WASHINGTON PERSPECTIVE

The new politics of risk assessment

Situated somewhere between science and witchcraft, depending on whose interests are affected, risk assessment is an arcane calling with methods and language all its own. The press and public usually give it little attention. But suddenly risk assessment is of acute political interest as a weapon against that prime bête noire of the political right, government regulation of health and safety. Greater reliance on risk assessment and cost-benefit analysis was pledged in the battle plan for the House Republican juggernaut, the Contract with America.

Regulation based on science, rather than alleged bureaucratic whim, is among the items promised for delivery or important progress within the first 100 days of the Republican takeover. Since the Clinton administration, committed to "reinventing government", is running its own campaign against federal regulations, the Republican thrust might pass as merely a stronger version of the same anti-regulatory spirit. But it is far more than that.

The leading legislative vehicle for the Republican goal is a bill whose unexceptionable title masks a slowdown, if not wholesale coagulation, in the application of science to risk—the Job Creation and Wage Enhancement Act of 1995. Under a section titled Risk Assessment and Cost-Benefit Analysis for New Regulations, the bill would restrain the government role in risk reduction by raising the evidentiary requirements for intervention.

Ironically, the remedy of the anti-regulators is to enmesh regulation in a tangle of procedures that would delay, maybe throttle, the imposition of new rules. Among the agencies that would be affected are the Food and Drug Administration, the Environmental Protection Agency, the Occupational Safety and Health Administration, and the Department of Transportation, all major targets on the anti-regulatory agenda.

Thus, for regulations estimated to have an annual economic impact of at least US$25 million a year in risk-reduction costs, the bill requires a favourable cost-benefit analysis by the would-be federal regulators. With government agencies trying to cope with budget restraints and staff reductions, the analytical requirement would greatly impede regulating at that low financial level, which is what it is intended to accomplish. But an unintended secondary effect is also expected. Within the regulatory agencies, and among their researchers in universities, the stiffer requirements for evidence of risk are feared as a drain on scarce research funds.

The $25-million trigger for cost-benefit analysis represents a concession to the regulatory camp: the original proposal set the mark at $1 million. When estimates of risk-reduction costs reach $100 million, the legislation raises the bar by prescribing cost-benefit analysis and scientific peer review, minus the customary conflict-of-interest exclusions. Members of firms affected by the proposed regulations would therefore be permitted to sit in judgment of regulatory changes.

At Congressional hearings on the proposed changes, administration officials have argued that reams of nonsensical and needlessly costly regulations have already been eliminated, and that federal agencies are now properly sensitive about adopting rules that might hamper business. The Republican bill, they insisted, would impose unreasonable restraints. The chief White House official for regulatory policy, Sally Katzen, warned that the changes would establish "endless analytic loops", and could snarl such simple matters as stricter standards for rear-view mirrors on school buses or restrictions on sales of explosives.

Although the fledgling Republican revolution is losing some of its impetus as differences develop in the ranks, regulatory reduction remains a centerpiece of the movement. In the bull's eye is the FDA, headed by David Kessler, a Bush-appointed holdover notable for two achievements: he rejuvenated a worn-out agency and, in the process of making it work better, aroused the enmity, if not the hatred, of the political right. With the *Wall Street Journal* leading the chorus, there are regular demands for Kessler's scalp in Washington.

Kessler's admirers and defenders are many. But the complexities of drug approval are difficult to explain to a public that is barraged with wild tales about wonder drugs that are available elsewhere but not here—because, Kessler's detractors argue, of the doltish intransigence of FDA bureaucrats.

As the heat rises, it must be recalled that assistance for loyalists in trouble is not a sterling characteristic of the Clinton White House.

Daniel S Greenberg

Australian Northern Territories to debate euthanasia

Later this month the Northern Territory parliament will debate a bill seeking to establish the territory as the world's only site of legalised euthanasia. It will be introduced as a private member's bill by the Chief Minister, Marshall Perron, in an attempt to remove the distortions of party politics and allow a conscience vote.

Under Perron's proposal, voluntary euthanasia would be allowed if a terminally ill, mentally competent adult asks in writing for assistance in hastening death. Medication could be self-administered, or given by doctors, who would face no sanctions for having taken part.

If passed, the territory's legislation would be different from that operating in the Netherlands, where euthanasia is still illegal, but prosecutions do not take place. That is the circumstance under which abortions are done in Australia. But the Perron legislation would establish euthanasia as a legal action.

Perron stated that he did not expect widespread demands for euthanasia if the legislation were passed. "The will to live is strong. Patients will hang on while their quality of life is acceptable, but the pain and distress of terminal illness is such that the patient should have the right to let go at the time of their choice. The law as it now stands forbids that and places doctors at risk of litigation. This proposal would end this anachronistic situation, conferring a right on terminally ill patients that they presently don't have, and protecting doctors at the same time", he said.

The proposal has been met with the expected mixed reaction. As usual, the federal health minister, Dr Carmen Lawrence, sought neutral ground. She avoided the issue of whether voluntary euthanasia was desirable by saying she hoped for uniform state and territory legislation, since she did not want people crossing state borders "to achieve a result".

But if the Northern Territory decided

to wait for a nationwide approach, the proposal would almost certainly be dropped. The states and territories find it difficult to agree on anything simple, and refuse to agree on anything difficult. Lawrence also argued that the legal position of passive euthanasia should first be clarified. She said euthanasia was a matter that had not really been debated, and on which community views had not been adequately expressed. No government would act on euthanasia without knowing fully the views of the community, she said.

The Australian Medical Association's president, Dr Brendan Nelson, said his organisation would not actively oppose such legislation, although Nelson had repeatedly spoken of his opposition to voluntary euthanasia. Various well-known commentators spoke out. The pro-euthanasia lobby argued that the practice is common, is essential, and allows people to die with dignity. The anti-euthanasia lobby argued that such legislation would provide "the first step on the slippery slope to murder of the weak and frail". As usual, parallels with Nazism were drawn. All that is needed is better palliative care, and nobody need die with pain, it was said.

Mark Ragg

India's kidney transplant racket?

The police in Bangalore city in the southern state of Karnataka claim to have uncovered a huge interstate kidney transplant racket whereby numerous young men have allegedly been duped of their kidneys unknowingly or without consent, or of offers of large sums of money or lucrative jobs promised for their kidneys.

Karnataka state has set up an inquiry into the affair, and the police have arrested four persons, including the head of the nephrology department of government-run Victoria Hospital, who was subsequently released on bail but suspended from his job. The Karnataka Medical Council has temporarily de-registered several doctors, including the medical director of the privately run Yellamma Dasappa Hospital.

The police claim to have uncovered over a hundred cases so far in two states. They suspect that the racket has been operating for more than two years, and estimate the numbers of cases may be a thousand. But senior doctors think the projected figures are inflated and do not rule out blackmail on the part of kidney sellers.

Meanwhile, the central government has just enacted the Transplantation of Human Organs Bill (*Lancet* 1994; **344:** 48), which bans commercial trading of organs.

Sanjay Kumar

Anxious times for German university hospitals

The German Science Council's proposals for restructuring the financing of clinical research would mean that state support for the 38 university hospitals will be allocated according to academic worth. It could also mean the closure of some of these hospitals.

At present, the sources of support, apart from specific research grants, are the state in which the hospital is sited and health insurance. The state component covers teaching and research, whereas health insurance pays for patient care. However, with the new health insurance law, which comes into force next year, insurance firms will not be paying actual hospital costs. Instead, they will be paying the agreed average costs for the type of care that a patient would need. University hospitals might find themselves facing a shortfall if they were unable to cut costs sufficiently, yet maintain the high standards of care—and of teaching—expected of an academic unit. Furthermore, such units can be expected to have a greater proportion of difficult cases than would be found in non-teaching units—the university hospitals have about 8% of hospital beds in Germany and 17% of the intensive-care beds. The Science Council has thus suggested that the federal minister for health should modify his proposed health insurance reform to take into account the special needs of the university hospitals.

However, the council expects the university hospitals to make their contribution too—by cooperating with neighbouring hospitals so that the number of beds in the teaching units can be reduced, or even by shutting down some university hospitals. In fact the council has recently recommended the closure of several hundred beds in three teaching hospitals in Munich.

With the council's recommendation that states take academic worth into account in allocating resources, the hospitals will have to compete hard for research grants, which are one of the criteria against which academic units are assessed. Another recommendation that the council makes in relation to state funding is that costs of teaching and of research be separated—which will be no easy task.

Annette Tuffs

France wavering about decriminalisation of drugs

The French task force on drugs and addiction has been split on whether or not to decriminalise recreational drugs. A weak majority (9 *vs* 8) voted in favour of "decriminalising the use of cannabis or its possession in small quantity", subject to certain controls. By the same narrow margin (9 *vs* 8), the commission voted for maintaining the illegal status of hard drugs (heroin, cocaine, crack), though with a major modification of the law.

The commission was led by gynaecologist and National Academy of Medicines member Prof Roger Henrion and set up 11 months ago. It was nearly disbanded three times and has substantially modified its text four times because of the very strong divergence of opinion among its members. Its report, released last week, arrived in the middle of the presidential election campaign, and a day after the Prime Minister Edouard Balladur (standing for election as President) said on television that he was against the decriminalisation.

The controls suggested for cannabis include banning its use by those aged under 16, prohibiting its use in public places, making it an offence to drive under the influence of cannabis, and banning of its use by certain occupational groups such as air traffic controllers, pilots, and drivers of heavy vehicles. Those who favour decriminalisation of the use of cannabis argue that if the situation does not worsen after two years, then "true" regulation of the drug's trade, with strict control by the state, would be considered. But if the situation worsened, "rescinding the decriminalisation could be considered, as was done in Sweden in 1977". Those members of the commission who advocated leaving the use of cannabis as a criminal offence suggested various forms of non-prison sentences for first-time offenders

The members of the commission did, however, manage to reach much better agreement on the need for research and for prevention. It has thus recommended the creation of a committee of media professionals to take charge of drug-education campaigns. It has also recommended strengthening epidemiological surveillance, through anonymous screening for biochemical indicators in the urine in groups such as pregnant women, national service conscripts, and road accident victims. Other proposals included the creation of an independent agency to be an "observatory of addictive behaviours" and to coordinate the epidemiological studies; the creation of a permanent unit to receive drug addicts in general hospitals; the setting up of more reception centres for addicts; and the extension of distribution programmes of methadone. The commission thinks it desirable that levo-alpha-acetylmethadol (LAMM), an oral preparation with longer-lasting effects than methadone, be used when it becomes licensed. It also emphasises the importance of extending the syringe-exchange programme.

Marc Gozlan