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UBS Evidence Lab

Genomics 2.0 – Consumer Genomics

UBS Evidence Lab: What's my genetic makeup?

There's an app for that

Equities

 Americas
 Healthcare

Jonathan Groberg

Analyst

jonathan.groberg@ubs.com

+1-212-713 4411

Harris Iqbal

Associate Analyst

harris.iqbal@ubs.com

+1-212-882 6924

Edmund Tu

Associate Analyst

edmund.tu@ubs.com

+1-212-713 3876

Demystifying, quantifying, and investing in Consumer Genomics

Consumer Genomics sits at the intersection of what we think are some of the most significant investor themes: Consumer-driven health spending; Big data; Social networking, and, of course, Genomics. However, for all of its potential, the field remains relatively nascent and niche. We have been revisiting the space following ILMN's Helix announcement, the re-launch of 23andMe, and the growth of Ancestry.com, and are increasingly optimistic on the potential of this market. Here are the key conclusions from our work: 1) Forecasters are most often wrong when predicting the future, so our \$2-7bn market estimate range is intentionally broad; 2) We conclude industry dynamics are ultimately likely to lead to a "natural monopoly;" 3) Scale, awareness, utility, and regulatory hurdles are key near-term barriers to adoption.

Evidence Lab survey shows just how new the offering is to consumers

Consumer genomics today is primarily a reference to DTC genetic tests which are marketed directly to consumers rather than through a physician. According to research by our Evidence Lab, ~80% of the US population claims awareness of these tests while fewer than 5% have had a test done with no physician input, indicative of how nascent this industry is. Testing interest is split, with 50% likely/undecided and 50% unlikely to be tested in the next 12 months. Full survey results are included in this research note.

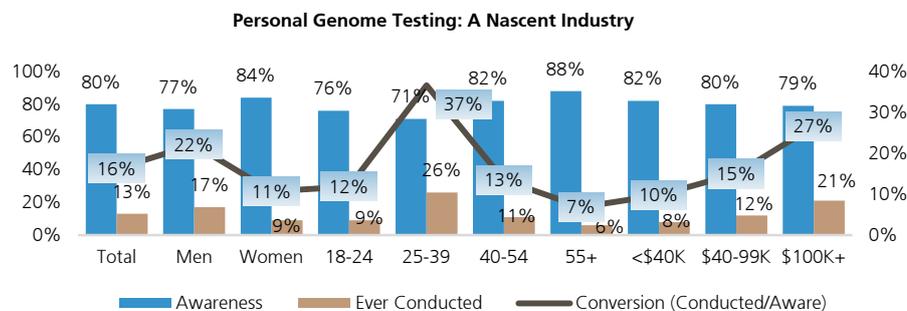
We think the market could be big, and ultimately dominated by one big player

We believe the total DTC market could be worth \$2-7bn per year, with numerous potential ancillary revenue streams such as pharma research partnerships, which we peg at a \$1.5bn opportunity. We think innovative business models will be key to unlock the market, and conclude the field ultimately lends itself to a "natural monopoly."

Who are the key players?

The consumer market today is quite fragmented with applications, but top-heavy in terms of samples processed. Private companies 23andMe (~1.2m global samples) and AncestryDNA (~1.5m) are dominant, followed by several smaller niche players. One option for public equity exposure to this theme is ILMN, which both supplies the test tools and also launched Helix, a consumer focused JV, in 2015. We see wide potential outcomes of value for Helix, from \$0 - \$20/share, and use \$5/share as our base case.

Figure 1: 80% of U.S. population claims awareness of consumer genomic tests



Source: UBS Evidence Lab.

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**UBS Evidence Lab provides our research analysts with rigorous primary research. The team conducts representative surveys of key sector decision-makers, mines the Internet, systematically collects observable data, and pulls information from other innovative sources. They apply a variety of advanced analytic techniques to derive insights from the data collected. This valuable resource supplies UBS analysts with differentiated information to support their forecasts and recommendations—in turn enhancing our ability to serve the needs of our clients.*

UBS conducted an online study among representative US adult population to understand the current awareness and usage of consumer genomics, with a view to get deeper insights into the behaviours as well as attitudes among current and potential genomics testing customers.

Genomics 2.0 – Consumer Genomics

Executive Summary

Consumer Genomics sits at the intersection of what we think are some of the most significant investor themes: **Consumer-driven health spending; Big data; Social networking**, and, of course, **Genomics**. However, for all of its potential, the field remains relatively nascent and niche.

Consumer Genomics sits at the intersection of consumer-driven health spending, big data, social networking, and genomics

We have been revisiting the space following ILMN's Helix announcement, the post FDA-clearance re-launch of 23andMe, and the growth of Ancestry.com, and are increasingly optimistic on the potential of this market.

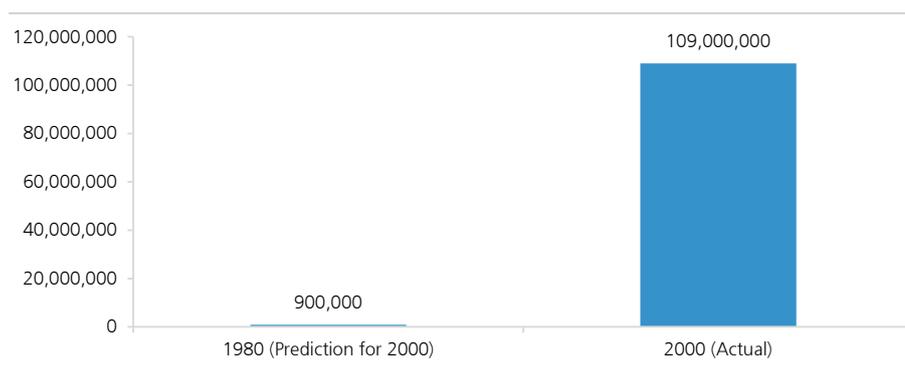
Here are the key conclusions from our work:

- 1) Forecasters are most often wrong when predicting the future, so our \$2-7bn market estimate range is intentionally broad.
- 2) Evidence Lab survey shows just how new the concept is to consumers and how nascent the market is.
- 3) Industry dynamics are ultimately likely to lead to a "natural monopoly."
- 4) Scale, awareness, utility, and regulatory hurdles are key near-term barriers to adoption.

Forecasters are most often wrong, so our market estimate range is intentionally broad

As an example of this point, In 1980 AT&T hired McKinsey & Co. to predict how many mobile subscribers there would be in the US by the year 2000. McKinsey estimated that there would likely be ~900k mobile phone subscribers then. So how close did their forecast approximate reality? In 2000 there were ~110m US mobile subscribers, so they were off by a factor of more than 100.

Figure 2: Number of U.S. Cell Phone Subscribers



Source: UBS, MIT, McKinsey.

We estimate a potential \$2-7bn Consumer Genomics opportunity. Our bull case \$7bn sizing assumes 80m users per year, each of whom spends \$60 per year on applications in an 'a la carte'/subscription model. Our bear case assumes more limited penetration and pricing.

Figure 3: ~\$2bn market size scenario

Consumer	Potential addressable market
Population (m)	
U.S.	316
Ex - U.S.	7,000
U.S. price per sample	
U.S.	\$ 49
Ex - U.S.	\$ 49
Market penetration	
U.S.	1.0%
Ex - U.S.	0.5%
Market size	
U.S.	\$ 155
Ex - U.S.	\$ 1,715
Total market size (\$m)	\$ 1,870

Source: UBS.

Figure 4: ~\$7bn market size scenario

Consumer (alternative model)	Potential addressable market
U.S. only	
Consumers age 18-55	160
% will never get tested (per Evidence Lab Consumer Survey)	50%
Potential market	80
Conversion	75%
Subscription (\$5 per month)	60
U.S. Market Size	3,600
Assume ex-U.S. same as U.S.	3,600
Total market size (\$m)	\$ 7,200

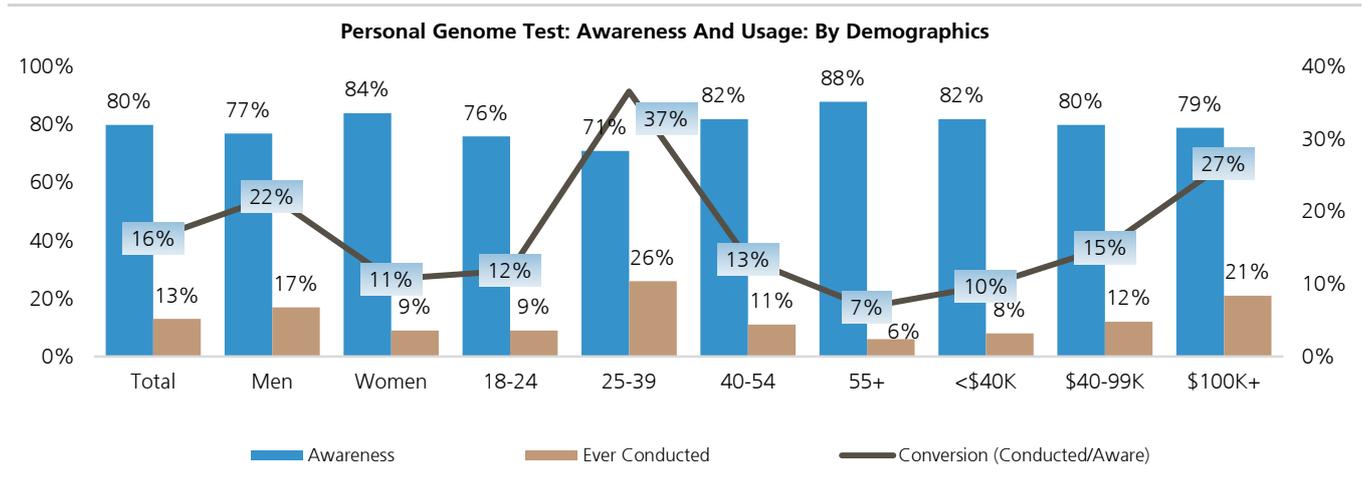
Source: UBS.

Evidence Lab survey results

Consumer genomics today is primarily a reference to DTC genetic tests which are marketed directly to consumers rather than through a physician and where consumers own their genomic information. We think it is important to think of consumer genomics as a branch of "self-pay" genomics, which we think could become a much broader market. For example, an individual might pay out of pocket if there were a reliable test to non-invasively detect early signs of cancer, even if insurance was slow to adopt coverage.

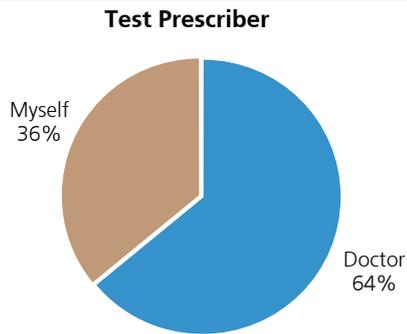
Our proprietary Evidence Lab survey shows just how new the offering is to consumers. According to research by our Evidence Lab, ~80% of the US population claims awareness of these tests while fewer than 5% have had a test done with no physician input, indicative of how nascent this industry is. Testing interest is split, with 50% likely/undecided and 50% unlikely to be tested in the next 12 months. Full survey results are included in this research note.

Figure 5: 13% of consumers surveyed claim to have taken a consumer genomics test but...



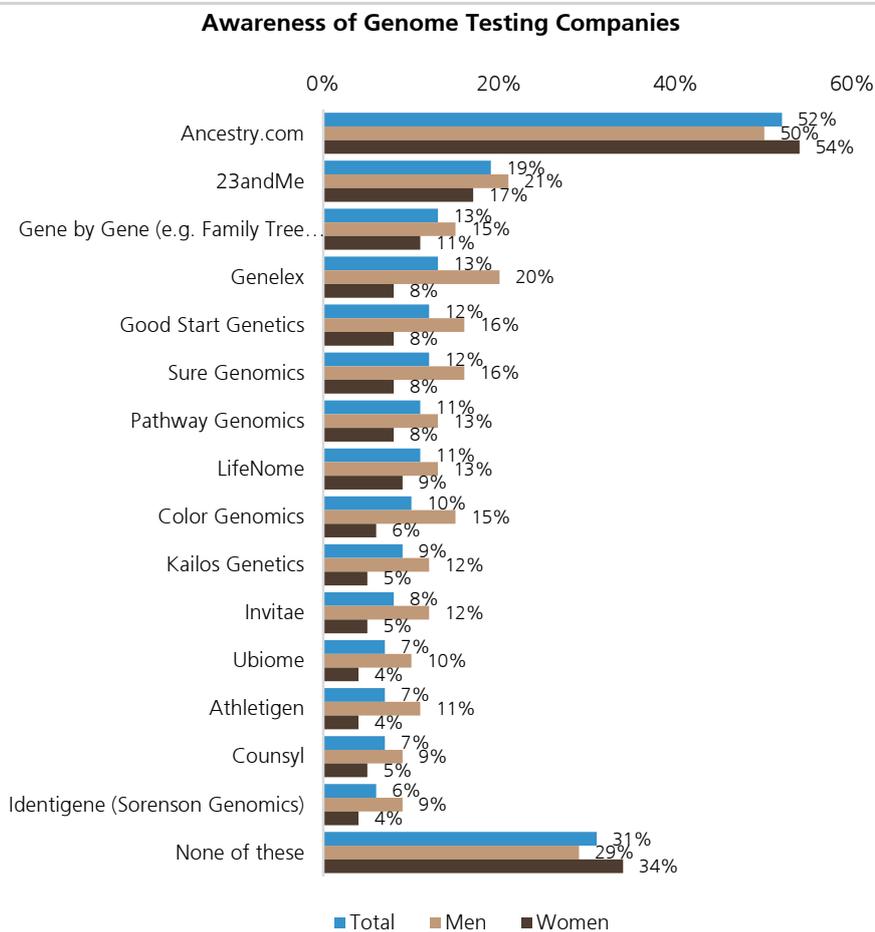
Source: UBS Evidence Lab.

Figure 6: Only 1/3 of those who have conducted the test primarily took the decision on their own



Source: UBS Evidence Lab.

Figure 7: Ancestry.com likely benefits from its brand "halo"

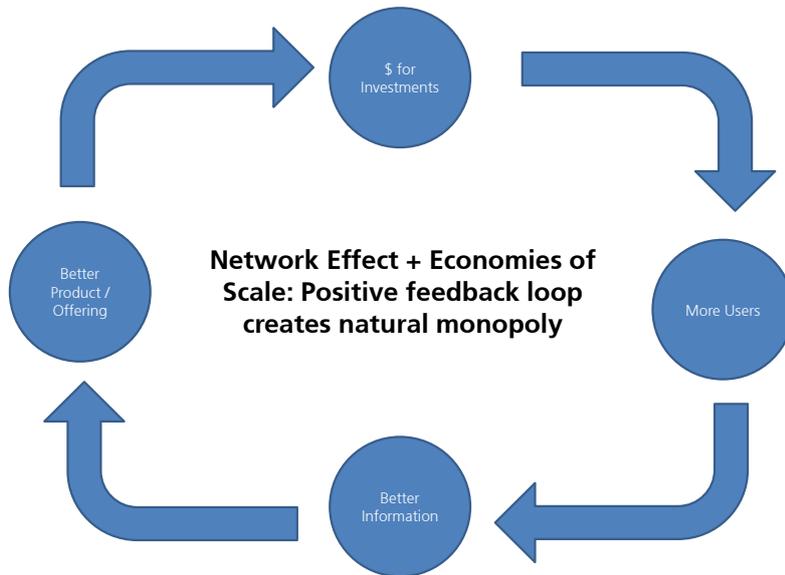


Source: UBS Evidence Lab.

Does industry lend itself to a "natural monopoly?"

As noted, we estimate the total DTC consumer genomics market could be worth \$2-7bn per year, with numerous potential ancillary revenue streams such as pharma research partnerships, which we peg at a \$1.5bn opportunity. We think innovative business models will be key to unlock the market, and conclude the field most likely lends itself to a "natural monopoly."

Figure 8: Network effect and economies of scale create a natural monopoly

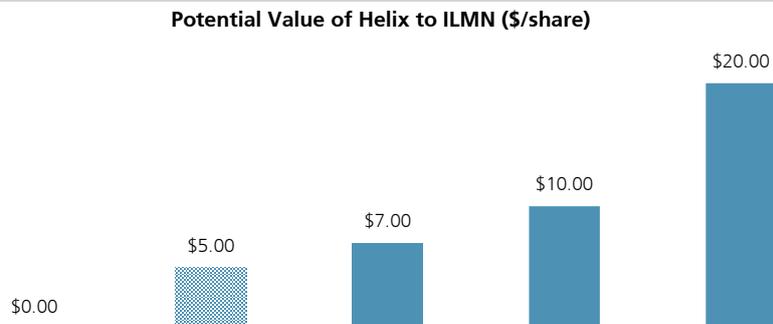


Source: UBS.

Who are the key players?

The consumer market today is quite fragmented with applications, but top-heavy in terms of samples processed. Private companies 23andMe (~1.2m global samples) and AncestryDNA (~1.5m) are dominant, followed by several smaller niche players. One option for public equity exposure to this theme is ILMN, which both supplies the test tools and in 2015 also launched Helix, a consumer focused JV. We see wide potential outcomes of value for Helix, from \$0 - \$20/share, and use \$5/share as our base case. Note ILMN is likely to benefit from the growth of this market regardless of the outcome with Helix, given its tool supplier status.

Figure 9: Wide range of Helix outcomes - \$5/share base case valuation



Source: UBS.

Will genomics ever go mainstream?

One of the Genomics 2.0 apps that we identified early on in our exploration of the Genomics of Things was what we called Consumer Genomics. Initially we were skeptical that the consumer market would be anything but a novelty. Since that time, however, our estimate of the potential market opportunity has continued to evolve, especially as we begin to consider the "self-pay" market in its totality. In addition, we have examined a number of other consumer markets that experts thought would be small and niche but that ended up being transformational, and we increasingly believe that our view of consumer genomics has been too pessimistic. With ILMN's announcement of its Helix initiative, the post FDA-clearance re-launch of 23andMe, and the growth of Ancestry.com we wanted to take a look at this market in more detail.

Here are the key conclusions from our work:

- 1) Forecasters are most often wrong when predicting the future, so our \$2-7bn market estimate range is intentionally broad.
- 2) Evidence Lab survey shows just how new the concept is to consumers, and how nascent the market is.
- 3) Industry dynamics are ultimately likely to lead to a "natural monopoly."
- 4) Scale, awareness, utility, and regulatory hurdles are key near-term barriers to adoption.

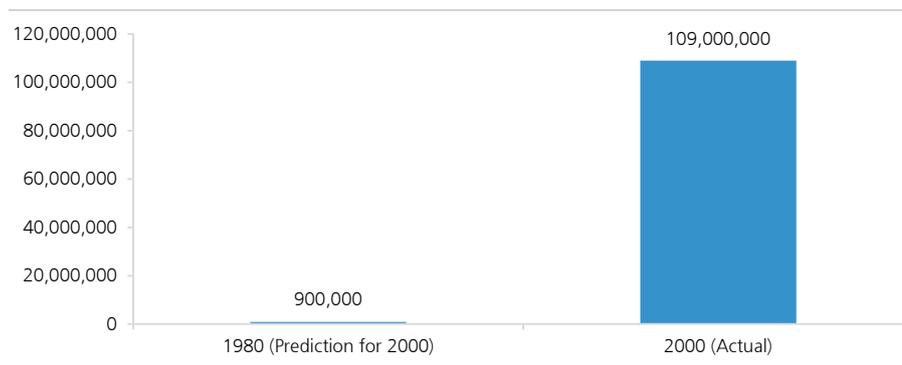
Forecasters often wrong when predicting future

Because we are talking about the consumer, let's start with a story.

In 1980 AT&T hired McKinsey & Co. to predict how many mobile subscribers there would be in the US by the year 2000. McKinsey came back with an estimate that there would likely be ~900k mobile phone subscribers by 2000. How close did their forecast approximate reality? In 2000 there were ~110m US mobile subscribers, so they were off by a factor of more than 100.

In 2000 there were ~110m US mobile subscribers, McKinsey had forecast 900k.

Figure 10: Number of U.S. Cell Phone Subscribers



Source: UBS, MIT, McKinsey.

We have no doubt that McKinsey employees back then were just as thorough and thoughtful as they are now. So what happened? We weren't in the room(s) where discussions took place at the time, so the best we can do is speculate. We can imagine that those working on the project looked at the existing form factor of phones, status of network coverage, entry and service cost, limited potential

applications, etc.; surveyed potential subscribers; tried to envision future technology improvement trajectories via expert discussions and deep internal industry knowledge; considered potential network effects; and made a reasonable forecast.

As Mark Twain once said: *It ain't what you don't know that gets you into trouble. It's what you know for sure that just ain't so.*

Could the same thing happen in consumer genomics? As prices fall, knowledge and utility rises, network effects grow, and technology advances we think it is possible that the consumer market could become much more deeply penetrated than most envision today.

What is consumer genomics/genetics?

First, what is the difference between genomics and genetics? Genomics is the study of all genes while genetics scrutinizes single genes. It used to be that looking at one gene was incredibly time-consuming, expensive, and difficult. Today, however, the ability to look at all genes quickly and inexpensively is changing the way we think about approaching DNA analysis.

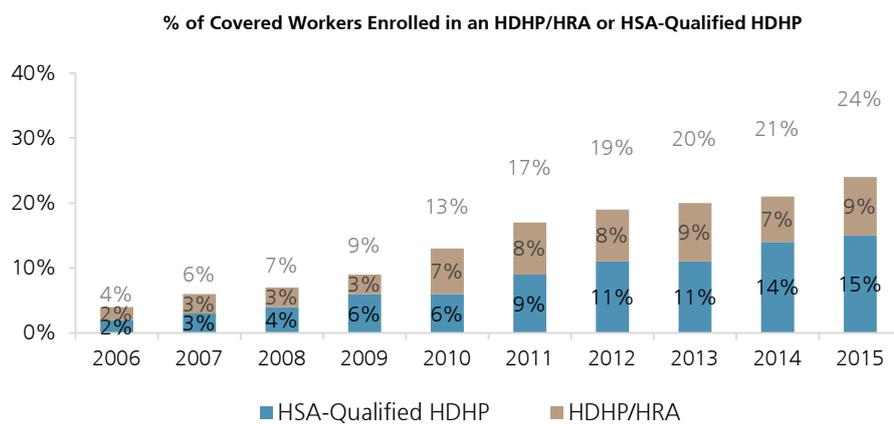
Consumer genomics today is primarily a reference to DTC genetic tests which are marketed directly to consumers rather than through a physician and where consumers own their genomic information. We think it is important to think of consumer genomics as a branch of "self-pay" genomics, which we think could become a much broader market. For example, an individual might pay out of pocket if there were a reliable test to non-invasively detect early signs of cancer, even if insurance was slow to adopt coverage.

Healthcare Consumerism a key macro driver

Until recently, the shift to consumerism in U.S. healthcare has evolved slowly. The Affordable Care Act, however, has accelerated this shift to consumerism, as evidenced by the combined 51 public exchanges created for a health insurance marketplace offering Americans a greater level of transparency into their healthcare. This transition begins to shift the selection and cost control of healthcare insurance from a Business-to-Business model to one that is now increasingly more Business-to-Consumer.

Among the driving factors of consumers taking a greater interest in their healthcare are higher deductibles and co-payments, improved transparency into provider performance and costs, and the rise of narrower networks and provider-led health plans. Since 2006, the percentage of covered workers enrolled in a HDHP/HRA or HSA-Qualified HDHP has increased from 4% to 24% today (See Figure 11).

Figure 11: Continued ramp in Americans on consumer driven plans



Source: UBS, Kaiser/HRET Survey.

As this trend continues to unfold, we believe the healthcare consumer is likely to take increasing involvement in preventive health measures, particularly as it relates to understanding their health risks, which we believe the era of Genomics 2.0 can provide. Consumer genomics is particularly well positioned as a beneficiary of these broader shifts in healthcare, as we believe consumers will want additional control and access to their genetic data to better understand their genetic predispositions and ultimately adopt more preventative health measures.

Consumer genomics today is primarily a reference to direct-to-consumer (DTC) genetic tests which are marketed directly to consumers and samples are collected in-home as opposed to a physician’s office. Consumers purchase these genetic tests, which are often mailed directly to them, at which time DNA is collected, typically by spitting inside a vial which is then sent back to the DTC company’s lab, or lab partner. The test results are then returned to the consumer via mail or, more often, through an online portal. Results sometimes include a live explanation with a genetic counsellor or other expert relevant to the specific test, such as a nutritionist or personal trainer for athletic tests.

Tests vary in the content of their information. Most today use genotyping panels which interrogate single nucleotide polymorphisms (SNPs) in targeted genes which can be used in establishing ancestry, carrier status, and predisposition to traits, diseases and conditions.

We note that some claimed DTC tests do require a physician prescription in order to run a test, though often the lab itself will provide access to the independent physician. We attempt to focus this report on those consumer genomic offerings that allow consumers to have access to their own genomic data in order to empower them to take more control of their health.

How big is the market?

We think the market size will be driven by 2 primary business opportunities: 1) Consumer driven revenues and 2) Ancillary revenue streams (e.g. research partnerships through which consumer genomics companies monetize database access to researchers, including academics and biopharma). We believe the total Consumer driven market could be worth \$2-7bn per year, but will need to be driven by innovative business models.

We believe the total Consumer Genomics market could be worth \$2-7bn per year.

Direct to consumer revenues

As we have tried to describe above, we think the success of the DTC market depends on many factors, similar to the example we gave of the evolution of the mobile phone market. We estimate a potential \$2-7bn opportunity. Our \$7bn bull case assumes 80m users per year, each of whom spend \$60 per year on applications in an 'a la carte'/subscription model where a customer is sequenced but can access individual apps on an ongoing basis. Most DTC tests today range from \$100 - \$200. As a broader range of applications become available and consumer appetite for control of their own healthcare information continues to ramp, we find this assumption reasonable. Our bear case assumes a fraction of the population buys a 1x test each year.

Figure 12: \$2bn market size scenario

Consumer	Potential addressable market
Population (m)	
U.S.	316
Ex - U.S.	7,000
U.S. price per sample	
U.S.	\$ 49
Ex - U.S.	\$ 49
Market penetration	
U.S.	1.0%
Ex - U.S.	0.5%
Market size	
U.S.	\$ 155
Ex - U.S.	\$ 1,715
Total market size (\$m)	\$ 1,870

Source: UBS.

Figure 13: \$7bn market size scenario

Consumer (alternative model)	Potential addressable market
U.S. only	
Consumers age 18-55	160
% will never get tested (per Evidence Lab Consumer Survey)	50%
Potential market	80
Conversion	75%
Subscription (\$5 per month)	60
U.S. Market Size	3600
Assume ex-U.S. same as U.S.	3600
Total market size (\$m)	\$ 7,200

Source: UBS.

To put this market opportunity into context, today 23andMe and Ancestry.com have processed a combined 2.7m samples, which amounts to 0.04% of the World population.

Figure 14: Only ~0.04% of the World's pop has taken a consumer genomic test



Source: UBS.

Ancillary revenue opportunities: Research partnership example

By their very nature, ancillary revenue streams are difficult to predict. One revenue stream that is already beginning to emerge is biopharmaceutical research partnerships.

Pharma partnerships could be the most lucrative ancillary revenue stream

Biopharma research partnerships represent perhaps the most lucrative "ancillary" revenue stream that has emerged thus far, based on recent partnership announcements. In fact, under certain conditions it is possible that this market opportunity trumps the size of the core DTC business.

The appeal of large consumer genetic data repositories is not only the genetic data, but additional information companies collect on users' personal lives which may aid in connecting the dots when interrogating the roots of diseases. DTC testing addresses a few key issues in drug research. The primary one being increased research accessibility to anyone that wants to participate in a study from the convenience of their home, as opposed to the typical pre-requisite of living near a clinical center. Pharma companies are increasingly partnering with such consumer genetic companies in one of two ways: 1) With either a very targeted need in which they are looking for patients with a significant disease; or 2) a broader partnership in which the pharma is evaluating large subsets of data to find an interesting/promising therapeutic target.

Figure 15: Recent flurry of pharma and genetic database partnerships represents a significant market opportunity

Recent Pharma / Genetic Database Transactions				
Sequencing Partner	Drug Developer	Date	Description	Financial Terms
Human Longevity	AstraZeneca	Apr. 2016	10-year deal, through which HLI will sequence whole genomes of up to 500k samples from AstraZeneca clinical trials. HLI will also provide its computational and genomics data analysis capabilities to drive future clinical trials & drug development	N/A
23andMe	Genentech	Jan. 2015	Genentech will be granted access to whole genome sequencing data of 3,000 customers with Parkinson's disease in order to identify new therapeutic targets.	N/A
23andMe	Pfizer	Jan. 2015	23andMe recruiting 5,000 lupus customers from existing database and by reaching out to new ones. Patients will be followed for 1-year to better understand the disease.	\$10m upfront; up to \$50m w/milestones
Human Longevity	Genentech	Jan. 2015	Multi-yr agreement by which HLI will use its proprietary tools and expertise to sequence whole genome sequencing of tens of thousands of de-identified samples from Genentech.	N/A
Ancestry DNA	Calico	July 2015	Partnership to analyze and investigate the role and influence of genetics on families experiencing unusual longevity using Ancestry's databases, tools and algorithms.	N/A
23andMe	Pfizer	Aug. 2014	Enrolling 10,000 people with IBD in the study, all of whom are not existing customers. Participants will receive 23andMe's spit kit at no cost. Aim is to better understand biology of disease.	N/A
Geisinger Health System	Regeneron Pharmaceuticals	Jan. 2014	5-year collaboration through which Geisinger will collect over 100k patient volunteers. Regeneron will perform sequencing and genotyping to ultimately identify and validate associations between genes and human disease to derive drug targets.	N/A

Source: UBS, company documents.

Regeneron (REGN) has been a pioneer in the world of pharma meets genomics through its relationship with the Geisinger Health System. As we learned from our [Genomics 2.0 Summit](#) keynote speaker, Dr. Alan Shuldiner (VP & Co-Head Regeneron Genetics Center), rare disorders will require the testing of at least several hundred thousand patients, meaning a comprehensive databank would consist of a few million patients. We noted following our Summit that we thought many other big biopharma firms would likely try to emulate what is being done at Regeneron, and moves from Amgen and AstraZeneca support that view. But another scenario, given the scarcity of quality set of large data, could be to partner with consumer genomics companies. For example, 23andMe has sold access rights to its Parkinson's cohort database to Genentech.

Using both a top-down and bottoms-up market sizing, we estimate the market size could conservatively be at least \$1.5bn. In Figure 16, we assume Regeneron’s 5% of R&D spend on genomics is replicated across the biopharma industry and that 20% of this amount is dedicated specifically to partnerships providing access to genomic databases. In Figure 17, we use terms from 23andMe’s recent deal with Pfizer as a proxy for how deals may be structured more broadly in the future.

We estimate the pharma DTC market size could conservatively be at least \$1.5bn

Figure 16: Top-down market sizing

Sizing up the Consumer Genetic data market	
Global Pharma R&D spend	\$150,000,000,000
% of Regeneron (REGN) R&D spent on genomics	5%
<i>Implied industry R&D spend on genomics</i>	<i>\$7,500,000,000</i>
% spent on accessing genomic databases	20%
Potential size of genomic data market	\$1,500,000,000

Source: UBS.

Figure 17: Bottoms-up market sizing

Sizing up the Consumer Genetic data market	
23andMe & Pfizer deal size (excluding milestones)	\$10,000,000
Number of lupus patients recruited for study	5,000
<i>Implied 23andMe revenue per patient</i>	<i>\$2,000</i>
Assumed # of patients per genomics/pharma study	1,000
Potential revenue per pharma contract	\$2,000,000
# of U.S. recruiting studies	15,000
<i>% of studies that leverage genomics data</i>	<i>5%</i>
Potential size of genomic data market	\$1,500,000,000

Source: UBS, company documents, clinicaltrials.gov.

UBS Evidence Lab Survey

In an effort to better understand the interest level and understanding of consumer genomics by the U.S. population, we called upon the UBS Evidence Lab to run a broad based survey of 1,000 U.S. adults age 18+. The main sample was weighted to be representative of population on age, gender, income, race, and Hispanic origin. All of the surveys were fielded using an Internet methodology. Conclusions based on the total sample of adults have a potential sampling error of 3 percentage points, at a 95% confidence level.

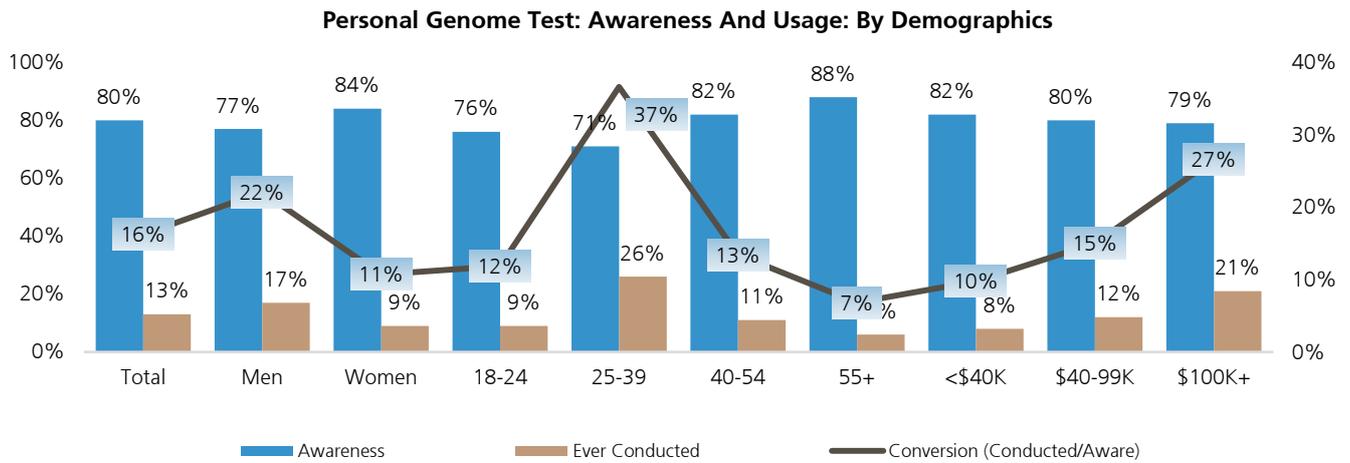
The key takeaways from our survey include:

- 1) Consumer genetic testing is still in its infancy, though consumer awareness appears high.
 - 2) Future interest and demand will be driven in large part by pricing.
 - 3) Greater consumer knowledge around the capabilities of testing could help convert high levels of awareness into higher test volumes.
- Question: How familiar are the consumers with genetic testing? Have they taken the test? Who is the driver of the test?

There is high claimed awareness of personal genome testing with 80% respondents stating that they have heard about the offering. Women have higher awareness compared to men and older age group (55+) have higher awareness compared to the younger respondents.

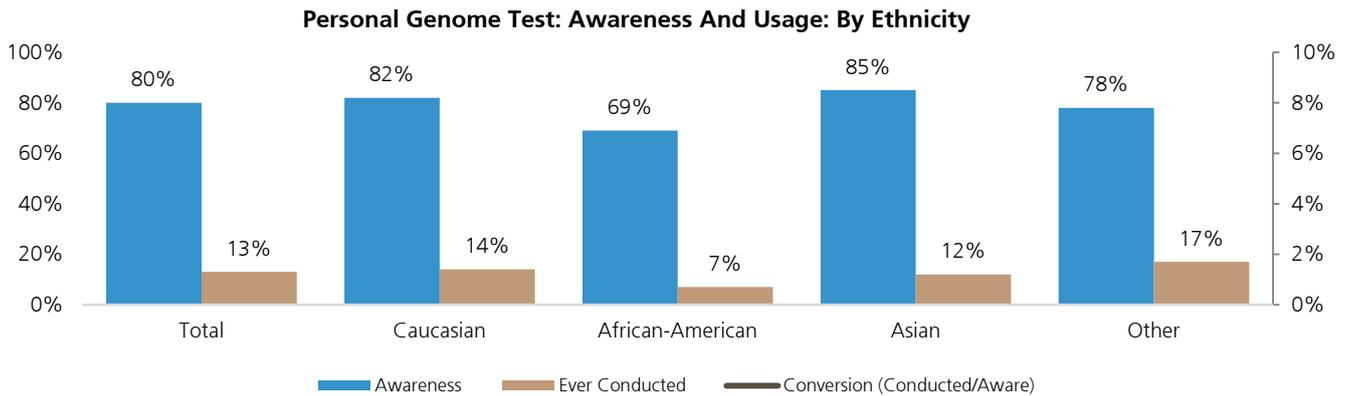
13% consumers have done this test. Here, men are more likely than women to have been tested and those in the 25-39 (26%) year age band are the most tested age group. Testing is highly correlated with the income of those earning above \$100k – thrice more likely than those earning less than \$40k to have been tested.

Figure 18: 13% of consumers surveyed have taken a consumer genomics test



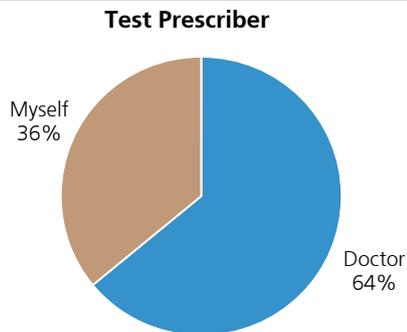
Source: UBS Evidence Lab.

Figure 19: Caucasians and Asians more likely than other groups to have their personal genome testing done



Source: UBS Evidence Lab.

Figure 20: Only 1/3 of those who have conducted the test primarily took the decision on their own

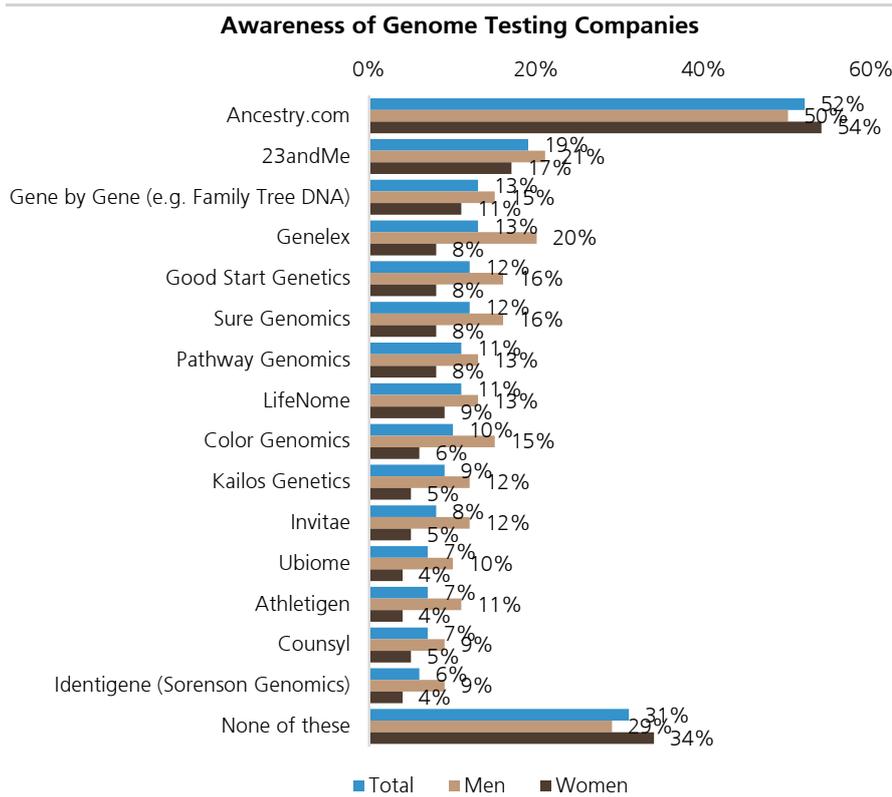


Source: UBS Evidence Lab.

- Question: Which are the most commonly known personal genome testing companies? How do consumers get to know about these companies?

Among respondents who are aware of personal genome testing, Ancestry.com is by far the most well-known company with over half (52%) of them stating that they have heard about it. 23andMe is known by every 1 in 5 respondents while Gene by Gene, Genelex, Good Start Genetics and Sure Genomics follow with 12%-13% awareness levels among respondents who are aware of personal genome testing.

Figure 21: Ancestry.com likely benefits from its brand "halo"

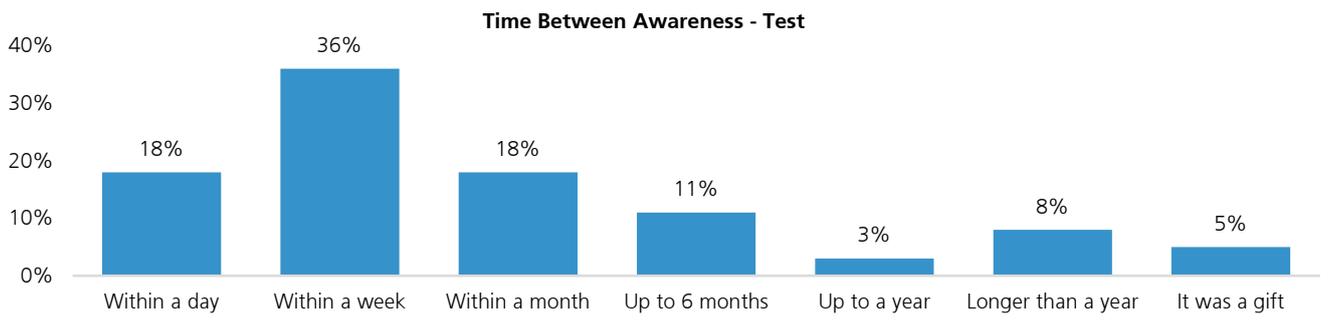


Source: UBS Evidence Lab.

- Question: How long does it take from awareness to action for a personal genome test?

Personal genome test appears to be a quick action decision with a short duration between becoming aware and going for the test – among those who are interested. More than half had the test done within a week and nearly three-fourths went ahead within a month.

Figure 22: More than half of those interested in a test, took one within a week



Source: UBS Evidence Lab.

- Question: What drives the need for a DNA test?

Interest in taking control of diagnosis without going to a Doctor is a clear winner as a reason for conducting a DNA test. Other top 3 reasons are also health associated – better health plan and response to medication.

Paternity and interest in ancestry are clearly not the top drivers while low scores for curiosity and entertainment means that DNA testing is purpose driven and is unlikely to be taken lightly.

Figure 23: Interest in taking control of diagnosis without going to a Doctor is a clear winner as a reason for conducting a DNA test



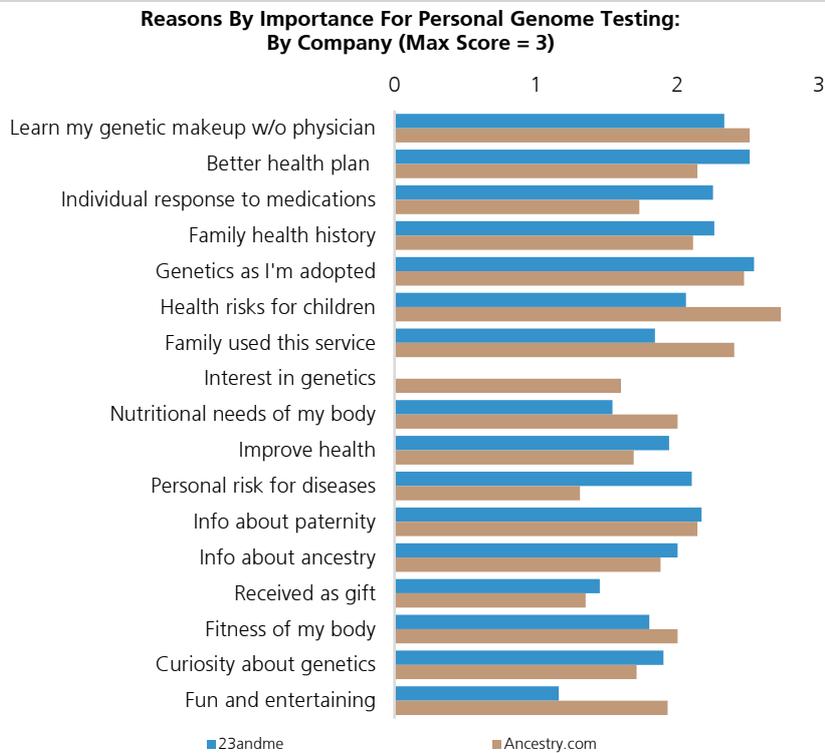
Source: UBS Evidence Lab.

Looking at the attribute importance differences between those who got tested through Ancestry.com and 23andMe, we see that Ancestry.com led 23andMe on the attributes of – health risk for children, family having used it before, interest in genetics, nutritional needs and fun.

23andMe was ranked superior to Ancestry.com for the reasons of better health plan, response to medication, and risk of disease.

It looks unlikely that there is a clear pattern of preference between the two. Potentially as 23andMe becomes more well-known and widely used, there may be convergence of reasons across both the providers.

Figure 24: 23andMe was ranked superior to Ancestry.com on better health plan, response to medication, and risk of disease.



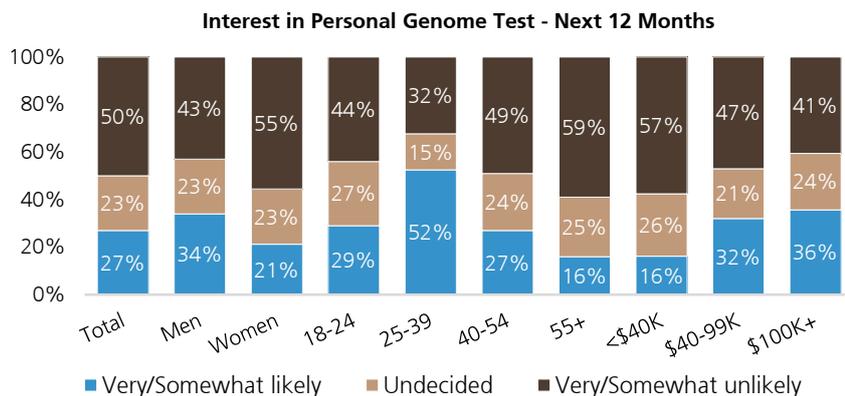
Source: UBS Evidence Lab.

- Question: What is the interest level among those who haven't had a test yet?

About one-fourth of the available market (aware but not tested yet) is likely to go for the DNA test in the next 12 months. Men are much more likely than women (34% vs. 21%) to get tested while those in the 25-39 year age group are about twice more likely than those in the 18-24 or 40-54 age group to go for the test. Those above the age of 55 years show the least interest in genetic testing.

It is important to note that there is a large proportion of the population (50%) that has no intention to test in the next 12 months and only about 23% who are undecided. One of the key challenges for companies offering consumer genome testing would be to create better awareness and interest (hooks) in the target population for these tests.

Figure 25: About one-fourth of the available market (aware but not tested yet) is likely to go for the DNA test in the next 12 months



Source: UBS Evidence Lab.

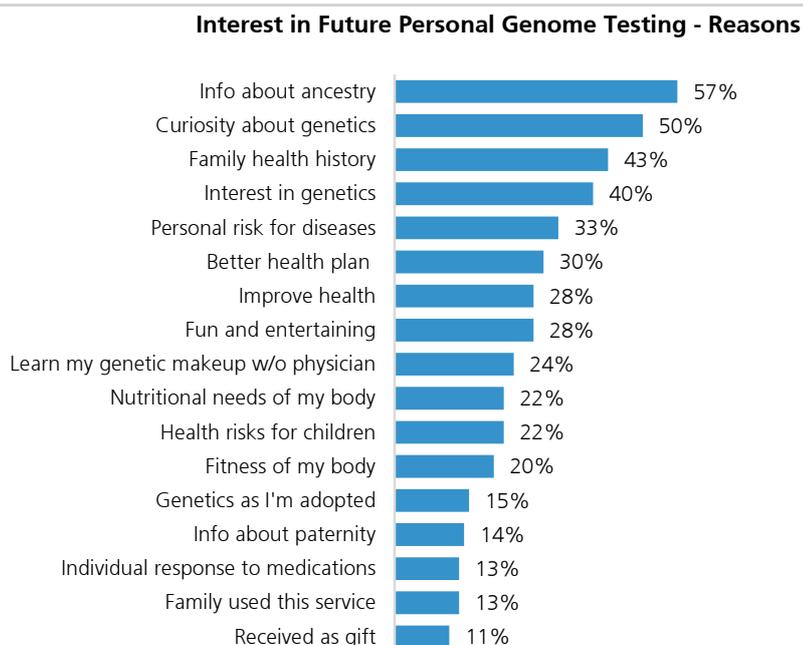
- Question: What drives this interest for a test sometime in next 12 months?

It is interesting to note that while the respondents who went in for the testing (Figure 23) primarily chose health management as the key reason, the interest among those planning to go for testing in the next 12 months is primarily driven by interest in ancestry and general curiosity.

While health reasons are mentioned in the other top 5 reasons for testing, it is clear that the interest is being driven more by non-health related drivers.

If the companies intend to drive a wider messaging on the benefits of genome testing then perhaps increasing the prominence of health management and risk mitigation related reasons and bringing those to the fore would be a good idea.

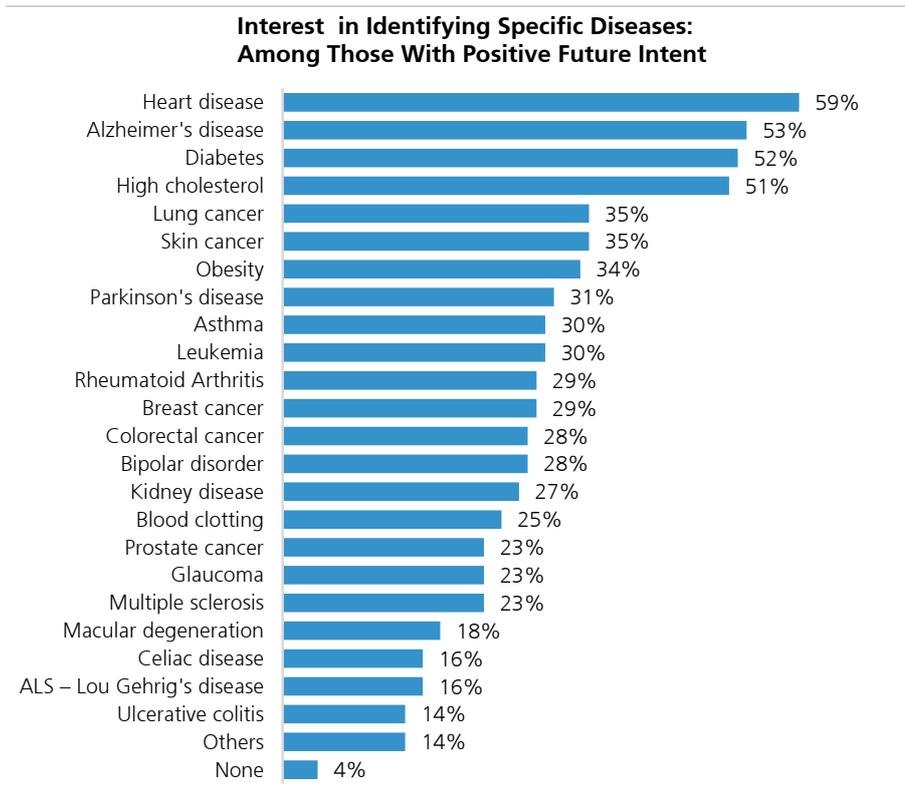
Figure 26: Ancestry information and curiosity of genetics the main reasons driving test interest



Source: UBS Evidence Lab.

- Question: Which diseases would the future testers like to identify?

Figure 27: Heart disease and Alzheimer’s are specific areas of test interest



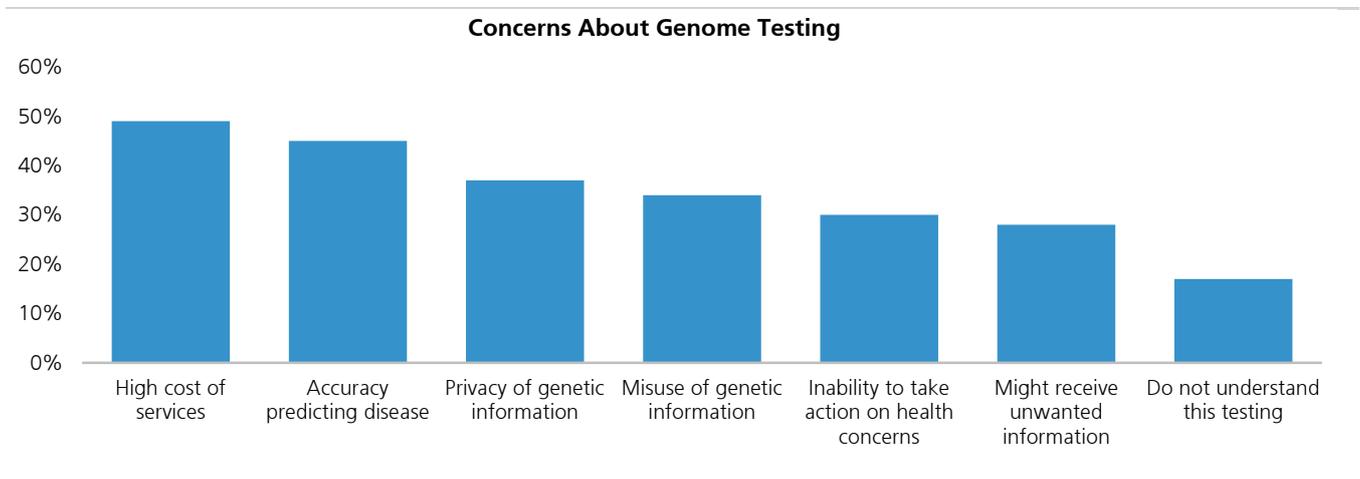
Source: UBS Evidence Lab.

- Question: What are the concerns with DNA testing?

While cost of the service is mentioned most often as the concern for genome testing, accuracy of the predictions comes a close second.

Privacy and misuse are mentioned by over one-third of the respondents indicating that while managing the price points may improve the interest level of the potential consumers, there are key concerns around use/misuse of the information as well as the science and accuracy behind all the effort.

Figure 28: Cost of the service and accuracy of the predictions key perceived issue with tests today



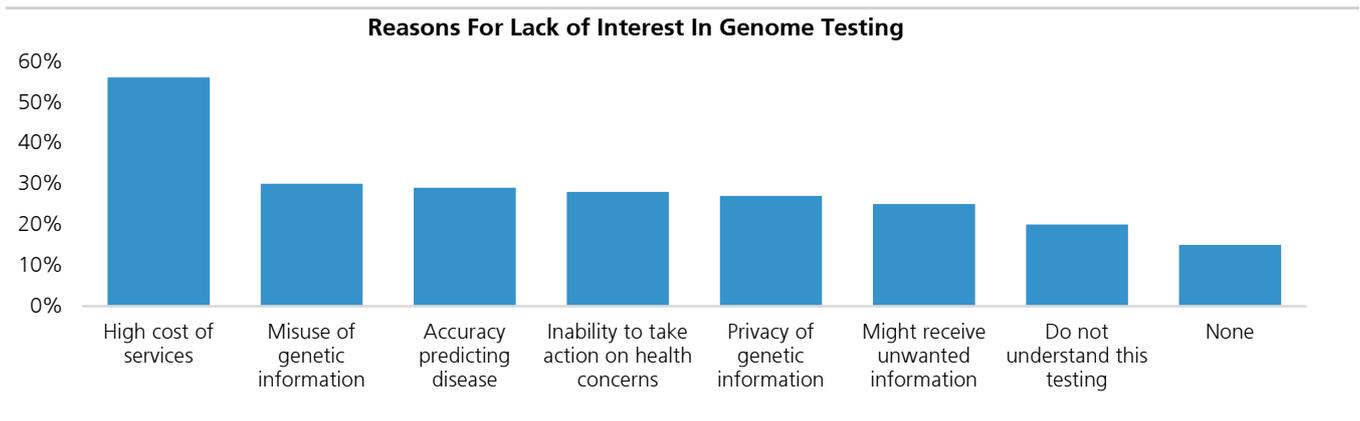
Source: UBS Evidence Lab.

- Question: Why are you not interested in DNA testing?

Among respondents who are aware but unwilling to undergo the test, cost acts as a deterrent for nearly 6 in 10 potential customers. Misuse and accuracy concerns are seen in nearly a third of the respondents.

Here again, while managing the price point may increase the interest, concerns around information management and analysis might impact the final decision.

Figure 29: Among respondents who are aware but unwilling to undergo the test, cost acts as a deterrent for nearly 6 in 10 potential customers.

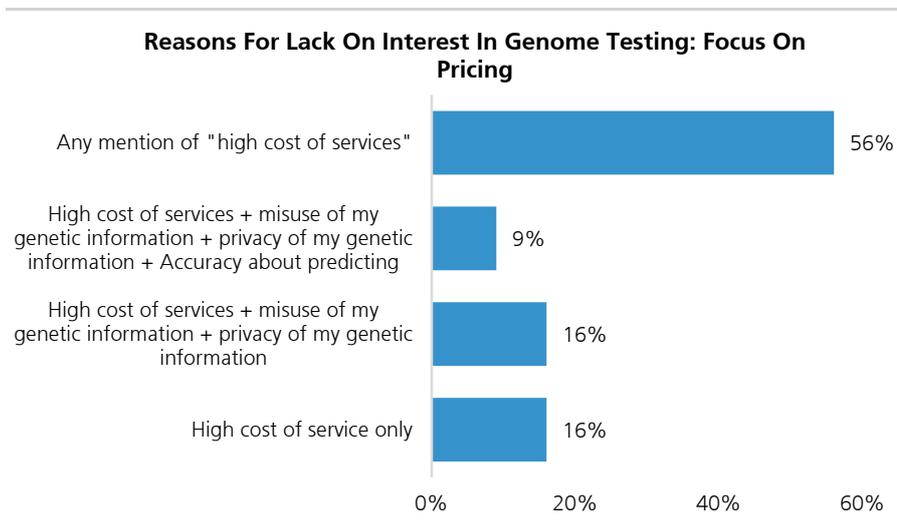


Source: UBS Evidence Lab.

- Question: Why are you not interested in DNA testing?

Price is the most noted test deterrent, although potential misuse of data and accuracy also factor into reasons for lack of interest.

Figure 30: High cost of service the main reason for lack of interest



Source: UBS Evidence Lab.

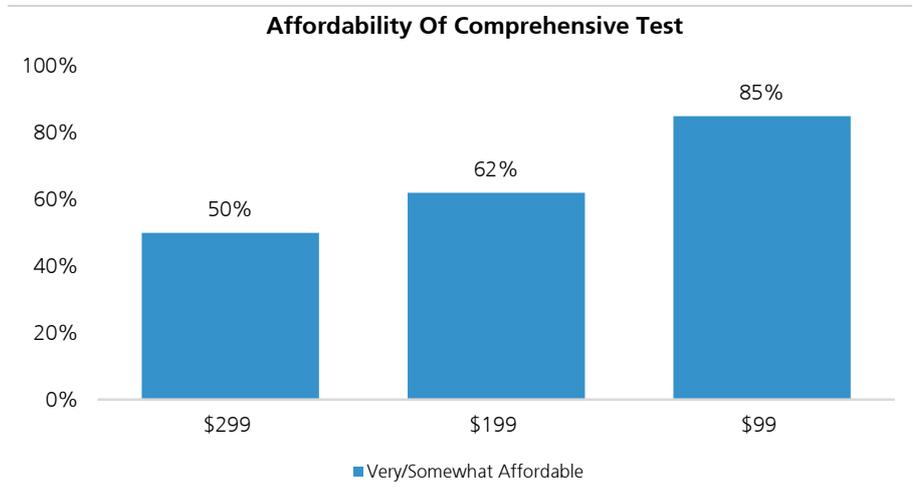
- Question: How do consumers react to the pricing for a comprehensive DNA test?

A comprehensive test at \$99 gets a very high score on affordability. With 85% of respondents feeling that \$99 is a very/somewhat affordable cost, it appears to be a good entry price point.

At \$199, the favorability drops to 62% and we have 50% respondents stating that \$299 is affordable.

It is important to note that even through the affordability score drops with increasing price, we have a healthy 50% feeling that \$299 is affordable.

Figure 31: A comprehensive test at \$99 gets very high score on affordability

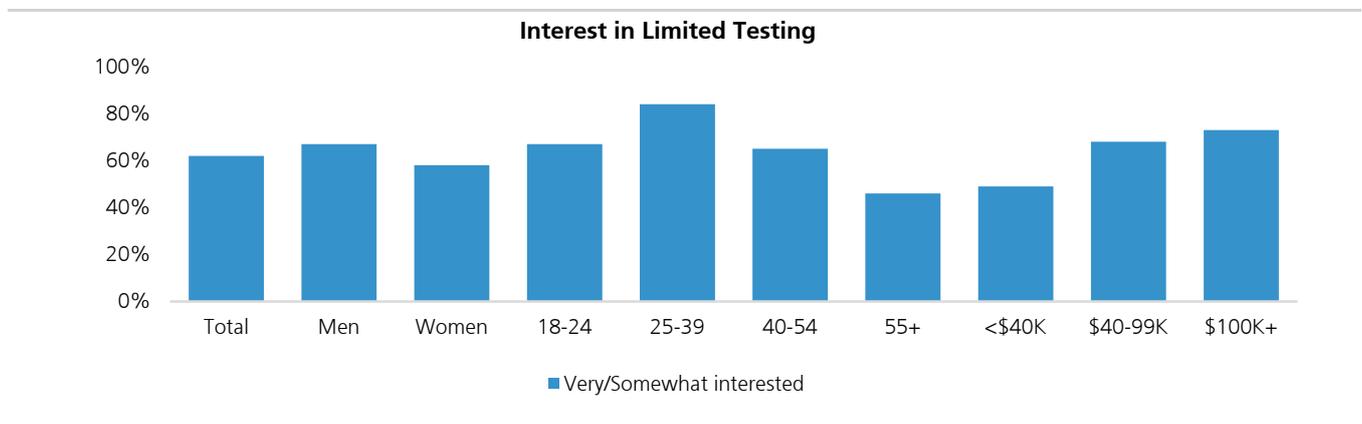


Source: UBS Evidence Lab.

- Question: Do consumers like the idea of a limited – issue based - DNA test?

Limited testing for specific issues finds high favor with nearly two-thirds interested in this service. Men have higher interest in this offer than the women and those in the age group of 25-39 show highest interest among all age groups.

Figure 32: Limited testing for specific issues finds high favor with nearly two-thirds interested in this service.



Source: UBS Evidence Lab.

We think ultimately one big winner is likely

In Figure 33 below, we have highlighted key companies competing today in consumer genomics. We note that the field is quite fragmented and our list incorporates large and well-known incumbents as well as smaller, yet interesting companies taking very unique approaches in how they use a customer's DNA. Take for example Instant Chemistry which uses genomics in matchmaking or NIMBL Diagnostics which creates art of a customer's genome – neither are obvious applications of consumer genomics, yet both are quite illustrative of the potentially vast applications for the field.

The pioneers of the DTC market include deCODEme, 23andMe, and Navigenics. Life Technologies bought Navigenics in July, 2012 but was more interested in the Company's CLIA-certified laboratory than the DTC genetic testing business which was shuttered. deCODEme was bought by Amgen in December, 2012 but Amgen decided to close their DTC business as well. One potential explanation is that deCODEme could not compete due to its relatively high pricing (\$1,000/test), for services 23andMe was offering for under \$300 at the time.

Figure 33: Direct-to-Consumer Genomics Testing Competitive Landscape*

Company	Product Name	Category	Description	List Price (USD)	Turnaround Time
23andMe	Ancestry (includes MyHeritage access)	Ancestry	Ancestry composition, maternal & paternal lineage, reantherthal, DNA relatives tool	\$199 (Includes all 4 tests)	6-8 weeks
	Carrier Status	Carrier	35+ conditions, including Cystic Fibrosis, Sickle Cell Anemia, hereditary hearing loss		
	Wellness Reports	Wellness	Caffeine consumption, lactose intolerance, alcohol flush reaction, muscle composition		
	Trait Reports (19+ traits)	Traits	Hair: color, loss, curliness Taste & Smell: sweet vs. salty, bitterness Facial Features: dimples, unibrow, freckles		
Ancestry.com	AncestryDNA	Ancestry	Ancestry composition (700k markers), identification of potential relatives in database	\$99	6-8 weeks
Athletigen	N/A	Wellness	Athleticism, nutrition & psychological predispositions (can import 23andMe or Ancestry data)	\$199	8 - 10 weeks
Color Genomics	Color Kit	Hereditary Cancer	19 genes for Breast and Ovarian Cancer	\$249	4 - 10 weeks
Counsyl	Family Prep Screen	Carrier	100+ conditions including Wilson disease, Phenylketonuria, Cystic Fibrosis, Bloom Syndrome, Canavan Disease		-2 weeks
	Informed Pregnancy Screen	NIPT	Down Syndrome (Trisomy 21), Edward's Syndrome (Trisomy 18), Patau Syndrome (Trisomy 13)		-1 week
	Inherited Cancer Screen	Hereditary Cancer	Up to 22 genes including Breast / Ovarian / Intestinal / Pancreatic / Prostate / Thyroid Cancers		-2 weeks
DNAFit	Fitness Diet Pro	Wellness	Fitness response including recovery and predisposition to injury and nutrition response (includes diet plan & supports 23andMe data)	-\$365	N/A
DNA Tribes	DNA Tribes Genetic Ancestry Analysis	Ancestry	Ancestry composition (26 markers)	\$149	2 - 3 weeks
DNA4Life	The Drug Sensitivity Report	Drug response	12 gene analysis that assesses sensitivity to 124 commonly prescribed medications	\$249	10 days
Family Tree DNA (Gene By Gene)	Y-DNA	Ancestry	Paternal ancestry (37,67,111-marker options)	\$169 - \$359	8 - 10 weeks
	Family Finder	Ancestry	Relative finder (within 5 generations across database)	\$99	4 - 6 weeks
	mtDNA	Ancestry	Maternal ancestry (validate&prove sibling or confirm links via mother's direct line)	\$199	6 - 8 weeks
	FitnessGenes	FitnessGenes System	Wellness	43 genetic variants tested to assess traits including endurance, speed, appetite. Add-on available for customized training & nutrition plans.	\$229 - \$289
Genetrics (Instant Chemistry)	N/A	Personality	Assess 3 genes to associate customer with 1 of 8 company derived personality types	-\$40	N/A
GenePartner	GenePartner	Matchmaking	Biological matching offering that uses genetic profile formula to assess compatibility between a couple (also offered through dating sites and Facebook)	\$249	-2 weeks
Genes for Good (Univ. Michigan)	N/A	Wellness / Ancestry	Study run through surveys in a Facebook app & provides participants w/ info on ancestry, sleep, stress, and physical activity	Free	N/A
Instant Chemistry	Instant Chemistry Kit	Matchmaking	Assesses genetic markers like Major Histocompatibility Complex and 5-HTTLPR along with psychological questionnaire to determine couple's compatibility	\$199	N/A
Karmagenes	Karmagenes Kit	Personality	Algorithm builds personalized profile from psychological assessment and 14 behavioral characteristics from DNA test	\$149	2 - 3 weeks
LifeNome	Nutrition & Metabolism report	Wellness	Absorption ability for 17 vitamins and 11 minerals & reaction to certain fats/proteins/carbs (tests require 23andMe or Ancestry genetic data file)	\$79	N/A
NIMBL Diagnostics	DNA Art	Art	Turns customer's DNA sequence into art	\$349	N/A
Pathway Genomics	PathwayFit	Wellness	75+ genetics markers associated with diet, exercise & health conditions (includes dietitian consultation + meal plans)	\$159	2 - 3 weeks
	Gut Kit	Microbiome	One sample from gut	\$89	4 - 6 weeks
Ubiome	Gut Time Lapse	Microbiome	3 samples from gut - 1 before, 1 during and 1 after diet or lifestyle change	\$199	4 - 6 weeks
	Five Site Kit	Microbiome	One-time sample of 5 sites (gut, mouth, nose, genitals & skin)	\$399	4 - 6 weeks
	Vitagene	N/A	Wellness	Genetic health report and personalized nutrition consultation accompanied by custom nutrition/supplement and exercise plan	\$159

* some tests have subscription fee which are not included in test prices listed in table; turnaround time represents weeks after Company receives sample from customer

Source: UBS, Company documents. *List intended to be representative of broad variety of apps and not inclusive of full range of competitors in each category.

The DTC market today is top-heavy in terms of samples processed, as private companies 23andMe (~1.2m samples processed) and Ancestry.com (~1.5m samples processed) dominate the market, followed by several smaller niche players. One option for public equity exposure to this theme is ILMN, which both supplies the test tools and also launched Helix, a consumer focused JV, in 2015.

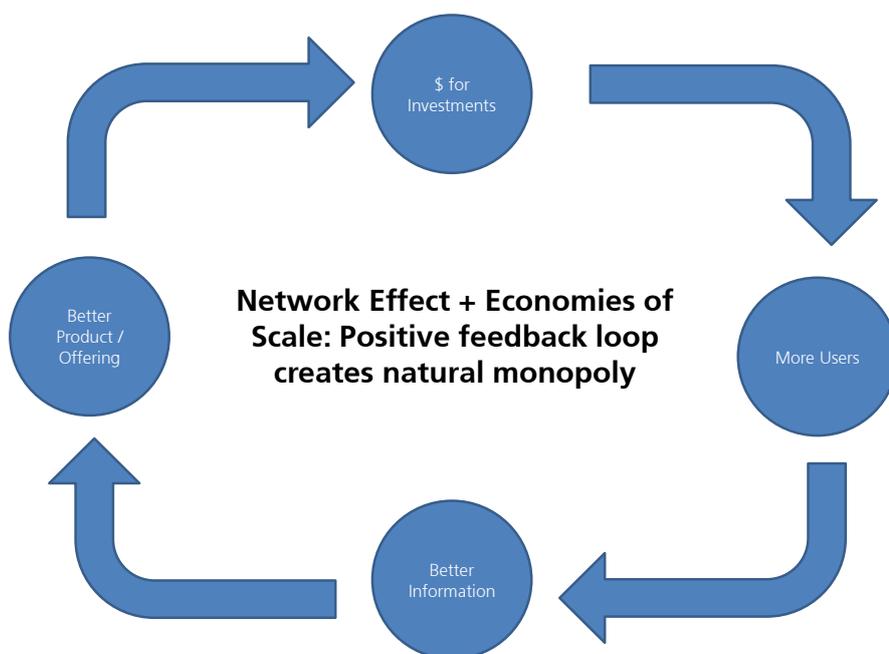
Why might the market end up a natural monopoly?

What is a natural monopoly? With a natural monopoly, continuous economies of scale means that average total costs (ATC) keep falling, and marginal cost (MC) is always below average total cost (ATC) over the whole range of possible output. With natural monopolies, economies of scale are very significant so that minimum efficient scale (MES) is not reached until the firm has become very large in relation to the total size of the market (MES is the lowest level of output at which all scale economies are exploited). If MES is only achieved when output is relatively high, it

is likely that few firms will be able to compete in the market. When MES can only be achieved when one firm has exploited the majority of economies of scale available, then no more firms can enter the market.

Classically, natural monopolies have been thought of in terms of significant fixed costs that lead to wasteful and duplicative expenditures (think 2 railways right next to each other down the same route). However, we think natural economies can also initially be driven by network effects. For example, if I want to connect with people I am most likely to find those people on Facebook, so I join Facebook, and others I know also end up joining Facebook. Facebook can then take those relationships and optimize its offerings to both customers and advertisers. And if I want to search for something on the internet, I am likely to use Google because most everyone who searches uses Google so the constantly improving search algorithm is likely to give me the best search results. And once these networks and their benefits are established, the firm is able to invest more in its business, attracting more users and improving its offering. It becomes a virtuous cycle and makes it very hard for other companies to break into the markets.

Figure 34: Network effect and economies of scale create a natural monopoly



Source: UBS.

Why is this relevant to Consumer Genomics?

Companies like 23andMe and AncestryDNA, who have each tested over 1 million customers, have an advantage in being able to more accurately connect genetic mutations with diseases as well as map out and connect ancestry information. For example, each of these companies can help identify distant or unknown relatives but, these relatives must have also been tested by the same firm, and be in the same database (unless someone made its database open) in order for the relationship to be identified. Or let's say that I want to find someone else who has the same rare mutation as I do? I want to be in the network where there is most likely to be someone else with a rare mutation – the largest network.

And from the firm's perspective, they should be able to create better customer experiences based on their more comprehensive data sets and user bases.

This is why we believe scale and network effects will be critical in determining a market winner and ultimately leave room for only one big market player.

We believe scale will be critical in determining a market winner and ultimately leave room for only one big market player.

Winner must be much more than just a database

To be clear, the winner will need to be much more than just a database. We think databases themselves could become somewhat commoditized over time. In fact, given the potential social benefit of these databases, many are likely to be free. Countries, philanthropists, public/private partnerships, and entrepreneurs are all making bets on creating large, data-rich, genotypic/phenotypic databases.

Here is just one example: On January 20th, 2015, President Obama announced the Precision Medicine Initiative (PMI). The idea of the PMI program is to build a national database of at least one million U.S. participants (79k by the end of 2016) representing social and racial/ethnic diversity across a variety of geographies, social environments, economic circumstances, age groups, and health statuses. A myriad of overarching conditions and factors have culminated in what appears to make now the "right time" for an initiative like the PMI. Chief among these factors are an American consumer increasingly active and responsible for their own healthcare, widely integrated electronic health records, mobile health technologies, and increasingly cost-effective next-gen sequencing technologies. While the initial focus of the program will be on cancer, efforts will ultimately broaden to encompass research in other common diseases such as diabetes, heart disease, Alzheimer's, obesity, and various forms of mental illness.

President Obama earmarked \$215m towards the initiative, of which \$130m will be dedicated to the NIH's efforts to build a large, national cohort of research participant, and \$70m will be used by the National Cancer Institute for its efforts in cancer genomics, as part of the PMI for Oncology. While these funds are a fraction of what will ultimately be needed to complete such an ambitious initiative, we think this is well recognized and that more funding will come.

There are multiple other initiatives as well, from Genomics England to Human Longevity to Regeneron/Geisinger. See Figure 35 for an illustrative list of the many initiatives that have been announced to date.

Figure 35: Widespread efforts to establish genome databases

List of select genome databases and initiatives
23andMe
Ancestry.com
AstraZeneca
Belgian Medical Genomics Initiative
Estonian Program for Personal Medicine
GenomeCanada / Canadian Institute of Health
Genomics England
Human Longevity
Icelandic Health Database / deCODE
Japan Implementation of Genomic Medicine Project
Korea Ulsan 10,000 Genome Project
Kuwait Genome Project
Qatar Human Genome Project
Regeneron / Geisinger
Saudi Human Genome Project
U.S. Precision Medicine Initiative (PMI)

Source: UBS.

Perhaps the greatest challenge with these initiatives will be around data management. According to Eric Dishman, general manager of Health and Life Sciences at Intel, sequencing the genomes of the 1.65 million individuals diagnosed with cancer annually amounts to four billion gigabytes of data. This amounts to over 400,000 times more information than what is held in the Library of Congress. On top of this, the data must be able to be shared seamlessly as patients move through the healthcare system.

While there will undoubtedly be value in databases, how much is difficult to determine. Factors such as the size, diversity, information quality, accessibility, ease-of-use, etc. will all be key in determining relative value.

A successful Consumer Genomics company will surely be able to participate in the database market, but we think the real value of a successful Consumer Genomics company will come not just with the size of the database but rather with the network it creates with its users: i.e. how the users grow, interact, evolve, and how new products created by the Consumer Genomics company help it remain relevant with users over time. We think this active user involvement and ongoing product enhancement capability will be the self-reinforcing network dynamic that likely creates the big winner.

For example, Facebook has a lot of valuable personal data, but much of this value comes from giving other applications on your phone access to your Facebook profile – you can log into many iPhone apps using your Facebook profile. This increases the value of the Facebook data. We could envision a similar dynamic where a Consumer Genomics company could increase its value by becoming the hub of personal health data, for example feeding into tools like Apple Health, or tying into lifestyle tools like FitBit.

Or you could sell customers varying account options. For example, 2-5% of LinkedIn users have a premium account, which is where they make much of their money. Or on apps like Pandora, you can remove annoying ads by buying a premium account.

Again, we think scale and network effects will work together as minimal necessary factors in determining a market winner and ultimately leave room for only one big market player. But execution will determine who the winner is.

Where does ILMN's Helix fit in?

In August, 2015, Illumina announced it formed a company, Helix, with Warburg Pincus and Sutter Hill Ventures including initial financing commitments in excess of \$100m. The idea behind Helix was to provide individuals with affordable access to their genomic sequence data, which could then be used towards a host of on-demand, third party applications made available by Helix's partners.

The model for Helix is a cutting-edge lab stocked with ILMN's instruments where customer samples are sent and sequenced and stored in a secure cloud-based genomic database where an individual's sequence can be queried frequently with a marketplace of applications from third-party partners.

The economics for Helix are undisclosed but the initial idea is to front the cost to sequence each customer's genome ("exome plus") and then charge per additional app. Helix's main proposition is to break down the cost of market entry for app companies by providing the infrastructure backbone which consists primarily of instrumentation and labs. Helix is meant to alleviate this burden. ILMN will front the cost of sequencing each customer, what we estimate to be \$20. The model will then rely on these customers returning multiple times to query their data, similar to a recurring royalty-type fee, although the revenues from each app will be split in some fashion with the third-party developer.

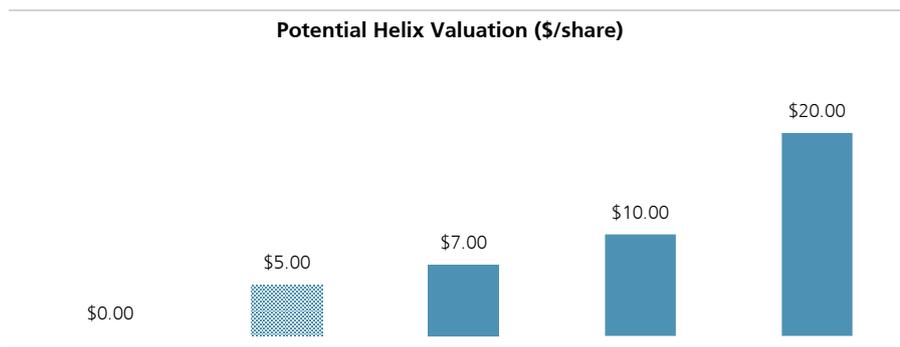
One of the key questions with Helix is how the initiative impacts ILMN's relationship with direct-to-consumer companies. We think the creation of Helix is a sign of ILMN wanting to enable broader adoption of genetic data rather than wanting to directly compete with its customers. For example, existing consumer genomics companies offer SNP data from arrays, not sequence data, given the desire to keep costs to consumer down. By lowering the fixed costs for consumer genomics companies, ILMN/Helix is accelerating the industry's transition from SNPs to NGS while also improving the quality and range of apps as sequencing provides more data that can be worked with. However, it remains to be seen how established companies like 23andMe and Ancestry will respond to the initiative as Helix's platform further develops and commercializes.

Valuing ILMN's interest in Helix

Most consumer genetic companies are private. Helix is being deemed a VIE by ILMN, is fully consolidated, and is loss making. Thus, we estimate investors are attributing a minimal valuation to the business. Helix is expected to be \$0.10 dilutive to 2016 results. Beyond this, the Company hasn't provided much color on the ramp in revenues except that profitability in 2017 is not their base case scenario. In Figure 37, we use a 10-year DCF of Helix to imply an enterprise value of ~\$800m, or nearly \$5 per share. For context, 23andMe's Series E financing valued the company at ~\$1.1bn (See Fig. 4).

We use a 10-year DCF of Helix to imply an enterprise value of ~\$800m, or nearly \$5 per share

Figure 36: Wide range of Helix outcomes - \$5/share base case valuation



Source: UBS.

Figure 37: We estimate Helix could today be worth ~\$5 per share to ILMN

Cost Assumptions		2016	2017	2018	2019	2020	Notes	
HiSeq X cost per genome	\$743	New Helix customers	5,000	50,000	250,000	750,000	1,500,000	
ILMN product gross margin	75%	Revenue per new customer	\$50	\$60	\$100	\$100	\$100	Assumes ramp as more apps available
Cost to ILMN for HiSeq X genome	\$186	Cumulative Customers	5,000	55,000	305,000	1,055,000	2,555,000	
Estimated cost for exome plus	\$20	Revenue per existing customer	\$0	\$40	\$40	\$40	\$40	Assume each customer spends ~\$150 in each of 4 years after joining
Helix COGs per new customer	\$20	Total Revenues (Helix retains 30%)	\$75,000	\$3,060,000	\$25,660,000	\$78,660,000	\$162,660,000	70/30 split w/third-party app company (Apple App store is 70/30)
		Cost to sequence a new customer	\$20	\$19	\$19	\$18	\$18	3% annual reduction in sequencing cost
		Total COGs	\$100,000	\$976,000	\$4,770,500	\$14,056,095	\$27,824,784	Assume 90% gross margin for existing customers
		Gross Margin	68%	81%	81%	82%	83%	Some cost for data storage/maintenance, marketing
		SG&A & other fixed costs	\$40,000,000	\$44,000,000	\$48,400,000	\$55,660,000	\$66,792,000	
		Operating Income	(\$40,025,000)	(\$41,916,000)	(\$27,510,500)	\$8,943,905	\$68,043,216	
		Operating Income Margin	-	-1369.8%	-107.2%	11.4%	41.8%	
		Less: Income Taxes	-	\$10,898,160	\$7,152,730	(\$2,325,415)	(\$17,691,236)	
		Tax Rate	-	26.0%	26.0%	26.0%	26.0%	
		Unlevered After-Tax Income	(\$40,025,000)	(\$31,017,840)	(\$20,357,770)	\$6,618,490	\$50,351,980	
		Less: Capex	(\$1,000,000.00)	(\$1,000,000.00)	(\$1,000,000.00)	(\$1,000,000.00)	(\$2,067,887.11)	
		Capex/Sales	-	33%	4%	1%	1%	
		Helix Free Cash Flow	(\$41,025,000)	(\$32,017,840)	(\$21,357,770)	\$5,618,490	\$48,284,093	
		ILMN Free Cash Flow (50% of total)	(\$20,512,500)	(\$16,008,920)	(\$10,678,885)	\$2,809,245	\$24,142,046	
		Discount Rate						
		Beta	1.2					
		Risk-free rate	3.0%					
		Equity Risk Premium	5.5%					
		ILMN Cost of Equity	9.6%					
		ILMN Cost of Debt	6.0%					
		Tax Rate	26.0%					
		Target Debt Ratio	25.0%					
		WACC	8.3%					
		DCF Calculations						
		PV of FCF					(\$22,751,753)	
		Terminal FCF Growth					6.0%	
		Terminal Value					\$1,107,816,841	
		PV of Terminal Value					\$804,996,032	
		Enterprise / Equity Value					\$782,244,279	
		Shares Outstanding					150,000,000	
		DCF Value					\$5.21	

Source: UBS, company documents.

In our DCF assumptions, we assume \$20 as the cost to ILMN for sequencing each new Helix customer. Although it has not yet been confirmed which instrumentation Helix will be using, we assume product specs for the HiSeq X and ILMN's current product gross margin of 75%. We project customers will on average spend \$50 on applications during their first year on the platform, and then another \$160 in the following 5 years. Using the Apple App store as an illustrative model of third-party app economics, we assume ILMN retains 30% of sales from each application. COGs will be higher for each customer in their first year, as this is when ILMN will front the cost to sequence their genome. In preceding years, we estimate gross margins reach 85%+ with some operating expenses for data storage, maintenance, and marketing.

Based on the 5-year FCF generated from the assumptions above, we believe ILMN's 50% stake in Helix could be worth at least \$5 per share. Note that this market may have a binary outcome – either it takes off and there are several million users globally (we estimate 2.6m by 2020 in our model), or it's a minimally profitable business that can at least help educate consumers on the value of genomics.

Figure 38: Recent Consumer Genomics Transactions

Recent Consumer Genomics Transactions				
Company	Transaction	Date	Investor / Acquirer	Valuation
Human Longevity	Series B financing	Apr. 2016	Illumina, Celgene, GE Ventures & Series A investors	\$1.2b
Ancestry.com	Sale of equity stake	Apr. 2016	Silver Lake & GIC	\$2.6b
23andMe	Series E financing	Oct. 2015	Fidelity, Casdin Capital, WuXi Healthcare Ventures, Xfund	~\$1.1b (based on \$79m investment, could reach \$150m on milestones)
DeCode Genetics	Acquisition	Dec. 2012	Amgen	\$415m

Source: UBS, company documents. Note that Ancestry at time of acquisition did not offer AncestryDNA service.

In our view, the key risk to our assumptions is the competitive threat to Helix from incumbent consumer genomics companies like 23andMe and Ancestry who already have large +1 million customer databases and an established marketing channel to showcase new applications. As we highlighted in Figure 33, many companies today allow customers to upload 23andMe and Ancestry.com genetic data into their site to access an application that were not already offered by the other two. This allows customers to receive a concession on their test price by bypassing the sequencing step and access their results in a fraction of the turnaround time.

In theory, 23andMe and Ancestry could create their own type of app store where they leverage existing customer relationships to market third-party apps who pay them a cut of the test price. In such a scenario all parties could benefit. On the flip side, both of these Companies today use arrays opposed to next generation sequencing which may limit the potential applications of their existing databases in the future, particularly in pharmaceutical research. Regardless, unless Helix can get 23andMe or Ancestry.com onto its platform, we think it likely that Helix's business model will need to change into more of a DTC play.

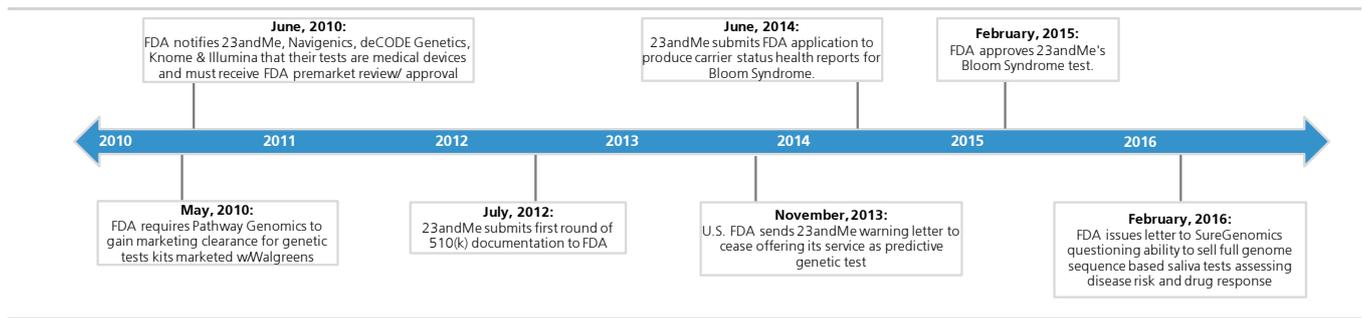
Barriers: Regulation and data fragmentation

Not unlike the broader world of genomics app markets, consumer genomics also suffers from a challenging regulatory backdrop. One factor this market benefits from, however, is the out-of-pocket nature of most tests which bypasses reimbursement hurdles that have been a headwind to adoption elsewhere. Recent progress between the FDA's regulation of 23andMe's Bloom Syndrome test is also encouraging as we are more optimistic on regulation relative to other genomics apps. An additional barrier that may limit the speed of adoption is the challenge in acquiring meaningful scale as the industry remains fragmented with few large, quality datasets to allow for more accurate apps.

1) Regulation of DTC tests progressing, but still an overhang

Many DTC companies at their inception several years ago would market their offerings as predictive genetic tests for various diseases. In November, 2013, however, the U.S. FDA issued a warning letter to 23andMe ordering the Company to cease sales of their predictive genetic tests as the agency deemed them as medical devices that had not received regulatory clearance or approval. The core debate at the center of the FDA's regulatory action was what level of access the public should have to its own genomic data? And what parameters should be built around this access?

Figure 39: The ups and downs of consumer genomics regulation



Source: UBS.

Critics have noted that clinically un-validated genetic information retrieved by consumers through DTC tests could lead to consumers taking unnecessary or wrong action that adversely impacts their health. On the other end of the spectrum, supporters argue that individuals are capable of understanding their own genetic data as well or better than many doctors and should have the right to this information without the intervention of regulators.

In 2010, the FDA took the side of critics when it notified companies including 23andMe, Navigenics, deCODE Genetics, Knome, Illumina, and Pathway Genetics that they must receive FDA premarket review and approval for their tests which the Administration was deeming to be medical devices.

Over the past few years, 23andMe has worked with regulators to develop an FDA friendly test which was recently approved the Company's Bloom Syndrome Carrier Status test in February, 2015. The approval marks the first DTC test to be granted marketing authority by the FDA and opens a pathway for future submission through the FDA's 510(k) pathway. The agency ultimately concluded that carrier tests possess a low risk for false-positive results as the carrier of one abnormal copy of a gene allele associated with a disorder doesn't have any disease symptoms. Therefore, in order for a false-positive to occur, a couple must each have a false positive which would be a rare occurrence.

On the back 23andMe's marketing authorization, the FDA also classified autosomal recessive carrier screening tests as Class II devices which makes the tests exempt from FDA premarket review. The ruling, however, came with a series of controls for labs marketing these tests.

Figure 40: FDA controls for labs marketing DTC tests

<ul style="list-style-type: none"> Labs must make available on their website clinical data on the markers being tested, from peer-reviewed publications and professional society guidelines. Tests assessing biomarkers not supported by guidelines must state this clearly on their website.
<ul style="list-style-type: none"> Detailed information on analytical performance of carrier tests must be available on the lab's website.
<ul style="list-style-type: none"> Sample collection devices must be indicated for use in DNA testing and be FDA cleared, approved, or 510(k) exempt. Additionally, labs cannot distribute their carrier tests to other CLIA labs.
<ul style="list-style-type: none"> The FDA will require labs to inform customers on test limitations and how they can obtain genetic counselling services.

Source: UBS, FDA.

As we have highlighted in [previous notes](#), the FDA's imminent regulation of lab-developed tests (LDTs) will be important to observe as there will be ramifications for consumer genomics tests, although action around 23andMe's test indicated some willingness by the FDA to be flexible in their oversight framework.

Recent FDA actions signal progress, although developments remain key to watch

2) Achieving minimal scale in a fragmented market

Consumer genomics represents a valuable tool for the accumulation of clinically relevant cohorts of genetic data across diverse populations. Depth of this data is also important as a strong majority of consumers consent to the use of their information in data banks which are ultimately used by the likes of pharma companies looking to identify new drug therapies or isolate targeted populations for clinical studies.

One of the main challenges in acquiring this scale, however, is the fragmentation of data cohorts amongst multiple companies. At our [Genomics 2.0 Summit](#), we hosted a consumer genomics panel in which one of the panelists suggested 10 million individuals as the number of sequences it would take to identify almost every genetic disease.

Still seeking the "killer app" to drive adoption

One of the biggest things to come out of the smartphone revolution, and perhaps a major enabler of it, was the rise of the mobile app. Apple first introduced its App Store on July 10th, 2008. The development of third-party apps caught on quickly and it quickly became clear to Apple that this was the future, as evidenced by the Company's subsequent release of a software developer kit allowing third-parties to seamlessly create and sell their apps through their internally developed platform.

To be clear, the Apple app store is more anecdotal and representative of the power of third-party collaboration than a direct comparison to ILMN's Helix. Apple's app store launch benefited from unique advantages such as an established mobile ecommerce infrastructure via iTunes, large-scale digital distribution capabilities, and substantial marketing muscle. These also let the firm lock-in a 30% share of all third-party app sales.

What will be important for Helix to gain traction and a more rapid inflection point will be a "killer app" which customers believe is a must-have.

Consumer genomics still lacks a must-have "killer app"

Among the first partners for Helix are the Mayo Clinic's Center for Individualized Medicine which is creating apps for consumer education and the Laboratory Corporation of America which is planning to develop analyses for treatable genetic diseases.

The Consumer Genomics Investor Playbook

Like many Genomics 2.0 app markets, the universe of publicly traded investment vehicles to express the consumer genomics theme is scarce today. Illumina is certainly one option with its Helix initiative as well as its entrenched position as the NGS instrumentation 'arms dealer' which we expect many consumer genomics companies to utilize. One could also make the argument that consumer genomics will have a more profound impact on NGS in that it serves as a gateway market to facilitate a broader and more in-depth understanding of genomics by the general public. We reiterate our Buy rating on ILMN as we believe the consumer genomics market to be an underappreciated call option, and estimate its Helix initiative could be worth \$5 per share to ILMN.

Appendix

UBS Evidence Lab U.S. Consumer Genomics Study

In an effort to better understand the interest level and understanding of consumer genomics by the U.S. population, we called upon the UBS Evidence Lab to run a broad based survey of 1,000 U.S. adults age 18+. The main sample was weighted to be representative of population on age, gender, income, race, and Hispanic origin. All of the surveys were fielded using an Internet methodology.

The key takeaways from our survey include:

- 1) Consumer genetic testing is still in its infancy, though consumer awareness appears high.
- 2) Future interest and demand will be driven in large part by pricing.
- 3) Greater consumer knowledge around the capabilities of testing could help convert high levels of awareness into higher test volumes.

Key debates and research insights:

How familiar are customers with genetic tests and companies that provide the service?

- 80% of the US population claims awareness of personal genome testing and about 13% have undertaken the test in past.
- The most commonly stated name among respondents who are aware of personal genome testing is Ancestry.com followed by 23andMe.

What are the sources of awareness for genetic testing?

- TV leads with close to 60% respondents getting aware through it followed by internet at 40%.

What are the key factors that will drive adoption of consumer genomics? Why did the consumers undergo genetic tests?

- Interest in taking control of diagnosis without going to a Doctor, better health plan and likely response to medication are the top 3 reasons.

Are consumers interested in genetic testing? What % of customers might ultimately adopt genetic testing?

- One-fourth of the available market is likely to go for the DNA test in the next 12 months. 50% of the target market has no intention to test in the next 12 months and only about 23% who are undecided.

What are the primary concerns behind pursuing a genetic test?

- While cost is a big deterrent, accuracy of the predictions comes as a close second. Privacy and misuse are mentioned by over one-third of the respondents.

How much are customers willing to pay for their genetic information?

- A comprehensive test at \$99 is seen as affordable by 85% respondents. Even at \$299, 50% respondents find it affordable.

Why are some customers not interested in pursuing a test?

- For the unwilling to undergo the test, cost acts as a deterrent for nearly 60% potential customers. Misuse and accuracy concerns are seen in nearly a third of the respondents. Managing the price point increases interest, however concerns around information management and analysis impact the trigger.

What is the profile of consumers who are interested?

- Those who have undergone the test are likely to be younger as well as richer than the respondents who have not been tested yet. More males are likely to have been tested and the future intent for being tested is also higher among men.
- Future interest is also higher among those who are better educated and better employed – in line with the profile of those who have been tested.

Figure 41: Survey Participant Summary

	Total	Aware personal genome test		Conducted personal genome test		Future Intent			Affordability		
		Aware	Not Aware	Conducted	Not conducted	Likely	Undecided	Unlikely	\$299 affordable	\$199 affordable	\$99 affordable
Age (Years)											
Mean Age	46	47	41	40	47	43	49	51	43	44	46
Gender											
Female	51%	53%	42%	35%	53%	44%	56%	62%	46%	49%	51%
Male	49%	47%	58%	65%	47%	56%	44%	38%	54%	51%	49%
Annual HH Income											
Mean (In Thousand)	72.4	72.0	73.7	94.3	69.3	83.3	65.9	60.6	83.8	79.9	75.8
Employment											
Employed full-time	44%	42%	54%	70%	40%	58%	27%	29%	54%	48%	45%
Employed part-time	13%	13%	14%	11%	13%	15%	11%	13%	14%	15%	14%
Unemployed, Retired, Student	43%	46%	33%	18%	47%	27%	61%	59%	32%	36%	41%
Education											
Graduated from high school or equivalent	17%	16%	20%	14%	17%	10%	19%	19%	14%	16%	15%
Some college, but no degree	21%	21%	21%	11%	22%	16%	24%	26%	17%	19%	20%
Graduate	40%	41%	36%	46%	39%	51%	40%	37%	45%	43%	43%
Post-graduate degree	20%	20%	22%	27%	19%	24%	15%	17%	24%	22%	21%

Source: UBS Evidence Lab.

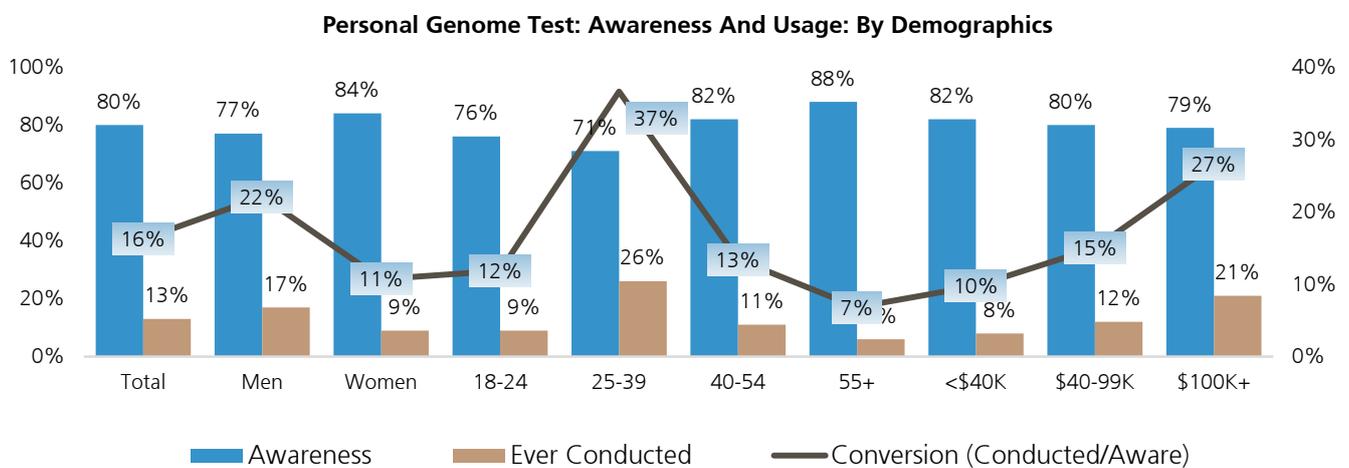
Awareness, Usage & Decision Making

- Question: How familiar are the consumers with genetic testing? Have they taken the test? Who is the driver of the test?

There is high claimed awareness of personal genome testing with 80% respondents stating that they have heard about the offering. Women have higher awareness compared to men and older age group (55+) have higher awareness compared to the younger respondents.

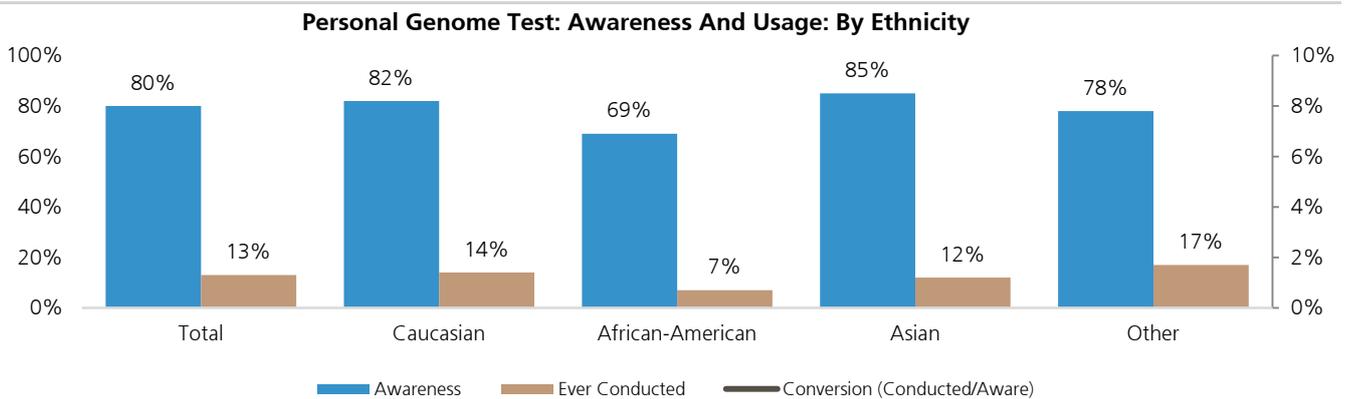
13% of consumers have done this test. Here, men are more likely than women to have been tested and those in the 25-39 (26%) year age band are the most tested age group. Testing is highly correlated with the income with those earning above \$100k – thrice more likely than those earning less than \$40k to have been tested.

Figure 42: 13% of consumers surveyed have taken a consumer genomics test



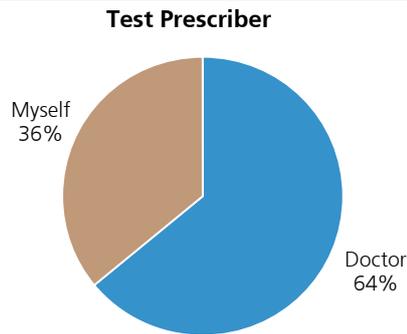
Source: UBS Evidence Lab.

Figure 43: Caucasians and Asians more likely than other groups to have their personal genome testing done



Source: UBS Evidence Lab.

Figure 44: One third of those who have conducted the test primarily took the decision on their own

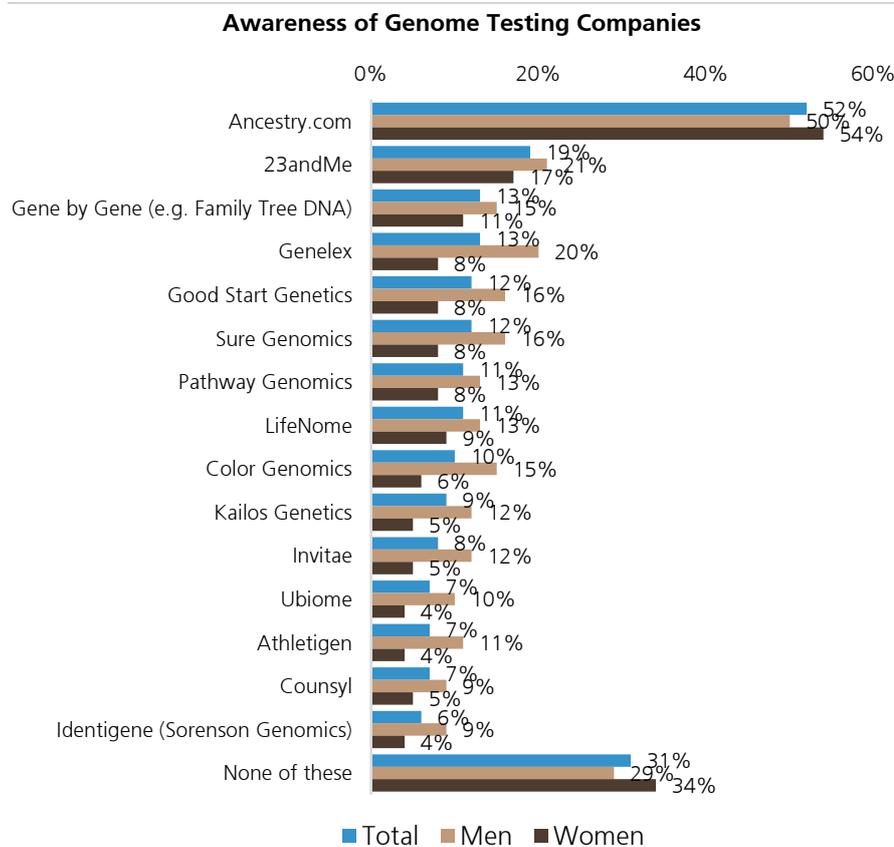


Source: UBS Evidence Lab.

- Question: Which are the most commonly known personal genome testing companies? How do consumers get to know about these companies?

Among respondents who are aware of personal genome testing, Ancestry.com is by far the most well-known company with over half (52%) of them stating that they have heard about it. 23andMe is known by every 1 in 5 respondents while Gene by Gene, Genelex, Good Start Genetics and Sure Genomics follow with 12%-13% awareness levels among respondents who are aware of personal genome testing.

Figure 45: Ancestry.com by far the most well-known company

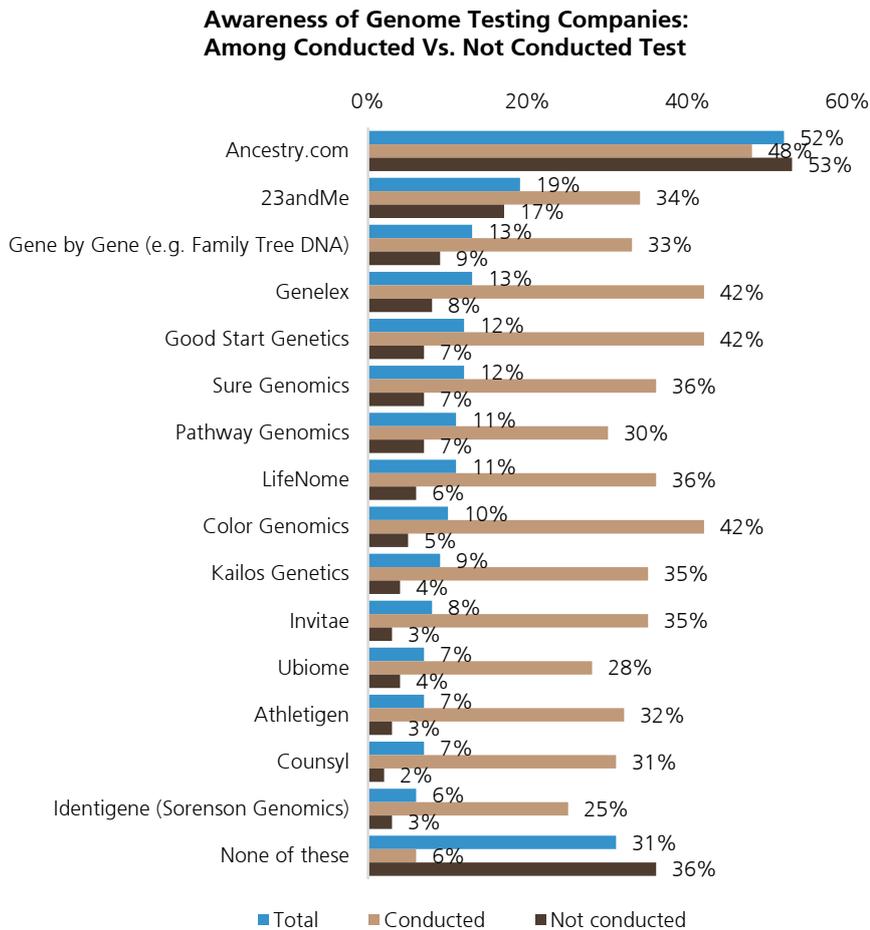


Source: UBS Evidence Lab.

However looking among those who have done the test versus those who have not – we see a more mixed picture. While Ancestry.com is still the most known (48%), it is closely followed by Genelex, Good Start Genetics and Color Genomics (42%).

23andMe is known among 34% respondents who took the DNA test. It is important to note that one in three respondents who are aware of personal genome testing do not know any of these companies.

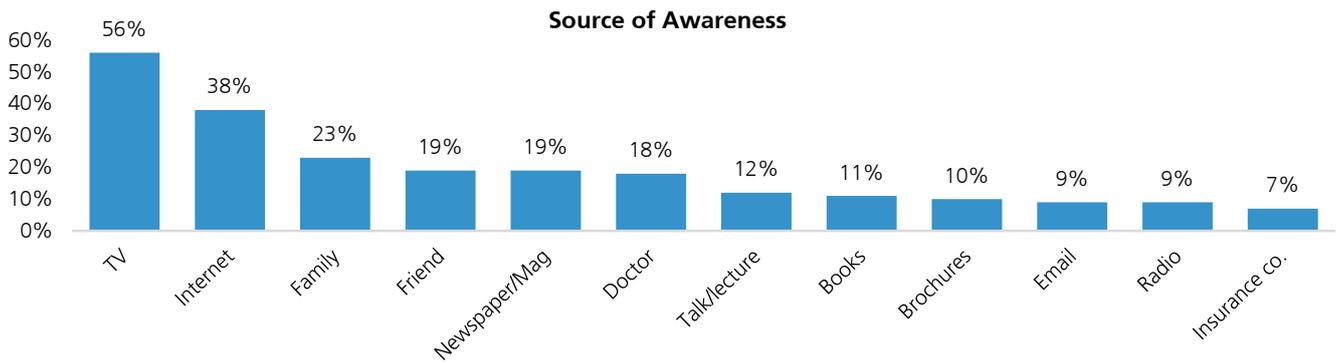
Figure 46: Ancestry.com by far the most well-known company



Source: UBS Evidence Lab.

TV is the primary source of awareness with close to 60% respondents becoming aware of genome testing through it. Nearly 4 in 10 got the information through the internet.

Figure 47: TV is the primary source of awareness



Source: UBS Evidence Lab.

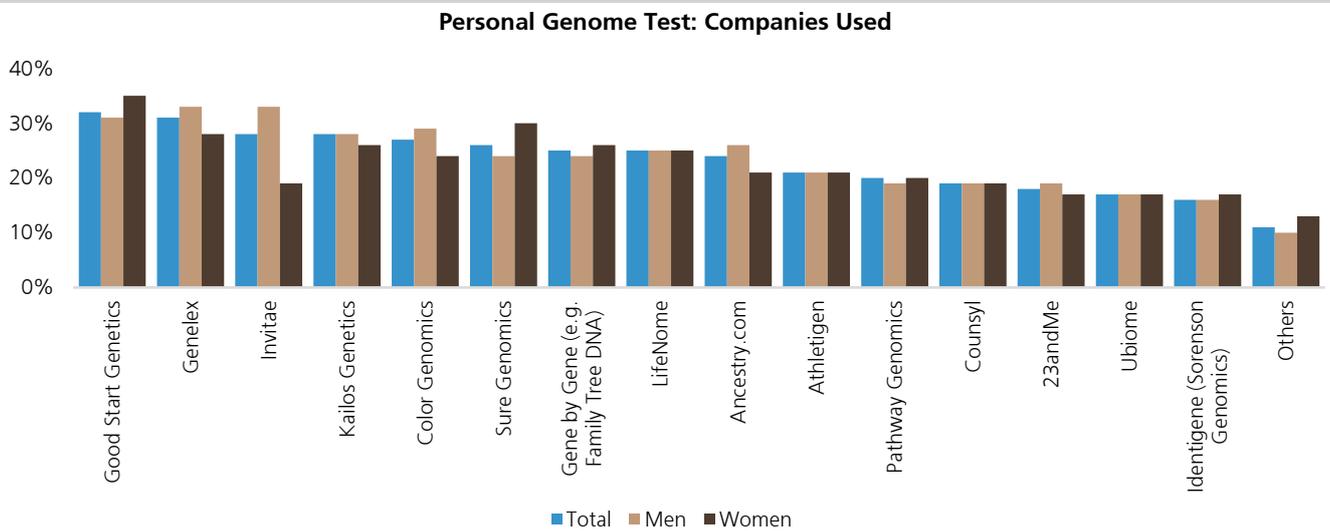
Companies used for testing, decision drivers

- Question: Which companies were used for personal genome testing?

Good Start Genetics and Genelex were the most commonly used companies for genetic testing. Invitae, Kailos Genetics and Color Genomics complete the list of top 5 companies used for genome testing. These results reflect the sample skew toward physician-driven testing.

Ancestry.com was mentioned by 24% respondents while 23andMe was used by 18% respondents who have taken a personal genome test.

Figure 48: Good Start Genetics most commonly used test among participants

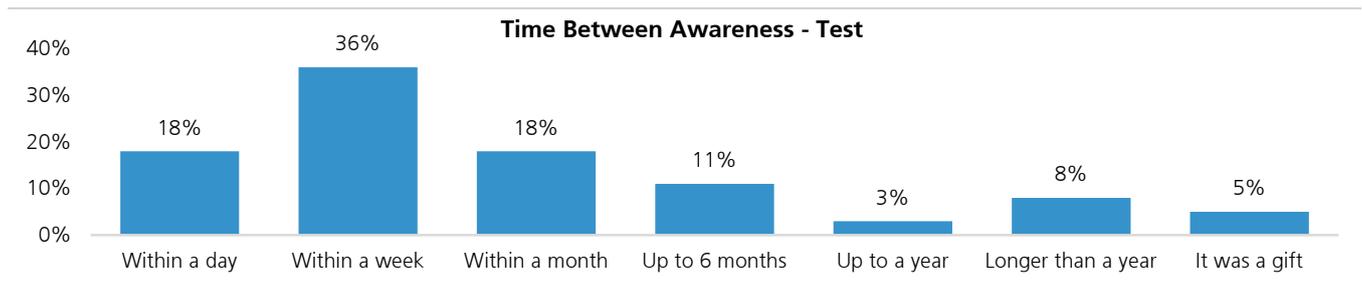


Source: UBS Evidence Lab.

- Question: How long does it take from awareness to action for a personal genome test?

Personal genome test appears to be a quick action decision with a short duration between becoming aware and going for the test – among those who are interested. More than half had the test done within a week and nearly three-fourths went ahead within a month.

Figure 49: More than half of those interested in a test, took one within a week



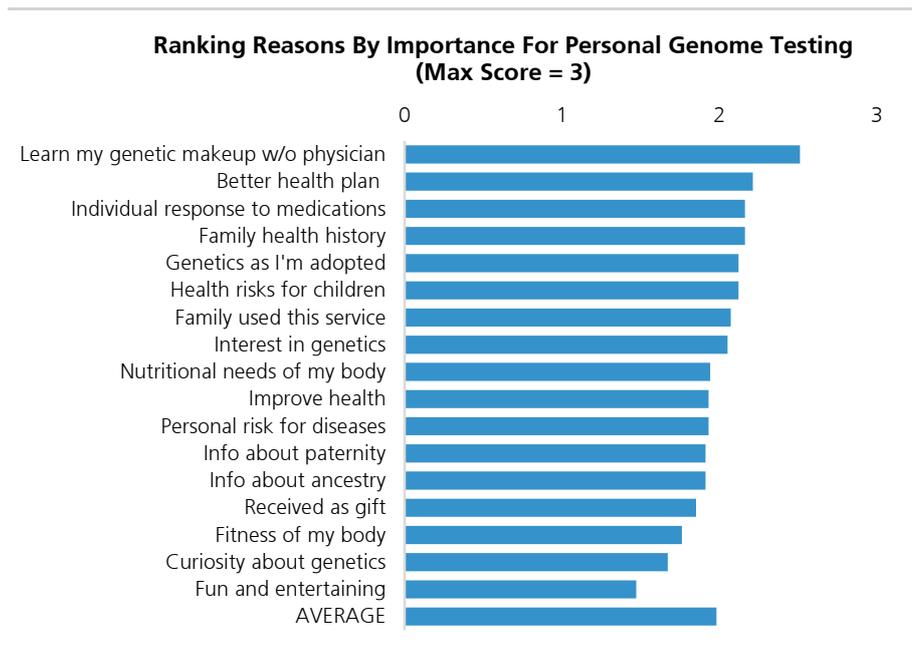
Source: UBS Evidence Lab.

- Question: What drives the need for a DNA test?

Interest in taking control of diagnosis without going to a Doctor is a clear winner as a reason for conducting a DNA test. Other top 3 reasons are also health associated – better health plan and response to medication.

Paternity and interest in ancestry are clearly not the top drivers while low scores for curiosity and entertainment means that DNA testing is purpose driven and is unlikely to be taken lightly.

Figure 50: Interest in taking control of diagnosis without going to a Doctor is a clear winner as a reason for conducting a DNA test



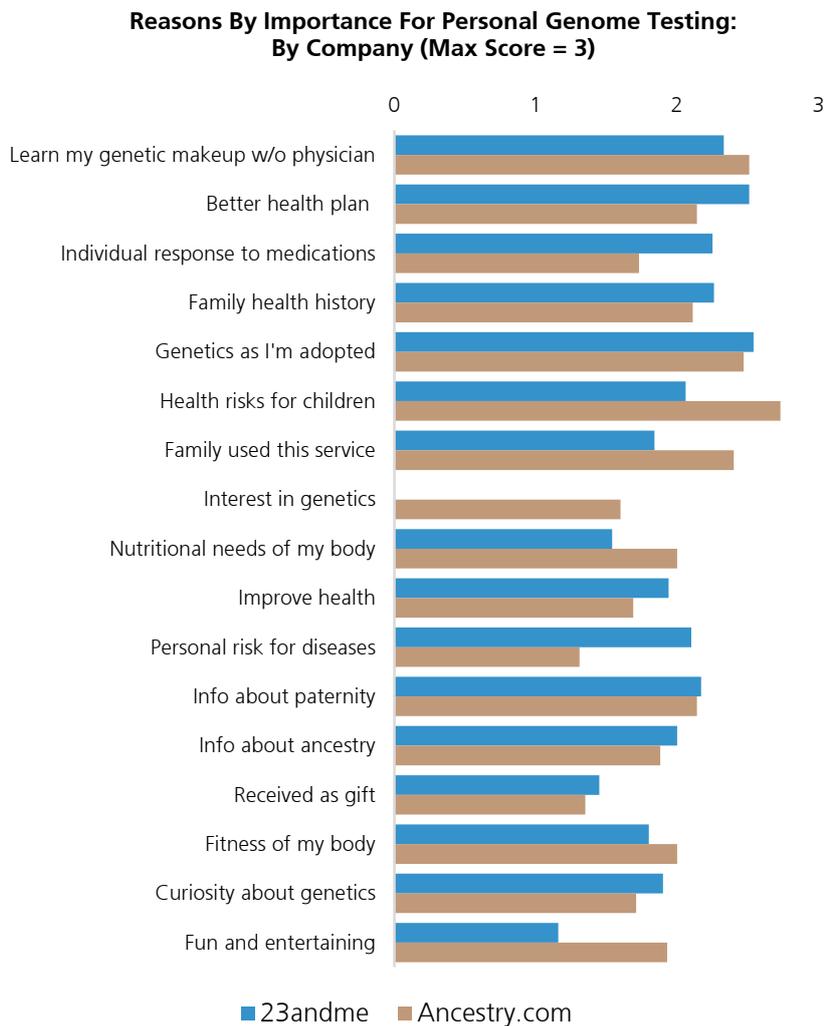
Source: UBS Evidence Lab.

Looking at the attribute importance differences between those who got tested through Ancestry.com and 23andMe, we see that Ancestry.com led 23andMe on the attribute of – health risk for children, family having used it before, interest in genetics, nutritional needs and fun.

23andMe was ranked superior to Ancestry.com on better health plan, response to medication, and risk of disease.

It looks unlikely that there is a clear pattern of preference between the two, which we think again reflects the newness of personal genome testing.

Figure 51: 23andMe was ranked superior to Ancestry.com on better health plan, response to medication, and risk of disease.



Source: UBS Evidence Lab.

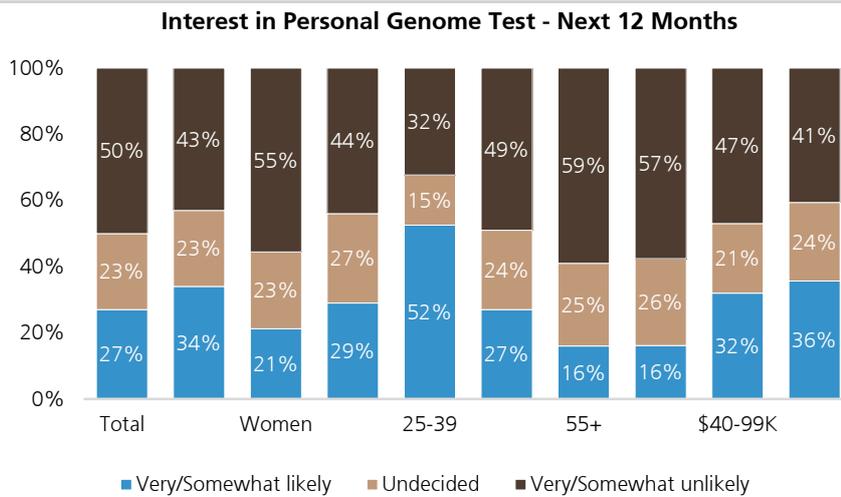
Future interest in testing

- Question: What is the interest level among those who haven't had a test yet?

About one-fourth of the available market (aware but not tested yet) is likely to go for the DNA test in the next 12 months. Men are much more likely than women (34% vs. 21%) to get tested while those in the 25-39 year age group are about twice more likely than those in the 18-24 or 40-54 age group to go for the test. Those above the age of 55 years show the least interest in genetic testing.

It is important to note that there is large proportion of the population (50%) that has no intention to test in the next 12 months and only about 23% who are undecided. One of the key challenges for companies offering consumer genome testing would be to create better awareness and interest (hooks) in the target population for these tests.

Figure 52: About one-fourth of the available market (aware but not tested yet) is likely to go for the DNA test in the next 12 months



Source: UBS Evidence Lab.

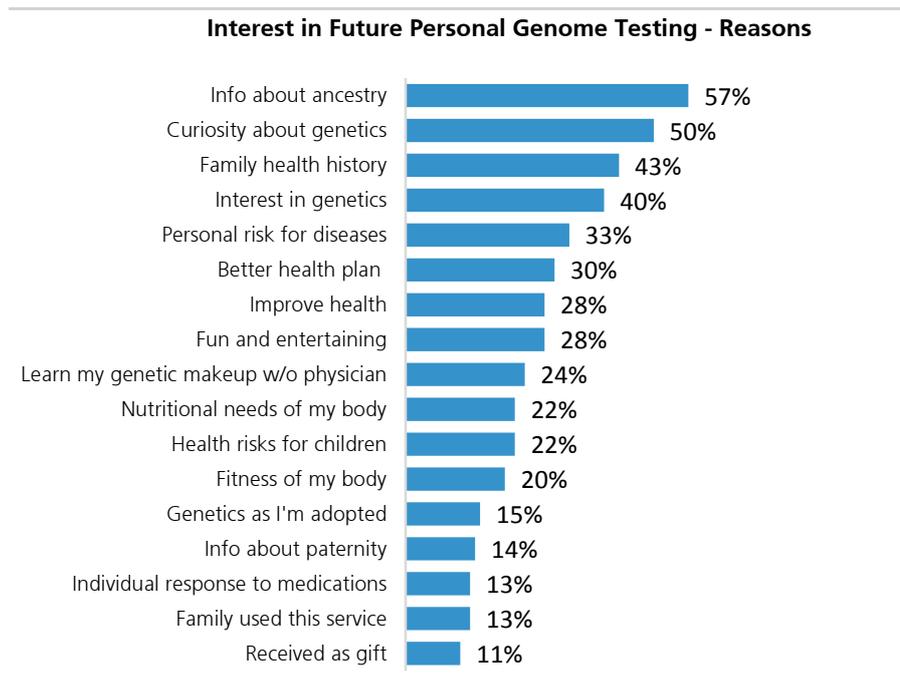
- Question: What drives this interest for a test sometime in next 12 months?

It is interesting to note that while the respondents who went in for the testing (Q5a earlier) primarily chose health management as the key reason, the interest among those planning to go for testing in the next 12 months is primarily driven by interest in ancestry and general curiosity.

While health reasons are mentioned in the other top 5 reasons mentioned for testing, it is clear that the interest is being driven more by non-health related drivers.

If the companies intend to drive a wider messaging on the benefits of genome testing then perhaps increasing the prominence of health management and risk mitigation related reasons and bring those to the fore would be a good idea.

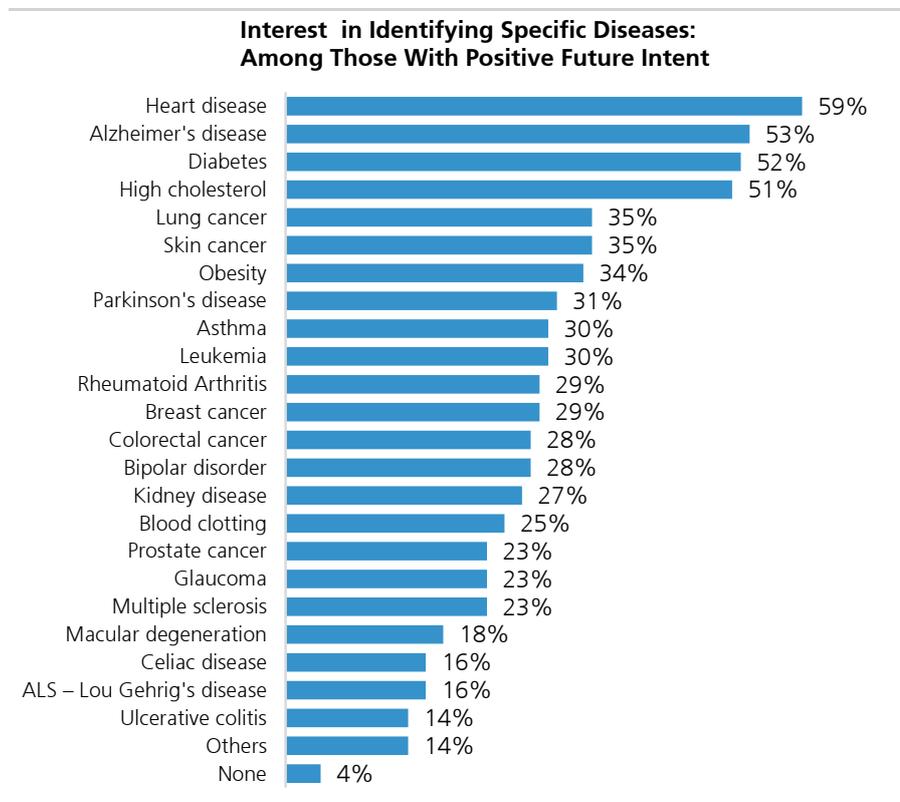
Figure 53: Ancestry information and curiosity of genetics the main reasons driving test interest



Source: UBS Evidence Lab.

- Question: Which diseases would the future testers like to identify?

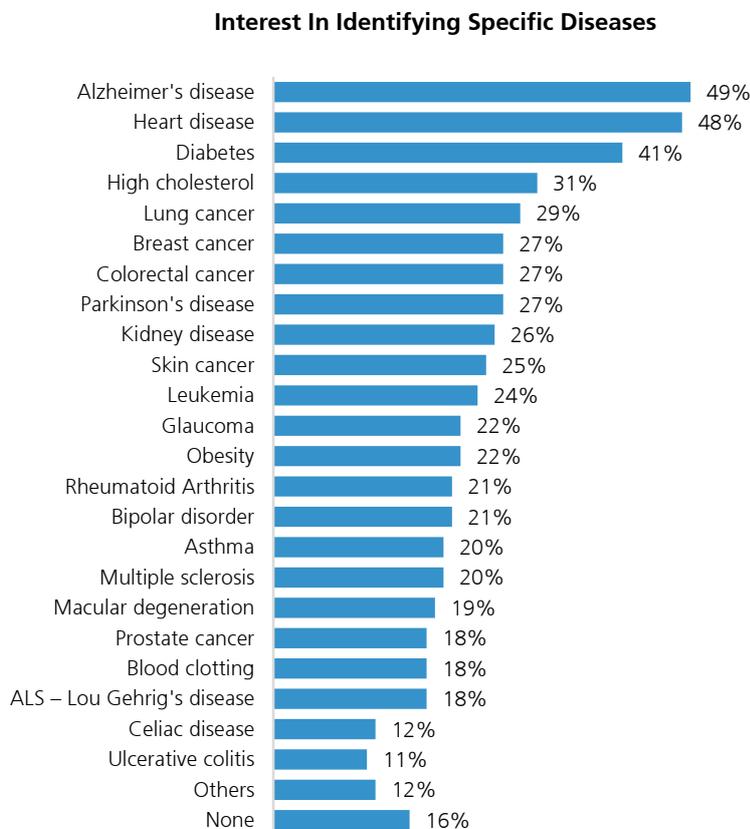
Figure 54: Heart disease and Alzheimer's are specific areas of test interest



Source: UBS Evidence Lab.

- Question: Which diseases would the future testers like to identify?

Figure 55: Alzheimer's, heart disease and diabetes diagnosis is most likely to drive diagnostic related testing.



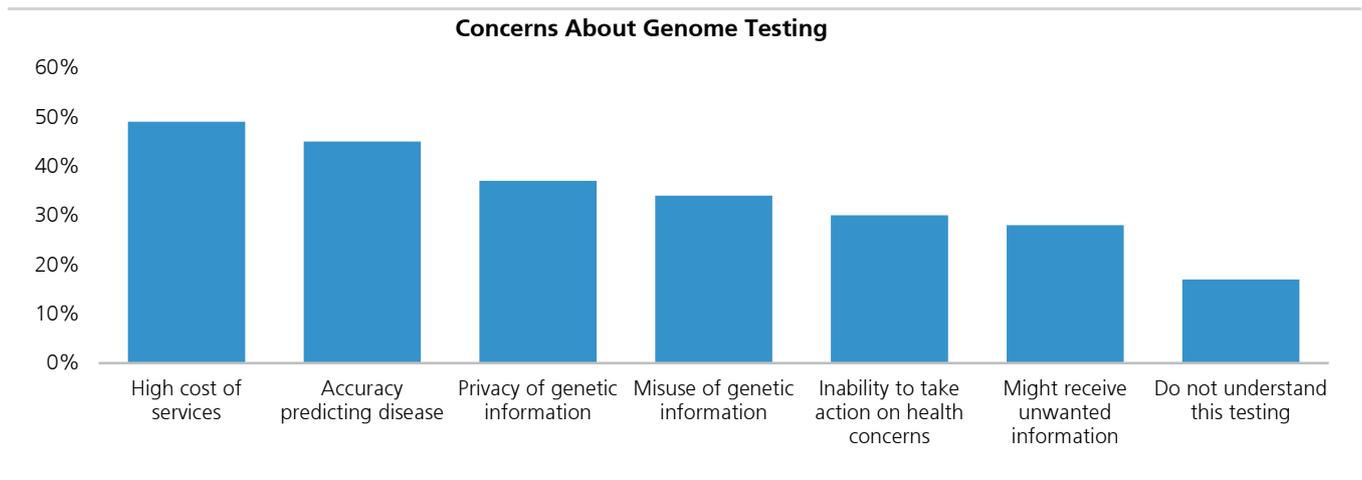
Source: UBS Evidence Lab.

- Question: What are the concerns with DNA testing?

While cost of the service is mentioned most often as the concern for genome testing, accuracy of the predictions comes a close second.

Privacy and misuse are mentioned by over one-third of the respondents indicating that while managing the price points may improve the interest level of the potential consumers, there are key concerns around use/misuse of the information as well as the science and accuracy behind all the effort.

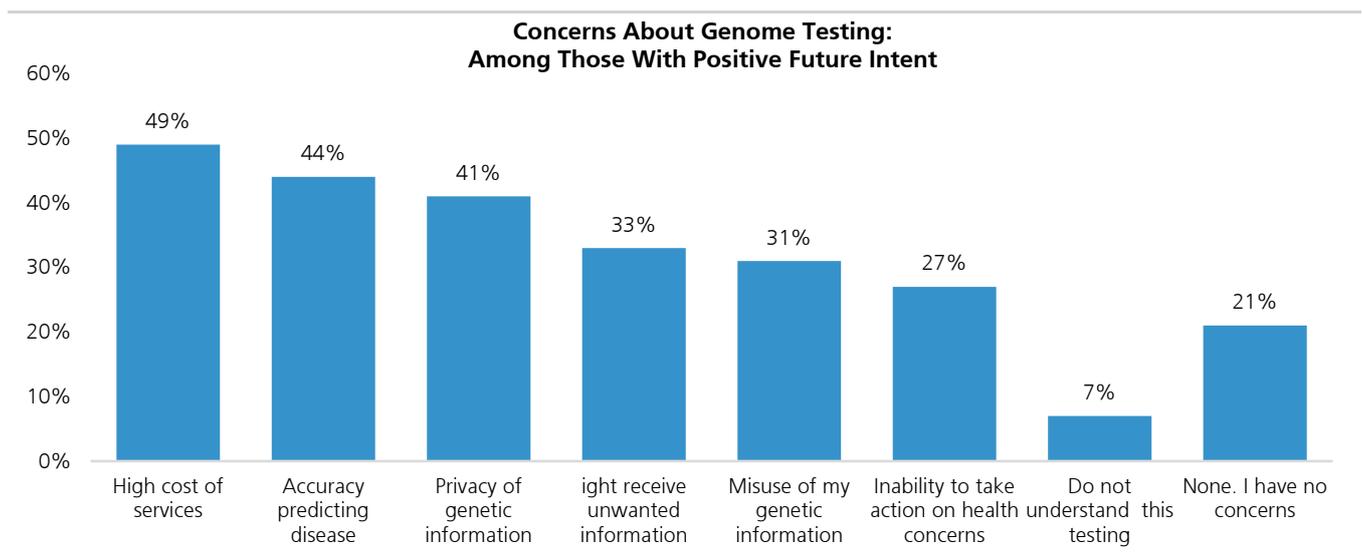
Figure 56: Cost of the service and accuracy of the predictions key perceived issue with tests today



Source: UBS Evidence Lab.

- Question: What are the concerns with DNA testing?

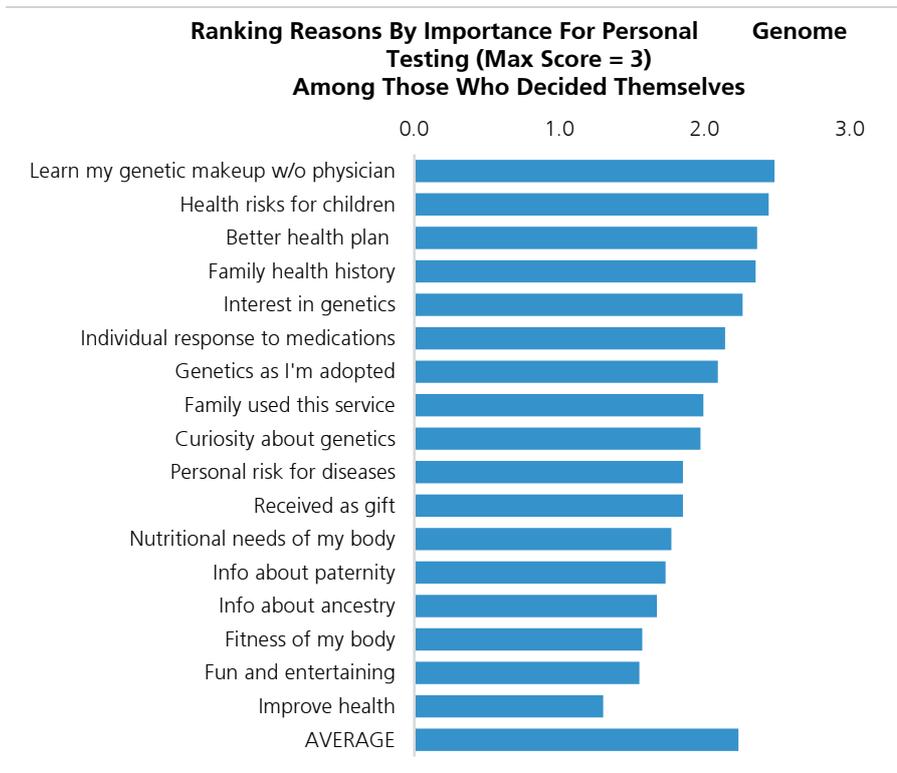
Figure 57: Cost of the service and accuracy of the predictions key perceived issue with tests today



Source: UBS Evidence Lab.

- Question: What drives the need for a DNA test?

Figure 58: Among those who pursued a test themselves, learning about their genetic makeup was a leading driver



Source: UBS Evidence Lab.

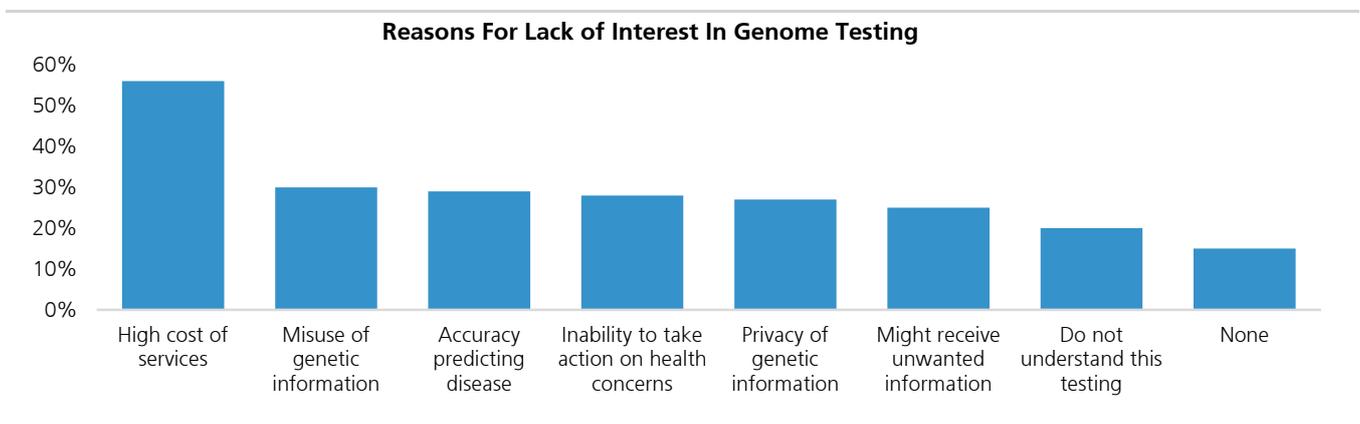
Consumers with no future interest

- Question: Why are you not interested in DNA testing?

Among respondents who are aware but unwilling to undergo the test, cost acts as a deterrent for nearly 6 in 10 potential customers. Misuse and accuracy concerns are seen in nearly a third of the respondents.

Here again, while managing the price point may increase the interest, concerns around information management and analysis might impact the final decision.

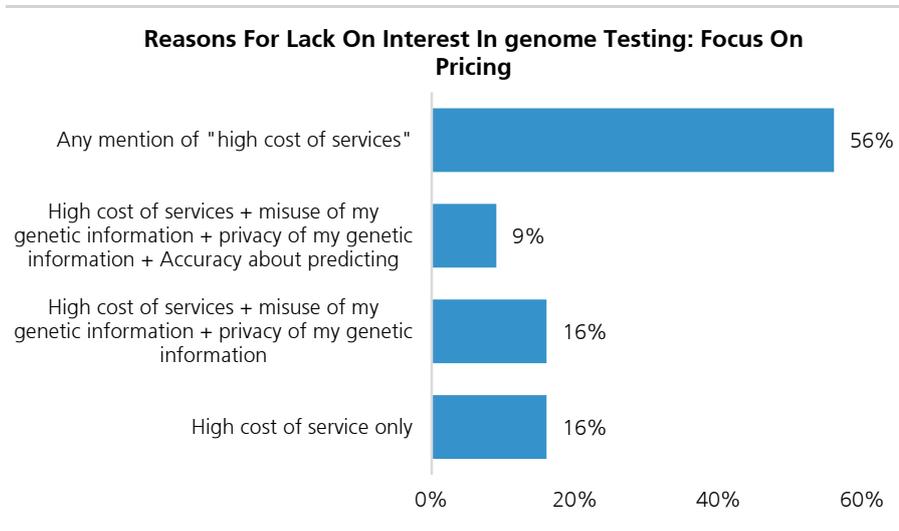
Figure 59: Among respondents who are aware but unwilling to undergo the test, cost acts as a deterrent for nearly 6 in 10 potential customers.



Source: UBS Evidence Lab.

- Question: Why are you not interested in DNA testing?

Figure 60: High cost of service an isolated reason for lack of interest



Source: UBS Evidence Lab.

Pricing & Bundling

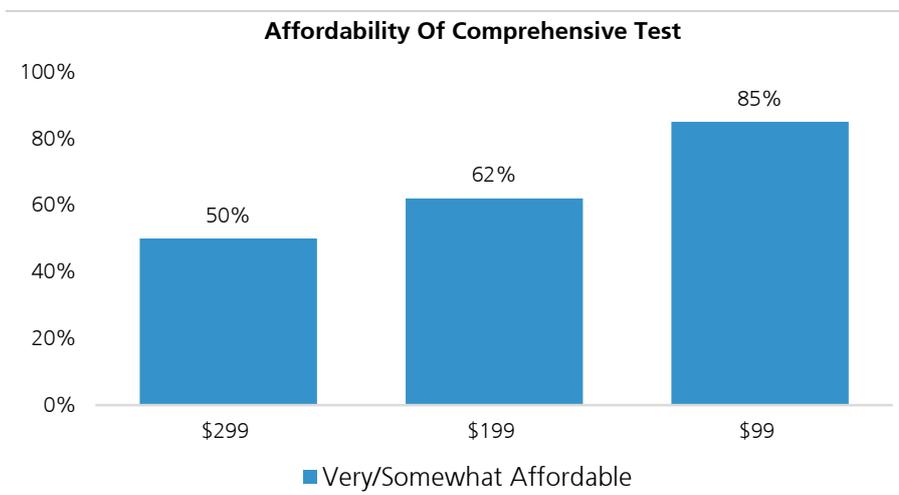
- Question: How do consumers react to the pricing for a comprehensive DNA test?

A comprehensive test at \$99 gets very high score on affordability. With 85% respondents feeling that \$99 is a very/somewhat affordable cost, it appears to be a good entry price point.

At \$199, the favorability drops to 62% and we have 50% respondents stating that \$299 is affordable.

It is important to note that even through the affordability score drops with increasing price, we have a healthy 50% feeling that \$299 is affordable.

Figure 61: A comprehensive test at \$99 gets very high score on affordability

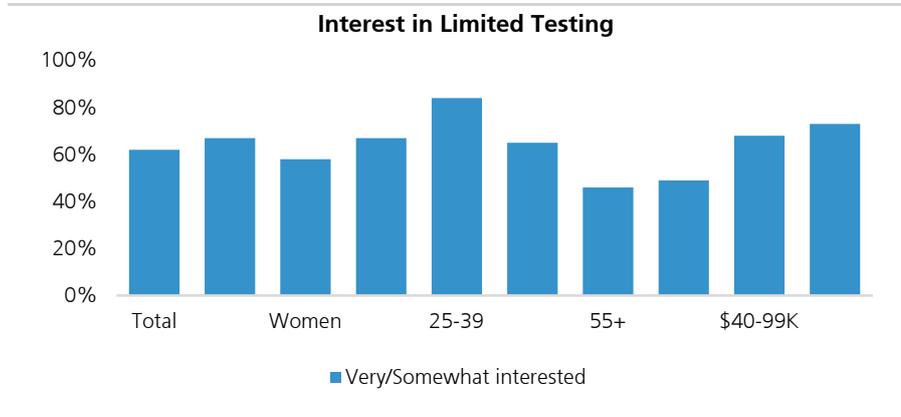


Source: UBS Evidence Lab.

- Question: Do consumers like the idea of a limited – issue based - DNA test?

Limited testing for specific issues finds high favor with nearly two-thirds interested in this service. Men have higher interest in this offer than the women and those in the age group of 25-39 show highest interest among all age groups.

Figure 62: Limited testing for specific issues finds high favor with nearly two-thirds interested in this service.



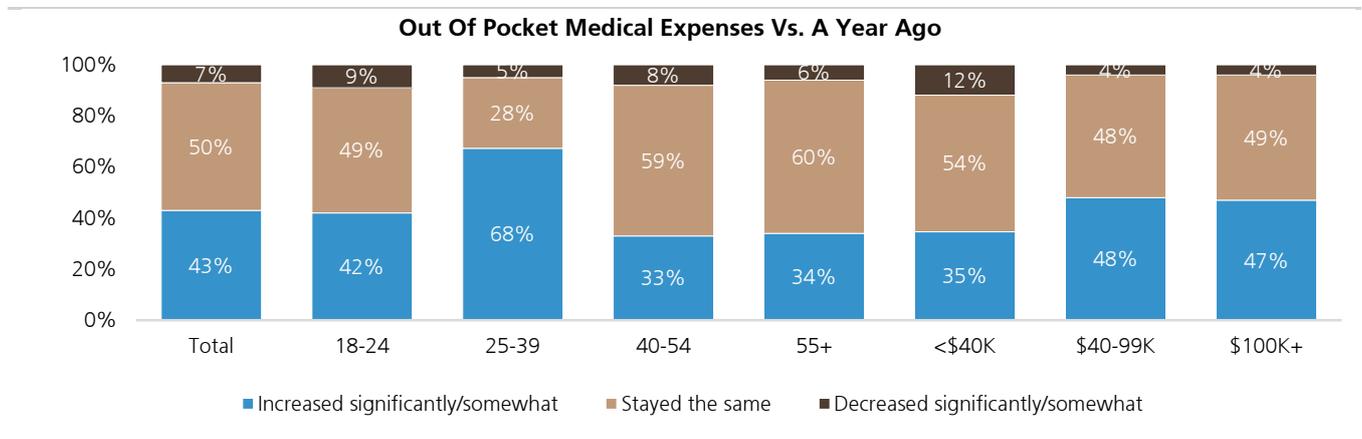
Source: UBS Evidence Lab.

Medical Expenses

- Question: Have the out of pocket health care costs changed in the past 12 months?

Nearly 1 in every 2 respondents felt that the out of pocket costs have gone up in the past year. Among the 25-39 years old, this was as high as 68%.

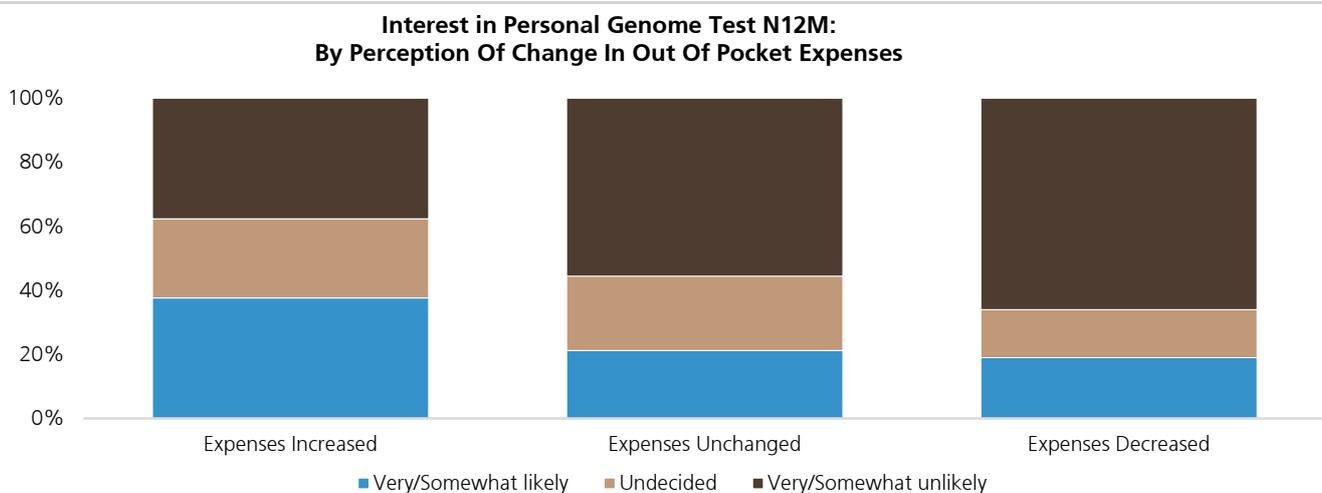
Figure 63: Nearly 1 in every 2 respondents felt that the out of pocket costs have gone up in the past year.



Source: UBS Evidence Lab.

- Question: What is the link between perception of change in out of pocket expenses and interest in genetic testing?

Figure 64: Decreasing out-of-pocket expenses could be a key driver of increased test interest



Source: UBS Evidence Lab.

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Valuation Method and Risk Statement

Life Science Tools, Clinical Dx & Supplies, and Genomics companies are impacted by a number of economic, regulatory, and reimbursement uncertainties. Investment risks include macro cyclicalities, product risk, technology risk, adverse reimbursement decisions, market share and price declines due to competitive pressures, heightened volatility in certain industrial end markets, government/academic funding pressures, pharmaceutical consolidation and increased regulation.

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12-Month Rating	Definition	Coverage ¹	IB Services ²
Buy	FSR is > 6% above the MRA.	49%	32%
Neutral	FSR is between -6% and 6% of the MRA.	38%	26%
Sell	FSR is > 6% below the MRA.	14%	19%
Short-Term Rating	Definition	Coverage ³	IB Services ⁴
Buy	Stock price expected to rise within three months from the time the rating was assigned because of a specific catalyst or event.	<1%	<1%
Sell	Stock price expected to fall within three months from the time the rating was assigned because of a specific catalyst or event.	<1%	<1%

Source: UBS. Rating allocations are as of 31 March 2016.

1:Percentage of companies under coverage globally within the 12-month rating category.

2:Percentage of companies within the 12-month rating category for which investment banking (IB) services were provided within the past 12 months.

3:Percentage of companies under coverage globally within the Short-Term rating category.

4:Percentage of companies within the Short-Term rating category for which investment banking (IB) services were provided within the past 12 months.

KEY DEFINITIONS: **Forecast Stock Return (FSR)** is defined as expected percentage price appreciation plus gross dividend yield over the next 12 months. **Market Return Assumption (MRA)** is defined as the one-year local market interest rate plus 5% (a proxy for, and not a forecast of, the equity risk premium). **Under Review (UR)** Stocks may be flagged as UR by the analyst, indicating that the stock's price target and/or rating are subject to possible change in the near term, usually in response to an event that may affect the investment case or valuation. **Short-Term Ratings** reflect the expected near-term (up to three months) performance of the stock and do not reflect any change in the fundamental view or investment case. **Equity Price Targets** have an investment horizon of 12 months.

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UBS Securities LLC: Jonathan Groberg; Harris Iqbal; Edmund Tu.

Company Disclosures

Company Name	Reuters	12-month rating	Short-term rating	Price	Price date
Illumina Inc ^{16, 18}	ILMN.O	Buy	N/A	US\$135.92	02 May 2016

Source: UBS. All prices as of local market close.

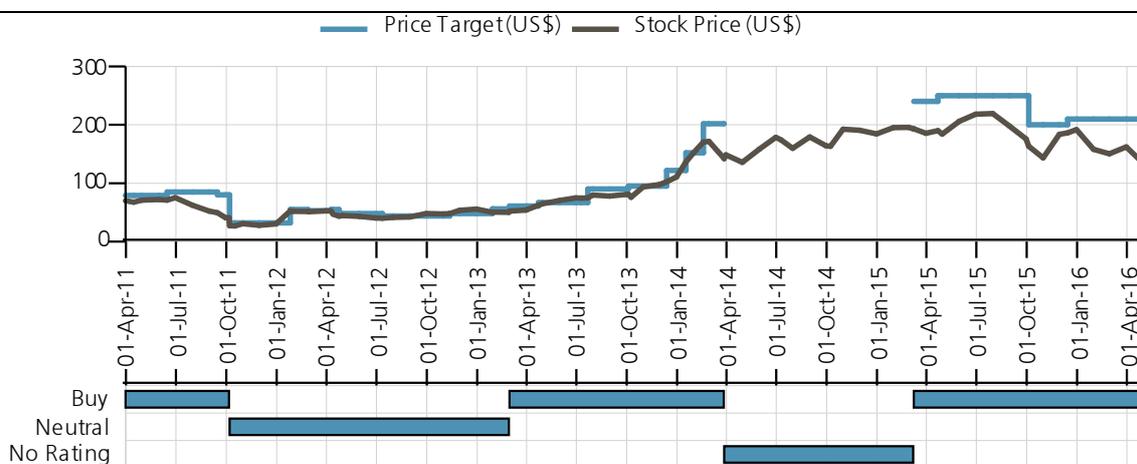
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16. UBS Securities LLC makes a market in the securities and/or ADRs of this company.

18. A U.S.-based global equity strategist, a member of his team, or one of their household members has a long common stock position in Illumina Inc.

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Illumina Inc (US\$)



Source: UBS; as of 02 May 2016

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