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SEPTEMBER 23, 2009

Stem cell lines: let the vetting begin

The day after the US National Institutes of Health (NIH) announced that it was <u>ready to start approving stem cell lines</u> for federal funding, the hallways of the <u>World Stem Cell Summit</u> in Baltimore, Maryland, were abuzz with excitement — and confusion.

In the morning, I chatted with Baldwin Wong, executive secretary of the NIH Stem Cell Task Force, who showed me the website that lists all the lines that have already been submitted for consideration. Two research groups were first out of the gate. After day one, 15 lines had been put forward by an investigator at Children's Hospital Boston in Massachusetts — presumably by George Daley, according to Wong — and another two lines were offered up by someone at The Rockefeller University in New York City. All of these lines were sent in with requests for special consideration by the NIH's nine-member panel — meaning they don't likely satisfy the strict criteria outlined in the NIH's new guidelines, but they can be 'grandfathered' in if they adhere to certain principles of informed consent.

Continue reading "Stem cell lines: let the vetting begin" »

Posted by Elie Dolgin on September 23, 2009

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Cracking down on stem cell companies

The International Society for Stem Cell Research (ISSCR) has convened a new committee tasked with weeding out companies that offer unapproved stem cell 'therapies', the ISSCR's new president Irving Weissman announced today at the World Stem Cell Summit in Baltimore, Maryland.

Last month, <u>Weissman</u>, who also directs the Stanford Institute for Stem Cell Biology and Regenerative Medicine in Palo Alto, California, wrote an opinion <u>article</u> in *Cell Stem Cell* calling for stem cell purveyors to be judged on three criteria. First, the company should be able to cite peer-reviewed papers from third party investigators showing that the therapy is possible. Second, there should be institutional review board oversight of the treatment. Third, the US Food and Drug Administration or an equivalent agency should give the final green light. "That's the minimum beginning," he said at the meeting.

Weissman revealed that he had convened an 18-member panel of lawyers, FDA regulators, medical ethicists, and stem cell scientists last week to look into the feasibility of establishing an online registry of wayward companies. His idea is for the ISSCR supervisory body to request documentation of the three requirements from all known global stem cell providers. Companies that don't comply would get blacklisted.



Weissman expects the committee to issue a preliminary report in December, with final guidelines published next March.

Image of Weissman by Kris Novak

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The Golden State's golden example

A theme that emerged time and again at this year's <u>World Stem Cell Summit</u> in Baltimore, Maryland, was the need for stable and reliable funding for the nascent and much-hyped science. Venture capital backers often expect returns after three to five years. Government-supported grants generally operate on a similar timescale. But stem cell research doesn't offer such quick turnarounds.



That's why Robert Klein, chair of the governing board of the <u>California Institute for Regenerative Medicine</u> (CIRM), described his state's far-reaching \$3 billion investment as a "legacy commitment to the future." He cited CIRM's reliance on long-term bonds as an appropriate way to align taxpayer investment in research with expected therapeutic and financial payoffs, which remain years or decades away. Klein outlined a new prototype loan program under consideration in which the state stem cell agency would get a kickback if research funding led to profitable spin-offs. Otherwise, the money would serve as a normal scientific grant.

In other CIRM-related news, Klein also publicly decried a recent *Nature* story chronicling a number of stalled building projects owing to Golden State's financial woes. "We think in this economy that to have 95% of our projects in construction is a good record," he said. And hot on the heels of <u>last week's partnership with Germany</u>, CIRM <u>announced a bicoastal collaboration</u> at the meeting with the <u>Maryland Technology Development Corporation</u>, which administers the <u>Maryland Stem Cell Research Fund</u>, to allow joint funding efforts.

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New stem cell bill in US Congress?

After the fanfare surrounding President Barack Obama's <u>executive order on 9 March</u>, which lifted Bush-era restrictions on funding human embryonic stem cell research, the White House has been noticeably quiet about further expanding the science — one of Obama's <u>campaign promises</u>. "We need to remind the President of this type of research," Delaware congressman <u>Michael Castle</u> (Republican) said today at the <u>World Stem Cell Summit</u> in Baltimore, Maryland, the fifth annual summit presented by the non-profit Wellington, Florida-based <u>Genetics Policy Institute</u>.

Castle, together with Colorado congresswoman <u>Diana DeGette</u> (Democrat), <u>previously introduced two bills</u> to expand researchers' access to human embryonic stem cell lines. Both bills were approved by Congress but vetoed by former President George W. Bush. Now, both House Representatives are at it again, working on new legislation to augment the executive order and prevent potential policy reversals from future residents of 1600 Pennsylvania Avenue. "I don't like to see science subject to the whim of politics at all," said Castle, who is also working to overturn the Dickey-Wicker amendment, which forbids the creation of embryos for research purposes on the taxpayer's dime.



The bill is unlikely to brought before Congress anytime this year, however. Olivia Kurtz, Castle's senior legislative assistant, told me that Castle and DeGette hope to roll out the bill before the current Congress's term ends in January 2011. In the meantime, they are watching what happens with the National Institutes of Health's expanded guidelines to identify potential shortfalls in the executive order that need remedying. Castle singled out nuclear cloning — the technique that produced Dolly the sheep — as one line of research that deserves further attention.

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