Australian report favors more monkey business

Conscious of the rapid advances in cloning research and the need for worldwide legislation on human aspects of this technique, in a new report, an advisory committee to the Australian government has backed the international call for a ban on cloning to produce a human being. And in line with Europe (*Nature Med.,* **5** 6; 1999), the Australian Health Ethics Committee (AHEC) of the National Health and Medical Research Council (NHMRC) supports human DNA and cell cloning and embryo research within strict limits.

In a surprising twist, the report calls for the establishment of a new, non-human primate center, which will apparently substitute for human research and serve as a means of boosting Australia's capacity for 'therapeutic cloning' research—the development of replacement organs and tissue. Some antipodean scientists are unconvinced of the value of such a facility and believe its inclusion in the report is the result of action by the country's powerful lobby of reproductive biology scientists that have traditionally favored primate research.

It is proposed that the primate center be used to test the feasibility of cloning techniques involving embryonic stem (ES) cell and cell lineage research. The report expresses concern that existing primate resources in Australia are insufficient for such work and small by international comparison. The new center may also be of value, says the report, to associated disciplines such as reproductive biology, gamete biology and endocrinology.

Director of Melbourne's Murdoch Institute, geneticist Bob Williamson, who was consulted by AHEC, argues that the primate option is outdated. He believes that Australia should be spending money on ethical ways of experimenting with ES cells in culture. "My personal view is that the days when primates should be sacrificed for biomedical research are probably for the most part over," says Williamson.

Australian National University's John Hearn, former director of the Wisconsin primate center, estimates that $AUS 5 million ($US 3 million) in capital and an annual maintenance budget of $AUS 3 million would be needed to improve on the handful of breeding colonies of marmosets, macaques and baboons scattered across the country. But others are divided on the desirability of such spending, and say the cost of a new center has been underestimated. "Some scientists were concerned it may deplete NHMRC resources, just as the Wills report has called for a doubling of the budget [*Nature Med.,* **5**, 9; 1999], and one of them called it `irresponsible' to make such a suggestion," conceded AHEC chairman and lawyer Don Chalmers. Even some of Australia's most senior IVF researchers—a group that has supported primate research for many years—think it would be more cost-effective to fund grants to enable Australian scientists to travel to established centers such as those in neighboring southeast Asia. This suggestion is included in the report as an alternative strategy to enhancing primate research.

Destined for the lab.

Under its terms of reference, AHEC was unable to make the primate center a formal recommendation. "We didn't feel it was our role to be recommending research infrastructure like that, and the proposal would have to come forward as an application to the NHMRC research committee," explains University of Queensland's John Mattick, who is on both committees. "Furthermore, a decision on its merits should be based, not on the cloning debate, but on whether or not it was a useful piece of infrastructure to have scientifically or medically," he adds. A copy of the report is available at http://www.health.gov.au/nhmrc/ ethics/clone.pdf

RADA ROUSE, BRISBANE

Henney calls for more science at FDA

Jane Henney

Newly appointed commissioner of the Food and Drug Administration (FDA), Jane Henney (*Nature Med.*, **4**, 262; 1998), has announced that "the discipline of science and a scientific approach must ground our decision-making," and has called for a strengthening of the agency's science base. Quite how this will be achieved is not certain. The move is likely in response to recent criticism suggesting that the agency has a poor research base.

Lobbyists representing industry and patients have criticized the delay and expense of the drug approval process, whereas, consumer watchdog groups claim that the FDA has allowed regulatory decisions to be driven by politics rather than public safety. Each year, the FDA is forced to retract its approval of some drugs and remove them from the market, or add warning labels to them.

Michael Friedman, Deputy Commissioner for Operations at the FDA, is naturally defensive: "[because] we never have all the information that we need to make a perfect decision, the agency must make the very best use of the data as it exists at that moment." Echoing Henney's position, he adds, "having the best scientists engaged leads to making the best decisions." Henney, the first woman to head the FDA and the first cancer specialist, was previously the vice president of the University of New Mexico Health Science Center.

Until now, scientists have not been evenly distributed among the FDA divisions. The Biologics division, for example, maintains a fully-fledged research facility on the campus of the National Institutes of Health, but no similar facility exists for the Drugs division. Henry Miller, a Fellow at Stanford University's Hoover Institution and the former head of the FDA's Biotechnology division, argues that Henney's push for more science at the agency therefore creates a dilemma: "If you think that research is an absolutely essential component of regulatory review and expertise, then it needs to be there for the people in Drugs. If it isn't necessary, then Biologics is maintaining a hugely expensive research enterprise that isn't needed."

Friedman concedes that the FDA, whose drug approval workload is increasing at a rate of 12 percent per year, has been unable to support as much science as it should. "FDA is the spigot through which this vast amount of new research is being applied, and the agency has been under tremendous pressures to discharge all of its responsibilities within a fixed budget ... one of the painful consequences has been insufficient investment in and attention to the scientific base of the agency," Friedman told *Nature Medicine*. A recent internal review concluded that the agency, which has an FY99 budget of approximately $1.1 billion, only completes 50–70 percent of its legally mandated duties on schedule, a fact that Friedman says reflects the shortage of resources.

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