

Bioethics

US Congress tries again

Washington

THE US Congress is trying to fill the gap left by the 1982 demise of the President's Commission on Bioethics. Last year's attempt failed when President Reagan vetoed the National Institutes of Health (NIH) authorization act, which included provisions for a panel to monitor human genetic engineering, protection of human research subjects and other issues in medical ethics.

Last month, the House of Representatives again passed the NIH bill proposed by Representative Henry Waxman (Democrat, California), largely unchanged from last year's version. A similar bill is pending in the Senate. But its fate must be uncertain. Both House and Senate bills retain the features its president found objectionable last year, in particular the detailed specification of each NIH institute's research mission labelled, in the veto message, as "micromanagement" by Congress. Both

also call for two new NIH institutes, one for arthritis and one for nursing. NIH has long opposed the creation of new institutes, which it says add to its administrative costs without augmenting or improving the research.

Even if there is a veto, the bioethics panel may survive. Senator Albert Gore (Democrat, Tennessee), a key supporter of the concept when he was in the House, has filed a separate measure much along the lines of the section of the House and Senate bills dealing with the panel. A bipartisan board would appoint a committee of biomedical researchers, physicians, ethicists and laymen to carry out studies of ethical problems in biomedicine. The committee would have no regulatory function and would operate as an agency of the legislative branch, akin to the Office of Technology Assessment and the General Accounting Office. There is a strong feeling among even supporters of human gene therapy that a high-level but nonregulatory panel would be the best way to evolve policy on its new medical technologies while disarming the more extremist critics. A less-favoured alternative is an expansion of NIH's Recombinant DNA Advisory Committee (RAC) which has begun to draft guidelines for human gene therapy experiments. But RAC, as part of an executive branch agency, also lacks the formal independence that many would like for an ethics panel.

Another role of the ethics panel would be to straighten out the muddle over fetal research. Under current rules, NIH may not support research posing "greater than minimal" or "unknown" risks to a fetus. Although the Secretary of Health and Human Services (HHS) is allowed to grant a waiver if an experiment has passed the scrutiny of the local Institutional Review Board, the advisory council of the relevant NIH institute and a specially empanelled Ethical Advisory Board, the Secretary of HHS has never been willing to appoint an Ethical Advisory Board. In effect, there is a total moratorium.

Under the House and Senate NIH bills, the ethics panel would be asked to study the question of experiments involving unknown or greater than minimal risks. Waxman said he had reluctantly agreed to go along with the Senate's insistence on a 3-year moratorium even on waivers in the hope that this would allow time while "tempers cool and rhetoric dies down". He noted, for example, that a study on the dangers of vaccinating pregnant women against rubella, which was carried out in 1969, before the current rules became effective, would probably now require a waiver. In that study, women planning to have therapeutic abortions were vaccinated; after the abortions took place

11 to 30 days later, fetal tissue was examined to determine if the vaccine virus was able to cross the placenta and infect the fetus. The answer, contrary to expectations from animal studies, was yes; and physicians were ordered not to administer the vaccine to pregnant women.

As a practical matter, however, the 3-year moratorium will not affect research, and Waxman said he hoped that after a "full and even-handed" review by the ethics panel, the Secretary of HHS would "proceed with the responsibilities to pursue research ethically and without regard to purely political pressures".

Stephen Budiansky

Ethics in science

Washington

ONE of tenets of the scientific method is that researchers are supposed to share their data with others who wish to verify or expand on their work. That that apparently does not always happen is the unstated but clear implication of a new report from the National Academy of Sciences* urging the adoption of guidelines by grant-making agencies and scientific journals that will normally require data-sharing.

The report recites the usual reasons for sharing data: encouraging open scientific inquiry; allowing for verification, refutation or refinement of original results; bringing multiple perspectives to bear; encouraging interdisciplinary use of data; and detecting the rare cases of fraud.

But, the report notes, researchers may be reluctant to hand over their data to other researchers for various reasons.

The report recommends that researchers make their data available by the time of publication of the initial major results: "the practice of withholding data until all possible analyses are exhausted is unnecessarily restrictive and too self-serving to advance science", it said. Those who request data should bear any incremental costs, however.

Government funding agencies, the report says, should require applicants to guarantee data-sharing or to justify explicitly, in their grant proposals, why they should be exempt from the requirement. The National Science Foundation (NSF), for example, already requires that "data banks or software" produced with NSF grant funds be made available to others; the report notes, however, that the policy could be strengthened.

Finally, the report recommends that scientific journals should require authors to provide peer reviewers with access to their original data and "strongly encourage" them to provide similar access to others, and should give more space to reports of secondary analyses and replications to encourage the process. Stephen Budiansky

*Sharing Research Data, Committee on National Statistics; National Academy Press, 1985.

Paris scents triumph

Paris

IN France, the feeling over Saturday's summit debacle over the European Community's Treaty of Rome appears to be one of sweet revenge over that De Gaulle of an Englishwoman, Mrs Margaret Thatcher, and for the years of confrontation over the British budget in Brussels. But the sweetness will certainly turn sour if the result is to damage the French-inspired Eureka project for European technology.

So far, however, all seems well. The summit has produced an agreement to hold here in Paris in the second half of this month a "technology conference" of European foreign and research ministers which should, at last, result in the definition of exactly what Eureka will be, who will run it and who is prepared to pay. But the fear among those closest to Eureka in Paris may be that the conference will be compromised by the arguments among their political masters in Europe over other issues.

The French sources were at pains on Monday to distance Eureka from the battle. "Mrs Thatcher showed herself quite constructive on technology", a French research minister spokesman said, and the split over veto rights and the Treaty of Rome was "quite another question".

The apparent conflict in Milan between François Mitterrand and the president of the European Commission, Jacques Delors, was also being played down in Paris this week. The view here is that the European Commission can be "closely involved" and that "Eureka is not in conflict with the Commission". The communique from Milan "took note of and endorsed" Delors' plan. Robert Walgate