## Who decides what's good for my baby?

■ The extraordinary developments in human genetics provide possibilities for the prevention, diagnosis and treatment of inherited monogenetic diseases as well as a wide spectrum of more common conditions which involve complex genetic and environmental interplay. The question to be considered is: how are we to deal with the new techniques of human genetics? How can we reap the fruits and also steer clear of the dangers'? The author discusses three alternatives: the Pure Nazi model in which the state chooses a gene pool and kills those who do not fit in; the Pure Eugenics model in which the state achieves the same ends, but through forced sterilisation, and the Liberal model, in which individuals are free to make decisions to control their genetic contributions. The author argues against a ban on any form of research, proposing, instead, that individuals be free to make their own choices, there is individual freedom and there is no socially decided ideal of what is 'good' or 'healthy'.

**Tansjo Torbjorn: Human genetics and the Nazi spectre.** ***Monash*** **Bioethics Review. 1999: 18 (1): 13-21.**

## Organ transplantation and the legal framework

■ Barely 30 years ago, organ transplantation was an essentially unsuccessful experimental procedure conducted in pioneering medical research centres. Today, renal transplantation is a widespread and routine procedure for an estimated 35,000 patients worldwide each year. However, this success led to an ever-increasing demand, a shortage of donors, and the commercialisation of the donor supply. "What policies should be instituted to help increase the availability of these precious tissues'?" The author, who earlier wrote an essay in defence of a commercial market, has reworked his ideas quite substantially. He answers the question in the context of the Transplantation of Human Organs Act, 1994, while examining its implications and the consequences of commercialisation — in terms of organ availability, social justice, exploitation and so on.

**Mukherjee Saugata: Organ transplantation: the legal framework re-examined.** ***Law and Medicine. 1998; 4: 21-44.***

## Sorry, out of stock

■ Drugs offer a simple, cost-effective solution to many health problems, provided they are available, affordable, and properly used. However, effective treatment is lacking in poor countries for many diseases, including African trypanosomiasis, Shigella dysentery, leishmaniasis, tuberculosis, and bacterial meningitis. Treatment may be precluded because no effective drug exists, it is too expensive, or it has been withdrawn from the market. Moreover, research and development in tropical diseases have come to a near standstill. The article focuses on the problems of access to quality drugs for the treatment of diseases that predominantly affect the developing world: (1) poor-quality and counterfeit drugs; (2) lack of availability of essential drugs due to fluctuating production or prohibitive cost; (3) need to develop field-based drug research to determine optimum utilisation and re-motivate research and development for new drugs for the developing world; and (4) potential consequences of recent World Trade Organization agreements on the availability of old and new drugs. These problems are related, and a result of the fundamental nature of the pharmaceutical market and the way it is regulated.

**Pecoul B et al: Access to Essential Drugs in Poor Countries: A Lost Battle?** ***JAMA*** **1999; 281:361-367**

## The infant food code

■ This study of the prevalence of violations of the international code of marketing of substitutes for breast milk, interviewed 1,468 pregnant women, 1582 mothers of infants aged less than six months, and 466 health workers, at 165 health facilities in one city in each of Bangladesh, Poland, South Africa, and Thailand. Women were asked whether they had received free samples of breast milk substitutes, bottles, or teats, and health workers were interviewed to assess whether the facility had received free samples, how they had been used, and whether gifts had been given to health workers by companies manufacturing or distributing breast milk substitutes.

Twenty-six per cent of Thai mothers reported receiving free samples, compared to 1 out of 385 mothers in Dhaka. Eight to 50% health facilities had received free samples which were not being used for research or professional evaluation; two to 18% health workers had received gifts from companies involved in the manufacturing or distribution of breast milk substitutes. At 15 to 56% of the health facilities, information violating the code had been provided by companies and was available to staff.

**Taylor Anna et al. Violations of the international code of marketing of breast milk substitutes: prevalence in four countries.** ***BMJ*** **1998;316: 11174122**

## Regulated research

■ This report comments on controversial proposed US government regulations governing research of people with retardation, mental illness and brain disease. While they would provide protection by regulating all such research, and requiring the involvement of people with the problem, or advocacy organisations, they would also legitimise research posing 'greater than minimal risk-benefit to subjects' even though the subjects cannot give their informed consent, if their guardians give consent.

**Regulating research involving persons with retardation.** ***The Newsletter of the***

*Network on Ethics and Intellectual Disability. 1999; 4 (1): I,* 6.

## /s informed consent always necessary?

■ Researchers must get specific informed consent of' patients in clinical trials, but doctors may sometimes offer the same therapy without such consent, in the name of innovation, The authors suggest that in many randomised, controlled trials, patients' par-ticipation should be presumed by their general consent for treatment. Criteria for a waiver: all treatments may be offered outside the trial without specific informed consent; they do not involve more than minimal additional risk compared to the al ternatives; genuine equipose exists; no reasonable person would prefer one treatment to the other; patients know that the institution uses the guidelines, and the institutional review board approves. These criteria should be interpreted narrowly and applied conservatively.

The authors hold that this will not lead to patient exploitation by researchers. Informed consent is not an ideal in itself' but is meant to ensure that the patient's right to self-determination is respected. Studies show patients rarely understand consent forms and randomisation. The most effective protection against exploitation c0mes from conscientious institutional review boards. Boards approving questionable studies on the assumption that the informed-consent process will protect research subjects are not doing their job.

The current situation also prevents many small but meaningful improvements in the quality of care when there is no reason to believe that the patient has any preference regarding participation in research;

**Truog Robert D et al. Is informed consent always necessary for randomized, controlled trials? *The New &gland Journal of Medicine* 1999 340 (10)**

## More *on the AZT trials and research ethics*

■ This comment on the controversial placebo-controlled trials clinical for maternal-foetal transmission of HIV may raise further debate. The author examines the ethics of AZT-equivalence and placebo-controlled trials in developing countries. Some of the points rnade: equivalence trials may result in fewer deaths among trial participants and arrive at inconclusive answers, but a placebo-controlled trial will provide clearer answers, thus providing more help to the general population even if fewer trial participants are benefited. Finally, discussants in the debate "have assumed that it is straightforwardly a good thing to reduce child deaths caused by perinatal transmission.... the brutal truth ... is that the more children they save, the worse these treatments will tend to make the AIDS orphan problem, for whom the only option is international adoption.

**Moore Andrew: Research ethics in poor (and not so poor) countries. *Otago Bioethics Report. 1998; 7* (1): 2-5.**

## *Why physician-assisted suicide ?*

■ On October 27, 1997, Oregon, USA, legalised physician-assisted suicide. Data on the 22 terminally ill Oregon residents who received prescriptions for lethal medications under the Oregon Death with Dignity Act and who died in 1998 were compared to those who died from similar illnesses but did not receive such prescriptions. The study concluded that during the first year of legalised physician-assisted suicide in Oregon, the decision to request and use a prescription for lethal medication -was associated with concern about loss of autonomy or control of bodily functions, not with fear of intractable pain or concern about financial loss. In addition, the choice of physician-assisted suicide was not associated with level of education or health insurance coverage.

**Chin, Arthur E et al. Legalized physician-assisted suicide in Oregon, USA — the first year's experience. *The New England Journal of Medicine* 1999;340 (7):577-83.**

## Books

**Legal and ethical aspects of HIV-related research. Sana Loue. 232 pp. Plenum Publishing, New York, 1995.** This volume summarises the basic legal and ethical principles related to HIV research: pre-study planning, the evolution of protections to research participants and the ethical principles governing the conduct of- scientific research; potential conflicts and issues that may arise during the course of a study, such as confidentiality and mandatory reporting of HIV status and scientific misconduct; issues that generally arise after the study's conclusion; an overview of the judicial, legislative and administrative systems.

**The ethics of biomedical research: an international perspective Baruch A. Brody. 386 pp. New York, Oxford University Press, 1998.** The book examines how the ethics of various at-eas of biomedical research are addressed by countries in North America, Western Europe, and the Pacific. It contains a compilation of 38 critical international, transnational, and national (US, British, Gel-man, French, Canadian, Australian, and Japanese) policies, regulations, and guidelines, from the Nuremberg Code (1947) through the revised version of the World Medical Association's Declaration of Helsinki, as well as less well publicised policies developed by the Council for International Organizations of Medical Sciences addressing such issues as the vulnerability of research subjects in less affluent societies, and the need to be sensitive to different cultures.