

Congress of the United States
Washington, DC 20515

Not According to
the Journal Nature

May 19, 2005

~~Listen to the Experts: Current Stem Cell Policy
Hinders Research~~

Dear Colleague,

Last month, a number of NIH Institute Directors expressed serious concern that federal policy is overly restrictive. These top experts expressed serious concern with you.

"The greatest roadblock to the development of human embryonic stem-cell research in the U.S. is WARF's fundamental patent."

According to *Nature* (May 19, 2005) the problem is not the current policy as suggested in their comments by Reps Baldwin and Bass, but rather financial greed. *Nature* states: "Licensing fees

".... Jeanne Loring, an embryologist at the Burnham Institute in La Jolla, California, knows all about the unrealized commercial promise of human embryonic stem-cell research.... in 1999 [she] founded Arcos BioScience to culture the [embryo stem] cells ... The company... couldn't find the \$100,000 up-front fee that would allow it to take out a commercial research licence from the Foundation (WARF).... It [WARF] holds broad patents on a method of deriving human embryonic stem cells and on the cells themselves.... Loring says it has a stranglehold on the field. 'The greatest roadblock to the development of human embryonic stem-cell research in the United States is WARF's fundamental patent,' she says. 'If it hadn't been for that patent, I would still be in biotech.'

The current situation is stifling industrial research and investment in this area," complains a senior executive at one firm...

"...Dozens of companies around the world are working on stem cells, exploring uses that range from drug discovery to drug screening, and from toxicology to cellular therapies for Parkinson's and heart disease. But most deal with stem cells derived from adults, which are out of the reach of WARF's patents. Those that invest seriously in embryonic stem-cell work can be counted on the fingers of two hands."

"... facing another major obstacle: exclusive licences held by Geron, based in Menlo Park, California, which paid for much of the Wisconsin research. Geron has secured exclusive US commercial rights to what are generally agreed to be the three most clinically promising types of cell derived from embryonic stem cells....Partly because Geron's control is so broad, 'things are moving more slowly than they otherwise would', says Rebecca Eisenberg, a law professor at the University of Michigan who specializes in intellectual-property issues in biotechnology.

... He doesn't deny that WARF is seeking six-figure sums a \$25,000 annual maintenance fee plus \$100,000 up-front fee from companies taking out commercial licences.... The disgruntled blames the small number of licences on WARF's prices and restrictions. 'It granted only seven commercial licences in seven years, on a technology that is hot, why?' demands the anonymous executive. He adds that US-based firms feel hamstrung by one requirement in particular: 'If we sign an agreement with WARF in the United States, it wants to place restrictions on us globally, even though the patents do not apply worldwide.'

Sincerely,

Rep. Dave Weldon, M.D.
Member of Congress

Tammy Baldwin
Member of Congress