

For reprint orders, please contact: [reprints@futuremedicine.com](mailto:reprints@futuremedicine.com)

# “It’s our DNA, we deserve the right to test!”

## A content analysis of a petition for the right to access direct-to-consumer genetic testing

**Aims:** Various companies are currently advertising or selling genetic tests over the internet using a model of provision referred to as ‘direct-to-consumer’ (DTC). This commercial offer of DTC genetic testing (GT) has fueled a number of scientific, ethical and policy debates. To date there have been few studies published regarding the users’ perspective. This study aimed to obtain information regarding the issues raised by individuals who signed a petition in support of DTC GT and the ‘unrestricted’ access to their genetic information. **Materials & methods:** We conducted qualitative content analysis of comments written by individuals who signed a public online petition initiated by DIYgenomics (CA, USA) to support “personal access to genetic information”. **Results:** Of the 523 individuals who signed the petition sponsored by DIYgenomics, 247 individuals also wrote individual comments. A content analysis of these comments reveals that petitioners raised six main issues in support of unrestricted access to DTC GT: that their ownership of their DNA should allow them to have unrestricted access to their genomic information; that they should have the right to their genomic information; that the government has no place in (further) regulating DTC GT; that healthcare professionals should not be placed as intermediaries when purchasing DTC GT services; that many petitioners who had already obtained DTC GT had positive experiences with this model of provision; and that genealogy or ancestry DNA testing is one of the main activities petitioners wish to have ‘unrestricted’ or ‘direct’ access. **Conclusion:** These results give insight into why individuals may support unrestricted access to their genomic information and confirm some of the motivations of users for purchasing DTC GT. Our analysis also brings to the forefront themes that have been raised less often in empirical studies involving motivations to purchase DTC GT services; these include the strongly held beliefs of some petitioners that, since they own their DNA, they should have the right to access the information without (further) government control or physician involvement. Interestingly, the comments left by petitioners also reveal a certain distrust of governmental agencies and healthcare professionals. This urges us to further study the public’s views of these services and the potential impact of these views in order to responsibly address the ongoing debate on DTC GT.

**KEYWORDS:** direct-to-consumer ■ genetic testing ■ petition ■ qualitative analysis

Yeyang Su<sup>1</sup>, Pascal Borry<sup>2</sup>, Ina C Otte<sup>3</sup> & Heidi C Howard<sup>\*4</sup>

<sup>1</sup>Department of Anthropology, Centre for Bionetworking, School of Global Studies, University of Sussex, BN1 9SJ, Brighton, UK

<sup>2</sup>Department of Public Health & Primary Care, KU Leuven, Kapucijnenvoer 35 Box 7001, 3000 Leuven, Belgium

<sup>3</sup>Institute for Biomedical Ethics, University of Basel, Bernoullistrasse 28, 4056 Basel, Switzerland

<sup>4</sup>Inserm, UMR 1027, Epidemiology & Public Health, Faculté de médecine Purpan, Université Paul Sabatier, 37 allées Jules Guesde, 31000, Toulouse, France

\*Author for correspondence: [heidi.howard@mail.mcgill.ca](mailto:heidi.howard@mail.mcgill.ca)

Various companies are currently advertising or selling genetic tests over the internet direct-to-consumer (DTC). This model of genetic test provision allows consumers to obtain information about disease risks, carrier status, and other health-related traits (i.e., pharmacogenomics) as well as nonhealth-related traits (i.e., eye color) outside of the traditional healthcare system and often without the intermediary of a healthcare professional (HCP) [1]. Some companies (also) sell genetic testing (GT) for ancestry or genealogy purposes. Different companies sell tests in different ways or in different packages. Some companies sell one single test for one trait, while other companies sell numerous tests for a group of traits (i.e., cardiovascular-associated traits) as part of one service or one product. Yet other companies perform genome-wide testing (also known as genome scanning), whereby hundreds of thousands to millions of different genetic variants

(often SNPs) are tested and results are returned for a large number of different traits (including health-related and/or nonhealth-related traits and/or genealogy). An example of a company selling the latter types of services is 23andme (CA, USA) [101].

As a new model of genetic test provision, the offer of DTC GT has fueled a number of scientific, ethical and policy debates. Critics of DTC GT companies have pointed to several problematic aspects, including the limited or non-existent clinical validity and utility of many of the genetic tests offered DTC for disease and health-related traits [2,3], the lack of genetic counseling [4], the potential misunderstanding and harm of receiving such information [5], the absence of medical supervision [6], and the potential downstream impact of such testing on the healthcare system [7]. Furthermore, problematic issues with the DTC GT of minors have also been raised [8].

**Table 1. List of themes and subthemes along with representative quotes obtained from the content analysis of comments left by petitioners of the DIYgenomics petition.**

Themes	Subthemes	Representative quotes
1. Individual ownership of genetic information	–	<p><i>"Genetic information is the property of the individual."</i>(P#436)</p> <p><i>"My genetic data is mine and no one should be able to prevent me from accessing my own genetic data. Its a Freedom of Information principle."</i> (P#382)</p>
2. Right to genetic information	<p>2a. Having the right, in general, to one's genetic information</p> <p>2b. Expression that this right is very important and is 'fundamental', 'natural' or 'human'</p>	<p><i>"My DNA = My RIGHT"</i> (P#236)</p> <p><i>"It is my natural right to have direct access to my own genetic information resulting from tests that I paid out of my own pocket, without having to consult (and likely pay) third party intermediates to interpret these results for me..."</i> (P#275)</p> <p><i>"...Denying people the right to know information about themselves is the most severe violation of human rights for information..."</i> (P#450)</p>
3. The role of government involvement in DTC GT	<p>3a. Regulations fall outside of government control</p> <p>3b. Government-imposed limits to access are paternalistic</p> <p>3c. Negative side effects of government control</p>	<p><i>"The decision to access and interpret my genetic information should be my own, not the governments."</i> (P#227)</p> <p><i>"I do not believe that the government is my mother and always knows what is best for me and mine!"</i> (P#102)</p> <p><i>"...I am hoping that full genome sequencing will become affordable in the near future, but my fear is that overreaching new government restrictions will effectively slow or kill this industry and its technological improvements."</i> (P#104)</p> <p><i>"We need MORE people testing to enhance the overall understanding of our results. Excessive regulation would result in higher costs and FEWER people testing."</i> (P#80)</p>
4. The role of HCPs in DTC GT	<p>4a. The (general) belief that HCPs provide no added value</p> <p>4b. HCPs are not needed for genealogy or ancestry testing</p> <p>4c. Involving HCPs only serves HCPs' interests</p> <p>4d. Including HCPs would increase the cost of testing</p>	<p><i>"...I don't believe that these third parties, such as doctors or 'genetic counselors', can interpret the results of these tests any better than I can on my own free time and will..."</i> (P#275)</p> <p><i>"...Most medical doctors are only marginally better informed about genetics than a person who has taken a DNA test and researched the results for them selves..."</i> (P#392)</p> <p><i>"...I resent any implication by the medical professionals that the rest of us aren't capable of understanding or coping with genetic test results without their assistance. If I want the assistance of a medical professional or genetic counselor, I'll ask for it! In addition, any attempt to lump genealogy/ancestry testing in with medical testing is ridiculous. I mean really, would those who are advising against ancestry testing also advise against traditional genealogy research just because we 'might' learn something about our ancestry that we weren't expecting?..."</i> (P#190)</p> <p><i>"...The only reason that legislation would restrict one's own personal information is for job security to those medical professionals that provide the counseling!..."</i> (P#367)</p> <p><i>"I oppose this, 'Nanny State' type legislation. It is an attempt by self interested groups, such as doctors, to maintain control over their status and earnings. The power to do so should be denied them."</i> (P#446)</p> <p><i>"There are many uses of DNA that have nothing to do with health. Requiring the use of a medical doctor as a conduit for this information will increase costs and in most cases not provide any meaningful interpretation."</i> (P#168)</p>
5. DTC GT as a positive experience	<p>5a. General positive experiences with DTC GT</p> <p>5b. Positive value of DTC GT testing for health reasons</p>	<p><i>"As a citizen with no science background when I began purchasing DTC DNA tests a decade ago, I have had only positive experiences..."</i> (P#92)</p> <p><i>"I have had genetic tests at 23andme, Navigenics, Family Tree DNA, and data interpreted at deCODEme, and I think it all have been very worthwhile and I have NOT been mislead..."</i> (P#298)</p> <p><i>"There has been nothing untoward happen to me or my wife as a result of the accurate genetic revelations that 23andme has provided us. It has been a postive event and had it happened 10 years ago and up to US\$100,000+ in after the event medical treatment potentially could have been saved with a significant reduction in personal anexity and stress caused by the Doctors here in Australia and the USA not knowing what was wrong wtih our two adult children. It's a great invotion and every home should have one just like they mostly do with the Internet..."</i> (P#131)</p>

The petitioners' comments in quotations were not corrected for spelling or grammar.  
DTC: Direct-to-consumer; GT: Genetic testing; HCP: Healthcare professional.

**Table 1. List of themes and subthemes along with representative quotes obtained from the content analysis of comments left by petitioners of the DIYgenomics petition (cont.).**

Themes	Subthemes	Representative quotes
6. Desire and need to obtain genealogy or ancestry testing DTC	6a. The utility of using DTC GT genealogy testing to find distant relatives or relatives in general	<i>"I used my DNA to connect to other family members lost over the years. It has been vital in genealogical research. I certainly don't need to pay a doctor to get permission to study my ancestors."</i> (P#317)
	6b. The need for DTC genealogy testing to find closer biological relatives (first-, second- or third-degree relatives)	<i>"I have used DNA testing for my 2 adopted children that were born in Guatemala. They now know their origins and they have also met cousins. Priceless for adoptees to know their own stories!"</i> (P#198)
	6c. Obtaining valuable health information through DTC genealogy testing	<i>"Access to my genetic information unhampered by the medical industry is very important to me. It has enabled me to bridge gaps that have occurred because of an adoption and it provided and provides me with more medical information that I might have inherited from my parents."</i> (P#112) <i>"We have family members that DO not have immediate access to birth parents &amp; DNA research is of VITAL importance re: their Health Issues. WE need to be able to pursue our own research &amp; DO NOT need RESTRICTED access to DNA info.!!!"</i> (P#327)

The petitioners' comments in quotations were not corrected for spelling or grammar.  
DTC: Direct-to-consumer; GT: Genetic testing; HCP: Healthcare professional.

Various professional organizations or governmental bodies (such as national bioethics committees) have published position statements, policy documents, guidelines or recommendations regarding DTC GT. In a recent review of this literature, Skirton *et al.* concluded "that professional and public bodies are more concerned about potential harms for patients that might ensue from DTC GT than they are supportive of possible benefits." [9]. Partly in reaction to the various policy recommendations, some countries or regions have elaborated steps to improve regulatory oversight of the various dimensions of test provision. This includes initiatives related to an increased premarket review, a control on laboratory processes and quality assurance, the canalization of genetic tests through medical professionals or even penalization of users [10].

Various researchers [11–13] have argued that stakeholders should have substantial input in structuring policy choices. Based on previous policy debates, however, it is clear that little input has been provided from users and consumers of DTC GT companies. At the research level, a recent review showed that only a limited number of studies have provided information about the views of users and potential consumers towards DTC GT [14]. Regarding the study of motivations to purchase DTC GT services, only two of these studies [15,16] report on actual users of DTC GT who purchased testing of their own volition, as opposed to being part of a research study that offered them GT [14].

Studies, including the latter two [15,16], highlight that one of the main reason consumers order DTC GT is to gain health information about themselves. In an interview study with early adopters of DTC GT services, McGowan *et al.* described that the "two most commonly cited reasons for having a personal genome scan were to gain health-related information and to learn about individual risk factors" [15]. In the same study, various respondents interviewed also reported having "professional and personal interests in being on the vanguard of adopting and testing the capabilities of new technologies" [15].

Health-related motivations and expectations, as well as a fascination with genomic science and the technology or information offered through DTC GT, were also recurring themes in the analysis of customers' stories performed by Su *et al.* [16]. This study reported that various customers (defined as actual users of DTC GT, not just potential users) expressed interest in genealogy-related motivations and expectations, such as tracing ancestors, tracing origins or finding potential relatives [16]. The interest to participate in research and recreational motivations and expectations complete the list of reasons to purchase DTC GT services [16].

In light of the limited direct input of users and potential users of DTC GT services regarding, among other subjects, the regulation(s) that may affect this business model, and the reasons individuals may want 'direct' access to their genomic information, the petition entitled

“Personal Access to Genetic Information” [102] initiated by DIYgenomics.org (CA, USA) supporting individual’s ‘unrestricted access’ to their personal genome information is noteworthy. As described on their website [103] “DIYgenomics is a nonprofit research organization founded in March 2010 to realize personalized medicine through crowdsourced health studies and apps”. The group basically facilitates the sharing of genomic data for research. Melanie Swan, the founder of the site, says that they can “facilitate this data-gathering process by offering a new way to conduct science that appeals to the subjects. ‘We aim to give individuals the opportunity to participate in citizen science research studies,’ says Swan. ‘The whole point is to experiment and find out what works best for you.’” [17]. The petition they initiated supports the position that individuals should have the “right to seek out, purchase, and interpret their own genetic information” without the need “to consult a doctor or genetic counselor”. A possible trigger for the initiation of this petition may have been related to the fact that in the Spring of 2010 the US FDA sent letters to over a dozen DTC GT companies informing them that their genetic tests could be considered medical devices and that the companies would need FDA approval to continue to sell their tests [104,18]. Furthermore, in July 2010, the FDA held a public meeting on the oversight of laboratory-developed tests or ‘home brews’ [105]. This is relevant to DTC GT since many of the tests offered by companies could be considered laboratory-developed tests. Although this event was held after the estimated date that the petition was started, it may account for the large number of signatures (over 60% of total signatures) gathered between 22 and 31 July of that year.

In order to document the public’s (including actual users’ and potential users’) perspectives on DTC GT, the comments provided, along with the signatures of the petitioners, provide an interesting and rich source of information. Therefore, the goal of this study was to analyze the reasons and issues raised by petitioners in their support of the unrestricted access to their genomic information via DTC GT services.

### Materials & methods

Comments written by individuals who signed a public online petition initiated by DIYgenomics.org to support “personal access to genetic information” [102] were analyzed using qualitative content analysis. Content analysis has often been employed as a research

method in communication studies, journalism, psychology and business as a ‘systematic and quantitative’ method [19]. However, in the last five decades, ‘qualitative content analysis’ has attracted attention from social science researchers, particularly in health research [20–22]. In this study, we employ inductive content analysis [22] informed by the applied thematic analysis developed by Guest *et al.*, to explore the petitioners’ views, while at the same time enhancing the internal validity of our analysis [23].

The core research question under scrutiny herein is what themes do petitioners raise in support of the claim to have unrestricted ‘personal access to genetic information’. Between July 2011 and March 2012, two researchers (HC Howard and Y Su) collected and analyzed the comments left by individuals on the online petition. The petition information was verified again and updated in March 2013. The original petitions (including signatures and comments) were stored as snapshots and webpage-print-out files. The focus of our content analysis was the comments left by a portion of petitioners (others simply chose to sign the petition and provided their geographic location without leaving a comment).

To begin with, two of the authors (HC Howard and Y Su) independently analyzed the petition comments, and initial themes or codes emerged and were defined separately. The authors independently analyzed the data manually to best capture the complexities of the petitioners’ views. The codes and their definitions and scopes were then discussed between the researchers. Although there were some minor differences in the initial codes obtained by each author, they acknowledged the characteristics of the independent work, and through discussion, reached an agreement to use five of the primary codes (which were most often cited by petitioners) as the analytical codes for recoding. The two researchers also agreed upon the scope of analysis. These analytical codes were subsequently used for recoding the texts manually to verify the scope and specify the definitions of these codes. They were further refined and major themes were proposed and verified by a third researcher (P Borry). At the last stage, discussions and decisions were made collaboratively among coauthors on how to summarize the findings, select the quotations, and present the results.

In the Results section, the different themes and subthemes are illustrated with quotes from the petition. The quotes provided were not corrected for spelling or grammar. Where available,

information on petitioner's geographic location was also noted.

In July 2011, the authors were aware of two petitions related to DTC GT. One petition was initiated by CelticCurse.org and promotes "the right to order genetic tests—like the one for hereditary hemochromatosis—without having to go through a doctor." [106]. The second petition – "Personal Access to Genetic Information" – initiated by DIYgenomics.org supports the right to unrestricted access to personal genetic information. They believe that "individuals have the right to seek out, purchase, and interpret their own genetic information" and that individuals should not have "to consult a doctor or genetic counselor before accessing our genetic information." ([102]; under 'petition'). The latter petition was chosen as the subject of this analysis since the comments left by petitioners could be accessed easily, which was not the case for the CelticCurse petition. The DIYgenomics' petition is US-based to the extent that DIYgenomics is an initiative started in the USA. It identifies US governmental organizations in the petition statement (i.e., FDA and US House of Representatives, among others) and the majority of petitioners who also included their geographic information were from the USA. Their aim is to obtain 10,000 signatures; there is no information on the petition site regarding how petitioners were contacted or made aware of the petition or whether the petition targeted a specific audience or subgroup of the population (i.e., actual consumers of DTC GT). Although the official date that this petition was started is not stated on their site (only times and dates without the year are presented with the signatures and comments), by perusing back through the dates presented from the time we first started studying the petition in July 2011, we have deduced that the petition was likely started in 2010, on or very near to, 21 May, which is the date of the first signature on the site.

## Results

Of the 523 individuals who signed the DIYgenomics.org petition as of March 2013, 247 individuals also wrote comments; these were the focus of our content analysis. An overwhelming majority of petitioners appear to live in the USA, with fewer than two dozen having identified themselves as living outside of the USA (i.e., Canada [eight], Australia [six], the UK [four], New Zealand [one], South Africa [one], Nepal [one], Romania [one], Norway [one], Switzerland [one] and so on).

The results of this analysis reveal that, when petitioning for unrestricted access to their genetic information, the petitioners invoke the following aspects or themes (TABLE 1):

- Individual ownership of genetic information;
- Individual right to genetic information;
- The role of government involvement in DTC GT;
- The role of HCPs in DTC GT;
- The overall positive experience of obtaining GT DTC;
- The desire and need to obtain genealogy or ancestry testing DTC.

All themes except for the 'ownership' theme (theme 1) were further divided into subthemes. Below, we elaborate on these six predominant overlapping themes and their respective subthemes and provide representative quotes.

### ■ Theme 1: individual ownership of genetic information

This theme relates to the expression by petitioners that each individual owns his/her DNA and that, by extension, they should be allowed to obtain their genetic information without constraints. This was one of the most frequently raised ideas throughout the petition.

*"My DNA, my choice. It's the most personal thing about me – I should be able to look at it when and how I want."* (P#1)

*"If my genetic information came directly from me, I am the owner and have sole rights to how it is used, disseminated, cared for, stored, sold, not sold, shared, tested etc. etc..."* (P#199)

### ■ Theme 2: right to genetic information

This theme pertains to petitioners expressing that they have the right to access their genetic information. This theme is often linked to the first theme in that many petitioners first state that they own their DNA and argue that, based on this ownership, they therefore have the right to obtain their genetic information.

#### Subtheme 2a

This theme pertains to having, in general, the right to one's genetic information:

*"It's very simple. If it comes from my body, or is a snapshot of the composition of my body, I should have a right to it."* (P#518)

**Subtheme 2b**

As an emphasis on the importance of this right, some petitioners have described this right as ‘fundamental’, ‘natural’ or ‘human’.

*“I have the fundamental right to learn about my own genetic make-up, without a government appointed gate-keeper in between.” (P#82)*

■ **Theme 3: the role of government involvement in DTC GT**

This theme is concerned with expressing any comment regarding governmental bodies or agencies (i.e., Congress, FDA, Center for Disease Control) trying to regulate or control the offer of DTC GT and, more specifically, to interfere with the public’s free or unrestricted access to such services.

**Subtheme 3a**

The notion that regulation of DTC GT falls outside of the realm of the government’s control.

*“I do not believe that government nor any entity has the right to involve themselves in my DNA or genetic research. I believe that my family, my ancestors and our genetic make up is no ones business but ours and I resent any attempt by our government to insinuate into this.” (P#400)*

*“No one’s rights are violated by obtaining information about their genetics. It is therefore outside the scope of a proper limited government to get involved. I respectfully recommend that instead of micromanaging citizens, the government try to do something like actually win a war in the next half century.” (P#412)*

**Subtheme 3b**

Petitioners further expressed the idea that limiting access to personal genetic information is paternalistic of the government.

*“...The government does not need to act as parent, protecting us from our own information...” (P#217)*

**Subtheme 3c**

Some petitioners expressed the idea that government control may have other side effects or consequences, including increasing costs, burdening the healthcare system, as well as hindering scientific research and industry development.

*“Let FDA and government put their efforts into educating people (to prevent imaginable*

*‘harm from the knowledge of their own DNA’) instead of putting doctors, lawyers and insurance companies in between. The cost of health services is high enough already without paying more to the intermediates.” (P#136)*

*“...Imposing excessive regulation will thwart innovation as well as highly beneficial advances in research.” (P#63)*

■ **Theme 4: the role of HCPs in DTC GT**

This theme reveals petitioners’ beliefs that there is no need to involve a HCP as an intermediate when purchasing DTC GT services.

**Subtheme 4a**

Some believe that HCPs would provide no added value for consumers of GT.

*“There are many uses of DNA that have nothing to do with health. Requiring the use of a medical doctor as a conduit for this information will increase costs and in most cases not provide any meaningful interpretation.” (P#168)*

Some petitioners doubt the competency of HCPs to interpret results. Among them, some even consider themselves as more knowledgeable than their doctors.

*“...Additionally, many medical doctors spend very little time in their training with regard to genetic conditions and therefore their opinion does not contribute significantly to the interpretation of the personal genetic data.” (P#106)*

**Subtheme 4b**

Many petitioners mentioned that HCPs are not necessary for genealogy or ancestry testing.

*“I use my DNA information for genealogical research. I don’t need to have a physician involved...” (P#312)*

**Subtheme 4c**

Other petitioners expressed the notion that involving a HCP as an intermediate would only serve the HCP’s own interests.

*“The AMA is a union like any other union. Its purpose is to lobby for legislation that will make more money for doctors. Its desire to legislate that no one receive genetic data without a doctor being paid should be seen as the transparently self-serving act that it is.” (P#40)*

**Subtheme 4d**

Related to the theme of ‘self-service’ to HCPs, some petitioners expressed the notion that involving HCPs in the process would increase the costs of testing.

*“I have been using DNA testing for Genealogy for 9 years and have recently tried some of the DTC GTs – which I will use with reasoned judgment. A Doctor or Genetic Counselor would only add cost and delay to these endeavors. Please do not use my Tax Dollars to regulate something that doesn’t need regulation.” (P#179)*

■ **Theme 5: obtaining DTC GT services is a positive experience**

Some petitioners express their general satisfaction by writing about their positive experiences or lack of negative consequences with purchasing DTC GT without a HCP; and by extension see no reason to change the model.

**Subtheme 5a**

Many petitioners expressed general satisfaction and positive experiences with DTC GT services.

*“I love the product and service I bought from 23andme. I do not feel at all that I have been deceived or misled, nor at anytime has anyone scared me with any information or sold me any items deceptively ...” (P#146)*

**Subtheme 5b**

Some petitioners saw positive value in DTC GT specifically for health reasons.

*“By testing with 23andMe I found out I have a greatly increased chance (45x) of having drug induced liver damage from taking the antibiotic floxacillin. This antibiotic is commonly prescribed in Europe where I live part of the year. No doctor would ever think to test me for this immune marker beforehand, because it is only present in a small percentage of the population, and not everyone who has it will experience liver damage. Still 45x is high enough for me to want to avoid it. There are plenty of other antibiotics. Why would someone want to protect me from information like this, that could save my life?” (P#205)*

■ **Theme 6: the desire and need to obtain genealogy or ancestry testing DTC**

The mention of DTC GT for genealogy or ancestry purposes was pervasive in the

comments left by petitioners. As mentioned earlier, some petitioners wrote that they did not need the intermediate of a HCP for such testing (subtheme 4a). One notion that came up often with respect to genealogy or ancestry was the great value, and even need, for such testing in the population. More particularly, many petitioners mentioned the need for such testing to find blood relatives.

**Subtheme 6a**

Some mentioned the utility of such DNA genealogy testing to find distant relatives or relatives in general, without specifying the degree of relationship.

*“In this age of broken and blended families this is a necessity.” (P#314)*

*“My husband and I were early testers. We solved and proved several genealogical questions this way. It’s our DNA, we deserve the right to test!” (P#464)*

**Subtheme 6b**

A number of petitioners also mentioned the need for DTC genealogy testing to find closer biological family links (i.e., for first-, second- or third-degree relatives); especially, for those ‘broken’ through the adoption process.

*“I am a genealogist and the only method that I could use to locate my own grandfather, due to census errors, was through DNA. It is a VITAL tool in our research...” (P#352)*

**Subtheme 6c**

Many petitioners also mentioned that finding out about these close family ties also provided valuable health-related information.

*“This is very crucial for people who have been adopted and have no information about their biological parents or what possible genetic defects they may, unknowingly, pass to their own children.” (P#315)*

**Discussion**

Of the 523 individuals who signed the petition initiated by DIYgenomics.org, 247 individuals also wrote individual comments. A content analysis of these comments reveals that petitioners raised six main themes in support of unrestricted access to DTC GT.

The first four themes addressed herein pertain to petitioners expressing that:

- The ownership of their DNA should allow them to have unrestricted access to their genomic information;
- They (should) have the right to their genomic information;
- The government has no place in (further) regulating DTC GT;
- HCPs should not be placed as intermediaries when purchasing DTC GT services.

These four themes are relatively novel when compared with previous empirical studies looking at users' motivations to purchase DTC GT.

This is not surprising given the different premises of the petition versus the individual interviews conducted by McGowan *et al.* [15] or the analysis of users' blogs by Su *et al.* [16], which were specifically aimed at elucidating the motivations to purchase DTC GT services. The online petition, on the other hand, had a directional statement describing the details of the stance the petition promotes. Individuals who sign the petition are therefore supporting this stance. Hence, it is anticipated that petitioners would bring up the same notions already mentioned in the petition statement. This type of 'comment bias', where petitioners may be 'parroting' what they read in the petition statement, rather than providing their genuine opinion, can be perceived as a weakness of this study. However, the fact that for themes 2, 3 and 4, petitioners further developed the notions beyond what was described in the petition statement, suggests that petitioners also provided their genuine opinions about unrestricted access to DTC GT. For example, in the 'rights' theme, petitioners expanded on what the petition statement contained by stating that the right to genetic information is a 'fundamental' or 'natural' right. The theme of government intervention was further dissected by some petitioners who gave reasons for why the government should not (further) regulate access (i.e., "*No one's rights are violated by obtaining information about their genetics. It is therefore outside the scope of a proper limited government to get involved.*" (P#412)). Other petitioners further characterized any additional government intervention as paternalistic. With respect to HCP involvement, again, petitioners went further than simply stating that they should not be involved; they also provided reasons why they believed this (i.e., HCPs would not understand results any better than consumers, and that HCPs are not needed for genealogy testing).

Furthermore, our results concerning petitioners' comments regarding governmental regulation are coherent with a recent study in which approximately 1000 customers of three different DTC GT companies were surveyed [24]. When respondents were specifically questioned about government oversight of these services, Bollinger and colleagues found that two-thirds (66%) of them felt that it was very (36%) or somewhat (30%) important that DTC GT be available to the public without governmental oversight [24]. That being said, the majority of respondents also felt that it was important that nongovernmental (84%) and governmental (73%) agencies monitor the claims made by DTC GT companies to ensure scientific validity [24].

Theme 5, where petitioners expressed that they had already obtained DTC GT and had positive experiences with this model of provision is, in part, to be expected as this petition is in support of such services. The specific mention of a positive experience because individuals obtained valuable health information, however, was not part of the petition statement and is in line with findings in studies on motivations to purchase DTC GT services [14]. The same can be said about the desire to use DTC GT for genealogy testing (theme 6) [16]. Interestingly, the issue of "legislation to ensure privacy and prevent discrimination based on genetic information", which is included in the petition statement, was mentioned by very few petitioners; perhaps indicating that privacy and discrimination may not be an important concern for this group of individuals in the context of DTC GT. Indeed, there may be some type of selection bias with respect to the persons who signed the petition in that they may be (more) comfortable with going online, signing a petition and publicly posting comments. Another limitation of this study involves the fact that, since the petition lacked consistent information regarding all petitioners (location, age, and gender), we were unable to determine whether there were any differences between those petitioners who left comments versus those who simply signed the petition without leaving a comment.

With respect to the theme of individual ownership of DNA, it is noteworthy to highlight that our results support a prediction made by Foster and Sharp in 2008 [25]. Just as DTC GT was gaining popularity, they forecasted that the DTC offer of GT (and genome sequencing) "may well create a greater expectation of individual ownership and control over sequence and other genetic information in research and clinical contexts."

Furthermore, with respect to the ‘rights’ theme, the idea that individuals have a right to their genomic information has also been raised in debates around the return of individual research results [26]. Next to various other arguments, one of the reported reasons that research participants would want individual research results is the fact that they feel that those results “belong to the participant” [27].

Furthermore, the themes expressed by petitioners regarding individual ownership of DNA and the consequent belief in the right to have unrestricted access to DTC GT and not wanting government involvement highlight a fundamental tension between individual rights and public health. Classic examples of such tension are witnessed in the mandatory immunization of children, which can clash with parental autonomy, as well as in tobacco control [28]. In the latter two cases, there are concrete physical benefits to be gained by restricting individual autonomy. In the case of DTC GT, the concerns do not center so much around individual physical harms, but rather around psychological, emotional harms, as well as other ethical considerations, including threats to privacy and confidentiality. Such harms can be much harder to properly assess than physical harms and, for now, remain potential concerns rather than documented harms. To date, only a few studies have specifically addressed the impact of DTC GT on consumers, including anxiety, worry and/or emotional distress and these have not revealed serious harms from testing [29–31]. However, such studies should continue to be conducted to monitor the impact of DTC GT testing, especially if more and more of the public (from different educational levels and backgrounds) choose to undergo testing. That being said, perhaps the wider concerns related to the potential overburdening of the public healthcare system [32], might provide sufficient reasons to implement regulatory measures towards DTC GT, despite potential individual opposition to it.

Finally, it is noteworthy to mention the primary material of analysis for this study, which was accessed from an openly accessible internet site. Although materials from the internet have previously been used for research in many different fields, we feel it is important to address some of the ethical issues related to using such material. Two of the concerns include the potential intrusiveness [33] and the potential harm [34] to individuals when using such data. Since we did not take an active part in a closed group (i.e., patient forum) but performed passive

analysis of data already made public, these two concerns are not particularly relevant here, or are at least minimized. That being said, the decision of whether the gathered data are public or private, and the level of perceived privacy of petitioners are important [34]. Informed consent is required, when the behavior of research participants occurs in a private context where an individual can reasonably expect that no observation or reporting is taking place [33]. Following Eysenbach and Till’s research involving observation of participants in political rallies, demonstrations or public meetings should not require any informed consent or Research Ethics Board reviews, since it can be expected that the participants are seeking public visibility [33]. Furthermore, Eysenbach and Till state that if a subscription or some form of registration is needed to gain access to the desired data, such as in some forums or discussion groups, “most of the subscribers are likely to regard shared conversations as ‘private’ [33]. As we utilized a petition and we did not need to subscribe to obtain the data we were looking for and, furthermore, it is reasonable to assume that the petitioners were seeking some form of public visibility to support their cause, we consider these data as existing in a ‘public place’ and hence did not obtain informed consent to conduct the research.

---

## Conclusion

These results shed additional light on the reasons why the public may support the ‘unrestricted’ offer of GT services DTC without the intermediate of a HCP. Our analysis reveals that, among various argumentations presented by 247 petitioners, the predominant themes expressed pertain to individual’s ownership and right to his/her DNA, as well as the cons of governmental control and of involving HCPs in the DTC offer of GT. Interestingly, the comments left by petitioners also reveal a certain distrust of governmental agencies and HCPs. This urges us to further study the public’s views of these services, and the potential impact of these views in order to responsibly address the ongoing debate on DTC GT.

This petition forms a unique way of illuminating the perspectives of active defenders of the DTC GT market. Policy debates around DTC GT have most often been informed by expert opinion, mostly in the form of guidelines, policy statements, recommendations or advisory reports. Perspectives from the public (including users) remain mostly underreported and therefore, studies such as this one, which bring to the

forefront the opinions of the public, are important contributions to the discussion and debate on DTC GT.

### Financial & competing interests disclosure

Part of this work was supported by COST Action IS1303 and the FWO-project 11Q5714N (Research Foundation Flanders). Y Su is funded by FP7-IDEAS-ERC research project "Bionetworking in Asia: A social science approach to international collaboration, informal exchanges, and responsible innovation in the life sciences" (project reference: 283219). HC Howard is funded by the European Commission FP7 Marie Curie career development award. The authors have no other relevant affiliations or financial

involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed.

No writing assistance was utilized in the production of this manuscript.

### Ethical conduct of research

The authors state that they have obtained appropriate institutional review board approval or have followed the principles outlined in the Declaration of Helsinki for all human or animal experimental investigations. In addition, for investigations involving human subjects, informed consent has been obtained from the participants involved.

### Executive summary

- Direct-to-consumer (DTC) genetic testing (GT) is a relatively novel model of provision of GT. It allows consumers to have GT and obtain information regarding health-related conditions (i.e., disease) outside of the traditional healthcare system and often without the intermediary of a healthcare professional. DTC GT also allows consumers to obtain information about nonhealth-related traits (i.e., eye color) and about genealogy or ancestry.
- More than 500 individuals signed a petition initiated by DIYgenomics to support unrestricted personal access to genetic information.
- A content analysis of the comments that were provided by 247 petitioners reveal six main themes raised in support of unrestricted access:
  - The individual ownership of genetic information;
  - The individual right to genetic information;
  - The role of government involvement;
  - The role of healthcare professionals;
  - The overall positive experience of obtaining DTC GT;
  - The desire and need to obtain genealogy or ancestry testing DTC.
- The results provide additional insight into the reasons why the public may support the offer of DTC GT and their motivations to purchase these tests. These views should be taken into consideration when discussing the policy issues surrounding DTC GT.

### References

Papers of special note have been highlighted as:

▪ of interest

▪▪ of considerable interest

- 1 Howard HC, Borry P. Is there a doctor in the house? The presence of physicians in the direct-to-consumer genetic testing context. *J. Comm. Genet.* 3(2), 105–112 (2012).
- 2 Becker F, van El CG, Ibarreta D *et al.* Genetic testing and common disorders in a public health framework: how to assess relevance and possibilities. Background Document to the ESHG recommendations on genetic testing and common disorders. *Eur. J. Hum. Genet.* 19(Suppl. 1), S6–S44 (2011).
- 3 Janssens AC, Gwinn M, Bradley LA, Oostra BA, van Duijn CM, Khoury MJ. A critical appraisal of the scientific basis of commercial genomic profiles used to assess health risks and personalize health interventions. *Am. J. Hum. Genet.* 82(3), 593–599 (2008).
- 4 European Society of Human Genetics. Statement of the ESHG on direct-to-consumer genetic testing for health-related purposes. *Eur. J. Hum. Genet.* 18(12), 1271–1273 (2010).
- 5 Ransohoff DF, Khoury MJ. Personal genomics: information can be harmful. *Eur. J. Clin. Invest.* 40(1), 64–68 (2010).
- 6 Magnus D, Cho MK, Cook-Deegan R. Direct-to-consumer genetic tests: beyond medical regulation? *Genome Med.* 1(2), 17 (2009).
- 7 Borry P, Caulfield T. DTC genetic testing: an international perspective on hype, harm and the policy debates. *Med. J. Aust.* (2013) (In Press).
- 8 Borry P, Howard HC, Senecal K, Avar D. Direct-to-consumer genome scanning services. Also for children? *Nat. Rev. Genet.* 10(1), 8 (2009).
- 9 Skirton H, Goldsmith L, Jackson L, O'Connor A. Direct to consumer genetic testing: a systematic review of position statements, policies and recommendations. *Clin. Genet.* 82(3), 210–218 (2012).
- 10 Rial-Sebbag EB, Borry P. Direct-to-consumer genetic testing: regulating offer or use? *Pers. Med.* 9(3), 315–317 (2012).
- 11 Aven T, Renn O. Stakeholder and Public Involvement. *Risk Manag. Gov.* 181–200 (2010).
- 12 Callard F, Rose D, Wykes T. Close to the bench as well as at the bedside: involving service users in all phases of translational research. *Health Expectations* 15(4), 389–400 (2012).
- 13 Maxian Rusche T. The European climate change program: an evaluation of stakeholder involvement and policy achievements. *Energy Policy* 38(10), 6349–6359 (2010).
- 14 Goldsmith L, Jackson L, O'Connor A, Skirton H. Direct-to-consumer genomic testing: systematic review of the literature on user perspectives. *Eur. J. Hum. Genet.* 20(8), 811–816 (2012).
- Provides a review of published articles reporting the results of studies of individuals who have undergone direct-to-consumer (DTC) genetic testing (GT). This includes those individuals who purchased testing on their own as well as those who took part in a research project and through this had DTC GT.
- 15 McGowan ML, Fishman JR, Lambrix MA. Personal genomics and individual identities: motivations and moral imperatives of early users. *New Genet. Society* 29(3), 261–290 (2010).

- **Relates information obtained from interviews with early adopters of DTC GT (individuals who purchased of their own accord). At the moment, this is the only in-depth interview study with this stakeholder group.**
- 16 Su Y, Howard HC, Borry P. Users' motivations to purchase direct-to-consumer genome-wide testing: an exploratory study of personal stories. *J. Comm. Genet.* 2(3), 135–146 (2011).
- **Relates information from individuals who purchased DTC GT of their own accord by looking at information these users left on blogs.**
- 17 Froad A. Technology: a flavour of the future. *Nature* 468(7327), S21–S22.
- 18 Allison M. Genetic testing clamp down. *Nat. Biotechnol.* 28(7), 633 (2010).
- 19 Neuendorf KA. *The Content Analysis Guidebook*. SAGE, CA, USA (2002).
- 20 Krippendorff K. *Content Analysis: an Introduction to its Methodology (2nd Edition)*. SAGE, CA, USA (2004).
- 21 Hsieh HF, Shannon SE. Three approaches to qualitative content analysis. *Qual. Health Res.* 15(9), 1277–1288 (2005).
- 22 Elo S, Kyngas H. The qualitative content analysis process. *J. Adv. Nurs.* 62(1), 107–115 (2008).
- 23 Guest G, MacQueen KM. *Applied Thematic Analysis*. SAGE, CA, USA (2012).
- 24 Bollinger JM, Green RC, Kaufman D. Attitudes about regulation among direct-to-consumer genetic testing customers. *Genet. Test. Mol. Biomarkers* 17(5), 424–428 (2013).
- **The largest survey conducted of users of DTC GT. Relates the fact that users want oversight of testings, but not necessarily more gatekeepers between them and obtaining a genetic test.**
- 25 Foster MW, Sharp RR. The contractual genome: how direct-to-consumer genomic services may help patients take ownership of their DNA. *Pers. Med.* 5(4), 399–404 (2008).
- 26 Murphy J, Scott J, Kaufman D, Geller G, Leroy L, Hudson K. Public expectations for return of results from large-cohort genetic research. *Am. J. Bioeth.* 8(11), 36–43 (2008).
- 27 Bollinger JM, Scott J, Dvoskin R, Kaufman D. Public preferences regarding the return of individual genetic research results: findings from a qualitative focus group study. *Genet. Med.* 14(4), 451–457 (2012).
- 28 Bayer R. The continuing tensions between individual rights and public health. *EMBO Rep.* 8(12), 1099–1103 (2007).
- 29 Francke U, Dijamco C, Kiefer Ak *et al.* Dealing with the unexpected. Consumer responses to direct-access *BRCA* mutation testing. *Peer J* 1, e8 (2013).
- **23andme's own analysis of the response of some consumers of obtaining *BRCA* results.**
- 30 James KM, Cowl CT, Tilburt JC *et al.* Impact of direct-to-consumer predictive genomic testing on risk perception and worry among patients receiving routine care in a preventive health clinic. *Mayo Clin. Proc.* 86(10), 933–940 (2011).
- 31 Bloss CS, Wineinger NE, Darst BF, Schork NJ, Topol EJ. Impact of direct-to-consumer genomic testing at long term follow-up. *J. Med. Genet.* 50(6), 393–400 (2013).
- 32 McGuire AL, Burke W. An unwelcome side effect of direct-to-consumer personal genome testing: raiding the medical commons. *JAMA* 300(22), 2669–2671 (2008).
- 33 Eysenbach G, Till J. Ethical issues in qualitative research on internet communities. *BMJ* 323(7321), 1103–1105 (2001).
- 34 Convery I, Cox D. A review of research ethics in internet-based research. *Prac. Res. Higher Educ.* 6, 1 (2012).

## ■ Websites

- 101 23andMe. [www.23andme.com](http://www.23andme.com)
- 102 Personal access to genetic information. The Petition Site. [www.thepetitionsite.com/1/mydna](http://www.thepetitionsite.com/1/mydna)
- 103 DIYgenomics. [www.diygenomics.org](http://www.diygenomics.org)
- 104 US FDA. *In vitro* diagnostics, news and events, letters sent to companies involved in direct-to-consumer advertising (2010). [www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm212830.htm](http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm212830.htm)
- 105 FDA. FDA/CDRH Public Meeting: oversight of laboratory developed tests (LDTs). (July 19–20, 2010). [www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/default.htm](http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/default.htm)
- 106 Fighting celtic curse (hereditary hemochromatosis). <http://celticcurse.org/genes>

Reproduced with permission of the copyright owner. Further reproduction prohibited without permission.