TOXIC TIDE

Urea pollution may have doomed Hitchcock's kamikaze gulls

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the state to go unregulated, argues state senator Tom George (Republican), who co-chairs the opposition group, Michigan Citizens Against Unrestricted Science and Experimentation.

That's simply not true, counters De Witt. He notes that state institutions that conduct human embryonic stem-cell research have internal ethics review boards to monitor the studies, and that researchers must also follow federal regulations regarding investigations into humans and human tissue. The same constraints would hold, he says, if researchers were allowed to derive their own lines.

The initiative has "major significance" because presidential candidates John McCain and Barack Obama have both hinted that, if elected, they would loosen federal restrictions on embryonic stem-cell research, says Stephen Rapundalo, executive director of MichBio in Ann Arbor, a non-profit organization trying to drive growth of the life-sciences industry in the state. Currently, federal research money can be used for work only on cell lines derived before

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9 August 2001, the date the federal restrictions came into effect. The University of Michigan uses 11 of these federally approved lines, which were grown using

mouse cells and which, they say, are less than ideal for human clinical research.

If federal law changes after the election but state law does not, Rapundalo says, stem-cell scientists in the state will be at a distinct disadvantage. Many fear that leading researchers will leave Michigan for other states that support the work, such as California and New York. Sue O'Shea, director of the Michigan Center for Human Embryonic Stem Cell Research in Ann Arbor, says she has seen many of her best students leave — especially those who want to work on embryonic rather than adult stem cells.

Morrison agrees. "We have already been at a disadvantage in recruiting faculty members who specialize in the area of human embryonic stem-cell research," he says. "If the proposal does not pass, this will not improve."

Nevertheless, unlike California's \$3-billion stem-cell agency, which was created through a ballot initiative, the Michigan initiative has no money attached to it. "So even if it does pass, it won't necessarily allow us to develop any new embryonic stem-cell lines," O'Shea says. "It will just make life easier knowing we can do it." ■

Ashley Yeager

See Editorial, page 1149.

Alzheimer's tests under fire

Genetic testing for Alzheimer's disease tells a cautionary tale about the legal, medical and ethical complications of personal genomics, as the story of a Pennsylvania company shows.

Smart Genetics, based in Philadelphia, has stopped offering its controversial 'Alzheimer's Mirror' genetic test just eight months after introducing it. The test checked for variants in a gene, called *APOE*, that bestow as much as a 15-fold increased risk of developing Alzheimer's. Soon after launching the test, though, Smart Genetics chief executive Julian Awad found himself in a controversy over whether it violated intellectual-property agreements covering *APOE* testing.

Smart Genetics' tests were performed by Athena Diagnostics, based in Worcester, Massachusetts. Athena had, in turn, licensed the patents from Duke University in Durham, North Carolina, where researcher Allen Roses discovered the *APOE* link to Alzheimer's in the early 1990s. Roses and Duke argue that Athena's licence covers *APOE* testing only in people who already have symptoms of dementia.

"The test was never intended to be used for wholesale screening of non-cognitively impaired individuals," adds Alan Herosian, director of corporate alliances for Duke University. He says he has contacted Athena many times in recent months to press this point.

Michael Henry, Athena's vice-president of business development, wouldn't comment on whether the company agreed with this interpretation of its licence. But Smart Genetics is no longer taking new orders for Alzheimer's Mirror. Its website says the test is currently unavailable because of "high demand". The company's phone lines have been disconnected, and a Philadelphia newspaper, the *Philadelphia Business Journal*, reported earlier this month that the company has closed.

Smart Genetics co-founder Richard Watson would not comment on the newspaper article, and Awad did not respond to e-mails or phone messages. But one member of the company's scientific advisory board, Andrew Faucett of

Emory University School of Medicine in Atlanta, Georgia, notes that the firm faced another roadblock: Smart Genetics was charging hundreds of dollars for one test, whereas other gene-scanning firms offer Alzheimer's risk assessments along with other tests. "The financial model was hard to support," he says.

The tests offered by other firms bring issues of their own. For instance, Navigenics of Redwood Shores, California, provides Alzheimer's risk assessments by testing variants of a gene called *APOC1*, which sits next to *APOE* on chromosome 19. Navigenics uses *APOC1* variants to predict *APOE* status on the basis of published reports that certain variants of the two genes are often inherited together. But *APOC1* is not a perfect proxy for *APOE*

variants. Navigenics chief operating officer Sean George says the company is switching to testing *APOE* variants directly.

Roses thinks genetic testing for the risk of Alzheimer's will only get more complex. He claims to have unpublished data suggesting that variants in another gene can be used with *APOE* variants to predict, to within

Can genes reliably predict risk for an Alzheimer's brain (left)?

5–10 years, the age at which a person will develop Alzheimer's disease.

But he also hopes that ethical aspects of risk assessments will change if clinical trials identify drugs to treat the disease. Currently, knowing one's risk of developing the disease may simply cause needless worry, as there is no prevention or treatment. But Roses notes that the firm for which he worked previously, GlaxoSmithKline based near London, has reported preliminary data that its drug rosiglitazone benefits patients with Alzheimer's if they don't carry a high-risk *APOE* variant (A. D. Roses *Alzheimer's Dementia* 4, 164–166; 2008). The company is scheduled to finish clinical trials next year to test whether the findings hold up in larger numbers of patients with Alzheimer's.

If they do, Roses notes, it will mean *APOE* tests might be more useful, as they could help identify patients who will benefit most from treatment: "That's where we are approaching very, very rapidly," he says. ■ Erika Check Hayden

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