information on new research and treatments well after they are established, making it almost impossible to set limits.

The risk is that politicians try to find the best excuses possible for allowing such research since it already exists. One good example of this is the case for allowing the use of brain cells from aborted fetuses for transplantation purposes in Sweden.

Ethical guidelines were drawn up after human fetal cells were successfully transplanted into rat brains to cure a Parkinson's-like disease. The doctors wanted to try the method on humans.

Ronne-Björkqvist states that the proposed law on IVF that the government has now laid before Parliament (after letting it sit for more than 3 years), misses an essential point. The most serious problem is that this technology makes fertilized eggs available for genetic manipulation.

The proposition states that “defective eggs” should not be used and that research on methods be allowed. Which defects count and how far such research can go is not stated. Not defining this opens the way for mapping genes, quality control and eliminating “defective” individuals. Several MPs voted against the proposition and called instead for a ban on IVF.

INGRID RONNE-BJÖRKQVIST. 1988. Splittrade beslut försvårar helhetssyn: Känsliga frågor förhalas i regeringen. *Läkartidningen* 85: 2847–2848.

**GENETIC ENGINEERING:  
AGRICULTURAL USES**

*Swedish farmers oppose agricultural genetic engineering*

Almost 90% of Swedish farmers are opposed for ethical reasons, to genetic engineering. They consider it immoral to produce crops that are engineered to withstand chemical pesticides. They would like to see a ban on such plants.

1988. Bönder mot genetik. *Dagens Nyheter* July 8: 27.

*Engineered bacteria against corn borer field-tested in USA*

A bacteria engineered to produce a substance toxic to the corn borer was tested on a government-owned field of corn in Maryland, USA, according to Christopher Joyce of *New Scientist*. The test was carried out without any protests from environmental groups.

The bacteria is produced by Crop Genetics International (CGI). The company started its fight to get permission for the field-test more than two years ago when it “recruited an elite corps of former government officials to defend it against environmentalist critics and sceptical bureaucrats,” Joyce writes. “For several

thousand dollars a piece, the company bought the advice of William Ruckelshaus and Douglas Costle, both former directors of the Environmental Protection Agency, the organisation that in May granted approval for the test.”

Elliot Richardson is a member of Crop Genetics International’s board of directors. “At various times Richardson has been the US’ secretary of defence, commerce, health, education, and welfare, as well as attorney general. Moreover, CGI convinced the department of agriculture to be a partner in one of its two field tests,” Joyce reports.

The test was opposed by the Washington-based Foundation on Economic Trends, a public interest group, and several environmentalist groups but no one has filed a lawsuit to stop the test because no one believes that the test will work.

Crop Genetics International itself admits that the bacteria does not produce enough of the toxin to kill the corn borers.

CHRISTOPHER JOYCE. 1988. Gene-spliced organism meets the corn borer. *New Scientist* July 7: 28.

#### *New method for gene transfer in plants*

A new method for inserting new genetic material into plants has been developed by biochemists at the Imperial College in London, according to *New Scientist*. The most common method of gene transfer into plants is to infect them with a bacteria called *Agro-bacterium tumefaciens* that has been genetically engineered to carry a new gene. But this bacteria only infects monocotyledon plants such as tomatoes and tobacco. It does not work with dicotyledons which include all the important crop plants (rice, wheat, oats, etc.).

The new method involves using tomato golden mosaic virus which has been genetically engineered to carry a new gene plus an extra gene for replication. The virus

can be injected into the stem where it then spreads to the rest of the plant.

The replication gene causes the virus to make 200–500 copies of the new foreign gene in each plant cell. This virus can infect both monocotyledon and dicotyledon plants and takes about 21 days to spread throughout the entire plant. The researchers hope that this new technique can be used to genetically engineer plants with increased resistance to pests.

1988. Better crops from foreign genes. *New Scientist* August 18: 31.

#### *First European patent on engineered plants*

“The biotechnology company Agrigenetics of Boulder, Colorado, has had an application approved by the European Patent Office in Munich [Federal Republic of Germany] for what is thought to be the first European patent on plants,” *Science* reports.

The patent covers a method for increasing protein levels in alfalfa as well as covering all plants produced by the method. This opens the way for patenting genetically engineered plants and animals in Europe.

Previously, it was not clear if this would be possible as the European Patent Convention of 1973 excludes patent production for “plant and animal varieties.” It also excludes patenting “essentially biological processes for the production of plants and animals.” Many interpret this to mean that genetically engineered plants and animals can be patented if the term “variety” is interpreted very narrowly.

*Science* states that this is the approach that “has been adopted in the draft of a directive seeking to clarify European patent law, which is currently being completed by the Commission of the European Economic Community (EEC) in Brussels.”

D.D. 1988. Europe grants first patent on plants. *Science* 240: 1142.

*Genetically engineered bacteria benefit from new genes*

"The release of genetically-engineered organisms carrying foreign DNA may be riskier than scientists have supposed," writes *New Scientist*. "New research by Judith Bouma and Richard Lenski of the University of California at Irvine suggests that bacteria can evolve so that they tolerate and even benefit from carrying extra genetic material."

Previously, it was believed that bacteria with extra genetic material could not compete as well against the native bacteria when spread out in the environment because the extra "baggage" would cost too much energy.

But Bouma and Lenski's research has shown that this may not be the case. "They produced a strain of the bacterium *Escherichia coli* that evolved a liking for its extra DNA," states *New Scientist*.

1988. Bacteria grow fitter on foreign DNA. *New Scientist* September 29: 42.

*Genetically engineered mushrooms*

Researchers at the University of Toronto, Canada, have produced a strain of mushrooms that are tolerant to changes in temperature and disease. The mushroom is a cross between two strains of the same species.

The strains were crossed by taking mycelial cells, thread-like growths that form mushrooms, and treating them to remove the cell wall. By fusing different cells, they could change the combinations of chromosomes to form new strains.

The researchers hope that such genetically engineered mushrooms will be "on the market in less than five years," writes *New Scientist*.

1988. Genetic first breeds hardy mushrooms. *New Scientist* September 22: 38.

*Genetically engineered tomato*

The biotechnology company Calgene, Inc. in Davis, California and researchers at the

University of Nottingham, England, have created a genetically engineered tomato, *Science* reports. Greenhouse tomatoes are usually picked when still green because they can tolerate being transported without bruising. However, they lack taste when they arrive at the supermarket.

The researchers have managed to engineer tomatoes that soften more slowly when they ripen so that they can be left on the vine longer, thus allowing them to develop more taste. The researchers have programmed the tomato to produce less of an enzyme that causes softening.

They do not know how the genetically engineered tomato rates when compared to normal tomatoes as yet. The tomato will be field tested in Mexico this fall.

LESLIE ROBERTS. 1988. Genetic engineers build a better tomato. *Science* 241: 1290.

*EEC committee wants patent law to cover engineered plants and animals*

A committee within the European Economic Community (EEC) has suggested that the European Patent Office be allowed to patent genetically engineered animals and plants. This suggestion follows in the wake of a decision by the US Patent Office that such plants and animals could be patented.

At present, only microorganisms and microbiological processes can be patented in Europe, according to *Ny Teknik*. Under the EEC proposition, cells would be defined as microorganisms.

The new rules would even allow the patenting of genetically manipulated human organs, something the US Patent Office does not allow.

Patenting plants and animals would have serious effects on farmers as they would have to pay royalties for breeding genetically altered animals. They would also lose the possibility to save seed from one crop to use for the next if the seed was patented.



STAFFAN DAHLLÖF. 1988. Patent på allt från möss till människor. *Ny Teknik* (Stockholm) 39: 10.

*Genentech receives another patent for TPA*

The California biotechnology company Genentech has received a patent in the US that covers their newest product, tissue plasminogen activator (TPA), according to *Nature*.

TPA has been shown to dissolve clots after heart attacks much better than any other treatment. The patent gives Genentech "ownership of the DNA sequences coding for human TPA, its exact amino acid sequence, and all recombinant vectors, microorganisms and cell lines which are used to produce it," states *Nature*.

A similar patent was filed in England and is presently being fought by another company, Wellcome plc, that has its own version of TPA.

C.E. 1988. Genentech patent. *Nature* 335: 105.

*Tax on plant genetic resources proposed*

A meeting was held in Copenhagen, Denmark in June by a coalition of nongovernmental organizations from developing countries called the Seeds Action Network. They proposed a tax on crops produced from genetic material "freely given by Third World countries," states *New Scientist*. The money obtained from such a tax would be taken care of by the UN Food and Agriculture Organization and used to improve plant breeding in developing countries.

1988. Campaigners urge levy on exports of germplasm. *New Scientist* June 16: 33.

*Biotechnology prioritized in Soviet Union*

"As part of General Secretary Mikhail Gorbachev's drive for economic reform, the Soviet Academy of Sciences and the

government ministries in charge of manufacturing have teamed up to form 21 different enterprises to collaborate on research and development and the manufacture of a wide variety of items, including biotechnology products for medicine and agriculture," Marjorie Sun of *Science* reports.

This enterprise is called the biotech association and under its guidance the Soviet Union hopes to become competitive in biotechnology. One of the stimuli for the program is the profit motive and it is hoped that this research will eventually be self-financing.

"The biotech association also hopes to set up joint ventures with foreign firms and to compete eventually in the international market," states Sun. "It just completed preliminary field trials of bovine growth hormone in cooperation with the Monsanto Company, for example."

MARJORIE SUN. 1988. A biotech enterprise Soviet style. *Science* 241: 1154-1155.

*The Soviet Union sings the biotechnology blues*

"A Soviet minister recently expressed frustration over the shutdown of a biotechnology facility that was prompted by protests from local citizens and an 'unobjective' press," states Marjorie Sun in *Science*.

According to Valery Bykov, Minister of the Medical and Microbiological Industry, a plant was set up in the town of Kirishi, 60 miles outside of Leningrad. The plant was to make cattle fodder protein "using biotechnology."

The protein turned out to cause allergic reactions and some of the dust escaped because of a bad cleaning system.

Bykov stated that those responsible for the release were fired but "our plant in Kirishi was made the scapegoat for an increase in illness." Kirishi is heavily industrialized and Bykov argued that the biotechnology plant

contributed very little to the total pollution of the town.

But “some people claimed that the plant was producing ‘biological bombs’ and that it was responsible for the deaths of a number of local people,” states *Science*. The press began to report on the problem and opposition to the plant in Kirishi “snowballed into a campaign against the entire industry – against biotechnology,” said Bykov.

Bykov’s solution is to encourage researchers to write popular science articles about biotechnology “explaining what it would do for the people,” states *Science*.

“Of course I’m for glasnost,” Bykov said, “but glasnost must be democratic. It’s no good at all if it’s based on unobjective facts.”

MARJORIE SUN. 1988. Soviet biotechnology meets glasnost. *Science* 241: 781.

#### *Controversy over licensing of biotech lab in FRG*

A new conflict between environmentalists and biotechnology has erupted in the Federal Republic of Germany (FRG). Invitron Corporation, a US biotechnology company, is currently building a laboratory in Hann-over.

“New regulations for production facilities using genetically engineered organisms took effect in West Germany [FRG] on 1 September,” states *Nature*. The new rules require public discussion in the licensing procedure.

However, Invitron got approval before the new rules were passed and has thus avoided a public discussion. The local Green Party has protested against the license.

STEVEN DICKMAN. 1988. Next round in West Germany’s biotechnology licensing struggle. *Nature* 335: 199.

#### *Little political interest in biotechnology during Swedish elections*

Swedish political parties have shown little political interest in questions concerning

biotechnology during election campaigns this fall. But several of the smaller parties have come up with some suggestions.

The Center Party demands a biotechnology law to regulate the industry and a Biotechnology Inspectorate.

The Communist Party has written a motion calling for the formation of a committee to continuously inform Parliament about what is happening in the biotechnology world.

The Green Party wants a five-year moratorium on all genetic engineering research. It proposes that the time be used for ethical discussions and discussions of genetic engineering’s future implications.

The Social Democrats, Conservatives and Liberals have no programs for biotechnology in their political platforms.

BIRGIT ANDERSSON. 1988. Nymornat intresse för biotekniken. *Ny Teknik* (Stockholm) 37: 15.

#### *Who will control Britain’s biotechnology?*

British researchers are being encouraged to “sell their research, and themselves, to industry, which sets a premium on commercial advantage rather than academic esteem,” states Steve Connor of *New Scientist*. British science research councils are low on funding and thus see collaboration with biotechnology companies as a way of funding university research.

The biotechnology companies are taking advantage of this change of view. The Science and Engineering Research Council, for instance, has established a Biotechnology Directorate which helps make links between universities and industry.

The Agriculture and Food Research Council and the Medical Research Council have gone a step further. “These two councils each established a company to exploit research,” states Connor. “The MRC established Celltech and the AFRC formed the Agricultural Genetics Company.”

The increasing dependence on industry for funding is worrying many researchers. For instance, the free flow of information is being hindered to protect trade secrets.

Because the entire funding system for British biotechnology is currently being reviewed, the different research councils are vying with each other over who will ultimately control biotechnology research.

STEVE CONNOR. 1988. The battle for Britain's biotechnology. *New Scientist* August 11:45-50.

*Molecular scissors new tool for treating viral disease*

"Genetic engineers have developed a new set of molecular scissors that may ultimately form novel weapons against viral diseases," *New Scientist* reports.

The "scissors" are called ribozymes and cut molecules of RNA at specific points. A gene coded by DNA is copied by RNA and the RNA transported out of the cell nucleus to parts of the cell that then "read" the gene (RNA) and make what it codes for.

The ribozymes work by pairing up with certain complementary bases of an RNA molecule and cutting it in two. The ribozymes can be tailored to cut RNA coding for specific genes, thus preventing the "reading" of the gene and the making of its product.

This could be used to destroy viral RNA that causes disease or to inactivate particular genes in plants or animals, according to *New Scientist*.

ALISON COOK. 1988. Molecular shears to attack viral diseases. *New Scientist* August 25:31.

**GENETIC ENGINEERING: NONHUMAN ANIMAL APPLICATIONS**

*Vaccine against cattle ticks developed using genetic engineering*

The cattle tick, *Boophilus microplus*, causes damage to cattle in Australia and Latin America worth millions of dollars, according to *New Scientist*. Researchers at the Commonwealth Scientific Industrial and Research Organisation (CSIRO) in Australia have developed a vaccine against the cattle tick in collaboration with Biotechnology Australia, a biotechnology company.

The vaccine was developed by identifying a protein produced by the tick which stimulates the cattle immune system. The gene for the protein could then be identified and cloned (copied) to produce a vaccine.

1988. Cattle vaccine turns the tables on ticks. *New Scientist* August 18: 34.

*US to decide on animal patents*

"The US House of Representatives committee on the Judiciary will [in mid-August] consider two drastically different ways to resolve the complex ethical, procedural, and economic issues surrounding the patenting of animals," Carroll Ezzell reports in *Nature*. "The committee will decide whether congress should establish a two-year moratorium on the granting of patents covering animals, or allow the patenting of animals to continue, but exempt researchers and farmers from paying royalty fees after breeding the animals."

The Animal Legal Defense Fund, an animal rights organization, is suing the US Patent Office for violating the Patent Act by allowing a genetically engineered mouse to be patented.

CAROL EZZELL. 1988. House of Representatives due to decide on animal patents. *Nature* 334: 369.

*Mice engineered to carry HIV genes*

Several mice have been genetically engineered to contain the genetic information for the virus that causes AIDS, the human

immunodeficiency virus (HIV) according to Sharon Kingman of *New Scientist*.

The researchers first injected the genetic material that codes for HIV into fertilized mice eggs and then placed the eggs in a surrogate mouse. One of the offspring had the virus and produced antibodies to it. This female mouse was mated to a normal male and has given birth to several litters.

In 15 of her 40 offspring, the researchers found the HIV genetic material and these 15 mice all became ill and died prematurely. According to the researchers, these mice may provide a model for studying treatments for AIDS.

SHARON KINGMAN. 1988. Modified mouse may help to combat AIDS. *New Scientist* June 30: 44.

#### *Critique of biotechnology in animals*

Writing in *New Scientist*, Professor John Webster, head of the department of animal husbandry at the University of Bristol, states that he is critical of the use of genetic engineering in animals.

"We need to consider what is important to know, and what knowledge merits exploitation," he states. Making bigger animals seems to be one aim of the biotechnology industry.

"Enhancing the efficiency with which food is converted into flesh is now the approach most likely to attract the biotechnologist, who can manipulate a genotype by inserting novel genes, supplement the animal's natural hormones with genetically engineered hormones or accelerate genetic change by in vitro fertilisation and embryo transfer," Webster states. "These techniques are certainly new, clever and therefore exciting. But are they achieving anything different from those of conventional genetic selection, and is the particular trait being manipulated worth changing in the first place?"

As an example, he discusses the use in Britain of bovine growth hormone (BST)

produced by genetic engineering methods. Cows injected with BST produce more milk. This, he states, may not be very good for the welfare of the cow but it is disastrous for the British dairy industry.

To produce the extra milk, cows need more food. If cows are fed more grain (high quality food) and less grass, more grassland is available for other money-making uses. But in many areas of Britain, grass is all that will grow so many farmers will lose in competition with those farmers who can make better use of their land.

Webster states that "consumers may be resistant to specific advances in biotechnology, not because they are biotechnology but because they appear pointless."

JOHN WEBSTER. 1988. Sense and sensibility down on the farm. *New Scientist* July 21: 41-44.

#### *USA report on the current state of biotechnology*

The biotechnology industry is financially supported by the US government and private industry in approximately equal amounts, according to a US Office of Technology Assessment (OTA) report released in July, *US Investment in Biotechnology*.

A total of 206 patents were approved on genetically engineered products in 1987, *New Scientist* reports, of these, 52 were diagnostic products, 37 were therapeutic agents and 20 were vaccines. Currently, 67 drugs produced by genetic engineering methods are being tested on humans.

CAROL EZZELL. 1988. Congress provides a rundown on US biotechnology. *Nature* 334: 283; CHRISTOPHER JOYCE. 1988. Americans confident about biotechnology. *New Scientist* July 21: 25.

#### *OECD report on European biotechnology*

"The Organisation for Economic Co-operation and Development (OECD), in a

report (*Biotechnology and the changing role of government*, OECD, Paing; 1988) just published, says that member states are not paying enough attention to the potential uses of biotechnology in the control of environmental pollution," *Nature* reports.

"The report suggests that widespread public hostility towards genetic engineering could 'cause considerable delays in the diffusion of many harmless and beneficial products and processes'." The report continues that it is in response to such hostility that many environment ministries are taking "a defensive position against hypothetical risks of the release of genetically altered microorganisms, instead of exploiting the many ways in which biotechnology might help them to monitor and clean up the environment," *Nature* adds.

The report finds that the lack of research into assessing the risks of releasing genetically engineered organisms into the environment is "rather disturbing." The lack of risk-assessment makes it difficult to talk biotechnology companies into producing pollution-eating microbes they may never be able to test.

PETER COLES. 1988. OECD report attacks national policies. *Nature* 333: 387.

#### *Genetically engineered drugs for animals discussed*

The European Parliament wants to assess drugs produced by genetic engineering methods that are intended for use in animals. It wants "manufacturers to demonstrate that such drugs are not damaging ecologically or 'socio-economically' by making European agriculture even more productive," states *New Scientist*. The main subject of interest right now is bovine somatotropin which makes cows produce more milk.

1988. Animal drugs vetted. *New Scientist* July 14:31.

## **GENETIC ENGINEERING: HUMAN APPLICATIONS**

### *British doctors discuss problems of genetic engineering*

The British Medical Association (BMA) came up with guidelines on using genetic engineering at its annual conference in July. "Dr. Ian Jessiman spoke of the possible dangers of allowing developments in genetics to proceed without regulation," *Nature* reports on the conference. "While genetic substitution could bring substantial benefits, Jessiman said, it could also have drawbacks including the production of what he called 'designer children' with pre-selected characteristics."

Jessiman "also warned that as testing for genetic defects became more sophisticated, people might demand abortion for increasingly trivial reasons. And he warned of the ecological implication of the accidental release of dangerous viruses into the environment."

CHRISTINE MCGOURTY. 1988. British physicians brood on HIV testing and 'designer children'. *Nature* 334: 94.

### *Researchers plan first human gene therapy test*

A group of scientists at the US National Institutes of Health (NIH) is currently seeking permission to perform preliminary experiments for human gene therapy. The news was reported in *Nature*, *Science*, and *New Scientist*.

"If authorized, it will be the first officially sanctioned experiment in which human cells altered by recombinant DNA techniques are returned to the body," states Carol Ezzell of *Nature*. Steven Rosenberg (National Cancer Institute) and W. French Anderson (National Heart, Lung and Blood Institute) want to genetically engineered lymphocytes taken from cancer patients by adding a gene for neomycin (an antibiotic) resistance.

Lymphocytes are blood cells that fight cancer when they have been activated by in-

terleukin-2 and Rosenberg and Anderson want to use these activated lymphocytes as anticancer agents.

They want to add the neomycin gene to lymphocytes in order to track what happens to the cells in the body. "By strict definition, the proposed experiment is not gene therapy, because it will not replace a gene whose absence or defect is causing disease," Ezzell reports. "Rather, the experiment can be likened to environmental releases of recombinant organisms."

The experiment must be approved by at least 4 different committees and ethical groups. So far it has received approval from 2 of these.

CAROL EZZELL. 1988. Plans for altered lymphocyte release in humans. *Nature* 333: 697; CHRISTOPHER JOYCE. 1988. Americans plan gene therapy on people. *New Scientist* August 4: 24; LESLIE ROBERTS. 1988. Human gene therapy test. *Science* 241: 419.

#### *European medical research councils approve gene therapy rules*

"The treatment of some hereditary diseases by gene therapy is likely to be 'clinically justified' in the near future, according to the medical research councils of Europe," states *New Scientist*. "In a joint statement published in *The Lancet*, the councils give guidelines for research into the genetic manipulation of humans."

The guidelines would allow the insertion of genes into body cells but would not allow such insertion into germ cells (sperm, eggs, embryos). Researchers are instead working on perfecting "preimplantation diagnosis" which would be used to screen embryos for genetic defects.

The research councils "also stress the issue of the safety of gene therapy," *New Scientist* reports. "Most researchers use modified retroviruses to carry foreign genes into cells, but this approach has problems. As it

integrates into the genetic material of human cells, the virus can cause mutations which might lead to cancer."

1988. Europe's researchers design code for gene therapy. *New Scientist* June 9: 37.

#### *DNA fingerprinting being tested in USA*

Three different companies are competing to sell their DNA fingerprinting services to the Federal Bureau of Investigation (FBI) in the USA, according to *New Scientist* and *Science*.

DNA fingerprinting can be used to identify an individual or determine relatedness and has been used successfully in several criminal and paternity cases. The three companies use different methods of identifying an individuals DNA.

Because the FBI wants to set up a computerized databank of DNA fingerprints from known criminals, this will require using the same method of fingerprinting, which in turn means a lucrative market for whichever of the companies wins the competition. The FBI will make its choice sometime this fall.

"Members of the US Armed Services and employees of the federal government are routinely fingerprinted, but DNA typing raises issues not raised by ordinary fingerprinting," *Science* adds. DNA also includes information about genetic diseases and predispositions which could also be used by an employer for purposes other than just identification.

CHRISTOPHER JOYCE. 1988. America warms to DNA fingerprints. *New Scientist* July 14: 31; JEAN L. MARX. 1988. DNA fingerprinting takes the witness stand. *Science* 240: 1616-1618.

#### *British government wants terrorists DNA fingerprinted by force*

The British government has proposed that suspected terrorists be forced to undergo a mouth swab that would then be used to prepare a DNA fingerprint. *New Scientist's* Steve

Connor reports that the method is especially aimed at suspects from Northern Ireland.

Critics have said that a mouth swab would not contain enough saliva to perform such a fingerprint.

In another *New Scientist* article, researchers at the Northern Ireland Forensic Science Laboratory claim that they have performed such mouth swabs on each other and obtained enough material for a genetic fingerprint. Several politicians want these experiments scrutinized and are insisting that limits be placed on any legislation on mouth swabs taken without consent so as to protect innocent individuals.

STEVE CONNOR. 1988. Flaw in DNA test for terrorists. *New Scientist* June 23: 27; 1988. King declares success with DNA test using mouth swab. *New Scientist* July 21: 30.

*DNA-fingerprinting used in unusual paternity suit in Sweden*

An eight-year long paternity suit is being solved using DNA fingerprinting, according to *Dagens Nyheter*. The case involves a pair of twins, a boy and a girl, who cannot possibly have the same father according to a number of tests.

When the children were born in 1980, the mother was unsure who their father was since she had had an extra-marital affair with another man. Blood tests showed that her husband could not be their father.

The man she had an affair with is probably the father of the boy but cannot be the girl's father. The woman's husband accuses her of having had an affair with a third man which she has denied under oath.

The National Forensic Laboratory in Sweden has performed DNA fingerprinting on samples from all involved parties and has confirmed the results of the blood tests.

1988. Tvillingar med två fäder. *Dagens Nyheter* (Stockholm) September 4: 16.

*Gene therapy for cancer treatment*

In some cases, cancer can be caused by so-called oncogenes, genes that if stimulated, cause cells to grow uncontrollably. Some viruses are also known to cause cancer by bringing an oncogene into the cell, according to *New Scientist*.

But some cancers are caused by a missing gene. This gene seems to be a cancer suppressing gene and when it is missing, cancer can grow and spread. A rare cancer of the eye called retinoblastoma is such a cancer. The missing retinoblastoma gene may also play a role in a bone cancer and some breast cancers. This may make it possible to screen people for the gene in order to monitor for cancer. Another possibility for the future is to use gene therapy to replace the missing gene.

GAIL VINES. 1988. Missing genes may 'hold back' cancer. *New Scientist* July 28: 37.

*Austrian protest against Vienna's molecular biology center*

"About fifty student demonstrators were on hand to mark the official opening at the end of May of a laboratory that is set to act as a focus for modern biological research in Vienna," states *Nature*. "The protestors, mainly students of Vienna University opposed to 'gene and reproduction technology', were particularly exercised by the fact that the new Research Institute of Molecular Pathology (IMP) is a joint venture of two commercial concerns."

The two are the biotechnology company Genentech of California and Boehringer Ingelheim, a pharmaceutical company in the Federal Republic of Germany. Senior politicians "were noticeable by their absence," *Nature* reports. "Plausible excuses were available, but the suspicion remained in some quarters that genetic manipulation may be set to become a public issue in Austria

and that some politicians wanted to keep their distance for that reason.”

PETER NEWMARK. 1988. Out of the woods for Viennese molecular biology? *New Scientist* June 9: 490.

*Biotech companies fight over patents for clot-dissolving drug*

Genentech, the California based biotechnology company has received patent protection for its clot-dissolving drug, tissue plasminogen activator (TPA), Carol Ezzell writes in *Nature*. But Genentech is also involved in numerous patent fights with other companies in various parts of the world over TPA.

Genentech has failed to halt clinical trials of a similar drug produced by Toyobo in Japan, according to David Swinbanks in *Nature*. This is the first patent dispute in Japan over a genetically engineered product. Genentech received its patent in Japan in April 1987 but the Japanese system allows other companies to object and file rival claims. Until all the claims are cleared, the other companies can continue testing their products.

Oxford University has also filed a patent for TPA in the USA. The Oxford TPA is not produced by genetic engineering methods and their patent covers TPA produced by normal cells in culture, according to Ezzell.

The work was supported by Monsanto, a chemical company, which will own the licence to the method. Currently there are at least 19 different companies working on different forms of TPA and many of them are believed to have filed patents.

In Britain, the patent fight is between Genentech and Wellcome. Both claim patent rights to TPA produced by genetic engineering methods, according to *New Scientist*. As soon as Genentech had its US patent, it tried to stop Wellcome from testing its TPA in the US. It is fighting in the London Court of Appeal for its

British patent, which was found invalid last year by a British court.

Genentech and Wellcome are also battling each other in the European court. The European Patent Office has already issued one patent for TPA to a research group at the University of Leuven in Belgium.

CAROL EZZELL. 1988. Genentech gets patent protection for tissue plasminogen activator. *Nature* 333: 790; DAVID SWINBANKS. 1988. Problems over TPA patent for Genentech in Japan. *Nature* 333: 587; CAROL EZZELL. 1988. First US patent on TPA for Oxford University. *Nature* 333: 383; STEVE CONNOR and IAN ANDERSON. 1988. Pharmaceuticals giants battle over clot-busting drug. *New Scientist* June 30: 39.

*New method for making multiple copies of DNA*

A new method for making millions of copies of a piece of DNA (genetic material) in only a few hours has been developed. The method is called polymerase chain reaction (PCR) and can work with very small pieces of broken down DNA as well as intact DNA.

Researchers have succeeded in analyzing small pieces of broken down DNA found in tissue from a 40,000 year-old mammoth found frozen in the ice using polymerase chain reaction. The method is expected to aid in forensic science where blood stains could be used to take DNA fingerprints even if the stains were very old.

The method can also be used to speed up prenatal diagnosis. The limiting factor in prenatal diagnosis has been that cells taken from the fetus contain too little DNA to test. Therefore, the cells have to be cultured and allowed to increase in number so as to obtain enough DNA, which requires several weeks. Polymerase chain reaction will eliminate this need since the DNA in one cell can be copied until enough is available for testing.



JEAN L. MARX. 1988. Multiplying genes by leaps and bounds. *Science* 240: 1408–1410.

*Review of use of genetically-based prenatal diagnosis in Sweden*

In late 1986, genetically-based screening and prenatal diagnosis was made available to couples in Sweden with family histories of Duchennes muscular dystrophy, hemophilia A and B or cystic fibrosis.

There are currently 5 clinical genetics centers that offer such diagnosis in Sweden. One of these is in Uppsala at the Institution of Medical Genetics at Uppsala University. A group of researchers at this institution has written an article in *Läkartidningen*, the Swedish medical journal, reviewing one year's use of these methods.

Tissue was removed using chorion villi biopsy. According to them, 26 families with hemophilia A have been studied. Prenatal diagnosis was performed on five pregnancies and two fetuses bore the gene. In both cases, the fetus was aborted.

Thirty-two families have been studied for Duchennes muscular dystrophy. Five pregnancies were tested and all showed healthy fetuses. Eleven families were studied for cystic fibrosis. Three pregnancies were tested. One could not be confirmed either way, the other two were found to bear the gene. Of these, only one was aborted.

GÖRAN ANNEREN, NIKLAS DAHL, KARL-HENRIK GUSTAVSON, ULF PETTERSSON and CLAES WADELIUS. 1988. Molekylärgenetisk diagnostik-erfarenheter från Uppsala. *Läkartidningen* 85: 2186–2187.

*US Post Office wants ban on sending dangerous microbes by mail*

"The Postal Service does not want to deliver disease-causing microorganisms any more," *Science* reports. After learning that the Army sends microorganisms used in biological weapons research such as anthrax, Q-fever and

plague by mail, the Postal Service has proposed a ban on mailing disease-causing organisms.

Such a ban would also cover other organisms used in medical research which has led many researchers to protest. The proposed ban comes after pressure from the Foundation on Economic Trends, a public interest group based in Washington, D.C., according to *Nature*.

WILLIAM BOOTH. 1988. Post office nixes germs by mail. *Science* 241: 15; CAROL EZZELL. 1988. Postal ban proposed on exchange of dangerous microbes. *Nature* 333: 793.

*More evidence that some genetic disease genes protect bearers*

Cystic fibrosis is a genetic disease that causes overproduction of mucus in the lungs. This in turn leads to lung infections and other problems which often lead to early death.

The gene for cystic fibrosis has to be inherited in two copies, one from each parent. Persons carrying one copy are bearers but do not get the disease themselves.

The cystic fibrosis gene is fairly common even though those who get the disease usually do not live long enough to have children. Several researchers have speculated as to why the cystic fibrosis gene does not die out.

One possibility is that it protects bearers from other diseases that others without the gene die of. This has been shown to be true with several other genetic diseases.

A research group at the University of Sheffield, England, speculate that the cystic fibrosis gene protects against diarrheal diseases caused by bacteria, according to *Nature*. They studied the ability of intestinal tissue to secrete chloride ions when exposed to coliform bacteria and cholera bacteria.

Some tissue was taken from children with cystic fibrosis and this tissue did not secrete chloride ions as did tissue from others without

the cystic fibrosis gene. The secretion of chloride ions is a part of the cause of diarrhea produced by these diseases.

Thus, it may be that those with one copy of the gene may also be partially protected from such diarrheal diseases.

P. S. BAXTER, J. GOLDHTLL, J. HARDCASTLE, P. T. HARDCASTLE and C. J. TAYLOR. 1988. Accounting for cystic fibrosis. *Nature* 335:211.

*Canada plans national genetic screening for Huntington's disease*

"Scientists in Canada have begun the world's first nationwide screening programme to identify people at risk of developing Huntington's disease," *New Scientist* reports.

The programme was announced at the 16th International Congress of Genetics held in Toronto, Canada. The project leader is Michael Hayden of the University of British Columbia.

Huntington's is a rare genetic disease that shows up first in middle age. The disease causes degeneration of the nervous system and the brain and eventually leads to death.

Most genetic diseases require inheriting the "diseased" gene from both parents but Huntington's can be inherited from either parent. This means that someone who has the gene, and who will later get the disease, has a 50% chance of passing the gene on to their children.

Hayden points out that if people know that they carry the gene, they can choose not to have children or to abort affected fetuses. The program will be "open on a voluntary basis to any Canadian who is 18 years of age or older, and who has a parent who either has Huntington's disease or who died from it." Hayden estimates that the screening may be "99-percent accurate" in predicting a particular person's risk of developing Huntington's.

SYLVIA DAYTON. 1988. Canada pioneers national screening for Huntington's disease. *New Scientist* September 22: 26.

*Genetic abnormalities may predict breast cancer relapses*

"Researchers [at the National Cancer Institute, USA] have identified specific gene abnormalities that appear to be correlated with an increased risk of [breast] cancer reoccurring after the primary tumor is removed surgically," Jean L. Marx writes in *Science*. Such abnormalities could be used to predict the 30% of women who need chemotherapy to prevent a relapse.

One abnormality found is a gene that causes amplification of an oncogene. This might lead to the over-production of a substance that stimulates cancer growth. The second abnormality found is the loss of a section of chromosome 11 which may contain a cancer-suppressing gene.

In a study of 150 women with breast cancer, the researchers found that "cancer reoccurred more frequently in women whose tumor cells had one or the other of the two abnormalities than in women whose tumor cells did not have either," states *Science*.

JEAN L. MARX. 1988. Progress in predicting breast cancer relapses. *Science* 241: 535.

*More than one gene linked to Alzheimer's disease*

Last year, researchers in the US thought they had found a link between the early onset of Alzheimer's disease and a possible gene on chromosome 21. The study included several generations in a number of families with a family history of Alzheimer's.

But another research group has not found such a link in other families that they are studying, according to *Science*. This may indicate that the cause of Alzheimer's disease is even more complicated than previously thought.

One difference between the two studies is that the second group studied late onset Alzheimer's which only shows up in old age. This may mean that "this form of the disease is caused by a gene located elsewhere or is not of genetic origin," *Science* reports.

This form may have an environmental cause instead.

JEAN L. MARX. 1988. Evidence uncovered for a second Alzheimer's gene. *Science* 241: 1432.

*First human gene therapy test postponed*

"Calling for additional data, a key NIH [National Institutes of Health] committee has deferred a decision on a proposed experiment that would put genetically engineered cells into human beings for the first time," states Leslie Roberts of *Science*.

The cells to be used were white blood cells activated to fight cancer. They were to contain a marker gene so that they could be tracked in the body to monitor their anticancer effect.

The research required approval from several committees and had received it from the first committee. But the second in line, the Human Gene Therapy Subcommittee of the NIH Recombinant DNA Advisory Committee "said they wanted to see data from experiments in another animal model before making a decision," Roberts reports.

LESLIE ROBERTS. 1988. Decision on gene test deferred. *Science* 241: 899.

*Future gene therapy using liver cells*

Research in gene therapy has focused mainly on inserting new genetic material into bone marrow cells to correct certain genetic disorders. These cells are relatively easy to take out and put back into the body but the genetic diseases that can be helped using these cells are too complicated and too poorly understood, according to *Science*.

What is needed instead is a way to work with diseases that "are simple enough to tackle

now," states Leslie Roberts in *Science*. A research group at the Whitehead Institute, USA, has inserted a foreign gene into liver cells and corrected a defect that causes hypercholesterolemia (high blood cholesterol levels).

The research has been carried out in rabbits only, but is the first time anyone has attempted gene therapy with other than bone marrow cells. Hypercholesterolemia is caused by a lack of receptors that remove cholesterol from the blood. This leads to early heart disease and can cause heart attacks in those affected while still teenagers.

The researchers inserted a gene that leads to the production of the receptor and have shown that it works in liver cells in culture. They are now working on reintroducing the liver cells back into rabbits.

LESLIE ROBERTS. 1988. New targets for human gene therapy. *Science* 241: 906.

*Head of new genome center appointed*

"Charles Cantor, a leading geneticist at Columbia University, has been named the first director of the new Human Genome Center at Lawrence Berkeley Laboratory in California," *Science* reports. Cantor's appointment gives the Department of Energy a headstart in the competition with the National Institutes of Health in leading the project to map and sequence the human genome (all human genes).

NIH has previously set up its own Office for Human Genome Research with James Watson (a Nobel laureate) as its head. Cantor plans to make Lawrence Berkeley Laboratory an international center for mapping and sequencing the human genome.

LESLIE ROBERTS. 1988. Cantor to head LBL genome center. *Science* 240: 1266.

*Status of Human Genome Project in Japan, internationally*

Japan is leaving all its options open when it comes to its role in the Human Genome Project. *Nature* reports that Japan's Ministry of Finance has not taken a position yet on whether to fund such research.

Internationally, however, "The genome project has now officially gone global with the founding of an international Human Genome Organization, already dubbed HUGO," states *Science*. HUGO is modelled after the European Molecular Biology Organization (EMBO) which is situated in Heidelberg, Federal Republic of Germany. HUGO will have three offices in North America, Europe, and Asia (including Australia and New Zealand). HUGO is meant to improve collaboration and communication internationally in the Human Genome Project.

DAVID SWTNBANKS. 1988. Japan keeps its options open on genome sequencing project. *Nature* 334: 5; LESLIE ROBERTS. 1988. Human Genome goes international. *Science* 241: 165.

#### *Support for Human Genome Project grows*

"The governments of Britain and France have agreed to help support a 72 million (US) dollar project being launched by a consortium of two major research institutes and two research equipment companies to develop an 'automated molecular biology laboratory' which is being referred to a LABIMAP," states *Science*.

A major part of the project will be to develop technologies for sequencing DNA (genetic material). Some of the financing will also come from the two companies involved – Amersham International and Bertin et Cie. The two research institutes involved are the Imperial Cancer Research Fund in London and the Centre d'Etudes de Polymorphismes Humaines (CEPH) in Paris. Both are involved in the Human Genome Project.

In the US, the Senate voted 88 to 1 to pass The Biotechnology Competitiveness190

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Act in June. The bill would create a Biotechnology Policy Board and a National Advisory Panel on the Human Genome.

The bill also reinstates the Biomedical Ethics Board which has been dormant since 1981. This was done to calm fears about eugenics and to monitor the ethical problems that may come from research on the human genome. The bill has now been sent to the House of Representatives.

D. D. 1988. Go-ahead for gene sequencing venture. *Science* 240: 1728; L. R. 1988. Senate passes genome bill. *Science* 240: 1728.

#### *Editorial praises international genome organization*

Earlier this fall, the Human Genome Organization (HUGO) was formed with the express purpose of organizing international cooperation in mapping the human genome. An editorial in *Nature* welcomes this new organization.

"So far as can be told, the objective is that HUGO should be an independent international body of self-appointed people whose interest is to encourage the genome project, to monitor progress and to anticipate problems," *Nature* writes.

"The trick that HUGO hopes to play is that of influencing the policies of governments and of international and national institutions. Success will depend on being smarter than the governments that will eventually have to pay for the project."

The editorial ends, "The ethical issues are more shadowy. Plainly, difficulties would arise, for example, if people carrying deleterious genes were able to tell their own status by referring to a sufficiently detailed genetic map. Physicians rightly ask that people carrying Huntington's disease should not be so informed without counselling."

"The more common worry, that there may be something about the constitution of the human genome that could be misused, is probably ill-founded but must nevertheless be countered intelligently if the project is to succeed. If HUGO can do this, it will be well worthwhile."

1988. Genome monitoring. *Nature* 335: 284.

*HUGO holds first meeting*

The Human Genome Organization (HUGO) met for the first time in Montreux, Switzerland, on September 6 and 7. The organization hopes to have international offices open by the end of 1988.

The HUGO Council consists of 42 scientists, 5 of whom are Nobel laureates and "the rest represent a *Who's Who* of molecular genetics," *Nature* writes. The scientists represent the US, Britain, Federal Republic of

Germany, France, Japan, Canada, Holland, Sweden, Australia, Greece, Italy, the Soviet Union, and Switzerland.

"HUGO has established five areas of special interest: data banks, physical mapping/sequencing, other species, ethics, and human disease," states *Nature*.

JOSEPH PALCA. 1988. Human genome organization is launched with a flourish. *Nature* 335: 286.

*NIH and DOE agree to cooperate on leading genome project*

In the US, the National Institutes of Health (NIH) and the Department of Energy (DOE) have been fighting over who should lead the human genome project.

In response, the US Congress is considering legislation presented by Senator Lawton Chiles that would create a national advisory panel on the human genome project "consisting of the Secretary of Energy, the directors of NIH, the National Science

Foundation and the National Library of Medicine as well as four representatives from private industry, four academic researchers, one bioethicist and one representative from charitable foundations," *Nature* reports. This panel would take on the leadership of the project.

NIH and DOE oppose this solution. To prevent it they have set rivalry aside and drafted a memorandum of understanding which "sets up a joint mechanism for receiving outside advice and otherwise provides for communication and cooperation between the two agencies," states *Science*.

The agreement also "calls for the creation of a joint scientific advisory group for both agencies that would draw members from the two existing advisory committees: DOE's Health and Environmental Research Advisory Committee and the newly created NIH Program Advisory Committee on the Human Genome," *Science* writes. Senator Chiles "is apparently willing to drop the genome section of the bill if the new agreement between NIH and DOE passes muster," *Science* continues.

JOSEPH PALCA. 1988. James Watson to head NIH human genome project. *Nature* 335: 193; LESLIE ROBERTS. 1988. NIH and DOE draft genome pact. *Science* 241: 1596.

*US scientists campaign to oppose biological weapons research*

Five hundred prominent researchers signed a pledge and started a campaign against the military use of biomedical research in the USA.

The pledge states that those who sign it are "not to engage knowingly in research and teaching that will further the development of biological or chemical weapons," states *Nature*. The pledge and the campaign are being organized by the Committee for Responsible Genetics (CRG) from Boston, Massachusetts.

“CRG hopes that the existence of the pledge will help stiffen scientists’ resolve not to take money for US Department of Defense biological research projects,” *Nature* reports. “More money has been on offer since the Reagan administration quadrupled the budget of the Biological Defense Program between 1983 and 1986.”

ALUN ANDERSON. 1988. Biological weapons research opposed. *Nature* 334: 279.

*Biological warfare lab in US scaled down*

The US army proposed building a high security laboratory at Dugway Proving Ground in Utah to test “defenses against biological warfare agents,” especially aerosols, *Science* reports. “The Army had been planning to construct a maximum-containment facility capable of handling the most dangerous pathogens known, including genetically engineered organisms.”

This was met by public protest and several lawsuits. The army has now scaled down its plans. However, this will not stop the army from testing biological warfare agents since the planned tests do not require the maximum-containment facility. Critics are not satisfied and plan to continue protests against any aerosol testing.

COLIN NORMAN. 1988. Army shifts on Dugway lab. *Science* 241: 1749.

*Genetic engineering comes to high school*

“The ‘DNA Learning Centre’ is the latest manifestation of the Cold Spring Harbor Laboratory’s policy of taking DNA to the people,” states Paul Wymer, coordinator of the National Centre for School Biotechnology at the University of Reading, Great Britain, in *New Scientist*.

“It will include a museum, library and computer graphics laboratory devoted to the study of DNA as well as the purpose-built teaching laboratory already in use.” According to Wymer, genetic engineering “is becoming so pervasive in pure and applied biological studies that it can no longer be ignored in schools.”

He thinks it is important that some aspects of this technology “should be considered as practical possibilities in the classroom.”

“It will be interesting to see whether technology courses are to remain heavily biased in favour of physics and engineering or whether a broader interpretation is envisaged which could incorporate aspects of biotechnology,” Wymer states. “There is little doubt that this would result in more girls opting for technological studies.”

PAUL WYMER. 1988. GENETIC ENGINEERING FOR SCHOOLS. *New Scientist* August 11: 63.