HOUSE OF COMMONS

Science and Technology Committee

Oral evidence: Commercial genomics, HC 33

Monday 28 October 2019

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Watch the meeting

Members present: Norman Lamb (Chair); Vicky Ford; Bill Grant; Darren Jones; Stephen Metcalfe; Carol Monaghan; Graham Stringer.

Questions 55 - 183

Witnesses

I: Kathy Hibbs, Chief Legal and Regulatory Officer, 23andMe; Avi Lasarow, Chief Executive Officer, DNAfit; and Carla Newell, Chief Legal Officer and Chief Risk Officer, Ancestry.com.

Written evidence from witnesses:

- 23andMe (1) and 23andMe (2)
- Prenetics International and DNAfit
- Ancestry.com

Examination of witnesses

Witnesses: Kathy Hibbs, Avi Lasarow and Carla Newell.

Q55 **Chair:** Welcome, all of you. Could we start with very brief introductions from each of you, please?

Kathy Hibbs: Good afternoon, and thank you for having me. I am Kathy Hibbs, the chief legal and regulatory officer for 23andMe.

Avi Lasarow: Good afternoon. My name is Avi Lasarow. I am the CEO of a company called DNAfit, as well as the international CEO of a company called Prenetics International, which acquired us approximately 18 months ago.

Carla Newell: Good afternoon. My name is Carla Newell. I am the chief legal and risk officer of Ancestry.com.

Q56 **Chair:** Excellent. I shall start with some questions, if I may. Can each of you briefly describe the services you offer?

Kathy Hibbs: 23andMe offers an over-the-counter and direct-to-consumer genetic test. We offer two varieties; one is ancestry only, non-health information. The second is an FDA-authorised and reviewed health service, which includes results for carrier screening and some genetic health risk. In future, it will also include an FDA-authorised response to certain pharmacogenetics—drug metabolism testing.

Avi Lasarow: As a company, we specialise in an area called wellness for the genetic tests we offer—genetic tests for the purpose of nutrition and fitness advice. In future, of course, we would look to go into other categories as well.

Carla Newell: As a company, Ancestry has been in the family history space for approximately 30 years, starting with, primarily, family history records from all over the world, democratising data and information about family history, and tree-building software. More recently, we have a DNA product that does ethnicity, origins and the matching of genetic relatives. We do not offer a health product in the UK, although we have recently launched a health product in the US market.

Q57 **Chair:** Thank you. Do you see yourselves as having a duty of care to your customers? If so, how do you understand that?

Kathy Hibbs: I can speak on behalf of 23andMe. We certainly see ourselves as having a duty of care for our customers. First and foremost, our mission has always been around health; it is to take the discoveries that have been made—many in the UK, which is obviously a leading sponsor of genetic sciences—and democratise and bring that information to individuals, so that they can benefit from it by having the potential to find out information when they might otherwise not be clinically qualified for testing. Testing in the UK as well as in the United States, when done

clinically, is generally done on the basis of either individual health or family health history. For example, in our testing in the health space, approximately 50% of the people whom we discovered have a deleterious mutation would not have been eligible for clinical testing.

Q58 **Chair:** But specifically on the duty of care, how do you interpret that?

Kathy Hibbs: We interpret it, obviously, as meaning that we meet the highest standards possible for the information we provide. We have met an established FDA standard. Our per cent. predictive value, positive or negative predictive value, is 99%, with a 95% confidence interval.

Q59 **Chair:** To pick you up on that, as I understand it, that certification refers to the validity of the testing rather than the validity of the interpretation of the test results.

Kathy Hibbs: No, that is not true. For us, our service starts at the collection kit, which is a registered medical device, in the EU as well as in the US, through the actual laboratory service to the results. It is our end-user result.

Q60 **Chair:** You are saying that the 99% figure relates to the correct interpretation of results.

Kathy Hibbs: Of the health results, yes. If we tell you that we have detected a mutation or not detected a mutation, it is that determination that is 99%, in our health results.

Q61 **Chair:** There is no more interpretation than that. You do not look at the implications of the mutation.

Kathy Hibbs: Well, on the implications of the mutation, we only report on mutations that are clinically valid, meaning that they also have to have met an FDA standard, but it is a fairly common standard around the world. It means that they have been published in at least two peer-reviewed journals and, generally speaking, are also in clinical care guidelines. We are not reporting on mutations that, for example, might be suspected to be associated with disease; we report only on mutations that are known and proven to be associated.

Q62 **Chair:** Avi Lasarow, how do you interpret any sense of a duty of care to customers?

Avi Lasarow: Since 2016, we have been quite public in self-regulation. We developed a code of principles that we operate, which of course includes making sure that, specifically in our wellness category, all our customers have access to a consultant, either before or after taking the test. The consultants are degree-educated individuals, with a degree in sports science, or in fact dietitians, who can help our customers understand the context of what role the DNA test plays in their lifestyle more generally.

The duty of care we give is making sure that there is a code of conduct and that there are good principles in how we include genes in our panel, and being transparent about what those genes are, so customers know exactly what they have been tested for. It is also about making sure that there is a minimum threshold of evidence that is published before we put the gene into our actual panel.

Q63 **Chair:** You will be aware of the correspondence that your company has had with Professor Timothy Frayling of the University of Exeter.

Avi Lasarow: Yes, that is correct. We are aware of the correspondence, and we welcome more correspondence, and to working with Tim and other stakeholders in the sector.

Q64 **Chair:** He says: "I have come to the conclusion that there is currently no evidence of utility to individuals and that companies selling diet and lifestyle advice tailored to DNA profiles are merely 'sexing up' standard diet and exercise advice to make money from people when there is no evidence of utility of their product."

Avi Lasarow: I have to say that we have, of course, a scientific advisory board, and on that is Dr Keith Grimaldi, who is a leader in the field and Cambridge educated, with just under 100 published papers. He specialises, and in fact in December 2017—

Q65 **Chair:** And he strongly disagrees with that view.

Avi Lasarow: In 2017, he published a paper—he was the lead author—calling for guidelines to how this evidence is essentially validated in relation to genetic and diet interactions. Professor Ildus Akhmetov, who is a world leader in genetics for sports genomics and a lecturer at Liverpool John Moores University, has also given us guidance on what we communicate and how we communicate it.

Q66 **Chair:** Do they disagree with the view given by Professor Frayling?

Avi Lasarow: They certainly have a different opinion. We have been engaged with Professor Frayling for a number of years and welcome debate. We think that scientific debate is what moves the industry forward, and we welcome him and other stakeholders in our sector to engage further on these topics.

Q67 **Chair:** He also says: "On their website, DNAfit claims to offer 'genetically-guided recipes for your DNA profile' and 'Genetically-matched training programs'. With the exception of specific diet disorders…there is no evidence that people with subtle DNA differences will benefit in any way from such 'genetically guided' advice. On challenging them to provide examples of diet and exercise regimes that differ by a person's genotype they have responded with 'the genetic test is just one part of the advice that comes as a package.' However, this is sophistry because of the lack of robust evidence that the advice should be any different between people carrying different versions of the genetic variants

tested." That is quite a strong criticism of your company.

Avi Lasarow: It is, certainly in the correspondence that he has sent to the Committee for consideration, but we definitely stand by the advice given to us by the scientific advisory board. Also, Chair, a meta-analysis was conducted across 32,000 publications last year in which it was clearly concluded that, when an individual is given a genetic test for the purpose of nutrition or fitness interventions, it motivates behavioural change. Certainly, that is the same with our data.

Q68 **Chair:** It might motivate behavioural change without its having any direct relevance to the advice on lifestyle that you might be giving them.

Avi Lasarow: We welcome Professor Frayling and other colleagues in the space scientifically to come and meet us to explore their concerns and allow us to address those concerns. We feel very clear that the advice we give is best in class out there in the market.

Q69 **Chair:** Carla Newell, how do you interpret any sense of duty of care that you have to your customers?

Carla Newell: Since, as I mentioned, we do not offer health products in the UK, our duty of care is around protecting our users' rights and their data. We have been a company founded on the trust of our customers; we have housed very important personal data to our users about their family history for 30 years, and we continue to do that with their DNA data.

Q70 **Chair:** Do you publish the full evidence base that each of your test results is based on, in such a way that it could be independently assessed by experts? I would like a very brief answer from each of you. Do you publish it all?

Kathy Hibbs: We do. With ours, obviously, because of the health results being FDA-authorised and reviewed, in our package insert there is summary data of the analytical validity and the citations to the specific clinical evidence. There is also, in each report, the scientific details present; there is also data in there with regards to the user comprehending the studies.

Q71 **Chair:** You do not give a link on your website to the clinical evidence behind the genetic variants that you search for.

Kathy Hibbs: It is actually in every report. It is not on a link.

Q72 **Chair:** What about independent researchers? They cannot go to your website and find it.

Kathy Hibbs: They can get to it, but they would have to click into the specific marker reports that are there. I can give the Committee a shortcut to do it. You have to know where to find it.

Q73 **Chair:** Do you publish all the evidence?

Avi Lasarow: Yes, we do. In fact, one of our code of principles, which we recommend to the Committee for consideration, is to make sure that all companies publish the SNPs and genes they use in their test. We think that is very important, and gives full transparency, which is what is needed in this sector.

Q74 **Chair:** Your website lists the genetic variants it searches for in its tests and provides a list of six scientific papers as references, despite saying that it uses hundreds of studies to inform its products. That does not sound like publishing all the evidence.

Avi Lasarow: Chair, actually there are numerous places where we can give customers information about the SNPs that are used.

Q75 **Chair:** Do you openly publish all the evidence—those hundreds of studies?

Avi Lasarow: We openly share what SNPs are inside our tests, how we have found those SNPs and what minimum threshold criteria they have met, which is very important.

Q76 **Chair:** How about you, Carla?

Carla Newell: The ethnicity space is a little bit different, because we are looking at a broad range of variants across different populations, against reference panels, so it is a different type of analysis. There is not a one-to-one correlation that you could publish. That being said, our scientists have published a number of articles in peer-reviewed journals that relate to the population genetics work that they do.

Q77 **Chair:** How do you ensure that the test results are relevant to the general population, not just to those with certain symptoms or family histories?

Avi Lasarow: In our testing, Chair, we are very clear in advocating two main things. One is what genetics is, but also what it is not; we think that consumers need to be very clear that genetics is not the magic thing that is going to change their life necessarily, certainly within the fitness/nutrition space. We are also very clear about being completely transparent about what information we give our customers.

Kathy Hibbs: For our test, with regards to the health genetics, most of the discoveries have been made in European populations and in the Ashkenazi Jewish population, but there are studies that show that the mutations have the same effect in other populations. For example, if you are a carrier of one of the cystic fibrosis markers and you are Ashkenazi Jewish, the likelihood may be higher that you will actually develop the actual condition if you have two copies of it, as opposed to in another ethnicity. But it is still considered medically important.

We provide information to individuals about how to consider ethnicity with regards to each report. It varies by report. In some instances, gender matters; certain things affect males more than females. For

example, haemochromatosis affects males more than females because, until the onset of menopause, women are protected from the ill effects through their monthly cycles. There is different information on the basis of not just ethnicity but also gender to contextualise the genetic health results that we provide.

Q78 **Chair:** How often do you review your tests to ensure that results are based on up-to-date science? Could I have a quick response?

Kathy Hibbs: We are required to do so frequently, so we do it on a constant basis.

Avi Lasarow: We usually have a biannual or quarterly scientific advisory board meeting, where the team looks at all the latest evidence of new literature that is coming out and then decides, together with a bioethicist on our team, what to include and how to interpret it in the context of the reports we offer.

Carla Newell: We update our ethnicity panels and our ethnicity results, based on changes in updates and science, approximately once a year. We have just released our ethnicity version for 2019 in the last month.

Q79 **Darren Jones:** I had a quick look at your websites. Can I check, for the record, that all your organisations work together? If I have done a 23andMe test, I think I can port my data, can't I, to your organisations, and vice versa? Is that right?

Kathy Hibbs: We do not work together.

Q80 **Darren Jones:** But it says on your website that you do.

Avi Lasarow: Until recently, 23andMe has had an API, which is essentially a technology integration that allowed certain partners—we were one of those partners—to allow their customers to upload data to our site to be interpreted with our reporting methodology. About one year ago, if I am not mistaken, 23andMe disabled that service, but there are still companies like ours that allow users, if they want to upload their data to our service, to interpret only the genes related to the reports we offer, for the purpose of fitness and nutrition, as opposed to anything else, such as cancers and more clinical-type interpretations.

Q81 **Darren Jones:** And Ancestry does not do so.

Carla Newell: We do not allow anyone to upload data to our site. We allow our users, should they choose, to download their data; we believe it is their data, so they are free to do with it what they want, but we also give them significant warnings about the use of that data in a context other than genealogy, which it was not intended for.

Q82 **Darren Jones:** That was going to be the basis of my question. On the DNAfit website, it says, "It's so easy—just connect your data and you'll have your reports in under 30 minutes." It sounds as if I am transporting them between the two, but that is not true: I have to download my data

and then upload it.

Avi Lasarow: Exactly. Existing Ancestry and 23andMe customers have the ability to own their data and use it as they wish.

Q83 **Chair:** Why does 23andMe not disable the link?

Kathy Hibbs: We did not have a commercial relationship with DNAfit or others. There is a recognition that people own their data and might want to download it, so we were simply trying to make it technologically simpler for people to do it, but we became concerned. We, too, have extensive warnings on the fact that the data should not be used for health interpretations, for example.

We report on approximately 300 SNPs that have been well validated, meet an FDA standard and are offered in the US, Canada and the UK for health interpretation. Our chip tests over half a million SNPs, so, obviously, there are other SNPs that do not meet that level of standard, and we did not feel that the warnings were sufficient to prevent third parties from making health or other specious interpretations, so we disabled the API. People can still download their data, but we want to make sure that they have to go through a technical spec to do that. We did not in any way want to endorse technologies that we did not feel were meeting scientific or ethical standards as they related to SNPs.

Q84 **Darren Jones:** The purpose of my question is about the level of understanding from consumers. Obviously, this is a technical area, and the language is quite difficult, unless you are used to talking it. At the headline level to begin with, could each of you explain how in your customer order journeys you make it clear to your customers what your products are for and not for, and what information you provide to them when the test is returned, so that they are very clear about the limitations?

Kathy Hibbs: Our test is unique. One of the things we did with regards to going through the FDA was numerous user comprehension studies. These are done, obviously, in the US population, and they include people with less than a high school diploma up through people with college education, both genders and all ethnicities, across the entire age spectrum. We had to prove for every concept used in the report that at least 90% of the individuals understood the concept, and we met that standard. Most of the concepts test much higher than that; importantly, the idea that the lack of a marker does not mean that you cannot get the disease tested much higher than that.

In addition, in the UK, prior to launching, we met MHRA and reviewed the particular warnings and limitations that we would use in the UK. We made certain changes with regards to the language they wanted to see for that. Following the launch in December 2014, we entered a voluntary post-market surveillance programme with MHRA, during which for the following year we reviewed with MHRA every customer question or

complaint that we got from the UK. During that time, there were no reportable incidents.

One of the things that was of the most interest to MHRA was whether there were reports not just of incorrect results—there were none—but whether there were reports either from individuals or physicians that results had been misinterpreted, misused or misapplied. There were also none. Because we are compliant with IDD right now in the EU, as well as our FDA quality standards, we continue of course to have a robust post-market quality system, and we have never had a reportable incident coming from any jurisdiction. That is one of the key issues that we are marking.

Q85 **Darren Jones:** My key question is about the consumer experience in trying to understand. On the 23andMe website, you have a fairly chunky legal disclaimer on your homepage. This is one example: "Our carrier status reports can be used to determine carrier status, but cannot determine if you have two copies of any genetic variant." Do you think the general population will understand what that means?

Kathy Hibbs: I think in context they do. That is FDA language; it is required warning label language from the agency.

Q86 **Darren Jones:** What does it mean?

Kathy Hibbs: It means that if you are a carrier for autosomal recessive diseases, which is what carrier testing is for, you need two copies. You need to inherit one from each parent to actually be affected with the disease. Otherwise, if you have one mutation yourself, you will not have the condition, but you have the ability to pass it on to your child; if you have a child with another affected carrier, that child has a 25% chance. In the carrier module, there are education modules that are available pre and post-test that go through each type of report and explain that.

Q87 **Darren Jones:** I am sorry, I will come to you guys in a second. It says that the product is, "not intended to diagnose any disease…to tell you anything about your current state of health, or to be used to make medical decisions." On a basic level, what is the product for if it is for none of those things?

Kathy Hibbs: The product is not to supplement or to replace clinical testing. If you have a history of disease, or if you are currently ill and trying to understand whether there is a genetic cause for that disease, those individuals should be seen in clinical care. We are trying to warn them off; we do not want people to use the product that way.

If that does not apply to you, you would be very unlikely, in the UK or in most countries, to be eligible for clinical testing, but you might be interested to find out whether you actually have any of those variants. As I said earlier, approximately 50% of the people for whom we detect a BRCA mutation, for example, do not have a family health history, do not know that it runs in their family and would not have been eligible for

clinical testing. The real point of the test is to broaden the scope of genetic testing to individuals who might be missed in clinical care.

Q88 **Darren Jones:** Do you know how many of your tests lead to patients going to the health service and then having a diagnosis that required something?

Kathy Hibbs: We have looked at that; we looked at it in the UK prior to launch and more recently. For most of our reports, it depends on what you are talking about; you could be a cystic fibrosis carrier, but if you have no intention of having children or are not at that point in your life, there would not be much need to talk to your physician about that.

Q89 **Darren Jones:** Do you have percentages?

Kathy Hibbs: Yes.

Q90 **Darren Jones:** If 100% of your customers in the UK get a positive response saying, "You have something," how many of those customers in the end require treatment through the health service?

Kathy Hibbs: It is a very small percentage. We put some statistics in our written evidence with regards to that. What we see is representative of the penetrance of the mutation. By that, I mean that we would expect that for every carrier we identify with a BRCA variant, because of the medical importance of that mutation, the report says that they should consult a physician.

If you get a positive haemochromatosis result, the report would tell you to tell your physician at your next visit, unless you have symptomology or it runs in your family, in which case you should consult one. When we have done surveys in the UK of our UK customers, we see that a very small percentage—approximately 2% of our customers—make a physician's appointment to discuss their results, and that is directly in line with the level of the mutations and the likelihood of their occurring in the general population.

Q91 **Darren Jones:** What is that number? Two per cent. of UK customers is how many?

Kathy Hibbs: Approximately 2%.

Q92 **Darren Jones:** But in real numbers, how many is that?

Kathy Hibbs: We have approximately 200,000 customers in the UK.

Q93 **Darren Jones:** On the customer order journey, when you explain to consumers what your product is and what it is not, how do you make that case?

Avi Lasarow: Consumers go through the process of ordering a DNA test online, or through a practitioner such as a personal trainer. There are thousands of them in the UK and we have offered training to help them understand the genetic tests we offer and how to interpret them to their

clients. They get the DNA testing swab and send it back, and within about 10 business days we have a fitness and nutrition report for the customer.

There is also access through an app and an online portal. Inside the portal it is very clear, again, what genetics is and is not. It emphasises that genetics is, of course, part of the picture, but when the customer accesses their online experience for the first time, they get prompted to enter some lifestyle-related questions, which help to assess their lifestyle. Most importantly, we pride ourselves as a company on employing a number of dietitians and sports scientists to help consumers—our customers—really understand how to apply the test in the context of their life.

In terms of our recommendation to the Committee, if any new or existing entrants are looking to work in the sector, they should take on the responsibility of educating consumers, whether through practitioners such as the ones I described or through good education, which it has to be mandatory to complete, throughout the process. On practitioners, there are thousands of personal trainers giving lifestyle advice about diet and exercise, and there are nutritionists and dietitians across the UK, and we have offered CPD training as well to make sure that those individuals are very well versed in what genetics is not but also, again, what it is.

Q94 **Darren Jones:** How can you do that on the order journey, though? If I am buying it online—forgive me, I have not bought one—does it flash up? I have been reading in your terms and conditions, because I tend to do things like that, that "Genetic Information provides limited insight into health and fitness." If I am buying a DNAfit test to look at my health and fitness, does your order journey say, "By the way, this provides limited insight into your health and fitness"?

Avi Lasarow: As a company, we are conscious about overstating the claims for genetics. In terms of recommendations and principles, companies like us tend to be much more conservative about what we say the power of genetics is.

Q95 **Chair:** Does it say that? Is it in your terms and conditions? Does it say that to the customer as they buy the product?

Avi Lasarow: No, it does not say that as they buy the product.

Carla Newell: For us it is a little bit different, because what we are providing is ethnicity, origins and genetic relatives. That is what all our marketing says, and that is what all our terms and conditions say. It is all very consistent to the consumer that that is in fact what they are buying, and not a health product, because there is no mention anywhere of anything relating to health.

Q96 **Darren Jones:** You say that it is just about genetic tracing, and you might be able to find relatives based on your DNA. Is that the idea?

Carla Newell: Yes. Not only that, we provide you with your ethnicity pie chart—I think everybody has seen it from the advertising—and community assignment, based on various genetic variants, as to what communities within that ethnicity you might be related to, and potential migration paths of your forebears. If you choose to opt in to that feature of our product, which is on an opt-in basis, you might see genetic relatives you can then choose to communicate with, if both parties choose to do so.

Q97 **Darren Jones:** This is my very last question: forgive me, but I am interested. How precise can it be? My understanding is that we share genetic traits with huge swathes of populations. How do you explain that to your customers? Am I going to find my long-lost uncle in Canada, or am I just going to know that maybe I have some Canadian relatives?

Carla Newell: It depends. You might be able to find your long-lost uncle in Canada if other members of the family have taken the test. One of the advantages of having 15 million people in our DNA database across all the countries we serve is that there are a lot of potential familial connections that you can make.

Q98 **Darren Jones:** Are there any stats on that, though? I am conscious that on your website it says that ancestry DNA is more precise than ever before, but, if it was not very precise to begin with, incrementally, I suppose that might be right. Do you explain to customers what they are going to get for it?

Carla Newell: I believe we do. The test is accurate as to where it assigns people, but, as you build up a bigger and bigger database and bigger and bigger reference panels, you can have more granularity. Having that granularity allows you to find out much more about communities and sub-communities in smaller areas. What we have been able to do as the database has grown and the science has evolved is provide more granularity to customers over time.

Q99 **Darren Jones:** My very very last question is whether you do consumer testing to check whether they understand what you are telling them. Yes or no?

Carla Newell: We do, obviously. We have done numerous studies that have been submitted to the FDA and reviewed by it, which have demonstrated that.

Avi Lasarow: We do user groups, and in fact there are some independent sites that verify customers' experiences with companies and products.

Q100 **Darren Jones:** And understanding.

Avi Lasarow: Yes, absolutely.

Q101 **Darren Jones:** They understand.

Avi Lasarow: Yes.

Q102 **Darren Jones:** Okay.

Carla Newell: We have a whole consumer insight script that does consumer focus testing.

Q103 **Darren Jones:** If possible, would you mind writing to us to tell us about the level of consumer understanding?

Chair: Is this your final, final question?

Darren Jones: It is. Are you able to share that information with us?

Kathy Hibbs: We have had to demonstrate that every concept in the health report scores at least 90% or higher, and that is readily available in the package insert. The studies are actually the FDA's own analysis.

Darren Jones: It is so that we can refer in our report to levels of consumer understanding. That would be great. Thank you.

Q104 **Chair:** When you produce your report on fitness recommendations, lifestyle and so forth, how much of the report is standard lifestyle recommendations about healthy living, diet and exercise, and how much is genuinely bespoke to the test results you have undertaken?

Avi Lasarow: To give you some examples of our reports and how we have produced differentiating results from standard advice, we published a study nearly two years ago in *Biology of Sport*; it was peer-reviewed. We took a group of student athletes and put them into a 12-week exercise intervention study based on their results. Of the two metrics we measured, one was a counter-movement jump for explosive power, and the other was an aerobic test for endurance.

After the 12-week intervention, we remeasured the cohort to see if they had a difference, and in fact they had three times the difference on those same metrics. That was looking at something called the power endurance score. When we do the fitness test for our customers, we have a power endurance percentage, and the direction and interventions we give them for exercise are based on those power endurance recommendations primarily.

For nutrition advice, we ultimately direct individuals to genetically tailored diets. For example, in a paper that is due to be published, we looked at 200 individuals undertaking a ketogenic diet as well as a nutrigenomic diet. We found that the individuals in the complete cohort all had some weight loss/health benefits. Two years later, when the same individuals were remeasured, those who were given nutrigenomic advice and interventions sustained their health benefits and such. The report we give on nutrition directs people to one of three different diets based on their genetic profile.

Q105 **Vicky Ford:** You have talked about people owning their own data and the

value of large datasets. If your customers wanted to share their data with a national repository like the UK Biobank or Genomics England, would they be able to?

Kathy Hibbs: They would be able to from our perspective, and we have had conversations with Genomics England and the NHS, and they are open to it, but the technology at their end does not exist for them to do it yet.

Avi Lasarow: Yes, absolutely. As we enter the more clinical-type categories, we are going to be using a technology called exome sequencing, which we believe is the standard for these sorts of tests, to avoid false negatives or false positives. That data, with consumers' consent, should be made available to those databases, if they want it to.

Carla Newell: As I said, consumers own their own data. If they wish to download it, they can share it.

Q106 **Vicky Ford:** Sure, but I think you said, Kathy, that there was not interoperability between different databases.

Kathy Hibbs: We have had conversations and continue to have conversations, and we would love to do it, but at the moment there has not been an ability on the NHS side to put those into the records.

Q107 **Vicky Ford:** How should the Government support that genomic data collection so that it can be shared across the industry?

Kathy Hibbs: There needs to be a data alignment strategy so that people can provide their results directly. At the moment, we are working to see if we can upload it at the Boots end, for Boots the pharmacy, for people who have Boots as their designated pharmacist. That may be one strategy to do it. We also have it available to people on their mobile devices, and we have versions of the report that can be easily printed to share with physicians. We have non-technical ways of solving the problem at the moment. We are very open to doing it.

Q108 **Vicky Ford:** Does anybody want to add to that?

Avi Lasarow: Yes, I think that is where the huge opportunity is.

Q109 **Vicky Ford:** But do you have any specific suggestions on how Government could help to make the data sharing easier?

Avi Lasarow: Exactly as my colleague was saying, there should be a more detailed data strategy that should be made available. It can accelerate the UK's already growing leadership position in the world of precision health.

Q110 **Bill Grant:** Can I touch on counselling, which is quite a sensitive subject? The tests seem to go for a range of aspects such as ancestry, nutrition, fitness and health. In a nutshell, how important is the provision of counselling for clients seeking to take up a genomic test? What importance do you place on counselling for your clients?

Avi Lasarow: In our company and our service, we put the utmost importance on that, which is why from the outset we have employed a team of experts who can help consumers who want extra information. There are some who just want to get their report, and that is it, but about 20% of our clients have multiple consultations with dietitians, as well as our sports scientists, to work out how to apply it and change their environment, based on the results.

In the context of the more clinical categories, there should be a duty of care for companies to employ their own genetic counsellors so that they can give the right advice at the right time and, potentially, remove the burden from the NHS, should there be one, of not having counsellors in the first place.

Q111 **Bill Grant:** Your company has access to trained genetic counsellors. You touched on that earlier and said that it was to degree standard. On that subject, is that part of the fee for the test, or is there an additional fee, which might put the client off?

Avi Lasarow: For the more clinical categories, which we will look to launch in future, we employ genetic counsellors, and that cost is included in the cost of the fee. Those genetic counsellors, of course, give consultation, if there is a report that shows that an individual has a higher risk for a particular category, to help them to understand what that means and how to interpret it.

Q112 **Bill Grant:** In your case, is it now or in the future that the test will be inclusive in the package of pre and post-counselling, for the one fee?

Avi Lasarow: Now, we provide counselling. If it is for a more clinical test, we use a board-certified genetic counsellor; if it is for the nutrition or fitness side, we use educated sports scientists and dietitians.

Q113 **Bill Grant:** For the one fee, inclusive.

Avi Lasarow: For the one fee, yes.

Q114 **Chair:** Is the counselling one session, or is it however much the individual needs?

Avi Lasarow: It is often multiple sessions, so an individual comes back more than once. For example, in the wellness category, initially they have an interest in their fitness, what that means and how to apply it, but then they come down the track of getting the nutritional context, too. They come back multiple times, which we are happy to do; it is very important.

Q115 **Bill Grant:** Carla, for Ancestry, is there counselling?

Carla Newell: As I mentioned, we do not provide a health product in the UK. For our US health product that we have just launched, we have multiple genetic counselling resources provided to users as part of the same price, including webinars with live chat, the ability to email genetic counsellors with various follow-up questions and, ultimately, speaking to

a genetic counsellor. In the health context, we provide genetic counselling resources as part of the same price.

Q116 **Chair:** But even outside health, the results you provide someone with could be extraordinarily traumatic and life-changing. Do you not offer counselling in those cases?

Carla Newell: In those cases, we are aware that there are some situations where people have surprising results. Anecdotally, we have seen that a very large percentage of those end up being quite positive, once the initial surprise is over. We have been working to provide recommendations on resources—

Q117 **Chair:** But you do not provide counselling in those cases.

Carla Newell: We do not provide psychiatric or psychological counselling, no.

Q118 **Bill Grant:** You let the person go ahead with the test without that support. You take the fee for the client without that support, possibly putting the client at risk if there is an outcome that is very negative.

Carla Newell: We do not provide psychological counselling on the ethnicity and origin side. We provide it in the health product, and that is included.

Q119 **Bill Grant:** Kathy?

Kathy Hibbs: Ours again is unique. We are the only company in the world that has over-the-counter authorisation for our product, and we did that by demonstrating user comprehension and the ability to use the product without a prescriber. We are not selling a prescription product to consumers and, therefore, we are not providing a medical service with the product.

However, we have resources available that we highlight to individuals about what the role of genetic counselling is and how to access it. There is a reference to genetic counselling in the UK, obviously. In addition, for three certain reports, because of the seriousness of the conditions—BRCA, Parkinson's and APOE, which is associated with late onset Alzheimer's disease—there is an additional module that you must go through for each of those reports. It is, essentially, a further education module, and it gives them information and tells them—

Q120 **Chair:** But you do not provide counselling for those people.

Kathy Hibbs: We do not provide counselling as part of the product. Given, again, that we have done post-market surveillance on the product through an EU-level quality system as well as a US-based quality system, and not had reportable incidents coming out of it, I think that with regards to our product we have demonstrated that it is safe and effective without the counselling.

Q121 **Bill Grant:** Can I recap and then move on? To recap, as a panel you

agree that it is important to have counselling, yet it strikes me that there is a fragmented counselling system. There is nothing quite positive about it in relation to counselling, yet you all think it is very important. At best, people can get electronic communication or remote communication, but very little face-to-face counselling. The psychological effect of some of the outcomes could be so traumatising, yet you appear to have no support provision for such an outcome.

Kathy Hibbs: We have very—

Q122 **Bill Grant:** For clarity, you do not have a positive support outcome. Is that correct?

Kathy Hibbs: No, I do not think that is correct. We have extensive customer care. We have physicians on staff as well as genetic counsellors on staff. The issue is that not every person wants or needs genetic counselling, so to mandate it for all would be to deny access.

Q123 **Chair:** No one is suggesting it is mandated for all; it is about making it available to those who need it. That is the point of Bill's question.

Kathy Hibbs: We make the resources available in our customer care, which is staffed with licensed medical professionals.

Q124 **Chair:** You say you make the resources available, but not counselling resources.

Kathy Hibbs: No, we have counselling resources. We do not ourselves offer genetic counselling. It would probably be inappropriate for us to integrate that.

Q125 **Chair:** But on your website you refer people to their healthcare provider or to the British Society for Genetic Medicine.

Kathy Hibbs: For independent counselling services.

Q126 **Bill Grant:** Sorry to be blunt, but is that just simply outsourcing that fairly significant problem, not for all clients but a significant problem for some clients? You are passing that on.

Kathy Hibbs: No. There were times when we offered genetic counselling, and only a tiny percentage of people ever utilised it. It is in recognition of the fact that the product is designed to be used without it, and the vast majority of customers do not want or need it and will not access it.

Q127 **Chair:** In a way, doesn't that make it more appropriate for it to be available to those who do need it?

Kathy Hibbs: Again, our product has been designed to be sold over the counter without provision of it.

Q128 **Chair:** But do you accept that the outcomes could be traumatic for the individual?

Kathy Hibbs: I certainly understand where the concern comes from. For reports that are most likely to cause a psychological concern—BRCA, Parkinson's and APOE, because of the level of intervention, which in the case of BRCA is a surgical intervention, and because in the case of Parkinson's there is limited treatment and in the case of APOE4 there is at the moment very little treatment—we designed the product to support customers and ensure that they make the right choice for them, to avoid having people who would probably be upset. In fact, the Alzheimer's report says, "You might be upset if you open this." It tells people that the patient groups actually oppose people finding out and testing their genetic status, and it gives them information to dissuade them from understanding the information and viewing their report unless they are well prepared to take that on.

Q129 **Bill Grant:** I think we all sense that the genetic testing industry is going to expand fairly rapidly over the next five to 10 years. Would it be reasonable to suggest that the industry seems to be taking the best and taking money from clients? Do you think the industry should maybe make some contribution to training or securing counsellors, instead of simply taking the test fee?

Kathy Hibbs: Again, I can tell you that, at the time when we had genetic counselling, we know that only a very tiny fraction of people ever expressed an interest in it.

The other thing, which could be different in the UK, but it is important to note that there is a change, is that the US historically had genetic counselling for two situations. One was BRCA, and the other was amniocentesis testing. That was largely driven by insurers' desire to limit the number of people who were utilising expensive services, but there are studies in the US that show that as many as 40% of women prescribed a BRCA test by their physician—meaning that these are women who met the clinical standard, who themselves either had a history of breast cancer or met the ethnicity or family health history of breast cancer—never actually utilised the test if genetic counselling was required pre-test. There are access issues that could be driven by imposing a counselling requirement as well.

Q130 **Chair:** I am keen to get an answer to Bill's question very quickly from each of you. Do you support or oppose any idea of a contribution from industry to the cost of training genetic counsellors?

Kathy Hibbs: No, we would not oppose that.

Avi Lasarow: We very much support that. Genetic counsellors are a rarity, and as the volume of this business is growing so significantly and genetic counsellors are becoming so few, perhaps our recommendation would be for Government to incentivise individuals to train to become genetic counsellors to cope with the future.

Carla Newell: We would support something of that nature. Obviously, it would depend on the specifics, but, yes, in general.

Q131 **Carol Monaghan:** Who owns the data that you collect?

Kathy Hibbs: Our customers own their data. They can withdraw their data at any time. We have to keep one copy of it for regulatory reasons, but it would not be used; we are fully compliant with GDPR. That is fundamentally the answer. Obviously, for customers who consent and participate in research, we have the rights prescribed to us under the IRB or, in the UK, the REC, to be able to use that data, consistent with their consent, and only consistent with their consent.

Q132 **Carol Monaghan:** I may come back to you on that.

Avi Lasarow: The customer owns their data. Naturally, we have requests to have data deleted, which we adhere to in accordance with GDPR as well as with ISO 27001, which is a data information security framework architecture that we are certified to.

Carla Newell: It is very similar. The customer owns their data and has the right to delete it. If they wish to participate in research, it is completely voluntary and opt-in, and it is done on de-identified data.

Q133 **Carol Monaghan:** Can I check with you? In your submission to the Committee, you talked about customers' routine ownership of their DNA samples, but no comment was made about the data itself.

Carla Newell: No, data as well, absolutely.

Q134 **Carol Monaghan:** Okay. Kathy, to come back to you, in 2018, 23andMe signed a deal with GlaxoSmithKline for "exclusive…collaboration"—on—"drug target discovery." Under the terms of the deal, GlaxoSmithKline will "have the right to work with 23andMe to analyse 23andMe's database for validation of GlaxoSmithKline's existing therapeutic portfolio"—blah, blah, blah. It goes on.

The deal announcement stated: "23andMe customers are in control of their data. Participating in 23andMe's research is always voluntary and requires customers to affirmatively consent to participate. For those who do consent, their information will be de-identified, so no individual will be identifiable to GlaxoSmithKline." Can I ask you about that specifically?

It requires customers to affirmatively consent to participate. I have a concern about that. The concern is that often we are asked when we fill in forms online to accept the terms, and we accept them because the type is often dense and small, and it is easier just to accept them. Can you tell me a bit about the consent?

Kathy Hibbs: Absolutely. I think this is something that, because the company has a health mission, was structured this way. First and foremost, terms of service are entirely separate from research consent. You can buy 23andMe and never consent to research. There is no tie

between whether you buy the service and consent to research or you do not; it is done separately.

If you are going to consent to research, there are three separate consents that have been reviewed by an IRB—an external ethical board—to determine that they give people the right amount of information to make it clear what they are consenting to and what the risks are. You can consent or not to the biobanking of your sample, and you can consent or not to research and to what is called individual level data. There are certain studies where we might actually want to be able to go back to individuals—say, in the Parkinson's community—and ask them if they would provide a punch biopsy sample. If they have not agreed to all three, we would not.

Q135 **Carol Monaghan:** In practice, how would that work? I decide that I want to have my DNA tested and I sign a user agreement, and that is fine. If you then want to share my data with GlaxoSmithKline, or whoever it may be, how would you do that? How would I know about that?

Kathy Hibbs: We would not.

Q136 **Carol Monaghan:** You are saying that I would need to consent to three things.

Kathy Hibbs: You must consent, yes.

Q137 **Carol Monaghan:** I want to know how that process works.

Kathy Hibbs: When you register your kit, when you take the service, you are asked whether you want to participate in research. You can click no, and you are never going to see it again; you can say, "I want to skip this for now, and maybe later I'll come back and consent," or you can step through the individual consents, consent to research and begin participating.

Participating in this type of research is answering survey questions. It is giving us phenotypic answers to things like, "Have you suffered from depression?", "Do you have a condition?" or, "Have you been diagnosed with an illness?" It is that matched information that is of interest for target discovery, because we can take the genetic information from consented consumers and match it to the answers of consented consumers and see a genetic signature that has not been seen before, or something unique. We may see customers who have the genetics of a condition but report never to have had that condition.

Q138 **Carol Monaghan:** We understand what the potential benefits are. I want to know about the consumer themselves and how that consent operates.

Kathy Hibbs: They have to proactively consent and then, presuming that they have consented, any time they are in their account it says at the top, "You're currently consented to research. Click here if you want to change that consent." It is very easy to remind them that they are consented and very easy for them to change.

The other thing we provide them with is that, if they have participated in research, they can actually see the papers that their research will end up in. Obviously, that takes time, because there is the research itself and then the publication. But if you are a customer of 23andMe who has participated for several years and has consented to research and provided surveys, you will see the publications where your data was in some fashion used for those publications.

Q139 **Carol Monaghan:** Can I ask all the panel, although this is probably less relevant for Ancestry, whether you share or allow access to customer data in de-identified form?

Kathy Hibbs: Ours is in de-identified form. That is how it is accessed. It is not the individual data that is interesting.

Q140 **Carol Monaghan:** Is it more companies than just GlaxoSmithKline?

Kathy Hibbs: At the moment, we have an exclusive deal with GlaxoSmithKline, but in the past we have also done deals with Genentech and Pfizer.

Avi Lasarow: We do not have any pharmaceutical fields. Individuals' data belongs to them. We protect it and we are very transparent about where the data flows and where it is exactly.

Q141 **Carol Monaghan:** What about non-pharmaceutical fields?

Avi Lasarow: The only thing we do is occasionally to ask our user base for survey information, or we try to see if there is a way that we could query certain aspects of their lifestyle and correlate that to data, in an anonymised way, but that is more of an exception than the norm.

Q142 **Carol Monaghan:** Carla?

Carla Newell: Our current collaborations on research are all with academic institutions, also under an institutional review board-approved protocol. That is completely voluntary for people.

Q143 **Carol Monaghan:** Would your customers have to opt in to that?

Carla Newell: Yes. We list all of those on our website, so it is very clear as to what we are doing.

Q144 **Carol Monaghan:** I am happy for any of you to answer this question, but it is probably directed more at Kathy. How does the income you generate from data sharing compare with the income you get from customers?

Kathy Hibbs: We generate more income from customers than we do from our data-sharing arrangements. We received financing from GSK, but it took a share of the company in exchange, so that is not revenue. It was capital put into the company specifically for the purposes of our ability to work on the clinical trials.

Carol Monaghan: If neither of you wants to comment, I am happy to move on.

Q145 **Bill Grant:** I have a brief question. There are links between other organisations and yourselves, Avi, with entrepreneurs. We need entrepreneurs. They are most welcome in the UK; the more, the merrier. There are links to nutrition and health. Are there any links to companies that provide supplements that would bolster a person who may need support? Are you linked to providers of materials—materials is a strange word—or supplements, we will call them, that could increase or enhance an individual's fitness and health?

Avi Lasarow: On links to third-party companies in terms of supplementation, we do not share any data with those companies. One of our code of conduct principles is that companies like ourselves in the industry need to be very transparent and up front to consumers in what we offer. For example, if you go to our website, you will see that we sell DNA testing, but we are starting to offer other sorts of tests, such as blood testing or, indeed, supplements. That is told up front, as opposed to examples of companies that might sell you a DNA test and, later down the line, you would discover that they were trying to sell you supplements.

The answer to your specific question is that we do not share users' data with supplement companies. Do we look to try to create bespoke formulas moving forward? Yes, that is certainly on our radar, but customers can see that up front. That is very important.

Q146 **Carol Monaghan:** Can I ask about the protections you have in place to ensure that any de-identified data you share cannot be combined with other datasets to be re-identified? For example, I might decide to do a DNA test, and the same week I might decide to try to take out health insurance or life assurance. I might also, on my credit card, have bought the booze for a party that I was planning for the weekend. Is there any possibility that those three things could be combined to say, "This person has a predisposition to this, and they are buying a whole lot of alcohol and taking out health insurance"? Is there any way the datasets can be combined? You are not invited, Stephen.

Stephen Metcalfe: Tragedy.

Kathy Hibbs: We prohibit the use of data for re-identification. That is something that is in all our agreements, including with academics. I do not think that what you are describing is quite possible. Of course, in the UK, there was originally a moratorium by insurance companies, which I believe has been formalised into a concordat with regards to them not utilising information. They have never sought it and, obviously, we have never provided it, and there is actually a rubric in the UK that opposes that.

Q147 **Carol Monaghan:** Are you looking at potential scenarios that could allow

the combination of data for re-identification?

Kathy Hibbs: As I said, we prohibit re-identification. Anybody we work with, whether an academic or a biopharmaceutical company, has to agree not to do that. We also keep the databases separate. We keep information on your credit card, email address and account information completely separate from genetic information, and I believe that others do that as well. It works in a similar way to the way banking works; only when you put your credentials into a secure website are the two files merged, to further protect the data in that way. Identifying information is kept separate from genetic information.

Avi Lasarow: As a company, we work with insurance companies, but we offer and build DNA-testing platforms for the purpose of value addition, as opposed to actually giving them any data. The data belongs to the user.

There is a moratorium on how insurance companies are allowed to use genetic data, but there is a growing need in the insurance industry to encourage users to be healthier. As we know from our own evidence, as well as peer-reviewed meta-analysis, when individuals have a genetic test, it encourages behaviour change. From an insurance perspective, that behaviour change is ultimately quite positive.

Carla Newell: We specify in our terms and conditions to our users that we will not share any genetic information with any insurance companies or with third-party marketers or employers, because we realised that those were things that were very sensitive to people. Similar to 23andMe, we keep all our genetic data in separate databases from any personally identified information and do not share any of that personally identified information with any third-party researcher under the IRB protocol, and that is all. Those questions are all answered as part of an FAQ that is part of the consent that the user has the opportunity to opt in to, should they want to do research.

Q148 **Stephen Metcalfe:** My question is around keeping databases separate, and only reunifying the data when appropriate credentials are entered. Does that mean that, if there were a security breach on either of your systems, it would be impossible for someone who wanted to act maliciously inside your systems to put those pieces of data back together?

Kathy Hibbs: That is certainly the intent.

Q149 **Stephen Metcalfe:** How rigorously do you test that?

Kathy Hibbs: Very rigorously.

Avi Lasarow: As part of the ISO 27001 data information security framework, quite often for external customers that sell our tests—corporates, for example, that want to keep their employees healthy by offering them a solution—we have to conduct external penetration testing

by third-party companies, and produce the reports on that to the B-to-B customers, let's call them, so their IT security framework signs off on it. We are as robust as we possibly can be in the context.

Q150 **Stephen Metcalfe:** Do you all do that?

Carla Newell: We do the same. You can never be assured in these days that anything is impossible, but by keeping the keys, the data and the personal identifying information separate, people would have to—

Q151 **Stephen Metcalfe:** It would require two breaches.

Carla Newell: Actually, it would require three. You would have to compromise three different systems to move across the system. Also, we apply a different and higher level of encryption to our DNA data than we do to other data to ensure that that data is protected to the extent it is possible.

Q152 **Chair:** Kathy, you say that you will not "sell, lease or rent personal data," but you gain value from data through your deal with GSK. Do you think your customers should be told, when they are asked to consent to the use of anonymised data for research, that you gain value from the use of that data?

Kathy Hibbs: We do, and they are told that. In fact, after the GSK deal and previous deals, we sent an email out to all our customers and said, "Here's our announcement. If this is in any way not what you would want to do, even though it is included in the consent, here's an easy way to click and change your consent." We have been extremely transparent and proactive about making sure that they understand.

Q153 **Bill Grant:** I think we all agree that genomics testing is relatively in its infancy, although it has been in the NHS for some 15 years, provided certain criteria are met. It is here to stay, and direct-to-consumer is likely to expand, as we said earlier.

I think Government have a role to play, and your submission from 23andMe, Kathy, urged the Committee to ask the Government how they intend to support the genomics sector, or industry, and in parallel, integrate it into the NHS long-term plan. Can I tease out what you thought about that? What is your aspiration? What would you like the genie to do for you in relation to Government? You've only got three wishes.

Kathy Hibbs: First, we recognise and appreciate the support of the UK Government. They have led the way on a lot of genomic discoveries historically, not the least of which is the Sanger sequencing that started it all here in the UK, as well as the Genomics England project. We really appreciate the UK's leadership with regards to this, and we think that is an important trend to continue.

Obviously, at the moment, IVDR is coming. We are fully compliant with IDD now, because we believe that the collection kit is already a medical

device. It is about making sure that there is thought with regards to the IVDR, which is coming fast upon us, and that we will be in a space to comply with that. I suggest that the UK, particularly at this point in time, should make sure to harmonise whatever additional regulatory requirements it may put in place with those that exist through the IVDR or in the US in similar regulations. That is important. It is clearly a worldwide testing situation; it is not localised in that regard, so harmonisation is quite important.

Avi Lasarow: This is a very exciting time, which ultimately can improve the health of the UK population. To make sure that companies like ours can exist without too much red tape, although we must always ensure that there is a code of practice that is perhaps enforceable in the sector, we as a company would love to collaborate with the sector and its stakeholders to help to shape that. We are conveying that sentiment here today.

I re-emphasise that there are so many opportunities to participate. I can very quickly give you one example. We give recommendations based on nutrition and fitness genetics. We are speaking to a number of biobanks, which are looking to build their biobank size and looking for volunteers to contribute their DNA, as with the 100,000 genomes project. Utilities and applications that we have built can be used as an incentive to the individuals who participate in research; through a company called Helix, in the US, we have worked, or intend them to work and be used, in the Healthy Nevada Project. In similar ways, companies like ours can add value to grow the industry, but doing it right.

Carla Newell: I agree with everything that has been said by the other panellists. It is important that the industry has some base level of regulation or best practices so that consumers have trust in the industry as a whole. We think that is incredibly important to a nascent industry like genomics because, unless consumers can trust the industry as a whole, none of us is going to be able to grow and provide the kind of services that we provide.

We have started to do some of that in the US. 23andMe, us, Helix and a few others have got together with the Future of Privacy Forum in the US to develop a set of best practices for genetic testing privacy. We think that type of industry action is very helpful to set the right kind of floor for the industry.

Q154 **Bill Grant:** I sense that there is a sort of partnership with the NHS, or some degree of involvement and working together with the NHS, or am I picking that up wrong? Is there a wee hint of regulation somewhere in there?

Kathy Hibbs: There are certainly regulations that apply right now in the EU, and are being applied in the UK, in the current situation. Our discussions with the MHRA indicate that it expects to follow and be compliant with the IVDR.

Q155 **Bill Grant:** That is in 2022.

Kathy Hibbs: It is 2022 for IVDR and 2020 for IDD.

Q156 **Bill Grant:** I leave you with one final question. Do you think that the NHS, as a body that gathers and secures data and, with the proper authority, shares that data, should be rewarded for its long-term work in data collection and genomics? Should you pay into the system?

Kathy Hibbs: That is certainly something we would be willing to hear more on and discuss.

Avi Lasarow: The NHS is playing such a pivotal role in the advancement of the sector that there should be some sort of reward for that interaction.

Carla Newell: That is not something we have thought much about, given that we have not moved into health in the UK.

Q157 **Stephen Metcalfe:** I want to expand a little bit on the regulatory framework. You referred to ISO 27001, which I presume is the standard against which tests are conducted. What is the regulatory framework now, and, if IVDR were to be introduced sooner than 2022, would you all be able to comply with it? It may not apply to all of you in the same way.

Kathy Hibbs: That regulation is a security regulation, as opposed to one for testing. We currently meet the EU regulations for IDD, which is basically a regulation covering the kit itself, the collection device as a medical device. That is CE marked, and our competent authority for that at the moment is the Netherlands.

As I stated, I think before you were in the room, prior to launching we met with the MHRA and confirmed that it agreed with our regulatory assessment that pre-market authorisation was not required in the UK. From my perspective, IVDR, for our tests and tests like it, would be a class C test; it would require a notified body third-party review, prior to being on the market, or to maintain it on the market.

DEKRA is our notified body third-party reviewer. We have engaged them and will have our ISO 13485 audit completed enough in advance that we expect our technical file review to be complete, and that we will be fully compliant with the IVDR by the deadline.

Avi Lasarow: In terms of the collection device, like 23andMe and others, we make sure that device is CE approved. Our laboratory is ISO accredited—15189 accredited. As 2022 dawns on us, we would make sure that we are okay with that regulation.

Carla Newell: If we were to expand into the UK market from the US market with a health product, we would obviously comply with those requirements.

Q158 **Chair:** Do you anticipate that you will expand the health product in the

UK market?

Carla Newell: At some point, we will. There is no current timeframe in which that would be the case.

Q159 **Stephen Metcalfe:** What we have described is a system where the device for collection and the test itself is regulated and conducted against a regulatory framework. Is there a necessity for the industry to have more regulation as a whole, to look at the whole issue around genomic testing and the implications for that, which go beyond just checking that the device itself and the test is compliant, because actually there is a bigger issue around regulation?

Kathy Hibbs: For our test, we are the only ones who have actually tested and been authorised by the FDA in the US from end to end, from collection all the way through to result.

Q160 **Chair:** To pick up on that very quickly, does that mean that the regulatory framework in the US is more stringent on this than the UK?

Kathy Hibbs: Yes and no. The written regulations probably are. Each of our clearances is itself a federal regulation that compels any other similar product to go through that framework.

Q161 **Chair:** And you would have to go through a similar process in the UK.

Kathy Hibbs: Not at the moment. IVDR will essentially replicate that process. The issue is that at the moment in the US, under the Trump Administration, the enforcement activities of the FDA have decreased by more than 70%, so there has not been a regulatory change, but a relaxing.

Q162 **Chair:** That is not necessarily a standard we would want to aspire to.

Kathy Hibbs: No, but it is important to understand that for our product it is not just that the collection kit portion of the service has been reviewed by the FDA. The full end-to-end service has been reviewed by the FDA for clinical validity and accuracy to a 99% level, as well as proof that users can comprehend the results at greater than 90% across the full demography.

Q163 **Stephen Metcalfe:** Do you think that IVDR will do that here in the UK?

Kathy Hibbs: Yes, I do. It is highly likely that IVDR will do that. Remember, IVDR is a broad framework. It is not test specific; it is a classification system. Then each notified body, in order to assess independently, will have to review the technical files and deem them sufficient for the risk that is presented by each individual test.

Q164 **Stephen Metcalfe:** Yes, and regulate the claims that any of your organisations may make about the accuracy, validity and so on of the testing.

Kathy Hibbs: Right—the marketing claims. Again, because we already have that and comply with that for 23andMe in the US under the FDA, we are obviously well positioned to meet those requirements.

Q165 **Stephen Metcalfe:** Does that go for yourselves as well?

Avi Lasarow: I am not sure that it claims what type of underlying technology should be used. Our view is that, when it comes to the more clinical and health categories, the underlying technology should be that of exome sequencing and whole genome sequencing, because of the number of data points it looks at. We are looking at 60 million data points versus 1 million, which ultimately means that those tests will be much more accurate. I am not sure that there is regulation for that in 2022, but it is something that this Committee should definitely consider.

Q166 **Stephen Metcalfe:** To widen the question, I suppose that regulating the industry or the sector as a whole, which includes claims about the way it operates, would apply to you, Carla, because you are providing information about someone's genetic make-up.

Carla Newell: Yes, as I said, it is important to have a baseline that the consumer can rely on in any of the kinds of genetic tests that are available. It is also important, given that the industry is at such an early stage and genomics itself is at such an early stage, that the regulatory framework should be more principles based and less prescriptive, to allow the industry to evolve over time.

Q167 **Stephen Metcalfe:** So that I am clear—because, as Kathy rightly pointed out, I missed the early part of the meeting, and I apologise for that—if I were to submit my DNA to Ancestry.com, how would I know that the results that I got back were as accurate as they could be? What is the regulation or framework against which you would operate?

Carla Newell: There is no regulation on any of our tests related to the ethnicity and origins piece of it. That science is evolving over time. It depends on the size of your database, which is why having larger databases makes it easier to get the granularity of the test. It is dependent on the type of reference panels you can use to determine and assign ethnicity, so the more samples you have of people in individual areas, the more granular the result can be. I am not sure that is an area that lends itself as much to regulation as potentially on the health side.

Q168 **Stephen Metcalfe:** To push back on that a touch, what guarantee do I have that you have even conducted a test and are not just sending me results based on my address and a quick scoot on the internet?

Carla Newell: We are all subject to regulatory regimes. For example, in the US, the FTC, state attorney generals and others have authority over false claims and advertising and what-not. There is a regulatory regime that applies that is much broader than genomics around false claims in all jurisdictions, and that is where that would come out.

Q169 **Stephen Metcalfe:** If we wanted to make recommendations to Government about strengthening regulation to help to reassure the public so that the sector can grow, are there any individual recommendations that any of you would like us to consider?

Avi Lasarow: Yes. There are two parts to the testing process. One of them is DNA extraction and the analytical piece. Laboratories should either have an existing accreditation or clearly show that they are working towards one. I mentioned previously ISO 15189, but there is also ISO 17025. That would be a minimum objective for this Committee, as a recommendation.

On interpretation, certainly on the wellness piece, we believe that it is important to have more than three peer-reviewed publications, at minimum, to help companies select the genes that go into their testing reports. Of course, consensus among the publications is very important as well. Naturally, as a company, if there were 10, and five said, "No, this gene does not have any effect," versus the other five, we would not include it. We think that is very important, as is being very clear and transparent as to what genes are actually being tested for.

Q170 **Stephen Metcalfe:** Do either of you want to make any recommendations that the Government could adopt?

Kathy Hibbs: As I say, I think MHRA is tracking very much the IDD and IVDR, so I expect to have those frameworks. They are already out and are obviously under way.

Q171 **Stephen Metcalfe:** Carla?

Carla Newell: From our standpoint, it is about making sure that people can be comfortable that their data will not be used for any inappropriate or unexpected secondary use without their consent. That is a big thing.

Q172 **Stephen Metcalfe:** Should that be to a BSI or ISO standard, which you get accredited to, so you can demonstrate that the data is never shared? How do you prove that you are doing that?

Carla Newell: It is more that people should be required to be very forthcoming in terms not only of claims but of their data use with third parties. That has been a focus of GDPR and of a number of the US proposals on privacy. Making sure that people are aware of how their data is used and that they consent to any secondary use of their data is very important for the industry.

Avi Lasarow: One final point, if I may, is that it is important for companies clearly to say what the limitations are of the tests, and not just the limitations but that genetics is only part of the picture and not the problem solver. Again, I am talking very clearly at this point about the category of wellness—nutrition, fitness, sleep and stress, for example. It should be very clear that there are limitations and that science evolves, and we should be aware of those things up front.

Stephen Metcalfe: Thank you very much.

Q173 **Chair:** Before we finish, I want to test further on the regulation point. Let us assume for a moment that all your companies meet the highest possible standards. Presumably, you agree that there are, however, companies out there that do not meet high standards, and, therefore, may mislead or indeed potentially traumatise consumers, so the need for a regulatory framework to provide trust to consumers seems to me very real.

The Royal College of Physicians and the Royal College of Pathologists go much further than you are talking about; they suggest the adoption of "a similar regulatory approach to that adopted for the pharmaceutical industry," with genomic tests approved either for "prescription-only" or for "over-the-counter" sale. That was also suggested by the Wellcome Sanger Institute. How do you respond to that? Would that not provide consumers with real safeguards about the standards that you are all offering?

Kathy Hibbs: Yes. Of course, as I have stated before, our test has met the FDA, the only standard in the world for over the counter.

Q174 **Chair:** Yes, in the States. I am wondering whether we ought to be providing something similar, and perhaps more robust than the States, given that it is now not being enforced properly in the States.

Kathy Hibbs: What we put forward to the notified third party for IVDR will also be the over-the-counter use. We will submit the same data, with the same 99% positive predictive value and negative predictive value, and 95% confidence in clinical validity.

Q175 **Chair:** Should everyone be required to do that and to meet that same high standard?

Kathy Hibbs: I think for health. If it is over the counter or sold to consumers, if it is consumer-initiated home use—obviously some folks are selling prescription products to consumers, so it is really the consumer who is purchasing it and not a medical professional who is using it—yes, ideally there should be a single standard.

Q176 **Chair:** Would you agree with that, Avi Lasarow?

Avi Lasarow: There is a role for such regulation. One just has to be conscious of over-regulating, which limits growth.

Q177 **Chair:** I understand that a balance always has to be struck. There have been several submissions to the Committee, including from Wellcome Sanger and the Royal Colleges of Physicians and Pathologists, advocating the establishment of a new regulator to oversee genomic testing in the UK. Reactions?

Kathy Hibbs: We have offered for four years to meet with the royal college. We have met with numerous groups; we have met with the NHS, obviously, numerous times, and with the MHRA several times.

Q178 **Chair:** And they have turned you down so far.

Kathy Hibbs: They have turned us down. We continue to be open and happy to meet with the royal college, but they have never taken us up on our offers to meet them. It would help for them to better understand our product.

Q179 **Chair:** How do you feel about their recommendation?

Kathy Hibbs: I understand what their concern might be, but if we had the opportunity to show them the data on our product, it would address many of the issues.

Q180 **Chair:** It is not so much about reassuring them about your product. Let's assume for the moment that you are doing everything perfectly. What about all the others?

Kathy Hibbs: I agree with what Carla said. In the main, it is just like any other situation. If there are people who are selling fraudulent tests, making fraudulent claims or not doing what they say they are doing, there is already a rubric to deal with that. It is not necessary for it to be regulated solely from the perspective that it has genetics in it.

Q181 **Chair:** But we need a regulatory system, don't we, that will drive out of the markets those who do not meet the highest possible standards? Do you agree with that?

Avi Lasarow: We would welcome even a new regulator that focuses on and understands this industry. Having a regulator will ensure that companies that might be ethically adrift are not allowed to enter the market in the first place. It is a very positive step to move forward on.

Q182 **Chair:** Any view from you, Carla?

Carla Newell: We would have to know more about exactly how that regulator would work and what they would regulate.

Q183 **Chair:** You are up for a discussion, are you?

Carla Newell: Yes, we are happy to discuss it. There is a need for some regulation, whether it is a separate regulator or whether it could be done by someone else. I do not know enough to comment.

Chair: Okay. There are no other questions, so we will conclude. Thank you very much indeed.