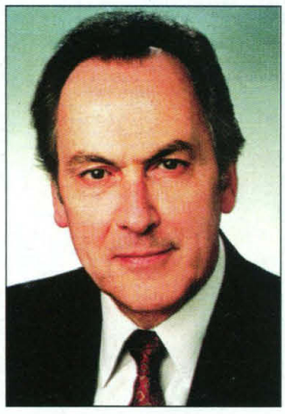
plans. He says his group "had argued all along the merits of a policy which allowed the carefully managed and monitored commercial introduction of [genetically modified] crops."

Meanwhile, former Agriculture Minister Jack Cunningham, now responsible for the Cabinet Office, announced the setting up of a new high-level committee on biotechnology and genetic modification. Robert May, the government's chief scientific adviser, who will attend the committee, says its aim is to coordinate policy to meet the interests of different departments. "We need to determine, across the range of interests, what countryside we want for the future," he says.



"No GM-free zone." U.K. Minister Jack Cunningham.

Ecologist Brian Johnson, an adviser to the conservation body English Nature, welcomes the government's decision to slow the commercial introduction of genetically modified crops. He says he is particularly concerned that "the use of genetically modified herbicide- and insect-resistant crops could greatly reduce weeds and insects on farmland, which might in turn threaten the survival of several species of farmland birds." But Doug Parr, Greenpeace's campaign director on genetically modified crops, wants a complete ban: "The government has been driven to respond to wide public antipathy on genetically modified organisms, but the biotechnology industry is still dictating the terms," he claims. Cunningham told a meeting last week of the Soil Association, which certifies organic farmers, that "there is no way in which the government can make the U.K. a GM-free zone."

The regulation of genetically modified crops was expected to be one of the responsibilities of the new independent food standards agency, promised by the Labour Party before it won power last year and outlined in a white paper in January (*Science*, 23 January, p. 472). But last week's announcements coincided with news that the government will delay establishing the new agency, leading to speculation that it will be shelved permanently. Despite the apparent stalling, Cunningham insists the agency will eventually go ahead.

Many see the agency as crucial to restoring confidence in the food industry following a series of food safety crises in recent years, including mad cow disease, salmonella-contaminated poultry, and outbreaks of *Escherichia coli* O157:H7. "I'm very concerned about any delay in establishing the new agency," says bacteriologist Hugh Pennington of the University of Aberdeen, who chaired the inquiry into a fatal *E. coli* O157:H7 outbreak in Scotland last year that killed 20 people. "The agency will make a significant difference in terms of research and advice," he says; any plans to scrap it would be "disastrous."

Researchers fear that the food industry has pressured the government into delaying the agency because of concerns that its research agenda would have an anti-industry bias. Publicly, however, many industry groups welcome plans for the new agency as a means of promoting public confidence. The apparent delay may be the result of a dispute about whether taxpayers or industry should stump up the initial $40 million budget. –NIGEL WILLIAMS

BIOETHICS

Panel Pulls Back Report After NIH Critique

A last-minute fax from the National Institutes of Health (NIH) last week has apparently sent the president's National Bioethics Advisory Commission (NBAC) scrambling to revise some of its recommendations on new research guidelines.

The guidelines, in the works for 14 months, are intended to tighten up rules on patient consent to ensure that subjects with mental disorders are capable of understanding the research projects they agree to join. A draft of the new standards would ask investigators and research institutions to accept the burden of assuring that patients are competent to give their consent. If the research involves greater than minimal risk, the guidelines would also recommend that independent professionals be used to evaluate the decision-making capacity of patients who offer to take part in research. There are 20 recommendations in all.

NBAC executive director Eric Meslin says he had expected the panel to "finalize" the recommendations at its 20 October meeting in Alexandria, Virginia, and was "surprised" when that didn't happen. But Meslin insists that the delay was not triggered by NIH's eight-page letter, faxed the previous afternoon, which claims that these new guidelines could bring some kinds of research to a grinding halt. NBAC's chair, Harold Shapiro, president of Princeton University, announced that NBAC will wait until its next meeting, on 17 to 18 November in Miami, to make a final decision on its report.

NIH's criticism, signed by associate director for policy Lana Skirboll, says that "many in the NIH community, and the research community more broadly, continue to be troubled" by aspects of the draft NBAC report. The letter says that NBAC should avoid focusing only on mental health and instead consider all brain disorders that might impair decision-making. This approach, Skirboll suggests, would require that the commission obtain advice from a broader group of experts than it has consulted thus far.

Skirboll also takes issue with the recommendation that independent professionals should judge whether patients are competent to take part in research. This may be "impossible to implement" without a better understanding of how to judge competence, Skirboll notes. In addition, she finds "very troubling" a suggestion that some patients might be permanently excluded from studies simply because they were judged incompetent in the past. Finally, Skirboll suggests that NBAC advocate the creation of a new category of research that would require only a modest amount of regulatory review—a category to include PET and MRI scans, which often do not offer any direct benefit to the subject. The letter included a four-page list of examples of research that "would be impeded or halted by NBAC's recommendations."

Meslin says that the fax is only the latest in a string of interactions with NIH staffers, including a private meeting earlier this fall between NIH director Harold Varmus and Shapiro. "The commission is trying to go out of its way to consider all views," says Meslin. "We're trying to be creative at the last hour." NBAC is completely "independent," he added, and has not been put off its pace by criticism of its draft, which was issued in July and revised on 19 October (www.bioethics.gov/briefings/oct98/oct20.pdf). Neither Varmus nor Shapiro could be reached for comment on the interaction between NIH and the commission.

Internal NBAC discussions are now focusing mainly on refinements in recommendations 8 through 12, which would establish new restrictions on admitting people with mental disorders into research studies.

CREDITS: (TOP) BRITISH INFORMATION SERVICES/NEW YORK; (BOTTOM) NATIONAL BIOETHICS ADVISORY COMMISSION

NBAC members also are debating a proposal that would ask the government to create a special committee that could review projects and grant regulatory waivers for research "of exceptional importance."

Despite the issues raised by the NIH fax, observers are betting that NBAC will adopt a report at the November meeting. NBAC is under "a lot of pressure" to move quickly, according to one policy analyst, because its last publication, on the ethics of cloning, appeared in June 1997. **–ELIOT MARSHALL**

HUMAN GENETICS

Opponents Criticize Iceland's Database

A bold plan to establish a database containing the medical records of the entire population of Iceland has generated a furious controversy in the isolated and sparsely populated island itself—but it has caused hardly a ripple beyond Iceland's shores. No longer. Geneticists, bioethicists, and privacy experts from Europe and the United States are rallying against the plan and are urging Iceland's parliament to think twice before approving a bill that would make it possible. They claim that the bill would permit privacy violations that would be allowed almost nowhere else in the world—and may even infringe on Icelanders' human rights.

"Quite troubled." Geneticist Mary-Claire King.

The criticism comes at a time when Althingi, the Icelandic parliament, is preparing to vote on a third version of the Health Database Bill. A first version was sent to parliament in March but withdrawn just weeks later after a storm of protest from Icelandic doctors, scientists, and patients' groups. A second, somewhat qualified draft was sent out for comment to dozens of organizations in late July (*Science*, 14 August, p. 890). The final version, put before Althingi on 9 October, is now under scrutiny by the Health Committee, after a first round of plenary debate.

Under the bill, health records of all Icelanders would be put in a central database. One company, deCODE Genetics in Reykjavik, founded by former Harvard geneticist Kari Stefansson, would be given a 12-year license to operate the database and sell access to third parties. Combined with biological samples and Iceland's detailed genealogical records, the database could be a valuable tool in tracing new disease-causing genetic mutations—a hunt that the Icelandic population is ideally suited for because of its unusual genetic homogeneity.

But even after the most recent refinements, critics still maintain that the bill is unacceptable. They have focused in particular on provisions that would permit people's medical data to be used for research without their informed, written consent. They also argue that safeguards to protect patients' privacy are inadequate and that it is unfair to grant one company use of the data while denying it to outside researchers whose studies might harm that company's commercial interests. Critics in Iceland are now being joined by colleagues from abroad, who Stefansson claims were misled by opponents who "spread misinformation about the bill all over the place."

Privacy concerns. Computer security expert Ross Anderson.

Geneticist Mary-Claire King of the University of Washington, Seattle, together with Henry Greely, a specialist in genetics and the law from Stanford University, recently wrote a letter to the Icelandic prime minister and the ministers of justice, health, and education, urging them to reconsider the plan. Although the idea of a database itself is "positive and exciting," King and Greely write, the current proposal is "quite troubling" in its "treatment of individuals, of the entire Icelandic community, and of science." Richard Lewontin, a geneticist at Harvard University, in a letter published in an Icelandic newspaper, objects to the bill granting exclusivity. Lewontin even says a scientific boycott of Iceland may be called for, "but only provided our Icelandic colleagues agree."

Some of the fiercest criticism, however, comes from Europe. At the request of the Icelandic Medical Association (IMA), computer safety expert Ross Anderson of the University of Cambridge studied the privacy provisions in the proposed new law. He concluded that simply stripping names, addresses, and birth dates from the data is not sufficient: In a country of less than 300,000 people, just a few pieces of data will often reveal a person's identity. The plan would therefore "cause serious conflict" with the ethical principle that identifiable health data must be kept secret unless the patient agrees, Anderson says. Moreover, after discussing deCODE's plans with company officials in Reykjavik, Anderson concludes that the company's "lack of competence at computer security is quite evident." He therefore advised the IMA to oppose the bill. Stefansson dismisses Anderson's criticism as the work of "a hired gun." The IMA, however, "shares Anderson's opinion until proven otherwise," says IMA chair Gudmundur Bjornsson.

Criticism has also come from legal experts. Sixteen of Europe's national Data Protection Commissioners—who oversee data-privacy laws—discussed the case in September during a meeting in Spain. They have urged Iceland's minister of justice to reconsider the plan because it may violate several European treaties, most notably the European Convention on Human Rights—a suggestion Stefansson calls "incredibly outrageous." If the bill becomes law, warns Dutch Data Protection Commissioner Peter Hustinx, Iceland may well risk a conviction by the European Court in Strasbourg.

Within Iceland, meanwhile, the "battle is getting harder," says geneticist Jorunn Eyfjord of the Icelandic Cancer Society. Recently, the IMA has clashed with Prime Minister David Oddsson and deCODE on several occasions. "At the moment, the atmosphere is spoiled," says Bjornsson. "They have tried to make us look unserious and untrustworthy. ... But we will have to find a way out of the trenches."

Indeed, many predict a resounding victory for the bill when votes are cast in Althingi next month. Only two members of the two governing center-right parties have declared themselves opposed to the plan so far. But with so much animosity surrounding the venture, implementing the database may be difficult, even if the bill is passed. After all, it is Icelandic doctors who will have to enter their patients' data into the computers. To Bjornsson, a boycott of the data collection, advised by Anderson in his report, is too serious a step. "We can't support breaking the law," he says; "that would be foolish. But it would put us in a difficult position. ... We do have basic ethical principles that we won't give up."

–MARTIN ENSERINK

Martin Enserink is a science writer in Amsterdam.

CREDIT (BOTTOM): DAN LAMONT