

Embryos to be treated as human subjects

The Bush Administration has revamped the charter of the federal advisory committee that addresses the safety of research volunteers, declaring for the first time that embryos used in research are 'human subjects' entitled to the same protections as fetuses, children and adults. "It begs the question of what is a human," says Harvard University's Douglas Melton. "Has the White House adopted the Catholic Church's position that life begins at fertilization?"

The move comes as no surprise to stem-cell scientists in the US who have long experienced political efforts to curtail their work. "It seems evident that the Bush administration's inclusion of embryos along with fetuses as 'human subjects' is intended to justify its prohibition of the use of *in vitro* fertilization-derived blastocysts

as a source of embryonic stem cells," says Nobel Laureate Paul Berg of Stanford University. "By

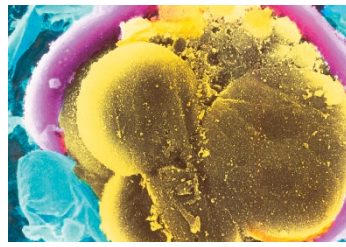
doing so, the president is standing in the way of achieving the goal he professed to be aiming for: creating new therapeutic approaches to life-threatening diseases. He does not seem to understand that most of the so-called stem-cell lines

he approved for use in 2001 do not exist, or are not available for the research to develop those therapies," says Berg.

Leonard Zon, professor of pediatric medicine at Harvard and a Howard

Hughes Investigator does not see an immediate negative impact on stem-cell research, but does agree that this is probably the intended goal. "This may be one of the steps taken to limit future experiments in the field," he says.

The amendment is not a rule of law; rather, it will take the form of a recommendation by the advisory committee to the Department of Health and Human Services. The committee itself has not yet been assembled, and some scientists fear that it



An early human embryo—now a 'human subject'?

will include prominent abortion foes who will encourage Congress to enact legislation that would convey such a status upon research embryos.

Marlene Cimons, Washington, D.C.

CWD research increases as US concern grows

Scientists working on chronic wasting disease (CWD), which affects deer and elk, are finding their finances suddenly bolstered. "CWD has become of national interest for several reasons," says Edward Hoover, a CWD researcher at Colorado State University, "the recognition of [bovine spongiform encephalopathy (BSE)] in Europe; CWD has spread east of the Mississippi valley; and the farmed deer and elk industry has been seriously affected."



CWD could be on the rise.

CWD is a fatal brain disorder from the class of transmissible spongiform encephalopathies (TSEs), which include BSE in cattle, scrapie in sheep and Creutzfeldt-Jakob disease in humans. Hoover heads a new center dedicated to CWD established with a 7-year, \$8.4-million grant from the National Institute of Allergy and Infectious Diseases (NIAID). The National Institutes of Health has requested \$26.4 million for TSE research in FY2003, a 9% increase over the previous year.

Until recently, CWD, which was first identified in 1967, was thought to be confined in the wild to a relatively small region of northeastern Colorado. But earlier this year it was discovered in other areas, including Wisconsin and South Dakota, and the Canadian province of Saskatchewan. It

is not clear how fast the disease is spreading, but in Wisconsin, where 40 infected deer have been found, state officials want hunters to kill a herd of 25,000 deer to eradicate the disease.

In scrapie, rogue prion proteins accumulate in the placenta, suggesting that this organ is the source of contamination, but in CWD, the source of infection remains elusive. "One primary interest is to

determine if CWD is contained in urine, feces, saliva and other bodily secretions," says Hoover, whose group will use antibody-based assays to look for CWD prions in these materials.

An even more pressing question is whether other animals are susceptible to CWD—in particular, cattle and people. Five years ago, Janice Miller, a researcher with the US Department of Agriculture, injected material from infected mule deer into the brains of cattle and 4 out of 14 animals have developed "a prion disease."

But there is no evidence, as yet, that the disease is transmitted through feeding, the likely mode of transmission in the wild. Elizabeth Williams at the University of Wyoming fed cattle CWD-infected tissue. Five years later "we don't see any evidence of transmission," says Williams, who plans to monitor the cows for another five years. In addition, scientists at NIAID's Rocky Mountain Laboratories will investigate whether the rogue CWD prion protein can be transmitted to monkeys who eat meat containing abnormal CWD prion proteins.

Laura Bonetta, Bethesda

Poor reports dog industry-academia liaison

It has been a bad few weeks for academic scientists involved in industry-sponsored research. Two new studies suggest that the relationship is not as healthy as it should be, and the US Food and Drug Administration (FDA) has placed restrictions on two academic scientists charged with adulterating patient records while working on clinical trials for industrial sponsors.

In 1998, companies spent \$2 billion on university studies, which accounted for about 9% of all academic research in the US, according to the American Council on

Education. Indeed, a growing number of academic scientists now work for industrial sponsors, preparing studies not for publication, but for FDA drug applications. Until now, Lois Katz, a nephrologist at New York University, and David Faxon, formerly the chief of cardiology at University of Southern California, were part of this cadre. But in late October, FDA inspectors charged each with falsifying data "deliberately to qualify the subject(s) for admission into the study."

Katz and Faxon had attributed the problem to staff members. However, FDA inves-