China's watchdog clamps down on genome sequencing services

Chinese regulators have allowed companies offering genetic tests to resume business on a trial basis, following an earlier government crackdown. On February 9, China's National Health and Family Planning Commission (NHFPC) and the China Food and Drug Administration (CFDA) ordered clinical genetic services to halt provision of all testing to customers while they drew up a regulatory pathway to control testing. The agencies' move was likely prompted by the flood in demand for unapproved noninvasive fetal trisomy (NIFTY) screens—the most frequent genomic testing in China, but also applies to all sequencing-related services and medical devices. The suspension has cast a pall over the sector but with genetic testing spreading at a furious pace across China, such a move was warranted.

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Sequencing services are marketed to healthy individuals in China as part of a general check-up.

As a first measure, the CFDA, the Chinese counterpart to the US Food and Drug Administration, is demanding that all equipment be officially approved, and clinical services registered with NHFPC, China's public health body. The new regulations include a requirement that testing be performed through hospitals and other health institutions. Providers will now have to register such tests and apply for governmental permission to conduct them.

NIFTY tests have had a phenomenal uptake and this has raised regulators' concerns, says Ming Li, chief scientist of Da An Gene. On April 1, Guobiao Gao, deputy director of medical equipment at CFDA, speaking on China National Radio, confirmed that most clinical sequencing tests, including NIFTY, are not approved.

NIFTY screens are offered to women after the 12th week of pregnancy. The tests use cell-free fetal DNA in a mother's blood to detect chromosomal rearrangement risks linked to trisomy 21 (Down syndrome), trisomy 13 (Patau syndrome) and trisomy 18 (Edwards syndrome) (*Nat. Biotechnol.* **31**, 595–601, 2013).

A NIFTY assay costs about 3,000 yuan ($483.9). Chinese media reported that more than 200,000 pregnant women have been tested with NIFTY in China (http://finance.ifeng.com/a/20130814/10426831_0.shtml).

Shenzhen-based BGI, the test's main supplier, was contacted for this article but could not comment. The other companies offering genetic testing to consumers are Shenzhen-based Da An Gene, Beijing-based Berry Genomics and Hunan-based Second Xiangya Hospital of Central South University.

Many Chinese hospitals market their sequencing services to healthy people, as part of a physical examination. The growing popularity of such tests might have raised regulatory flags. "If each person pays tens of thousands [of yuan] to access their genomic information, it becomes a very big market," says Xinqing Zhang, an associate professor of bioethics at Beijing-based Peking Union Medical College, who has been a close policy advisor to NHFPC.

Other sequencing providers have started to offer cancer susceptibility tests and individual genetic screening for diseases such as Down syndrome and sickle cell anemia. "The NHFPC and CFDA must have felt that, without supervision, commercial clinical services would flood the market. So they urgently issued the suspension order," says Zhang. He adds that, "Some Chinese sequencing service providers intentionally confuse susceptibility genes and genetic causality to lure people into paying more for further screening."

Although many support tighter regulation of the burgeoning Chinese sequencing market, the decision by NHFPC and CFDA is still being contested. In early March, during the annual plenary meeting of the National Political Consultative Committee of China, China's honorary upper parliament, several committee delegates from the scientific community, headed by Zihe Rao, of Tianjin-based Nankai University, put forward a motion to support China's genome sequencing industry. Rao told local media that, although he understood the authorities were acting as watchdogs, the suspension would hurt the nascent sequencing industry. He also suggested the authorities consider incorporating genome sequencing into regular clinical examinations to support the industry. But Li of Da An Gene favors some intervention. "If the government completely gives up regulation, the market will become a mess with players rushing in," Li says.

What is needed are criteria to select qualified providers, argues Daru Lu, a professor of biomedicine at Shanghai-based Fudan University, something the new order fails to do. Lu also says sequencing regulation should go beyond registering equipment and services to include a selection of genomic targets for screening and the criteria to define susceptibility, and to set common standards between sequencing firms.

Ethical issues may have been weighed, too, in the suspension. "Who should have the right to decide who is going to be screened? How should sequencing providers deal with genetic defects? Who should own and dispose of the huge amount of DNA data as a result of general sequencing?" asks Zhang. All these issues need to be considered in the policymaking process. The model of ELSI (Ethical, Legal and Social Implications of biomedical research) in the US should be copied when developing clinical applications of genome sequencing, says Zhang.

Hepeng Jia *Ithaca, New York*