Why you should worry about the privatization of genetic data

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Credit: AI-generated image (disclaimer)

President Obama has promised to support a bold future for medicine where diagnostic testing and treatments aren't just what's best for most people – they're what's best for you.

This "precision medicine" takes individual variations in our genes and

environments into account. Getting there will require genetic and health data from as many people as possible to uncover the relationship between genetic differences and medical outcomes.

This why Obama's Precision Medicine Initiative (PMI) includes the creation of a million-person research cohort. Participants will provide blood and urine samples, share information from their electronic health records and answer questions about health and lifestyle. The hope is that this trove of data will reveal the genetic underpinnings for a variety of diseases, leading to personalized diagnostics and treatments.

It's a bold goal, and one that private companies have a head start on. For instance, 23andMe, a direct-to-consumer genetic testing company, already has a 1.2 million person genetic database.

But genetic data banks amassed by private companies don't necessarily have to follow the same regulations regarding access to their data that federally funded researchers do. And a recent proposal to change consent regulations for human research may make it cheaper for private companies to collect and use this data than public ones.

As bioethicists (myself included) have warned, we need to pay attention to concerns about how these private genetic data banks are used and accessed before we enable a system where the future of public genetic research lies in private hands.

Who can access genetic data?

If you go to a clinic or a hospital to have your blood drawn for a diagnostic test or tissue removed, many will keep that biospecimen, and put it or the data derived from it into a "bio-" or "data bank" for future research.

As long as future research with your specimen or associated data doesn't include any information that links it back to you (like your name), researchers don't need your consent to do their work (though this may change).

If researchers receive federal funding, they often have to submit their data to a public data bank such as the National Institutes of Health's dbGaP, which charges other researchers little to nothing to access this data for future work. Open accessibility is also the goal for the PMI Cohort.

In contrast, private companies like 23andMe, the breast cancer testing company Myriad or the carrier-screening company Counsyl generally get their biospecimens and health data from paying customers who buy genetic tests from them.

Some of these private companies are sharing data with other researchers. For instance, 23andMe collaborated with researchers at Pfizer and Massachusetts General Hospital on the largest-ever study about the genetic causes of major depression. The company also collaborated with Stanford School of Medicine on a study about skin cancer. Both studies were made possible by data from the company's consumers (the financial details of these arrangements are unclear).

Also recently, Counsyl, collaborating with a researcher at Columbia University Medical Center, published a large study on expanded carrier screening (the genetic test it sells).

It's great that these research collaborations are happening, but collaboration isn't the same thing as open access. Private companies are still the ultimate gatekeeper for their data. They choose whom they share their data with. And researchers generally don't have the same level of access to private data banks that they do from existing "public" data

banks or (hopefully) the future PMI Cohort.

When research is done using genetic data that aren't accessible, it is harder for other researchers to check scientific claims – a concern most recently brought up in an editorial accompanying the research based on Counsyl's private data bank.

Some companies can sell genetic data

23andMe can keep and sell its customers' genetic information to others because consumers consent to the sale of their anonymous and aggregate information just by purchasing the product and agreeing to its privacy statement. The company can also sell deidentified individual-level data if you sign the research consent document – which 80 percent of consumers do.

These data are valuable: 23andMe recently announced that the drug company Genetech offered to pay up to US$60 million to use its database to conduct Parkinson's research.

And the fact 23andMe can sell data puts a worrying spin on the proposed changes to consent for federally funded human research.

At the moment, federally funded researchers and private companies have the same standards for consent: If human biospecimens are not "identifiable," they don't have to ask for consent to use them for research.

However, the government recently proposed revisions to the federal human subjects research regulations that would require federally funded researchers to get what is called "broad consent" from people to use their biospecimens (it is unclear what effect this would have on private/public collaborations at the moment). This would apply even if researchers

won't know who the specimens came from. Broad consent would include a general description of types of research that might be conducted with the biospecimen.

While many reasonably argue that this is the right thing to do, it will be expensive. One medical school recently estimated that it would cost them an additional $4 million a year to spend the predicted extra 10 minutes per participant to get informed consent and track who said what. But there are other potential unintended consequences.

For example, these new requirements won't necessarily apply to private companies. This difference in consent standards could encourage a system (as I recently argued) where private companies bring in biospecimens and data, deidentify them, and sell them back to publicly funded researchers – for less than it would cost for the researchers to collect samples and donor consent themselves.

The future of genetic research

If the future of medicine is being launched from biospecimens and related data, we need to think through their storage and access thoughtfully. It's all too easy to create monopolies, which can have dire implications for equitable access.

Take Myriad Genetics. It provides the best diagnostic testing for uncommon genetic variants associated with breast and ovarian cancer (BRCA1 and BRCA2). Myriad held a patent on these genes for over a decade, until 2013, preventing anyone else from doing this type of testing. Even though its patents were invalidated, Myriad still has the biggest BRCA database on the market and remains the leader in the field .

The advantage of Myriad's monopoly is cyclical: The patents allowed it

to accumulate the best data, the best data allow it to offer the best results and the best results mean people keep contributing their data. In this cycle, genetic data with incredible health research potential become just another business asset.

Private industry partnerships can and should play a critical and helpful role in the future of medical research. But our medical information is more than a business asset for private leverage. We need to make sure that public genetics researchers are private industry's partners, not dependents, and that we enable public banks so private ones do not become monopolies.

The future of precision medicine must come from pieces and data from us all – and we need to ensure a data banking system that will be able to benefit us all in return.

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