IN brief

China's $2.4 billion splurge

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Biopharma projects will receive billions.

The Chinese government is pouring an estimated 16 billion yuan ($2.4 billion) to shore up drug development while introducing policies to promote the biotech sector. The new policies—designed to boost seven emerging strategic industries, from sustainable energies to biotech—came under a resolution issued by the State Council, China's cabinet, on September 8. China's key new drug R&D scheme was launched in 2009. In its first stage, which will last until 2011, central government will invest nearly 6 billion yuan ($882.5 million) to support more than 900 drug development projects as well as several innovative technology platforms. This is followed by a second stage, running from 2011 to 2015, with an expected 10 billion yuan ($1.47 billion). The biopharma sector is expected to be one of the main beneficiaries of this funding push, although the government's recent announcement did not provide a breakdown of the investments. Central government plans to couple this financial support with moves to strengthen intellectual property protection, and promote favorable taxation and lending policies. Zailin Yu, chairman and CEO of Tianjin-based protein drug developer SinoBiotech, who is funded by the scheme, says there is no preference for biologics or chemical drugs, as long as the proposals are strong. Mingde Yu, president of China Pharmaceutical Enterprise Management Association, in Beijing, says Chinese firms are unlikely to develop original chemical compounds, and he believes the opportunities lie in developing biotech drugs. But despite this strong governmental support, biopharma researchers complain the money is spread thin among hundreds of projects. The promised funding also arrives late, takes a long time to reach scientists and is too tightly regulated, leaving researchers little flexibility to modify their research plans. In addition, most contract research organizations (CROs) and large international pharma with facilities in China are not invited to participate in the scheme, despite their expertise manufacturing to international standards. "In China, most of the huge government support goes to academics who lack industrial experience and to state-owned pharmaceuticals because of the gap between the public institutions and privately and foreign-owned industries. This is a big loss to innovative drug development," says Shoufu Lu, founder and CEO of Shanghai's Zhangjiang-based startup Aqbio Pharma. "We CROs charge more, so academics do not accept us. But we are happy to cut our prices in order to be involved in the State-funded projects as long as there is mutual understanding between academics and us," says the CEO of a leading CRO in Shanghai's Zhangjiang, who requested anonymity. *Hepeng Jia*

mediums used in many university laboratories carry safety risks whereas the push toward animal product–free media during commercial scale-ups can create the phenotypic drift everyone worries about. "And," says Rowley, "if there is too big a change (in phenotype) you may have to re-run expensive preclinical or even early human clinical trials."

Clinical trial design is a further challenge. Traditional small molecules and antibodies have a limited life in the body. If you cease administering the drug the body eventually washes it out. But hESCs and other specialized stem cells don't leave the body; they become part of it in a manner akin to the implantation of a medical device. "In many cases, the introduction of cells into a human patient, at least with current technology, is often an irreversible intervention," says Goldstein.

Stem cells' idiosyncratic biology creates as well unique intellectual property issues for people looking for ways of standardizing patent claim processes. "There are patent thickets everywhere," says Debra Mathews, assistant director for science programs, the Johns Hopkins Berman Institute of Bioethics, and principal investigator in the Hinxton Group Project. Her institute is trying to come up with ways of optimizing stem cell innovation while at the same time ensuring its products reach as many people as quickly as possible (*Nat. Biotechnol.* **28**, 544–546, 2010). "The unique property of [hESCs] makes for a particularly sticky wicket, as a pluripotent stem cell is a gateway technology," says Mathews. "And patent control over a line of [hESCs] gives the patent holder control over downstream research, such as that which differentiates stem cells into neurons, islet cells, isolate proteins, et cetera," she says.

And to all of the above must be added what is described as the 'low hanging fruit' complication. There are already treatments for most simple conditions, and stem cells are held up as a treatment for the high hanging and as-yet intractable conditions. Geron's potential treatment to restore limb movement after a spinal injury is a classic example. Benchmarking effectiveness of a therapy in such a condition is a substantial challenge.

Finally, the plethora of standardization uncertainty can translate into a translational funding paralysis. "It is clear not enough information is available for new investors to make informed decisions," remarks Robert Deans, senior vice president of Regenerative Medicine of Cleveland-based Athersys, and chair of the ISCT Commercialization Committee.

Unsurprisingly, the multiplicity of issues to be resolved has created a certain caution in those groups seeking to have various parts of the translation process become more standardized. Deans says the ISCT is not at this point programmatic but seeks rather to bring industry and researchers together to arrive at a consensus. "We want to give regulators, such as the FDA, exposure to certain tests and scientific models and let them hear from a number of academic investigators what the bottom line should be," he says.

Elona Baum, general counsel for CIRM and the point person in CIRM's efforts to come up with standards, says that her organization has actively begun to investigate what the standardization priorities should be. Working with the Washington, DC–based lobbying group, the Alliance for Regenerative Medicine, they are looking at what existing standards and guidelines exist and are asking key players in the field what should be done and in what order. "We all agree with the need to move ahead, now we are trying to identify what our priorities should be," she says. Goldstein says ISSCR's core belief is that "the most important thing is protection of the people who will participate in the trials, or who will potentially purchase marketed therapies."

With this in mind ISSCR recently created a website to provide information by which patients and physicians can judge the bona fides of stem cell–based cures being promoted on the internet by clinics around the world. (*Nat. Biotechnol.* **28**, 885, 2010). In Europe, EMA has been pushing active consultations on various areas of stem cell research and applications that need regularization. It hopes to have a guidance document adopted by November, which should go up on their website soon after.

But with all the push for adopting uniform standards, some in the field fear more regulatory paralysis. University of Nantes's Mohty points out that a European directive in 2001 that aimed to standardize all clinical trial procedures and thus speed up the approval process actually has had the opposite effect when it comes to stem cells. "It is very difficult, maybe even nearly impossible, to perform clinical trials in the field of hematopoietic stem cell transplantation because this activity cannot be compared with single drugs," he says. "Consequently, there has been a big drop in the number of clinical trials performed in Europe after that directive." Simply put, the regulatory approval bar has been raised too high.

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