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NORD Issues Gene Patenting Statement

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rectives concerning the use of placebo control subjects in clinical research studies. October 2000 revisions to the 1996 version of the Declaration further restrict placebo use in human research trials. Some researchers are calling for changes that might alleviate the restrictions imposed in the 2000 revision.

While most changes done in October were embraced by the research community, extensive controversy still surrounds Article 29. This section declares, "the benefits, risks, burdens and effectiveness of a new method should be tested against those of the best current prophylactic, diagnostic, and therapeutic methods. This does not exclude the use of placebo, or no treatment, in studies where no proven prophylactic, diagnostic or therapeutic method exists." In other words, contrary to many national research protocols, which allow the more liberal use of placebo controls, the new international directive restricts the use of placebos in cases where a current treatment might otherwise improve the health condition of a study patient.

The Council for International Organizations of Medical Sciences (CIOMS) represents the views of researchers in opposition to the current version of the Declaration of Helsinki. CIOMS is a non-governmental, international organization established by the World Health Organization (WHO) and the United Nations Educational, Scientific and Cultural Organization (UNESCO) in 1949 to serve the scientific interests of the international biomedical community. They argue that withholding the best current treatment from placebo control groups results in no serious adverse consequences. Patients are likely to experience only temporary discomfort. It is therefore implied that the benefits of withholding short-term treatment far outweigh the long-term risks to the patient.

They go on to insist that the scientific and ethical suitability of placebo-controlled studies is expanded when patients are switched to active treatments under circumstances where intolerable symptoms continue. Further, researchers argue that lack of a negative control, provided by an untreated placebo group, will compromise the scientific results of the trial. No reliable data will be yielded in a comparison of two treatments without such a control group.

The Declaration of Helsinki is a widely held international code of ethics, establishing principles for medical research involving human subjects. It has been revised only five times since its initial adoption in 1964. The current version can be found at http://www.wma.net/. If the workgroup appointed by the WMA agrees on the need for further modifications, the issue will be addressed at the WMA assembly this fall. **MD*

GENETIC SCREENING FOR ABNORMAL EMBRYOS

The Human Fertilisation and Embryology Authority (HFEA), the body that *regulates in vitro* fertilization (IVF) in the UK, has agreed in principle to allow embryos to be screened for an abnormal number of chromosomes. The technique called aneuploidy can screen out embryos that are aneuploid (contain more or less than 46 chromosomes). Embryos that contain an abnormal number of chromosomes usually result in a failure to implant in the womb that can lead to miscarriage. For such reasons, HFEA contends that aneuploidy screening would be of particular benefit to women who have suffered repeated miscarriages or unsuccessful IVF. Additionally, the screening would also likely increase the success rate of IVF by eliminating embryos that have little chance of implanting in the womb.

A fertilization clinic in London and another in Nottingham have applied for licenses to conduct aneuploidy screening. A spokesman for HFEA stated that "any such license would be subject to satisfactory inspection of the intended laboratories; approval of clinic staff; the provision of detailed technical and patient information; and ongoing monitoring." HFEA recognizes that although the technique is used in a number of fertilization clinics around the world, it is still in its early stages of utilization and needs to be overseen.

Paul Scriven, a principal scientist at Guy's and St. Thomas's Hospitals NHS Trust in London, said that with present aneuploidy testing methods, "it is too easy to misdiagnose a normal embryo as abnormal and therefore not attempt to transfer it into the womb." Other opponents of the screening are concerned that it is another step toward designing a "perfect" baby. Richard Nicholson, editor of the *Bulletin of Medical Ethics*, said that, "it is important to realize that the same technique has be used to screen out other abnormalities like Down's and Turner's syndrome." Until now, fertility specialists in the UK have only been permitted to screen for specific genetic disorders. However, aneuploidy screening can detect a whole range of genetic abnormalities, leading some to worry about indiscriminate screening that could "eliminate" an embryo for what most would now consider a minor genetic flaw.

No licenses for aneuploidy screening have been issued yet. Further information on HFEA can be found on the WWW at: http://www.hfea.gov.uk/. **RJG*

NORD ISSUES GENE PATENTING STATEMENT

In May 2001, the National Organization for Rare Disorders (NORD) issued a statement condemning the U.S. Patent and Trademark Office's (PTO) policy of allowing scientists and corporations to patent genes and gene sequences even before any applications of this knowledge are known.

NORD's policy position regarding the patenting of genes states that the practice restricts scientific research, thereby limiting the development of therapies and pharmaceuticals that could benefit millions of people. It argues that preventing research on any illness, particularly those with a genetic basis, is "unethical." The organization calls on PTO and the federal government to disallow future patenting of genes or gene sequences. According to the statement, Congress should enact a "compulsory licensing law" that requires free access to genes by researchers without having to pay fees or sign confidentiality agreements. Claiming that genes are not *inventions* (and thus protected by PTO as such), NORD calls for the federal government to monitor current gene patent holders so that the latter could not require royalty payments or secrecy agreements unless the gene or gene sequence has been changed or engineered in order to create a product for commercial use. According to NORD, until such time, free access to genes should be mandated in order to foster research. The full statement can be found at http://www.rarediseases.org **VG*

IN THE SOCIETIES

AMA ADOPTS NEW PRINCIPLES OF MEDICAL ETHICS

For the first time in twenty-one years, the American Medical Association (AMA) adopted two new principles and revised existing principles as a part of its Medical Ethics. On June 17, 2001, the *Revised Principles of Medical Ethics* were adopted. The action represents a change toward emphasizing patient care and providing access to medical care for all people.

The most notable change to the document is the addition of Principles VIII and IX.

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