ered to be inappropriate for child-bearing from a medical point of view; the two may be married only if both sides agree to take long-term contraceptive measures or to take ligation operation for sterility." And Article 16 holds that "If a physician detects or suspects that a married couple of child-bearing age suffers from genetic disease of a serious nature, the physician shall give medical advice to the couple, and the couple in their child-bearing age shall take measures in accordance with the physician's medical advice."

These two articles of the new law have

generated a great deal of international concern. For example, the UK Genetical Society intends to boycott the 1998 International Congress of Genetics, scheduled to take place in Beijing. Furthermore, the Society has suspended its affiliation with the International Genetics Federation, which organizes the international conference. David Sherratt, president of the Genetical Society says the society members "believe this law should bar the People's Republic of China from hosting the Congress," adding that the loose wording of the two clauses would allow

the law to be used against minorities.

Brandys says, however, that Genset's joint venture with the Chinese will adhere to the same ethical standards currently practiced in the West, ensuring patient consent and anonymity. "If the Chinese want to use genetic information they don't need us, because such knowledge is publicly available," he argues, adding that Genset is "not interested in genetic diseases, but in the genetic component of common diseases."

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German law clashes with state of reproductive medicine

The eyes of Germany's human reproduction specialists are on Lubeck, a small city in the northern part of Germany. Lubeck, which until now was famous only for its Christmas marzipan, is the home of the first German doctor to apply for permission to perform a preimplantation diagnosis (PID) on embryos made by *in vitro* fertilization (IVF). By proposing PID for test-tube embryos before implanting them into the uterus, Klaus Diedrich, head of the gynecology clinic at the University of Lubeck, has not only established a legal and ethical precedent; he has touched on a long-kept taboo in Germany and set off a media frenzy.

Although Diedrich's application, entitled *The preimplantation diagnosis of the cystic fibrosis DF508 mutation in case of parents at high risk of having offspring affected with this genetic disorder*, is the first of its kind in Germany, PIDs of human embryos are already conducted as a service for couples worldwide. A total of 328 embryo transfers following PID resulted in 83 pregnancies, with at least 40 healthy babies born (predominantly in Belgium, the Netherlands, the United Kingdom and the United States), according to Joyce Harper of the Hammersmith Hospital in London. Hammersmith Hospital is the place where Alan Handyside has developed the PID technique, and the place where the world's first PID baby was born (in 1992).

Embryos examined by PID are generally at their four- to eight-cell stage. One or two single cells, called blastomeres, are removed from the embryo for analysis, while the remaining embryo lives on. The DNA of a single blastomere will then be amplified and analyzed for genetic mutations. When screening comes up with a positive result, only the nonaffected embryos get transferred into the woman's uterus; embryos bearing the mutation are rejected.

The controversy that has erupted in Germany is over whether PID is a welcome procedure to avoid life-threatening diseases, or whether it opens doors for unethical embryo research that can ultimately lead to designer babies. PID critics argue that if an early prenatal diagnosis gives evidence to a genetic defect, the embryo will be "rejected" by the mother, which would be illegal under the German embryo protection law (known as "ESchG") that came into force in 1991. Under ESchG, interventions with embryos are permitted only when they result in the preservation of the embryo.

Despite the apparent straightforwardness of the law, the local ethics committee at the University of Lubeck gave Diedrich an ambiguous answer to his application, and shifted decision-making responsibility to the German Federal Ministry of Health and the Ministry of Justice. The ethics committee said it felt that PID is ethical and medically reasonable, but that it also appears to be illegal, because the ESchG does not allow disposal of embryos, even when they are genetically unhealthy.

At the moment, the Federal Ministries of Health and Justice, both of which have responsibility for aspects of reproductive medicine in Germany, are trying to find a solution to the dilemma. Meanwhile, Diedrich is awaiting an interim answer from a newly formed ethical working group at the Health ministry.

"We are quite sure that PID contravenes the embryo protection law, because this method uses omnipotent embryonic cells [cells from early-stage embryos]," says Richard Neidert, who is responsible for

reproductive issues within the ministry of health. "But on the other side, PID might be the method of choice for a small subset of couples. We might have to modify the existing law or [to] generate a new one next year." Whether or not Dietrich's group can

circumvent the law by using embryos at a later stage remains an open question.

Many German couples considering PID believe the law is inconsistent with modern reproductive medicine. "In Germany, an embryo is protected much better in a test tube than is a child *in utero*," says Otmar Bauer, senior Assistant medical director

at University of Lübeck, referring to the fact that if an IVF embryo is discovered to be defective after implantation, the pregnant mother has the right to interrupt the pregnancy within the first three months.

The couple behind the Lubeck case — each of them a carrier of one mutated cystic fibrosis gene — has a 25 percent risk of conceiving a child with both mutated genes. They already gave birth to one such child, who did not survive. Two later pregnancies showed the same defect by amniocentesis and were ended.

It is up to the federal ministries in Bonn either to interpret the ESchG appropriately for PID, to modify the ESchG, or to pass a new law on reproductive medicine that will include PID applications. Until then, German couples that are candidates for PID are left only with the option of seeking diagnostic and reproductive technologies outside Germany — at their own expense and risk. "We should not not solve our problems by exporting them to other countries," says Bauer.

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