

Patient choice in clinical trials

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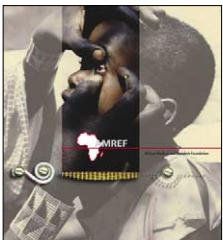
Two patients with Parkinson's disease are at the centre of an ongoing court case being held in New York against Amgen, which last year stopped a phase II trial of GDNF (glial-cell-line derived neurotrophic factor) to treat Parkinson's disease because of safety concerns. The patients, who were both participants in the trial, claim they experienced no adverse effects from the therapy and that the treatment reduced their tremors. They want the judge to rule that Amgen cannot withhold treatment.

Amgen says it made the decision to halt the trial after reviewing preclinical data, which emerged after the start of the phase II trial, showing that monkeys given an infusion of GDNF developed cerebellar lesions. The company cited additional concerns that the treatment might cause production of antibodies that react to endogenous GDNF, thereby worsening the patients' symptoms. But some scientists dispute these findings, saying that no such side-effects were observed in trial participants and that the monkeys received a very high dose of drug. GDNF is still a candidate treatment in Amgen's pipeline, but the

company says more investigations need to be done to understand how GDNF affects the brain. Patient advocacy groups have seized on the controversy surrounding the trial to mount a vocal campaign to make the therapy available for trial participants and to encourage more research.

This case highlights several important clinical issues, but chief among these is patient choice. Amgen reacted responsibly to potential safety risks of a treatment with uncertain benefit by stopping the trial. But in looking for a consistent effect among the population of participants, the company could not exclude the potential benefit of the therapy to some individuals. The fact that the case has ended up in the courts highlights the lack of a suitable mechanism through which evidence from individuals can be taken into account in decision-making about experimental treatments. The case also shows that although patient choice has become a mantra for health services, when it comes to setting the research agenda, patients have barely any involvement at all. ■ *The Lancet*

AMREF: good news for Africa



Press attention has focused on the increasingly heated public debate about whether Live8, the simultaneous concerts coinciding with the G8 summit next month and planned by Bob Geldof to draw attention to poverty in Africa, is a good idea or not. A far more important piece of news has gone largely unnoticed. Last week, the African Medical and Research Foundation (AMREF) won the US\$1 million Gates Award for Global Health, the world's largest prize for international health, for their outstanding efforts to improve health in Africa's communities by strengthening local health infrastructure as a means to escape poverty.

AMREF can indeed be proud of its achievements. Having started as Flying Doctors of East Africa in 1957, it is now the largest aid organisation based in Africa with over 600 staff, 97% of whom are African. From its inception, it concentrated on bringing health and education to local communities and has embraced technology as integral to improving health. In one of its latest projects, AMREF has begun to install videoconferencing facilities in rural areas so that health workers and patients can consult with

specialists based in cities. Activities and programmes are channelled into six priority areas: HIV/AIDS, tuberculosis and malaria; water and basic sanitation; family health, including sexual and reproductive health; clinical outreach; disaster management and emergency response; and training and development of health learning materials. In this last category, AMREF runs, for example, a 1-year Diploma in Community Health course in Nairobi, Kenya, where its headquarters are based.

Unlike many other agencies, AMREF closely monitors and assesses the effect of its programmes, with a firm eye on cost-effectiveness, and then publishes the findings. All programmes are designed to be replicated on a larger scale and are usually planned in close partnership with national governments to ensure long-term sustainability.

Although an additional \$1 million will not solve Africa's problems in 2005, an extraordinary organisation, which has quietly worked away for almost 50 years, has rightly been awarded its due recognition on the world stage and deserves more attention by donors in the future. ■ *The Lancet*