

The Big Read **Genomics**

## **Biotechnology: the US-China dispute over genetic data**

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The FBI is beginning to raise national security questions about genetic data going overseas

YESTERDAY by: David J Lynch

There are not many agents in the Federal Bureau of Investigation like Ed You. In a workforce that cultivates anonymity, his clean-shaven head gleams. While most of his colleagues are notoriously tight-lipped, Mr You is the chatty star of technology conferences such as South-by-Southwest and DEFCON.

He is also at the forefront of a potential dispute between the US and China, which could have implications for both commercial relations between the world's two biggest economies and for the future of biomedical research.

The high profile that Mr You has adopted is part of an unusual FBI campaign to highlight the risks in America's headlong pursuit to unlock the secrets of the human genome. A supervisory special agent in the bureau's biological countermeasures unit, Mr You warns that the US is not protecting the genomic data used to create lucrative new medicines — but which can also be used to develop fearsome bioweapons.

“We don't know how much bio data has left our shores,” he says. “Our concept for biological security needs to be broadened.”

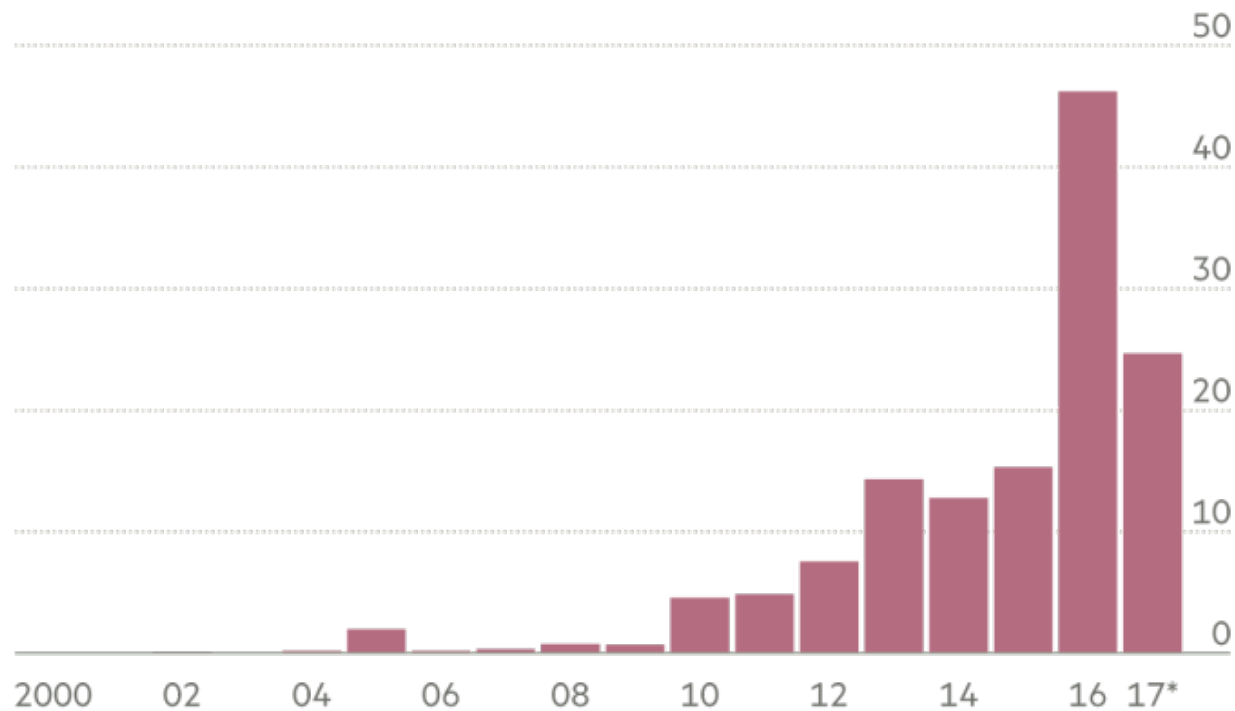


Sophie Liu, a research scientist at California's Complete Genomics. In 2013 it was bought by China's BGI-Shenzhen © Bloomberg

That has led him to focus on China, which the veteran lawman says is gaining access to US genomic data — the biological software that governs human organisms. In recent years, Chinese investors have purchased stakes in, or partnered with, US biomedical companies that specialise in genomics. At the same time, state-sponsored hackers believed to be Chinese have penetrated the laboratories, health insurers and hospitals where other valuable patient records reside. Mr You suggests stricter controls might be needed on what sort of health data can be transferred overseas — to China and elsewhere.

## Chinese foreign direct investment into the US

\$bn



\* Year to date

Source: China Investment Monitor, Rhodium Group

FT

Nearly two decades after the first human genome was decoded, the field is one of the most exciting in biomedical research — and one that relies on an open network of international collaboration.

But it is also the latest area where national security questions — about Chinese objectives and the links between its companies and the state — are leading to calls for important sectors of the US economy to be ringfenced.

Since the [2014 decision to bar Huawei](#) from selling into parts of the US telecoms infrastructure market, America has blocked Chinese acquisitions of a wind turbine company in Oregon, a California cloud computing firm, and the US-based division of a German semiconductor maker. The Pentagon has raised concerns about Chinese investment in artificial intelligence.



FBI agent Ed You has called for limits on the kind of biodata that can be sold or transmitted outside US borders © FBI

Traditionally, the FBI's weapons of mass destruction directorate has concentrated on preventing toxins such as Ebola or anthrax from falling into the wrong hands — and contributing to the spread of new germ weapons.

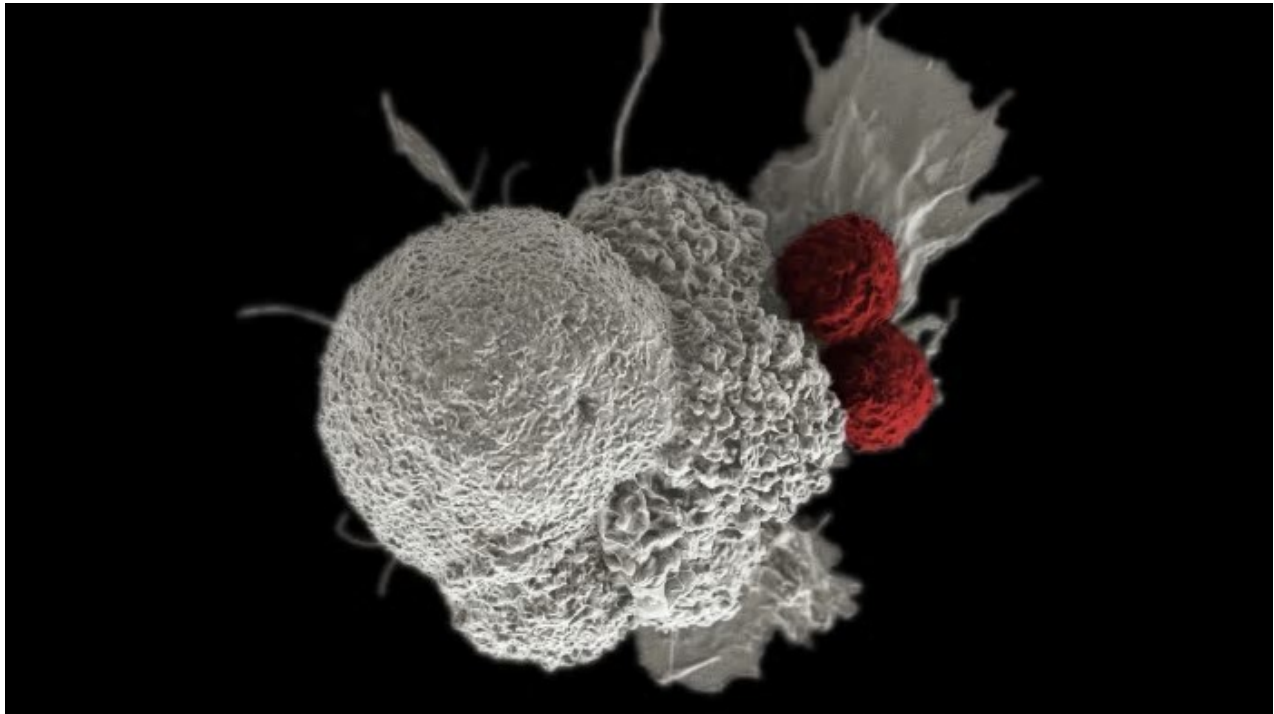
Now, the bureau fears that digital data sets may prove just as lethal. The concerns about large volumes of US genetic data being scooped up help explain why a law enforcement agency is tracking the potential loss of US competitive advantage. “The economic impact is the principal near-term threat — the monetisation of large data sets,” says Mr You.

Some observers believe the US government is right to ask questions about the implications of Chinese investment in genomics. “I’ve never seen an agency, the FBI, come out of the woodwork like this,” said Michael Wessel, a member of the US-China Economic and Security Review Commission, a congressionally-chartered advisory body. “This is a critical area that needs a lot more attention . . . It’s a real threat.”

Others worry that it would be damaging for the US to put up excessive barriers to Chinese biomedical investment. Dan Rosen, founding partner at the Rhodium Group in New York, points out that China has invested more than \$3.2bn in the US biotech and pharmaceuticals sector over the past five years — cash that often brings with it talented Chinese scientists. In some disciplines, such as large-scale, low-cost gene sequencing,

China leads the US. If Chinese companies become less welcome in the US, he says, they will go elsewhere.

“I don’t think drawing a line around biotech and calling the entire industry a critical sector is going to do the trick,” said Mr Rosen. “We’re going to have to maintain the ability to look at investments case by case.”



A cancer cell being attacked by two cytotoxic T-cells. Genome sequencing could bring a better understanding of who is at risk of developing cancer and personalised treatments © Rita Elena Serda/Duncan Comprehensive Cancer Centre at Baylor College of Medicine; NCI/NIH

The promise of genomics is a new era of precision targeted drugs that make traditional one-size-fits-all medicine look like a second world war dumb bomb. But treatments that are customised for a patient’s individual genetic make-up remain in their early stages.

Both the US, the acknowledged global leader, and China are pursuing personalised treatments for diseases such as cancer, cystic fibrosis or Alzheimer’s. China last year unveiled a \$9bn 15-year research initiative, dwarfing an Obama-era plan that earmarked \$215m for the National Institutes of Health.

DNA science has leapfrogged since 2000 when the human genome was first sequenced. What once required years of work and cost billions of dollars now takes less than a week

and costs just \$1,000. The US is gathering genetic data from more than 1m volunteers, so that automated lab systems can investigate how individual genes interact.

“The first problem is having access to data . . . You need a lot of data,” says Eleonore Pauwels at the Wilson Center in Washington.

Beijing’s ambitions in this area have led some Chinese companies to go on the acquisition trail — especially in the US. In January, for example, iCarbonX of Shenzhen, which aims to create personalised health treatments by combining AI with large pools of genetic data, invested more than \$100m in PatientsLikeMe. The US company says it is the world’s largest personalised health network with more than 500,000 individuals sharing their medical details. PatientsLikeMe, based in Cambridge, Massachusetts, says that its data are anonymised and retained on US-based servers.

That kind of data — stored in 100 gigabyte to 1 terabyte digital files — could be used to develop new drugs. Laboratories gather enormous numbers of such files, then combine them with detailed demographic, diet, health and lifestyle records. Supercomputers search for patterns, identifying genetic malfunctions and suggesting new remedies.



Researchers in a laboratory in Tianjin. China has made genome sequencing a research priority © Reuters

The same data sets can, however, be used to develop bioweapons. The FBI, which first raised its biomedicine concerns in late 2014, has not officially offered any policy recommendations. Mr You, who has a masters degree in biochemistry and molecular biology, suggests tightening regulations on health records to make it harder to transfer them overseas.

Although most of the Trump administration's top science jobs are vacant, Mr You insists the FBI's concerns are "starting to get more traction" inside government.

Outside Washington, views are mixed. "I don't think he's an alarmist. He's raising some questions that need to be asked and answered," says Ben Shobert, senior associate at the National Bureau of Asian Research.

But Bernard Munos, senior fellow at the Milken Institute's FasterCures, says the bureau's concerns are exaggerated. "What they can steal from us is data," he says of competitors. "Data are a necessary ingredient, but not sufficient. You need bright people who are going to extract knowledge from that data and from that knowledge imagine potential new treatments. At the moment, the capabilities of the Chinese to do that are limited."

FBI officials recognise that science is a global endeavour that would wither if confined within national borders.

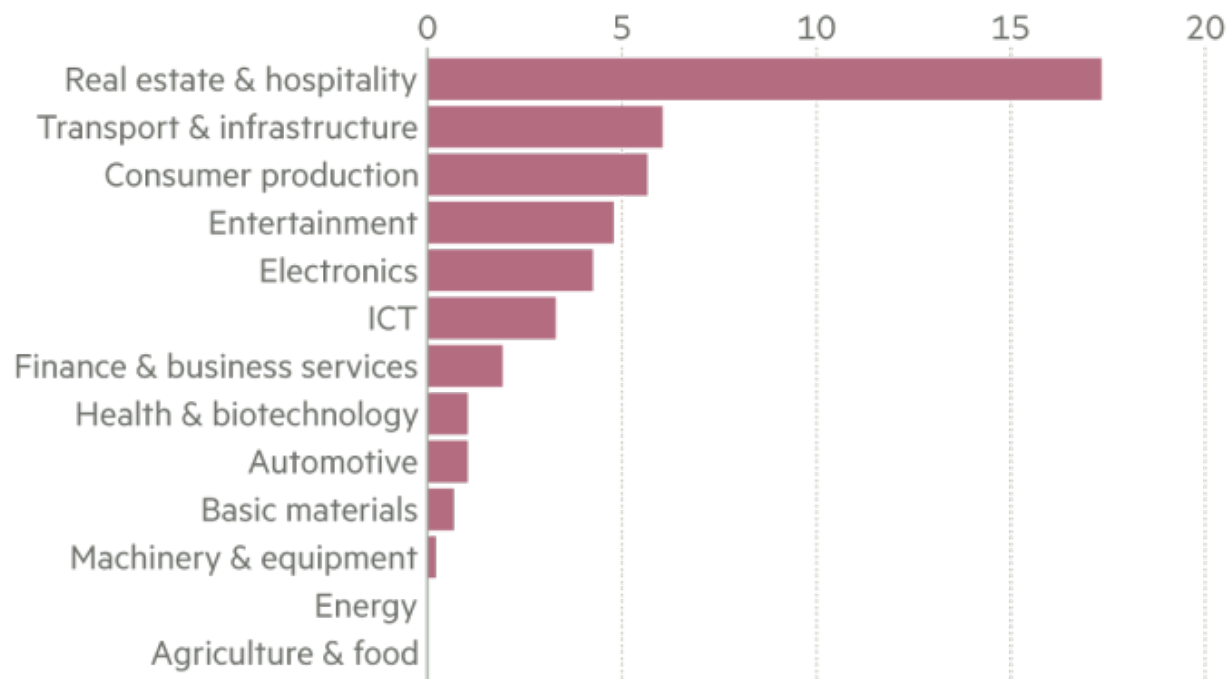
The US Human Genome Project, for instance, would have taken far longer without help from the UK, Germany, France, Japan and China. And roughly 40 per cent of the biomedical scientists in the US hail from China or India, according to Mr Munos.

"US biomedical research could hardly function today without this contingent of people," he says. "The collaboration is an essential part."

That's why cross-border deals so far have faced few objections. In 2013, the US government's committee on foreign investment (Cfius) approved BGI-Shenzhen's purchase of [Complete Genomics](#) in California, which has sequenced more than 20,000 human genomes.

## China's FDI in the US by sector

2016 (\$bn)



Source: China Investment Monitor, Rhodium Group

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Today such a deal might be rejected, says Mr Wessel, a member of the US-China Commission. One reason is a lack of reciprocity. Even as Chinese groups take stakes in US biomedical companies, Chinese regulations prevent foreign companies from taking genetic data out of China, according to Mr Shobert.

Cfius also does not track most foreign loans, non-controlling investments of less than 10 per cent — such as the iCarbonX deal — or stakes in start-ups.

“That’s what’s scaring the crap out of the FBI,” says Mr Rosen. “That the most early-stage interesting stuff, the stuff happening in garages, could get sort of infiltrated with Chinese money.”

In Congress, Senator John Cornyn, a member of the Republican leadership, plans to introduce legislation to expand government reviews of foreign investments to include joint ventures and other technology company acquisitions. “The status quo on investment from China is simply unsustainable,” Mr Cornyn said at a June Council on Foreign Relations event.





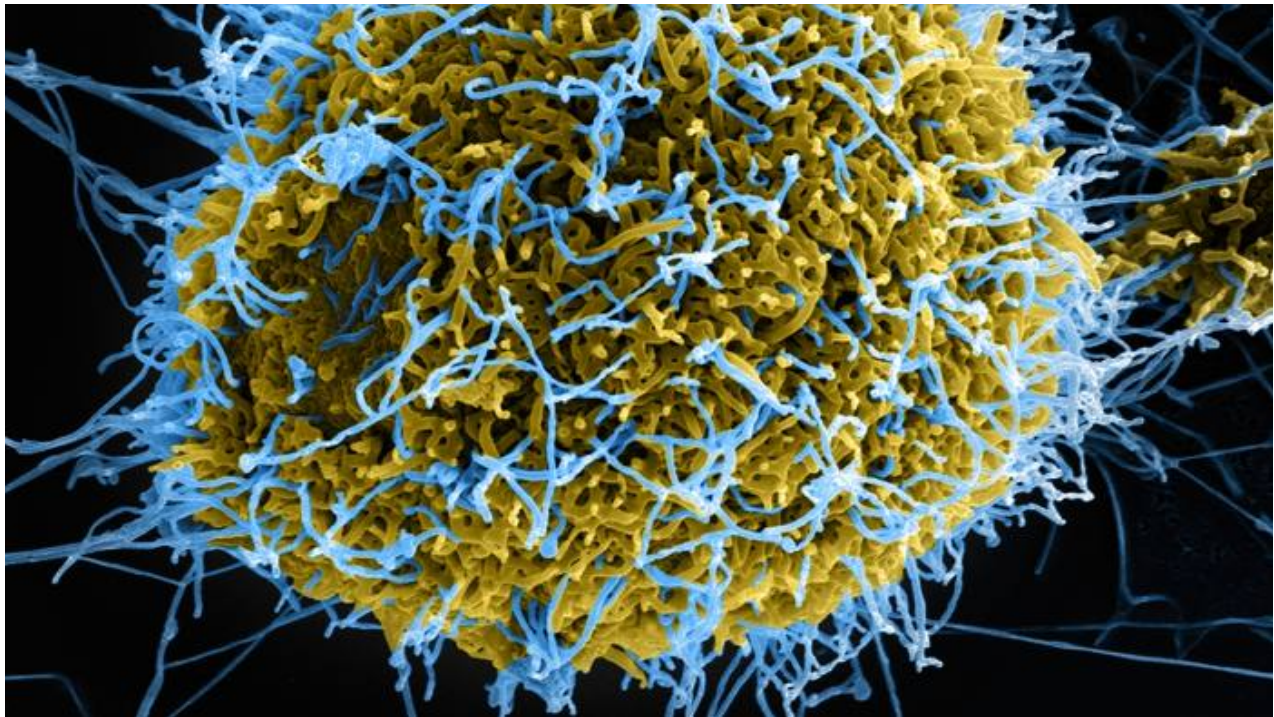
Senator John Cornyn wants to expand legislation on foreign investment to cover joint ventures © Getty

Cross-border deals are not the only risks to US genetic data. The healthcare industry is notoriously vulnerable to cyber attacks. Though most public attention to date has centred on identity theft or pilfered credit card details, patient medical records are even more valuable, says Mr You. Some recent hacks involved “actual penetration and acquisition of clinical data”, he told the US-China commission in March.

In December, hackers infiltrated Quest Diagnostics, which boasts the world’s largest clinical lab database, and gained access to 34,000 patient records, including laboratory results.

Although there is no evidence of foreign involvement in that episode, hackers who US officials believe were operating on behalf of the Chinese government broke into Anthem’s networks in 2014 and spent a year rummaging through records of 78.8m customers, California regulators said in announcing a January settlement with the insurer.

“The healthcare industry in general is far less secure than many other industries and sectors out there. So the ability for a determined actor to get access to that type of information is certainly feasible if they’re motivated to do so,” says Charles Carmakal, vice-president at Mandiant, a cyber security company. “We just haven’t seen it yet.”



Genome sequencing could enable researchers to weaponise or adapt deadly diseases such as ebola. Pictured, a scanning electron micrograph of Ebola virus particles budding from an infected cell © National Institute of Allergy and Infectious Diseases; NIH

Meanwhile, national security risks loom. The US government has long invested in defences against about 60 pathogens and 10 toxins that pose a “severe” health risk, including the Ebola virus, the H1N1 flu virus and ricin.

But advances such as gene editing and next-generation DNA sequencing allow scientists to weaponise new viruses, perhaps including custom pathogens engineered to overcome existing immunities or to be impervious to current drugs. Some experts warn of bioweapons engineered to kill specific populations or even individuals.

Last year, James Clapper, director of national intelligence, included gene editing aimed at producing new biological weapons as among the nation’s top security threats. “The risks are real,” a White House scientific advisory panel said in November, “and will only grow as biotechnology becomes more sophisticated in the years ahead.”

### **Insider threat: Scientist accused of stealing trade secrets**

With a PhD in biological chemistry and four patents to her name, Yu Xue was “one of the top protein biochemists in the world”, prosecutors

said when they charged her with stealing trade secrets from her employer.

Sitting in her GlaxoSmithKline office, across from a golf course in Upper Merion, Pennsylvania, **Ms Xue** emailed confidential documents to her alleged co-conspirators while downloading others on to a thumb drive.

Ms Xue was helping develop a monoclonal antibody, which acts as a homing device to carry a medical agent directly to cancer cells in order to slow or kill the cancer. It is an early example of the precision medicine that offers so much promise for tackling tough diseases — and keeping western drug companies in the global lead. The case highlights what US officials allege is a comprehensive Chinese campaign to acquire US technological secrets.

The alleged conspirators established a company in Nanjing, China, called Renopharma Inc. to market the stolen secrets, which included “step-by-step instructions” for performing tests, GSK’s process for purifying proteins to be injected into patients, as well as experiment results, according to an updated indictment filed on May 24 in the US District Court in Philadelphia.

Renopharma received Chinese government funding, easy loans, a tax holiday and a 4,000-square-foot laboratory rent-free, according to Tao Li, a co-owner who also faces charges.

“Governments in different levels have helped us a lot,” he wrote in an email cited by prosecutors. “This confirmed [to] us that the road we chose is right.”

The group expected Renopharma to have almost \$75m in sales this year, by producing “a new type of drug which possesses Chinese intellectual property rights”, said another email.

Mr Li, Ms Xue and her twin sister Tian Xue, who was also charged, pleaded not guilty. Lucy Xi, who also worked at GlaxoSmithKline, the

UK-based company, has not yet entered a plea and no attorney is listed in court filings for Yan Mei, the final defendant.

At one point, Ms Xue emailed an article about an Eli Lilly scientist indicted for theft. “So scary,” she said.

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