

23andMe: Future of Personal Genomics Services Business?

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Introduction

Anne Wojcicki, CEO of 23andMe, was deeply concerned about the warning letter she received from the Federal Drug Administration (FDA) that could greatly affect the future direction of the firm. 23andMe had ignored previous FDA warnings about its direct-to-consumers approach for genetic reports based on its saliva test kits. On November 22, 2013, the FDA sent a formal notice to 23andMe indicating that its genetic testing service was a “medical device” that needed FDA approval before marketing (see Appendix A). The FDA warned the firm to stop marketing its personal genome service.

In response to the letter, 23andMe suspended preparing genetic reports, but continued to sell testing kits as shown in the 23andMe Key Events Timeline (see Table 1). The 23andMe saliva test kits and genetic reports were gaining customers; however, some customers, clinicians, and government officials were concerned about the accuracy of the tests and reports, the privacy of customers, and the health consequences of selling direct to consumers (United Health Group, 2012).

Was the FDA warning letter merely a bump in the road or a major crossroad? Observers denoted Wojcicki’s reactions and her continued emphasis on the firm’s mission. However, selling the test kits and ancestry reports created serious ethical, regulatory, and strategic challenges for the firm (Annas, Roche & Green, 2008; United Health Group, 2012; Hiltzik, 2013; Ormond & Cho, 2014).

23andMe’s Business Model

CEO Anne Wojcicki said the company’s vision was, “*to help people access and learn from their genetic data, get the general public to become a part of a mission-based culture by joining their gene pool.*” The mission was, “*to be the world’s trusted source of personal genetic information.*” Keeping in mind the vision and mission, 23andMe claimed that its goals were to contribute to the scientific research and advancements in genetic knowledge. The company believed to achieve this; they needed to collaborate with other scientific organizations.

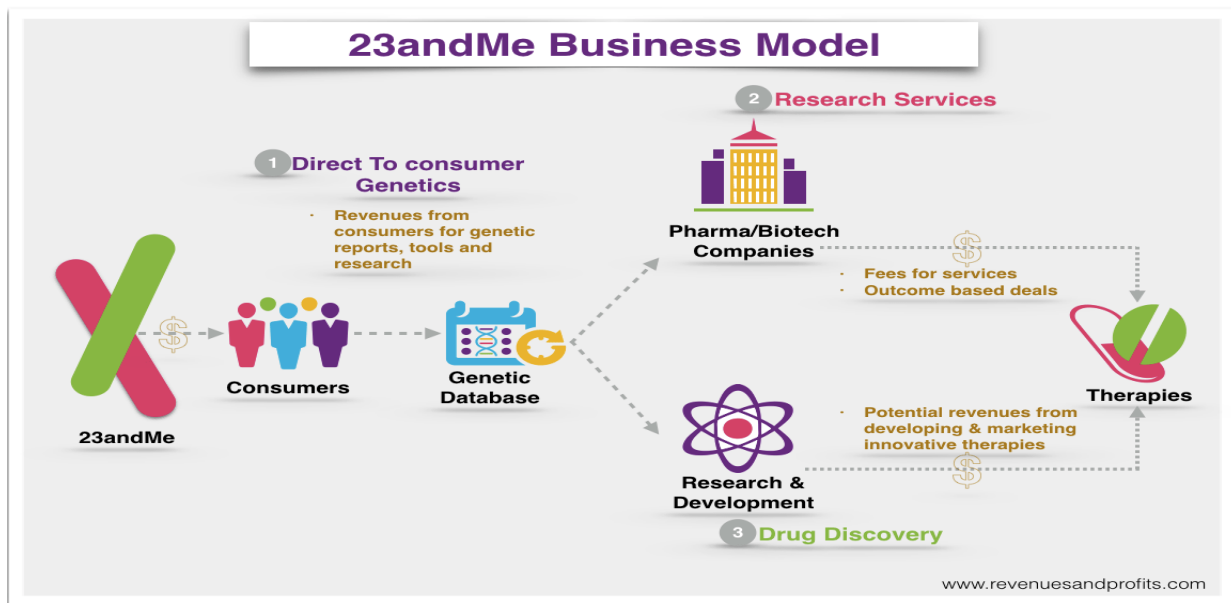
Figure 1 depicts 23andMe's business model evolved since the firm's founding in 2006 to include three lines of business. The 23andMe Direct to Consumer (DTC) genetic line of business was the front end for collecting massive health information that feed the other two product lines (Revenuesandprofits.com, 2017). The company sold reports to consumers based on the results of genetic tests of customers' DNA provided in saliva kits sent in the mail. The consumers' DNA results were added to 23andMe's database, which allowed the company to produce reports about consumers' ancestry and the susceptibility to certain diseases based on their genetic code.

In the DTC genetics business, the firm sold mail order kits for genome sequencing to individual customers. After buying the kit for \$99 to \$199 and registering their profile online, users mailed their saliva sample to 23andMe. The company used sequencing analysis to generate more than 60 reports with unique information on carrier status, wellness, genetic ancestry, and health traits. The company stored customer genetic information against the user profile and shared it with the users online in an easy to understand format. 23andMe combined genetic information from its database with voluntary information shared by the consumer volunteers to find possible genetic links to people's traits.

Through this process, 23andMe generated data for genetic research. Information in this second line of business (Research Services) was sold to Pharmaceutical and Biotech firms, including facilitation of enrollment of patients in clinical research (Revenuesandprofits.com, 2017).

In addition, 23andMe conducted its own in-house research. It had ambitious plans for this new, Research & Development third line of business to disrupt the R&D process and enter the drug discovery space (Revenuesandprofits.com, 2017).

Figure 1. 23andMe Business Model



Source: (Revenuesandprofits.com, 2017; 23andMe.com, 2017)

In 2011, 23andMe reduced its price for the test kits from \$ 999 to \$ 799 to \$ 299 and eventually \$ 99-\$ 199 to gain market share and deter competition (Delevett, 2011; Timmerman, 2011; Murphy, 2013).

23andMe's long-range goal was to collect a massive biobank of genetic information that could be used for medical research and potentially lead to patentable discoveries (Annas & Elias, 2014). The large database of genetic information from 23andMe customers had the potential to transform the way biotech companies conducted research to receive FDA approval and market its products (Somerville, 2014). Since most medical studies took months or years to solicit enough volunteers for clinical trials, the 23and Me genetic information would allow medical studies to be fast-tracked and new treatments to make their way into hospitals sooner, experts say, giving patients with chronic diseases a better quality of life (Somerville, 2014). *"Instead of actually having to do clinical trials the old-fashioned way, we can enable researchers to get their answers instantaneously,"* Wojcicki said in an interview with a newspaper. *"And they pay us for that"* (Somerville, 2014).

Legal and Regulatory Issues

The Regulatory Environment

The federal Food, Drug, and Cosmetic Act passed by Congress in 1938 to regulate the safety of drugs for the U.S. public included genetics, according to the Food and Drug Administration (FDA, 2014). The view of the FDA was genetic test kits fell into the medical device category that required FDA approval. Medical devices included in vitro diagnostics that detected diseases, conditions, or infections used in laboratory, other health professional settings or for consumers to use at home (FDA, 2014). The sale of genetic products directly to consumers without the involvement of a licensed practitioner had multiple health care risks. The FDA was mainly concerned that inaccurate genetic tests could lead to poor diagnosis and unwarranted customer concerns and actions (Eisen, 2013).

The agency seemed to be less concerned about 23andMe selling genetic data to third party companies, research institutions, and nonprofits. Relations between 23andMe and the FDA had been positive but became sporadic in 2013. When 23andMe's cooperation with the FDA stopped in 2013, the FDA's view was that it needed to take action on behalf of the public.

On November 22, 2013, the FDA sent a formal notice to 23andMe indicating that its genetic testing service was a "medical device" that needed FDA approval before marketing. The FDA ordered the firm to stop marketing the personal genome service (see Appendix A).

Following the FDA notice, 23andMe continued to sell the test kits but suspended their DTC genetic reporting service and in early 2014, management was concerned about its impact on the direction of the firm. In response to the FDA letter, Wojcicki said, *"We remain firmly committed to fulfilling our long-term mission to help people everywhere have access to their own genetic data and have the ability to use that information to improve their lives. Our goal is to work cooperatively with the FDA to provide that opportunity in a way that clearly demonstrates the benefit to people"* (Hof, 2013).

GINA - Genetic Information and Non-discrimination Act

Numerous state and federal laws covered the role genetic information played in preventing access and upward mobility in employment (i.e., HIPAA, ERISA, and California Privacy Law). The federal Genetic Information and Nondiscrimination Act (GINA) of 2008 focused on discrimination in employment and health insurance based on genetic disposition (Pub.L.110-233, 2008). This federal law barred employers from using an individual's genetic information when making hiring, firing, job placement, or promotion decisions and prohibited health insurers from denying coverage or charging higher premiums based on an individual's genetic disposition or likelihood of developing a disease in the future.

GINA provided broad coverage of genetic information but it did not include an analysis of proteins or metabolites that is directly related to a manifested disease (Annas et al., 2008). These authors (Annas et al., 2008) concluded GINA did not change the rules on how group health plans and insurers acquired or used information about an enrollee's history of genetic or any other type of illness. However, it did not prevent the insurance company from increasing an employer's premium based on the manifestation of a disease of an employee already enrolled in the plan nor did it cover other types of insurance, such as long-term care insurance and disability insurance (Annas et al., 2008).

Ethical Issues

In addition to any legal and regulatory issues, there were concerns that 23andMe's services, operating methods, and business models presented unresolved ethical issues in seven areas.

1. Consent

On the 23andMe website, customers were required to give their consent for genetic indication of disease susceptibility, and to opt in or out of future research. This consent was given without input from a physician or genetics counsellor, and perhaps without the customer's full understanding of what the consent really meant. In addition, customers gave consent to sharing their DNA and self-reported data with 23andMe as well as third party researchers.

Some customers feared that many types of sensitive data were embedded in their genetic code and spelled trouble if it fell into the wrong hands. For example, they feared information stored in their genes might be used to discriminate against them or used to send targeted ads.

2. Interpretation of Results

23andMe provided its reports directly to consumers on its website. No trained medical professional discussed the results with customers, who were left to interpret the results by themselves or seek additional support in their interpretation from their own doctor. Therefore, customers likely had very little understanding of the impact that a genetic test result could have on them or their families, or what it might actually mean.

3. Accuracy

Clinician scepticism about 23andMe's Saliva Collection Kit and Personal Genome Service was not a new thing. In 2012, UnitedHealth Group published a report expressing concern about the accuracy and affordability of 23andMe's kits (UnitedHealth Group, 2012).

4. Privacy

23andMe offered customers an option to take part in further research. Although GINA prohibited discrimination by employers and insurance companies based on genetic information, there remained the major ethical issue of privacy. If 23andMe could sell mailing lists to drug companies, to what extent would that violate an individual's privacy?

5. Access to data for the public good

With its for-profit business model, 23andMe was potentially limiting access by research institutions to invaluable data, which could slow down scientific searches for disease treatments as well as promote a bias in the type of diseases studied (Maxwell, 2016). Some customers believed that in addition to learning something interesting about themselves, they were contributing to the fight against disease by providing valuable genetic information. This may have been so, but there were critics. Marcy Darnovsky, Executive Director of the Center for Genetics and Society, commented: *"Many of us would be delighted to contribute to medical advances. But handing over reams of our genetic, health and personal information to companies like 23andMe – and paying them for the privilege – isn't the best way to do that"* (Darnovsky, 2015).

6. Misrepresentation and False Advertising

23andMe had been accused of misrepresenting the accuracy of its testing and its applicability to all ethnic groups. One dissatisfied customer, upon learning that fewer than 100 Koreans had submitted DNA to the 23andMe database wrote, *"I doubt that most 23andMe users realize how paltry the company's data is for non-Caucasians"* (Hong 2016). In 2013, Lisa Casey and others filed a \$5 million class action suit against 23andMe, alleging that the company used false and misleading advertising to promote its services, and that the test results were "meaningless." Mark Ankorn, lawyer who filed suit on behalf of Casey, said, *"It seems to me to be a very thinly disguised way of getting people to pay them to build a DNA database."* Previously mentioned critic, Darnovsky, suspects this had been 23andMe's plan from the very beginning: *"This wasn't a change in their business plan, it was the fulfillment of the next phase of the plan they've had since the beginning. To some people, it was clear all along what the business plan must be because they can't keep up a business selling spit kits, especially at only \$99. It was buried in the fine print for years"* (Paul, 2015).

7. Conflict of interest

23andMe's proximity to Google was also a concern. Anne Wojcicki was the ex-wife of Google co-founder Sergey Brin. Google and Brin had invested heavily in 23andMe. The possibility that Google, in the business of acquiring users' web-browsing data, might also have access to genetic data – and the ability to match the two – truly frightened some observers (Maxwell, 2016). Ormond & Cho (2014) asserted that technical and clinical challenges regarding genetic testing brought up ethical issues that were similar to but qualitatively different from those clinicians were accustomed to dealing with for traditional medical genetics. Hence, the vast amount of information that genome sequencing produced caused clinicians to rethink ethical principles related to informed consent, privacy, and data ownership and sharing, technology regulation, issues of access, particularly as new technology was integrated into clinical practice, and issues of potential stigma and impact on perceptions of disability (Ormond & Cho, 2014).

Industry Background

It was generally thought that the personalized genomics industry was initially comprised of proactive people with money, knowledge, and above average awareness about genomics but the industry expanded. Murphy (2013) indicated that online business marketing expert, Brandon Gaille, estimated the personalized genomics (PGS) niche within the biotechnology industry reached approximately 500,000 customers in 2013. Major niche players were categorized as the medical laboratories, SIC code 8071, and under the business category as medical laboratories miscellaneous (Manta.com, 2013; NAICS Association, 2012). A year earlier, the UnitedHealth Group published a report indicating that spending on genetic tests in the United States had reached an estimated \$5 billion annually and could top \$25 billion within a decade (UnitedHealth Group, 2012). Color Genomics, Counsyl, and Pathway Genomics competed in this niche and companies such as Ancestry DNA, Family Tree DNA, Home DNA, and Geno 2.0 also offered saliva test kits based on their individual business objectives. Murphy (2013) denoted that initially deCODEme, Navigenics, and Pathway genomics were the major competitors for the dominate player, 23andMe, in the PGS space. Each competitor used similar saliva testing technology to gather genetic information and substitute techniques such as blood samples were deemed more invasive for customers and costlier.

It was customary in biotechnology to fund operations by raising venture capital (VC) funds prior to FDA approval. Hence, the dominate player, 23andMe, was heavily financed through several product development stages from Google, VC firms, health science companies, government grants from the National Institute of Health (NIH), and strategic angel investors (23andMe, 2012/2017). The PGS customer base was expanding and companies used different laboratories to do testing of the kits. Yet, Illumina was the only industry supplier for the DNA sequencing equipment that PGS companies needed for generating genetic reports from their test kits. Although Illumina was a sole supplier, it had not indicated interest in vertically integrating and getting into the business of their PGS customer. There was price competition in the industry and 23andMe offered the lowest unit price (\$99 for ancestry kit and \$199 for ancestry kit and health report) compared to DeCode Genetics \$985, and Navigenics \$2,499 (Murphy, 2013). This price competition helped to expand the PGS market; yet, pricing made it difficult for new firms to enter the niche market. Pricing, branding, and financial backing of 23andMe reduced rivalry that often existed in expanding markets. Moreover, the low-cost service helped dominate player 23andMe to amass a huge database of genomic information associated with a number of diseases such as Parkinson's etc. that researchers and large pharmaceuticals coveted.

Company Background

23andMe was founded in Mountain View, California in April 2006 by Anne Wojcicki, Linda Avey, and Paul Cusenza. The name 23andMe was based on the 23 pairs of chromosomes in human cells (23andMe, 2012/2017). This privately held personal genomics company was concerned with sequencing and analysing an individual's DNA but depended on external funding to cover its operations (23andMe Inc., 2012). The firm's Key Events Timeline showed 23andMe had experienced tremendous growth from April 2009 to March 2014 to become the dominate company in its medical laboratories market niche (see Table 1).

Table 1. 23andMe Key Events Timeline

Year	Key Company Events
April 2006	Founded by Anne Wojcicki, Linda Avey and Paul Cusenza.
May 2007	Google invested approximately \$3.9 million in the Series A preferred stock financing of 23andMe.
February 2009	Teamed up with MJ Fox Foundation and Parkinson’s Institute for the Parkinson’s Project to study genetics of Parkinson’s disease with human database.
June 2009	Google invested approximately \$2.6 million in the Series B preferred stock financing of 23andMe. Google also entered a lease agreement with 23andMe.
December 2012	Yuri Milner, the Russian billionaire that invested in Facebook, Twitter, and Airbnb, joined as a financial backer.
September 2013	US patent awarded to 23andMe for gamete donor selection based on genetic calculation giving exclusive rights to genetic and computer technologies and enable prospective parents to handpick a sperm or egg donor.
November 2013	FDA wrote letter to 23andMe asking them to stop marketing their personal genomics service.
December 2013	23andMe discontinued consumer access to its health-related genetic tests.
February 2014	23andMe response to FDA and resumed marketing of ancestry reports with test kits.
March 2014	FDA responds to 23andMe compliance to stop advertising availability of health reports.

Source: Authors’ Notes

Management Team Backgrounds

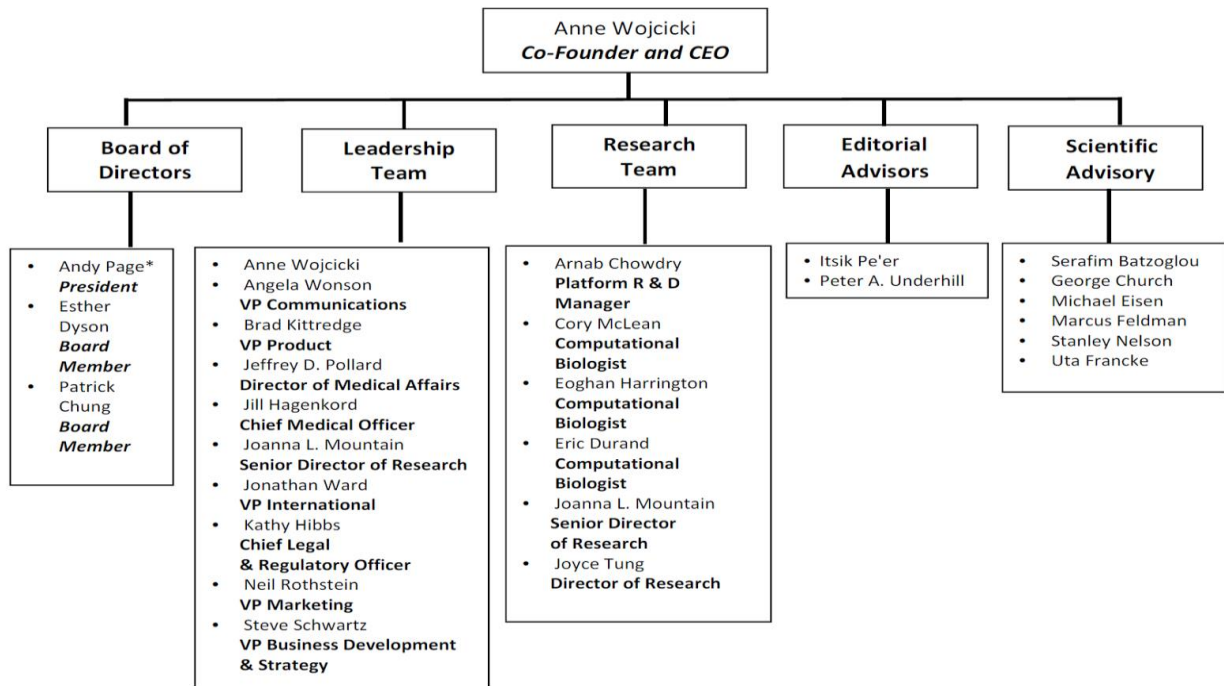
As the company grew, the top management team consisted of the CEO, Anne Wojcicki and the Board of Directors (BOD); Andy Page, Esther Dyson, and Patrick Chung. Wojcicki graduated from college with a B.S. in biology and did molecular biology research at the National Institutes of Health and the University of California, San Diego. After graduating, she worked as a health care consultant at Passport Capital, a San Francisco-based investment fund and at Investor AB. She was a health care investment analyst for 4 years, overseeing health care investments, focusing on biotech companies. She became disillusioned by the closed culture of Wall Street and its attitude towards health care. Wojcicki quit her job in 2000 and decided to focus on research that led to her co-founding 23andMe (CNBC, 2017b).

Organizational Structure

Andy Page, joined 23andMe as President of the company and BOD member to boost executive experience in the firm. Page had extensive management, industry, and financial experience; however, Wojcicki was the founder, visionary, and key decision-maker (23andMe, 2012). The leadership team, research team, editorial team, and scientific advisory team formed the top level

in the company's hierarchy. All teams at 23andMe reported directly to the CEO of the company (see Figure 2). The leadership team, the largest team in the organization as it appeared on the company's website, was comprised of Vice Presidents of Marketing, Communications, Products, Business Development of Strategy to name a few of the top management positions (see Figure 2). The divisions (not shown in Figure 2) reporting to these teams followed a functional structure. For example, 23andMe had functional divisions such as research and development, scientific advisory, and sales.

Figure 2. 23andMe Organizational Chart



Source: (23andMe, 2012)

Most employees in the divisions were from similar scientific and biotechnology backgrounds, but few had a management background (23andMe, 2012). This job similarity created a job or company task culture that helped to meet company goals but might have prevented needed change. For instance, initial lack of a strong team for regulatory affairs had turned out to be a concern for 23andMe when they had conflicts with the FDA. Patents were another area that did not appear to have enough structural focus early on because of strong scientific similarity and lack of management experience in monetizing scientific innovation. The patents 23andMe possessed were unclear because they were unable to monetize the value of information (Hogarth, 2012, Jeffries, 2012). Wojcicki saw similarity with politicians that got in the way of making change in the genetic health area and said, "I just suddenly realized that there are so many people trying to make money off the inefficiencies in the system that it's never going to change from within." (Cha, 2008). This reflection about the "sameness" in Washington politics, the Wall Street closed culture, and current company internal challenges caused Wojcicki to make internal changes in her organizational structure (CNBC, 2017a; CNBC, 2017b).

Leadership

Leadership can be a strategic competitive advantage and like company culture, it was an important part of the 23andMe's strategic implementation (David, 2009; Barney, 2010; Rothaermel, 2015). Some observers described Anne Wojcicki's leadership style as charismatic and altruistic while others described her style as transformational because she founded this innovative company to transform how the world looked at genetics. Wojcicki's leadership approach appeared to be different inside the firm than with the FDA and different with each level of 23andMe management but did her style evolve as the company evolved? In a recent interview with Anne Wojcicki by Fast Company regarding how to have a more fulfilling and productive relationship with your boss, she stressed not micromanaging and how to get periodic feedback from your boss (Fast Company, 2016). In another interview with Glassdoor about looking back at her career, Wojcicki indicated she tried to be educational and inspirational about how the world viewed genetics and health, while staying task-focused internally regarding how to get it accomplished (Jackson, 2016). The Jackson (2016) interview revealed Wojcicki was a multi-tasker and goal-oriented at the personal level. The company vision and mission were shaped by the CEO and provided some insight into Wojcicki's leadership style. Additionally, the initial organizational structure of 23andMe reflected her team-based orientation. Wojcicki became more combative and transactional in 2013 as frustration on both sides increased (Parmar, 2013). Observers suggested that as the company's relationship with the FDA changed, she changed.

Organizational Culture

The "right" culture was a culture that closely fitted the direction and strategy of a particular organization as it confronted its own issues and the challenges of a particular time (The Tipster, 2013; Jones & George, 2017). Did the culture fit the evolving challenges (see Table 1) that 23andMe faced as it evolved? Glassdoor conducted several interviews with Anne Wojcicki and she described the company culture as values oriented, mission-driven, inquisitive, stimulating, fun, and rewarding with an opportunity for everyone to grow. Wojcicki indicated employee's individual interests were encouraged and were believed essential to form a well-rounded team (Fast Company, 2016; Jackson, 2016). However, Wojcicki also encouraged her employees to work in teams as a family. Management researchers suggested there were four types of organizational cultures and clan (family) culture was one effective way to mobilize culture to reinforce company goals (Tipster, 2013; Jones & George, 2017). The company's organizational structure emphasis on teams also suggested it was a team and family-based culture (see Figure 2). Employees described the company culture as very casual and employee friendly with numerous perks for health and personal benefits (Fast Company, 2016; Jackson, 2016).

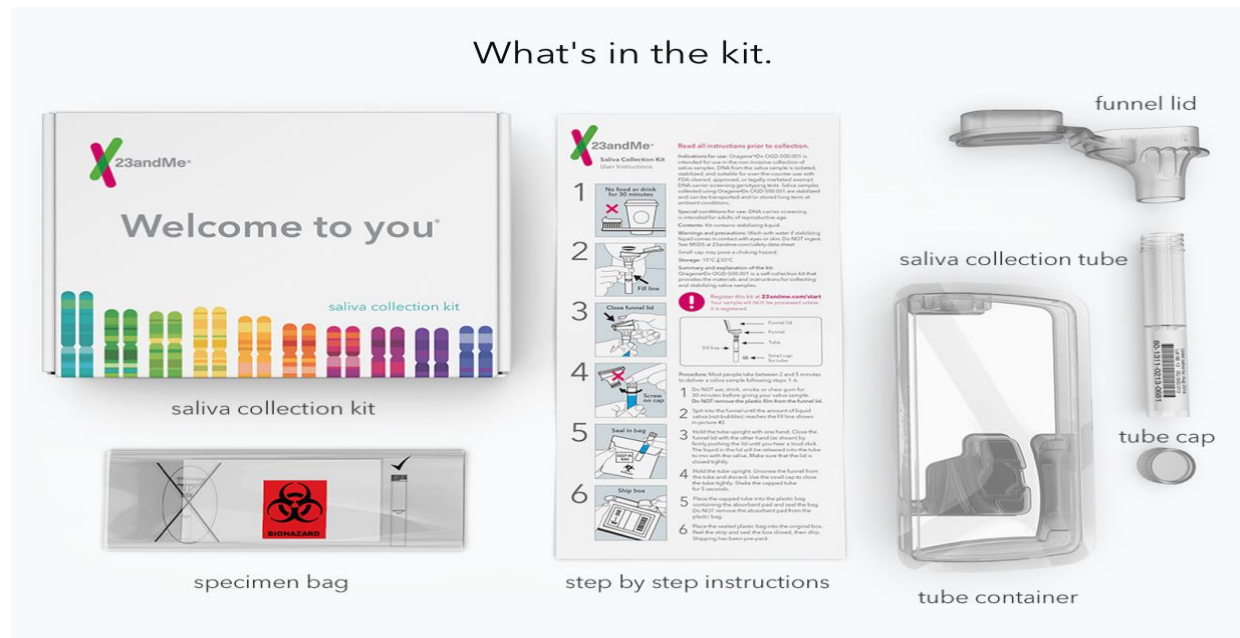
Product Marketing Considerations

Product

The company provided customers with a Spit Collection Kit comprising of a tube in which they gave their saliva sample to be sequenced and analysed (genotyped). 23andMe's services relied on single-nucleotide polymorphism (SNP) technology to identify genetic markers associated with 254 specific diseases and conditions (the list grew over time), and the company advertised it could inform people about their health and how to take steps to improve it (Annas & Elias, 2014). 23andMe used Illumina HumanOmniExpress-24 format chip with a custom panel of

probes for detecting genetic variations (Bloomberg, 2017; 23andMe, 2017). Each customer's DNA was genotyped to understand their ancestry and probability of occurrence of any genetic diseases. Uninterpreted data was made available on the 23andMe website.

Figure 3. What is in the 23andMe Kit?



Source: (23andMe.com, 2017)

Price

When 23andMe was founded, the personal genomics service and the saliva tool kit (see Figure 3) were priced at \$999. However, to achieve their goal of reaching one million entries on their database, they reduced their price to \$99 (\$99 for ancestry kit and \$199 for ancestry kit and health report) in 2013 to increase their popularity and deter competition (Delevett, 2011; Timmerman, 2011; Murphy, 2013). 23andMe made revenue with this direct to consumer (DTC) approach for personal genetic tests with two products, the ancestry discovery report (\$99 per report) and ancestry plus health conditions (\$199 per report) covering over 240 diseases before branching out into research services and drug discovery. 23andMe became the best-known name in the industry with the innovative idea of connecting directly to the customers. The DTC service of 23andMe resulted in the company's marketing approach named 'invention of the year' by Time magazine in 2008 (Hamilton, 2008). Additionally, the company gave its customers an opportunity to leverage their personal data by contributing it to the study of genomics. With approximately 300,000 DNA samples in their customer base, the goal was one million customers (Hamilton, 2008). Thus, 23andMe had access to the most precious data a person can give - personal genetic data.

Promotion

The direct to consumer marketing (DTC) was not a new marketing mix idea for consumer-oriented companies (Vitale, Giglierano & Pfoertsch, 2010; Kotler & Armstrong, 2013). The

DTC marketing approach reduced selling expenses for the typical company and provided pricing flexibility to meet competition. 23andMe sold mail order kits for genome sequencing to individual customers. DTC was a novel marketing approach for biotech companies when 23andMe introduced DTC marketing in 2006 because it eliminated the licensed practitioner that usually interpreted information about medical devices and gave medical advice about test results. Direct marketing the saliva kit was a big resource saving and branding deal for 23andMe. However, DTC became controversial when 23andMe began to bypass the industry regulator, FDA. 23andMe used Internet ads in addition to in store, direct mail advertising, and television. The company had a national advertising budget of \$5 million for 2013 (Hiltzik, 2013).

Place

The California-based 23andMe was a global company that generated most customer contact through the company website. 23andMe believed the combination of in-store and on-line contact with customers was the best approach. Co-founder and CEO Anne Wojcicki argued that her company was one of personal health empowerment; in fact, she said, “a massive chunk of the two million-plus 23andMe customers around the globe have made lifestyle adjustments based on information gleaned from their tests” (Mukherjee, 2017).

Funding Sources

Since its founding as a private company in 2006, 23andMe had received large amounts of external funding from VC firms, health science companies, government grants from the National Institute of Health (NIH), and strategic angel investors (23andMe, 2017; Crunchbase, 2017). It was customary in the biotechnology industry to raise venture capital (VC) funds in rounds/stages (series A, B, C, etc.) according to the product development stage results (see Table 2).

Table 2. 23and Me Funding Rounds

Date	Round	# of Investors	Amount \$ Raised	Main Investor
Dec 21, 2012	Series D - 23andMe	6	\$ 50,000,000	Yuri Milner + Others
Jan 7, 2011	Series C - 23andMe	2	\$ 9,000,000	-
Nov 9, 2010	Series C - 23andMe	3	\$ 22,220,289	Johnson & Johnson Dev. Corp. + Others
Dec 23, 2009	Series B - 23andMe	-	\$ 14,200,000	Google + Others
Jun 18, 2009	Series B - 23andMe	3	\$ 13,600,000	Google + Others
Oct 3, 2007	Series A - 23andMe	5	\$ 8,953,320	Google + Others
May 2007	Series A -23andMe	-	\$ 3,900,000	Google

Source: (Crunchbase, 2017; 23andMe, 2017)

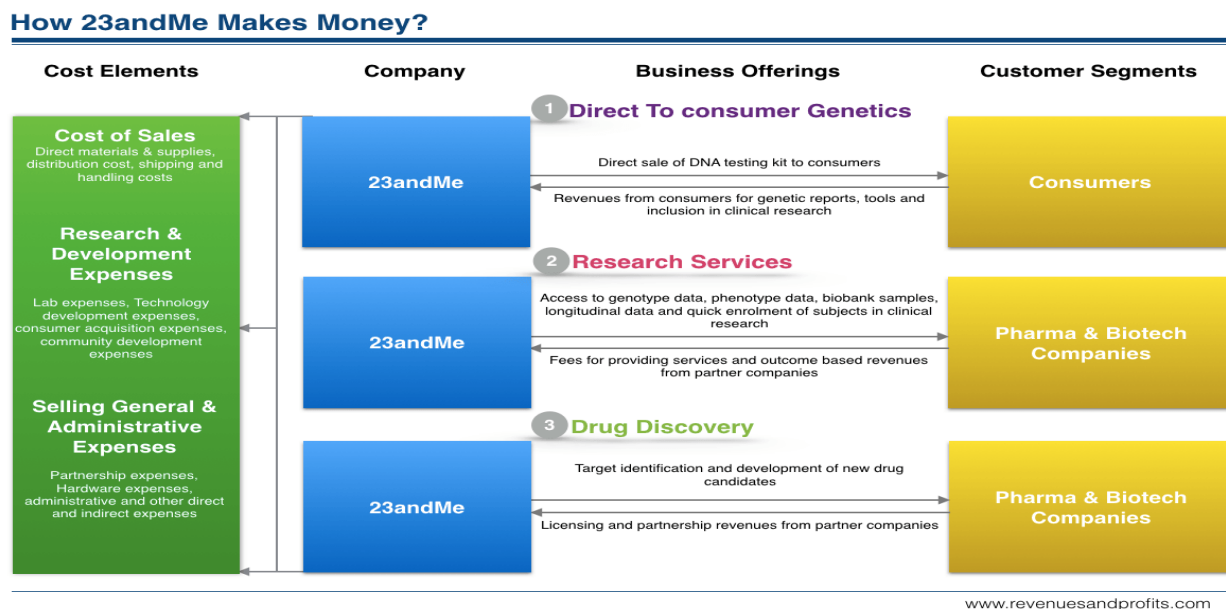
At the start, Wojcicki received an investment of \$3.9 million in Series A preferred stock investment from her husband and his firm (Google) to finance the company (Helft, 2007). In 2009, Google along with others invested \$2.6 million in Series B preferred stock. Among many other high-profile individuals who invested in the firm was a multi billionaire, Yuri Milner (see Table 1). Other investors included Johnson & Johnson Development Corporation who invested

\$9 million, New Enterprise Associates which did a Series B financing, MPM Capital, and the Roche Venture Funds.

23andMe received most of its revenue from the \$99-\$199 customers paid in return for test-tube kits and results customers get back after they send off spit-filled tubes (Murphy, 2013). *"The long game here is not to make money selling kits, although the kits are essential to get the base level data,"* says Patrick Chung, a 23andMe board member and partner at the venture-capital firm NEA. *"Once you have the data, the company does actually become the Google of personalized health care"* (Murphy, 2013).

Figure 4 does not equate revenue to net income or profit. As of December 2013, 23andMe was a privately held company, thus annual public financial statements were not available.

Figure 4. How 23andMe Makes Money



Source: (Revenuesandprofits.com, 2017)

Some industry observers indicated that genetic data on a massive scale was likely to be an extremely valuable commodity to pharmaceutical companies, hospitals, and even governments (Murphy, 2013). Chung stated, *"This is where the real growth potential is and as 23andMe scales, its business model will shift"* (Murphy, 2013). 23andMe continued to raise money for expanding the business in these new directions and began to look beyond VCs, government grants, health companies, and angel investors and considered big Pharma business partners for funding (Hamilton, 2007). Typically, late stage biotech companies had waited at least a year since its last round of VC to go public (IPO); however, the need for fresh capital to expand might force a reluctant Wojcicki to reconsider (Buhr, Lynley, Roof & Loizos, 2017). CEO Anne Wojcicki remained silent on whether the company will go public anytime soon. Yet, with a valuation of more than \$1 billion, according to PitchBook, and the recent spate of good news from the FDA plus a favorable stock market, this situation could soon change (CNBC, 2017a).

The Management Challenges

Prior to the November 22, 2013 FDA warning letter that was sent to 23andMe to stop marketing genetic-based health reports based on its saliva test kits, the firm had been successful attracting resources to develop the technology for its test kits and market these kits directly to customers (see Table 1 and 2). The 23andMe business model and sustainability were dependent on these test kits for ancestry reports, reports that customers might develop specific diseases based on their genetic code, and dependent on collecting information for genetic research (see Figures 1, 3, and 4). The company wanted to reach 1,000,000 customers, and if 23andMe decided to permanently discontinue these kits, the sustainability of 23andMe was in doubt.

Should Wojcicki lead 23andMe in a proactive, goal-focused manner or should the firm become reactive and continue its focus on the saliva test kits and reports marketed directly to consumers with a low-cost pricing strategy to discourage competition? Hence, Wojcicki needed to decide what actions to take regarding the November 22, 2013 FDA ruling. In response to the 2013 FDA letter, 23andMe suspended selling genetic reports, but continued to sell testing kits and ancestry reports (Annas & Elias, 2014; see Table 1). Looking back from an early 2014 leadership and strategic perspective, how effective was the firm's business model after this company decision and what change – if any – should the CEO make to the business model? Additionally, how should the CEO assess the various ethical issues the firm needs to improve in the seven areas: consent, interpretation, accuracy, privacy, access to data for public good, misrepresentation, and potential conflict of interest? Since important stakeholders such as some disgruntled customers, concerned health care providers, and health care agencies had voiced privacy and other ethical concerns about data security and commercialization of data, what actions should the CEO take to assess and improve 23AndMe's conduct regarding these concerns?

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Appendix A
FDA warning Letter (23andMe, 2013)

23andMe, Inc. 11/22/13



Department of Health and Human Services

Public Health Service
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Nov 22, 2013

Ann Wojcicki
CEO
23andMe, Inc.
1390 Shoreline Way
Mountain View, CA 94043

Document Number: GEN1300666
Re: Personal Genome Service (PGS)

WARNING LETTER

Dear Ms. Wojcicki,

The Food and Drug Administration (FDA) is sending you this letter because you are marketing the 23andMe Saliva Collection Kit and Personal Genome Service (PGS) without marketing clearance or approval in violation of the Federal Food, Drug and Cosmetic Act (the FD&C Act).

This product is a device within the meaning of section 201(h) of the FD&C Act, 21 U.S.C. 321(h), because it is intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure or function of the body. For example, your company's website at www.23andme.com/health (most recently viewed on November 6, 2013) markets the PGS for providing "health reports on 254 diseases and conditions," including categories such as "carrier status," "health risks," and "drug response," and specifically as a "first step in prevention" that enables users to "take steps toward mitigating serious diseases" such as diabetes, coronary heart disease, and breast cancer. Most of the intended uses for PGS listed on your website, a list that has grown over time, are medical device uses under section 201(h) of the FD&C Act. Most of these uses have not been classified and thus require premarket approval or de novo classification, as FDA has explained to you on numerous occasions.

Some of the uses for which PGS is intended are particularly concerning, such as assessments for BRCA-related genetic risk and drug responses (e.g., warfarin sensitivity, clopidogrel response, and 5-fluorouracil toxicity) because of the potential health consequences that could result from false positive or false negative assessments for high-risk indications such as these. For instance, if the BRCA-related risk assessment for breast or ovarian cancer reports a false positive, it could lead a patient to undergo prophylactic surgery, chemoprevention, intensive screening, or other morbidity-inducing actions, while a false negative could result in a failure to recognize an actual risk that may exist. Assessments for drug responses carry the risks that patients relying on such tests may begin to self-manage their treatments through dose changes or even abandon certain therapies depending on the outcome of the assessment. For example, false genotype results for your warfarin drug response test could have significant unreasonable risk of illness, injury, or death to the patient due to thrombosis or bleeding events that occur from treatment with a drug at a dose that does not provide the appropriately calibrated anticoagulant effect. These risks are typically mitigated by International Normalized Ratio (INR) management under a physician's care. The risk of serious injury or death is known to be high when patients are either non-compliant or not properly dosed; combined with the risk that a direct-to-consumer test result may be used by a patient to self-manage, serious concerns are raised if test results are not adequately understood by patients or if incorrect test results are reported.

Your company submitted 510(k)s for PGS on July 2, 2012 and September 4, 2012, for several of these indications for use. However, to date, your company has failed to address the issues described during previous interactions with the Agency or provide the additional information identified in our September 13, 2012 letter for (b)(4) and in our November 20, 2012 letter for (b)(4), as required under 21 CFR 807.87(1). Consequently, the 510(k)s are considered withdrawn, *see* 21 C.F.R. 807.87(1), as we explained in our letters to you on March 12, 2013 and May 21, 2013. To date, 23andMe has failed to provide adequate information to support a determination that the PGS is substantially equivalent to a legally marketed predicate for any of the uses for which you are marketing it; no other submission for the PGS device that you are marketing has been provided under section 510(k) of the Act, 21 U.S.C. § 360(k).

The Office of In Vitro Diagnostics and Radiological Health (OIR) has a long history of working with companies to help them come into compliance with the FD&C Act. Since July of 2009, we have been diligently working to help you comply with regulatory requirements regarding safety and effectiveness and obtain marketing authorization for your PGS device. FDA has spent significant time evaluating the intended uses of the PGS to determine

whether certain uses might be appropriately classified into class II, thus requiring only 510(k) clearance or de novo classification and not PMA approval, and we have proposed modifications to the device's labeling that could mitigate risks and render certain intended uses appropriate for de novo classification. Further, we provided ample detailed feedback to 23andMe regarding the types of data it needs to submit for the intended uses of the PGS. As part of our interactions with you, including more than 14 face-to-face and teleconference meetings, hundreds of email exchanges, and dozens of written communications, we provided you with specific feedback on study protocols and clinical and analytical validation requirements, discussed potential classifications and regulatory pathways (including reasonable submission timelines), provided statistical advice, and discussed potential risk mitigation strategies. As discussed above, FDA is concerned about the public health consequences of inaccurate results from the PGS device; the main purpose of compliance with FDA's regulatory requirements is to ensure that the tests work.

However, even after these many interactions with 23andMe, we still do not have any assurance that the firm has analytically or clinically validated the PGS for its intended uses, which have expanded from the uses that the firm identified in its submissions. In your letter dated January 9, 2013, you stated that the firm is "completing the additional analytical and clinical validations for the tests that have been submitted" and is "planning extensive labeling studies that will take several months to complete." Thus, months after you submitted your 510(k)s and more than 5 years after you began marketing, you still had not completed some of the studies and had not even started other studies necessary to support a marketing submission for the PGS. It is now eleven months later, and you have yet to provide FDA with any new information about these tests. You have not worked with us toward de novo classification, did not provide the additional information we requested necessary to complete review of your 510(k)s, and FDA has not received any communication from 23andMe since May. Instead, we have become aware that you have initiated new marketing campaigns, including television commercials that, together with an increasing list of indications, show that you plan to expand the PGS's uses and consumer base without obtaining marketing authorization from FDA.

Therefore, 23andMe must immediately discontinue marketing the PGS until such time as it receives FDA marketing authorization for the device. The PGS is in class III under section 513(f) of the FD&C Act, 21 U.S.C. 360c(f). Because there is no approved application for premarket approval in effect pursuant to section 515(a) of the FD&C Act, 21 U.S.C. 360e(a), or an approved application for an investigational device exemption (IDE) under section 520(g) of the FD&C Act, 21 U.S.C. 360j(g), the PGS is adulterated under section 501(f)(1)(B) of the FD&C Act, 21 U.S.C. 351(f)(1)(B). Additionally, the PGS is misbranded under section 502(o) of the Act, 21 U.S.C. § 352(o), because notice or other information respecting the device was not provided to FDA as required by section 510(k) of the Act, 21 U.S.C. § 360(k).

Please notify this office in writing within fifteen (15) working days from the date you receive this letter of the specific actions you have taken to address all issues noted above. Include documentation of the corrective actions you have taken. If your actions will occur over time, please include a timetable for implementation of those actions. If corrective actions cannot be completed within 15 working days, state the reason for the delay and the time within which the actions will be completed. Failure to take adequate corrective action may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and civil money penalties.

We have assigned a unique document number that is cited above. The requested information should reference this document number and should be submitted to:

James L. Woods, WO66-5688
Deputy Director
Patient Safety and Product Quality
Office of In vitro Diagnostics and Radiological Health
10903 New Hampshire Avenue
Silver Spring, MD 20993

If you have questions relating to this matter, please feel free to call Courtney Lias, Ph.D. at 301-796-5458, or log onto our web site at www.fda.gov for general information relating to FDA device requirements.

Sincerely yours,
/S/
Alberto Gutierrez
Director
Office of In vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health