

East Asia faces unique challenges, opportunities for stem cell innovation

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Tension is the theme running through the new consensus statement issued by the Hinxton Group, an international working group on stem cell research and regulation. Specifically, tension between intellectual property policies and scientific norms of free exchange, but also between eastern and western cultures, national and international interests, and privatized vs. nationalized health care systems.

The consensus, titled *Statement on Data and Materials Sharing and Intellectual Property in Pluripotent Stem* <u>Cell Science</u> *in Japan and China*, was released on the Hinxton Group's website Monday, November 19, 2012.

"China and Japan are among the world's leading nations in stem cell research, but because of challenges distinct from western nations, they are dramatically underrepresented in terms of patents and licensing," says Debra Mathews, PhD, MA, assistant director of Science Programs at the Johns Hopkins Berman Institute of <u>Bioethics</u> and a founding member of the Hinxton Group. Mathews was one of 22 co-signers of the <u>consensus statement</u>.

"We thought it was crucial, with the science advancing incredibly rapidly, and as intellectual property policies evolve in <u>East Asia</u>, to examine our 2010 global recommendations for proprietary issues in stem cell research in that regional context," Mathews says.

Strengthening national stem cell innovation was the top goal articulated



in Kobe, the statement says. Whereas in the West there is a robust and mature infrastructure for encouraging and supporting the development of <u>intellectual property rights</u> such as patents, East Asian nations like China and Japan have comparatively less well-developed, younger systems, the group observes. While this can make it more difficult to bring new inventions to <u>international markets</u>, the statement says, the opportunities created by the regional environment in Japan and China provide valuable lessons for the global development of this field.

"For example, as noted in the statement, Japan and China each have a large and highly qualified scientific workforce, paired with substantial national investment in stem cell research," says Mathews. "This combination of factors means that both countries are well-situated to take the kinds of collective action that will be required to move the field forward efficiently and translate basic science discoveries into products and therapies."

An area where Japan and China exercise strong state control to the possible benefit of stem cell-based invention is their national health care systems, the statement notes. In the West, strong intellectual property rights have encouraged the "development of stand-alone blockbuster products," the group says, whereas the national health systems in East Asia may allow patients access to more individualized, innovative treatments. This, the group posits, could be a model for stem cell-based therapies.

"Innovation in China and Japan occurs in the context of national commitments to public health, and as a practical matter that should make access to cell-based therapies more equitable," Mathews says.

The statement also notes the significant cultural differences that contribute to challenges—and opportunities—with intellectual property policy, practice and <u>stem cell research</u> in the region. The group notes



that Japan and China are "markedly less litigious" than western nations, and recognition for scientific work and publication priority are highly valued. "Secrecy appears to be a relatively more common mode of protecting researchers' raw [intellectual property rights], as opposed to more formalized legal systems of protection, such as patenting," the statement says. In light of this, an appropriate incentive to sharing data and materials among scientists in the region would be the protection of their interests and rights, perhaps through a grace or priority period, the group says, during which the data is public but the original scientists have exclusive rights to publish.

The statement also discusses the challenges of sharing data and materials internationally, noting an "underlying tension between national and international interests." In China, for example, samples donated by citizens are considered <u>intellectual property</u> of the state and are governed by strict polices that create roadblocks to international sharing and access. Such policies, varying country by country, may present significant challenges to the Hinxton Group's goal of creating an internationally coordinated stem cell bank, the statement says.

"There will always be tensions between national and international and between public and private," as far as innovation and the protection of that innovation, the group says. "Within the biomedical sciences, the key is to strike a balance that both promotes innovation and improves global health," the statement concludes.

More information: Consensus Statement: www.hinxtongroup.org/consensus_hg12_final.pdf

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