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RESEARCH ETHICS

Panel Tightens Rules On Mental Disorders

A presidential panel's call for stronger protection of mental patients who take part in research is drawing fire from clinical psychiatrists and some advocacy groups. The clinicians say that the report, a final draft of which was approved on 12 November by the National Bioethics Advisory Commission (NBAC), would impose too many constraints on research and would further stigmatize an already vulnerable population by singling out people with mental disorders for competency tests. Some patient advocates, on the other hand, complain that the new rules would still permit some research to go ahead without a patient's approval.

The commission, which took up the issue 15 months ago on its own initiative, proposes 20 measures to protect people with mental disorders from exposure to risk in clinical trials. The panel—composed of ethicists, biologists, physicians, and patient advocates (but no psychiatrists)—says in its report that it isn't responding to a crisis. But with clinical studies of brain disorders such as schizophrenia and depression increasing, NBAC sought to "clarify the ethical framework" for such research. "I do not believe this will have any adverse effect on the research agenda," says commission chair Harold Shapiro, president of Princeton University. He predicts that the "public will be much more supportive" of research knowing that stronger safeguards are in place.

Clinical researchers, however, are alarmed at some of NBAC's recommendations, especially one that would require an "independent, qualified professional" to evaluate the competence of a subject in any study posing greater than minimal risk (see diagram). In general, says NBAC, only people judged capable of making a decision to enroll in such studies should be allowed to do so. Current guidelines, NBAC says, are murky and "inadequate." NBAC would also like to see the government create a standing committee to set guidelines and review protocols for "exceptionally important" research, for which the consent requirements might be loosened.

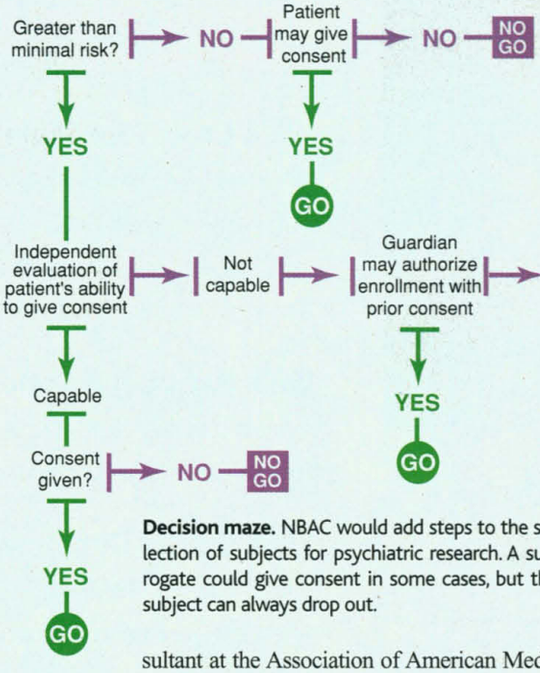
But this and many of NBAC's other proposals, if implemented, would constitute "a tragedy" for mental health research, says psychiatrist Roger Meyer, former vice president for medical affairs at George Washington University in Washington, D.C. Meyer, a consultant at the Association of American Medical Colleges, says the additional procedures would be a roadblock to recruiting subjects. Even noninvasive brain studies using PET or MRI scans would become "untenable" in many cases, he says, because under NBAC's scheme, these probably would be classified as posing more than minimal risk, making them off limits to many patients. Meyer also finds it "very scary" that a presidential commission has singled out this area of biomedicine for controls. He thinks NBAC members seemed "overtly hostile" to psychiatrists who testified publicly about the harm that might come from additional restrictions.

The report "sets us back 20 years," says Herbert Pardes, medical dean of Columbia University's College of Physicians and Surgeons. Pardes and federal research administrators met last month with NBAC members to argue that the focus not be restricted to people with mental disorders. They also suggested that the commission define a moderate-risk category of research that would permit brain scans and other routine procedures without a full competency review of each subject, an approach also suggested by the National Institutes of Health (*Science*, 30 October, p. 857). Both were rejected.

Constance Lieber, president of a nonprofit advocacy group, National Alliance for Research on Schizophrenia and Depression, also thinks NBAC's plan would hinder research without benefiting patients. She says the new procedures may "drive up costs" and "discourage young investigators." However, Lieber is pleased with NBAC's recommendations that local institutional review boards involve patients and their advocates more directly in vetting research protocols.

NBAC is getting some criticism from the opposite flank, too. Vera Hassner Sharav, head of the New York City group Citizens for Responsible Care & Research, calls NBAC's recommendations "outrageous" because they "legitimize nonconsensual, nontherapeutic research." NBAC's proposal to allow exceptional research to go forward—even when patients are not competent to give consent—violates the basic ethical principles medical researchers have followed since World War II, she says.

NBAC's report now goes to the interagency National Science and Technology Council and then on to the 17 federal departments that could be called upon to implement the changes. **–ELIOT MARSHALL**



Decision maze. NBAC would add steps to the selection of subjects for psychiatric research. A surrogate could give consent in some cases, but the subject can always drop out.

SOURCE: NBAC

DEVELOPMENTAL BIOLOGY

Hairy Mice Offer Hope For Baldness Remedy

Hairbrained as it may sound, a better understanding of cancer could lead to a cure for baldness. Recently, researchers have linked overactivity in one of the cell's major biochemical routes for relaying developmental messages to the nucleus, the Wnt signaling pathway, to colon and other cancers (*Science*, 4 September, pp. 1438 and 1509). Now, researchers at the University of Chicago have shown that a key player in that pathway, a protein called β-catenin, can stimulate the growth of new hair follicles in mice.

In work reported in the 25 November issue of *Cell*, Elaine Fuchs and her team have found that mice engineered so that their skin makes extra β-catenin grow more hair than