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Commentary

"The Google of Healthcare": enabling the privatization of genetic bio/databanking

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ABSTRACT

Purpose: 23andMe is back on the market as the first direct-to-consumer genetic testing company that "includes reports that meet Food and Drug Administration (FDA) standards…." But, whereas its front-end product is selling individual genetic tests online, its back-end business model is amassing one of the largest privately owned genetic databases in the world. What is the effect, however, of the private control of bio/databases on genetic epidemiology and public health research?
Methods: The recent federal government notices of proposed rulemaking for: (1) revisions to regulations governing human subjects research and (2) whether certain direct-to-consumer genetic tests should require premarket FDA review, were reviewed and related to the 23andMe product, business model, and consumer agreements.
Results: FDA regulatory action so far has focused on the return of consumer test reports but it should also consider the broader misuse of data and information not otherwise protected by human subjects research regulations.
Conclusions: As the federal government revises its decades-old human subjects research structure, the Executive Office of the President (EOP) should consider a cohesive approach to regulating private genetic bio/databanks. This strategy should allow the FDA and other agencies to play a role in expanding current regulatory coverage.

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Introduction

23andMe is back on the market as the first direct-to-consumer (DTC) genetic testing company that "includes reports that meet Food and Drug Administration (FDA) standards for being clinically and scientifically valid [1]." Its current product includes 36 health-related carrier-status reports and consumers' raw genetic data (in addition to ancestry and other nonmedical "wellness and trait" information) [1]. Forbes has reported that recent investors estimate its value at $1.1 billion [2].

But, that valuation is not on the basis of 23andMe's $199 test kits. Whereas its front-end product is selling individual genetic tests online, its back-end business model is amassing one of the largest genetic bio/databanks in the world [3,4]. Since 2007, 23andMe has offered an inexpensive product to consumers (personalized genetic analysis) to generate broader consumer data and then leveraged that data to generate profit, becoming—as board member Patrick Chung put it—"the Google of personalized health care [3]." And 23andMe recently surpassed its goal of 1 million consumers [5].

Although the focus of the governmental and academic debate surrounding DTC genetic testing has been on whether FDA regulation is enough to protect consumers receiving sensitive medical information without a clinician intermediary [6], the more important question moving forward will be how to manage increasingly large and valuable private bio/databanks. As the U.S. federal government, and in particular the Department of Health and Human Services (HHS), considers revisions to its regulations governing human subjects research to include de-identified human biospecimens and whether certain DTC genetic tests should require premarket FDA review, this article argues that the Executive Office of the President (EOP) should take into consideration potential enabling of the private genetic bio/databank market when contemplating the individual and public health effects of its administrative rulemaking.

The 23andMe bio/databank

When consumers purchase the 23andMe product, the company analyzes hundreds of thousands of their single nucleotide polymorphisms to produce genetic information [7]. In so doing,

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consumers contribute both their saliva specimen to 23andMe's *bio*bank and their genetic analysis to its *data*bank. No matter whether 23andMe is returning ancestry, wellness, trait, or carrier-screening information to the consumer, the genetic data it is generating can be much more robust. Consumers are asked if they would like to have their biospecimen destroyed after their genetic data is analyzed; however, 23andMe's *Full Privacy Statement* adds that it will only do so if "legal and regulatory requirements" do not require it to maintain biospecimens [8]—making it unclear whether and under what circumstances they are destroyed.

In addition to personalized genetic information, 23andMe consumers can also contribute "self-reported information," which includes all information that the consumer explicitly provides, or that 23andMe can track while consumers are signed in to their 23andMe account (note that this means that 23andMe can get data from other websites the consumer is using as long as they are also signed in to 23andMe.com) [8]. This self-reported information includes answers to continuous pop-up surveys on the 23andMe website regarding trait, heritage, health, and family history information. 23andMe consumers answer almost two million questions each week to contribute to its database and it recently launched an "app" to make surveys accessible from mobile devices as well [9,10].

According to the *Full Privacy Statement*, by virtue of "using our Services," all 23andMe consumers agree (among other things) to allow 23andMe to:

- Use *individual-level* genetic and self-reported information to "perform research and development activities;" and
- Share *aggregate* genetic and self-reported information with third parties (including commercial entities) [8].

Of the ~1 million 23andMe consumers, over 800,000 also signed a *Research Consent Document* [9,11]. If a consumer signs this research consent, there appear to be only two major differences from the *Full Privacy Statement*. Research participants additionally consent to:

1. 23andMe providing their deidentified *individual-level* genetic and self-reported information to third parties (including commercial entities); and
2. Enabling 23andMe researchers to receive federal funding for their work and/or publish it in peer-reviewed literature [8,11].

Note that although "research" is typically defined as a "systematic investigation … designed to develop or contribute to generalizable knowledge" [12], 23andMe limits its definition of "research" in its *Research Consent Document* to systemic investigations "aimed at publication in peer-reviewed journals and other research funded by the federal government … " [8,11]. Therefore, 23andMe's definition of research turns on whether a third party will hold it accountable to research industry standards. Information that research participants agree to share also includes "any information you submitted *prior to giving consent* to research (emphasis added) [11]." In addition, if consumers have their sample stored, 23andMe might "use the results of further analysis of your sample [11]."

Lay consumers, or those not reading the *Full Privacy Statement* and *Research Consent Document* carefully and in conjunction, might assume that purchasing 23andMe means that they consent to personally receiving their genetic information and that they will only be involved in research if they sign the *Research Consent*. But, that does not appear to be the case. The major difference between 23andMe consumers and research participants is whether 23andMe can share aggregate or individual-level data with third parties such as commercial entities and how 23andMe can fund and publish the research to which all consumers have already consented via their purchase.

The established breadth of data and dynamic cohort 23andMe has created with these agreements has made it an attractive business partner. The company has access agreements with 30 pharmaceutical and biotech companies—including Alnylam Pharmaceuticals, Biogen, Gentech, Pfizer, and P&G Beauty—in addition to partnerships with academic and nonprofit organizations [9,13]. As the owners of the most samples from participants with Parkinson's disease, for example, 23andMe recently entered into a $60 million whole genome sequencing deal with Genentech. Anne Wojcicki, cofounder and CEO of 23andMe, was blunt: "we can do things much faster and more efficiently than any other research means in the world [14]."

Potential problems with the 23andMe cohort

Although some companies vie for the opportunity to collaborate with and gain access to 23andMe's database, there are others who have voiced caution. A first concern is related to demographic bias. Private data sets are much more likely to be populated with educated, wealthy, white participants (a selection bias problem 23andMe itself has tried to address [15]). Such cohort disparities can skew research agendas in the future as researchers only have access to data from a limited portion of the population [4].

A second concern is the intended outcomes of such a private database. Although 23andMe has advertised its research agenda as creating a cohort to "produce revolutionary findings that will benefit us all," its actual outcomes have been more limited. Some 23andMe consumers, for example, were surprised on May 28, 2012 when 23andMe announced it had filed for and received a patent on "polymorphisms associated with Parkinson's disease." Some consumers complained on the 23andMe website about the perceived lack or miscommunication about appropriate outcomes of its Parkinson's research [16]. A similar issue (unrelated to 23andMe) was litigated in a 2003 Florida case where over 100 families affected by the genetic disorder Canavan disease donated money, blood, tissue samples, and health information to researchers at Miami Children's Hospital to support their research in isolating the genetic variant associated with Canavan to help other families. When Miami researchers did so, they patented the diagnostic test. The families sued the researchers, but a Florida court found that (although they might have had a case for unjust enrichment) because the families had voluntarily "donated" their specimens, they could not prevent the patent and collection of related licensing fees [17].

Third are potential privacy issues. Although the current regulatory structure, discussed in the following section, largely bases its protections on whether data are *identifiable* or not, large-scale and whole genome sequencing have resulted in genetic data that, while perhaps not readily identifiable, are uniquely identifiable as belonging to only one possible individual [18]. For example, in 2013, Gymrek et al. reidentified the deidentified personal genomes of over 50 consumers of a genetic genealogy database [19]. Beyond outsider misuse of data is also the possibility of *sponsor* misuse such as, for example, in 2010 when 23andMe mistakenly sent the wrong genetic test results to 96 customers [20].

Last (for the purposes of this article) is the issue of data access. Beginning with the Human Genome Project in 1990, policy makers and public health professionals have emphasized the importance of public access to genetic databases [21]. Although some argue that commercial interest and funding is critical to encourage innovation of therapies, others point out that it is only through open access that researchers can support and work with as much data as possible—as well as verify the results of such research [21,22]. Genetic epidemiology can contribute to preventative public health measures by, for example, isolating environmental versus genetic risk factors. But, access to a large data set is required to do this research, with some hypothesizing that a genetic cohort would need at least

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