WORKING PAPER 53

Patients, Consumers & (Bio)Citizenship in Brazil: lessons from the UK's regulatory experience with personalised/precision medicine

Rising Powers Research

funded by the

Economic and Social Research Council (UK ESRC)

M. Sharmila A. Sousa

Global Biopolitics Research Centre
Department of Political Economy
King's College London
London
United Kingdom

September 2015

Email: sharmila.sousa@gmail.com

Abstract

Personalised/precision medicine has become a rather delicate issue for policy-makers and regulators for over twenty years. As genetic tests moved from the bench to the bedside and, more recently, also to the Internet, with the direct-to-consumer approach, various developed countries have adopted opposing regulatory approaches on the direct-to-consumer genetic testing matter to neither halt novel biotechnology development and implementation in the translational field of public genomics health, nor leave their patients *qua* health consumers unprotected. Following this trend, we have observed the rise of demand for clinical usership of genetic tests as diagnostic tools also at developing countries such as Brazil (Sousa et al., 2015, Sousa and Maciel, 2015). Curious about the current regulatory context for personalised/precision medicine in Brazil, we developed a case study to observe if and/or how policy-makers from Euro-North American countries could better inform the marketing introduction of such tests in a developing country scenario before they flood Brazilian clinics. Using an approach inspired by grounded theory, the triangulation of participant observation fieldwork notes and critical discourse analysis of forty-one Brazilian stakeholders' oral life history narratives and four UK experts' interviews' transcripts illuminated the ways by which our respondents discussed a series of ethical, social and legal consequences of the ongoing initial use of diagnostic genetic tests in Brazil, as well as on health consumerism in Brazil and the UK. Such debates substantiated policy and regulatory opportunities for the personalised/precision medicine field in Brazil, namely: regulatory demands for both the genetic testing and counselling activities, and for personal genetic data confidentiality; policy claims for better (continuing) medical education on molecular biology and personalised/precision medicine.

Keywords: personalised/precision medicine; (bio)citizenship; health consumerism; Brazil; UK; regulation.

1. Introduction

Since the worldwide web access brought us together as a global village, personal genomics has been heralded as having no boundaries in this 21st century. Beneficial outcomes from the Human

Genome Project are meant to stimulate continuing investigation for ever newer and faster performing biotechnologies to attend the public health's demands for improved prevention, diagnosis and treatment of several diseases, especially non-communicable multifactorial illnesses, such as cancer, obesity, diabetes mellitus and heart diseases (Prainsack and Vayena, 2013). Although debate over personal genomics implementation into routine clinical practice has lasted for over twenty years, experts argue that not only health professionals and experts but also lay people's voices and views must be taken into account for the formulation of policies to guide its uses. In this sense, personalised/precision medicine has become a rather delicate issue among policy-makers and regulators worldwide (Condit, 1999, Evans et al., 2011, Kerr, 2003, Kerr et al., 1998b, Kerr et al., 1998c, Kerr et al., 1998a, Marteau et al., 2010, Marteau and Weinman, 2006, O'Doherty and Suthers, 2007, Parsons, 1992, Prior, 2001, Prior, 2003, Prior, 2007, Scott et al., 2005).

1.1. Direct-To-Consumer Genetic Testing – The 'Do-It-Yourself' Revolution in Clinical Research and Assistance

One of the major controversies around direct-to-consumer genetic tests (DTCGT) started with the screening process that happens outside the clinical setting, waiving essential clinical pre-requisites for appropriate diagnosis, such as informed consent, education and support through pre- and post-test counselling (Gray et al., 2009, Tracy, 2007, Tracy, 2008). All such activities started being performed by patient/consumers themselves – a term coined as a hybrid of patient and client (Scott et al., 2005). In this sense, the greater commercial availability of genetic tests by online laboratories – due to the combination of free-market and scientific innovation – offered autonomy for those interested in personal genetic data. Such engagement with DTCGT allowed patient/consumers to voluntarily commit with higher responsibilities towards self-regulating their health status, as it has been promoted for the past years by governmental initiatives (Janssens et al., 2008).

This 'regime of the self', where "a prudent yet enterprising individual actively shapes his or her life course through acts of choice" (Rose and Novas, 2002, p. 5) – biocitizenship – is one of the ways governments found to shift such responsibilities onto their citizens (Salter, 2002 in Webster, 2007). In this sense, these empowered patients/consumers shape new ways of understanding, judging and acting

on themselves, as well as on those to whom they owe responsibilities – offspring, family members, health professionals, co-citizens and ultimately, their community and society at large. However, as public concern increased over misuse and misinterpretation of the low predictive value and probabilistic nature of genetic tests' results, authors have extensively discussed some of the potential ethical and health consequences that may rise under distinct sociocultural and political economic contexts (Aldhous and Reilly, 2009, Bradbury et al., 2009, Gibbon et al., 2014, Gurwitz and Bregman-Eschet, 2009, Hunter et al., 2008, Janssens et al., 2008, Joly et al., 2013, Khoury et al., 2008, Khoury et al., 2009, Lora-Wainwright, 2009, Low et al., 1998, McGuire and Burke, 2008, Mozersky, 2012, Platt, 2009, Van Hoyweghen, 2010).

As DTCGT inaugurated a step further on the 'personalised' trend, shifting emphasis of care from treatment to prevention and pre-clinical detection of diseases, it has turned patient/consumers into experts and introduced a brand new paradigm through which people can (and should) analyse and help construct concepts of health, illness and healthcare (Tutton and Prainsack, 2011). This type of empowerment is arguably beneficial for patients and/or the society as it does not involve formal educational goals and rather requires even higher investments from patient/consumers themselves and governmental resources due to further potential consequences from misinformation in key areas of healthcare (Matloff and Caplan, 2008, Myers et al., 2006, Wilfond et al., 2003).

Notably, Downie and colleagues (Downie and Randall, 2008, Downie et al., 2000) further discussed how the consumerist approach – that we also find attached to personal genomics – has seriously affected both clinical judgement and the patient-physician relationship. By confusing the ethical and legal right of 'respect for the decisions of the autonomous patient' with the 'rights of the patient to require the doctor to make available a specific treatment', physicians may end favouring the ethics of consumerism to those of professionalism. Consequently, it has been suggested that personalised/precision medicine will enhance not only the 'geneticisation of our social lives' (Gray, 2003, Koch and Svendsen, 2005), but also health consumerism, reinforcing the idea that health and its information is a commodity for the curious and/or entrepreneurial patient/consumer (Samuel et al., 2010).

This perspective poses a threat to the (humane) clinical judgement – whereby health professionals loose the right of veto to treatment that is professionally considered useless or harmful – and to the idea of the health professional, who becomes a supplier of goods and services (Downie and Randall, 2008, Downie et al., 2000). In this sense, although personal genomics envisaged people's empowerment, by enhancing patients/consumers' autonomy, privacy, access to genetic tests and general consumer education, findings in the literature have suggested that neither patients (Barlow-Stewart et al., 2009, Geransar and Einsiedel, 2008, Gray, 2003, Gray et al., 2009, Lowery et al., 2008, Wilfond et al., 2003) nor physicians (Mouchawar et al., 2005, Myers et al., 2006, Tracy, 2007) are prepared to manage and/or inform public and individual engagement with such new 'technologies of the self'.

1.2. Brazil Case Study – How to Regulate Personalised/Precision Medicine in a Developing Country Environment?

Putting the regulatory matter forward, this work aims to discuss whether regulators should "protect individuals from their own curiosity" (Gurwitz and Bregman-Eschet 2009, p. 884). A group of authors have argued that there is no place for genetic exceptionalism anymore, as patient/consumers are both capable and better informed about most pros and cons of genetic testing for certain inherited diseases than most physicians nowadays (Nature, 2008, Prainsack, 2011, Prainsack and Wolinsky, 2010, Tutton and Prainsack, 2011, Wright, 2010). The opposing argumentation has advised that the personal genomics field remains *sui generis* enough – concerning the fast pace at which new biotechnologies are directly translated from scientific publications for patient/consumers – to be self-regulated. According to the latter (Andermann et al., 2011, Andermann et al., 2010, Hogarth, 2010, Hogarth et al., 2007, Patch et al., 2009a, Patch et al., 2009b), the remaining lack of solid evidence on analytical validity, clinical validity and utility for most of such genetic tests has prevented policy-makers from officially legislating for free-market availability this far.

Interestingly, however, those who oppose the DTC approach have also discussed how people from different developed countries have been more comfortable with such direct access, and all

streaming consequences from it, than others (Taylor, 2008). In this sense, the US regulatory scenario is changing at a faster pace, whereby the Food and Drug Agency (FDA), the Federal Trade Commission (FTC) and the National Institutes of Heath (NIH) joined forces to formal regulate the DTCGT sector. The FDA has issued several letters to biotechnology laboratories in the US, prohibiting the commercialisation of over-the-counter (OTC) genetic testing kits and interpretation services, as "it appear[ed] to meet the definition of a device and may therefore require FDA approval" (Annes et al., p. 1100, HGC, 2011). The FDA has also judicially contended with Myriad over *BRCA1/BRCA2* biomarkers for breast and ovary cancer intellectual property rights (Hopkins and Hogarth, 2012), arguing against it. By such means, the US agency is pursuing the overall protection of the public from further risks of harm potentially elicited by tests that are neither analytically nor clinically accurate, so that patient/consumers are not misled by incorrect test results or unsupported clinical interpretations for which they have paid (Annes et al., 2010).

On the other hand, while other European countries with advanced and rich in resources national health systems have put a ban on DTCGT, such as Germany, France and Switzerland, the UK with its National Health Service (NHS) has adopted a more balanced approach and still presents no formal regulation on the DTCGT matter. According to the Human Genetics Commission (HGC) – the UK's former government strategic advisory committee, which gathered advice information and shifted emphasis onto transparent consultation – putting an indiscriminate ban on DTCGT services cannot prevent genetic tests from being purchased from companies based outside the UK, or the European Union (EU). In this sense, all social actors who hold an interest in personalised/precision medicine have discussed the need for better regulatory framework in the UK – i.e. patients, health professionals, experts, governmental agencies and a few serious biotechnology laboratories who offer such online services (Borry, 2008, Borry and Howard, 2008, HGC, 2007, Hogarth et al., 2008).

Their fears lie on the premature implementation of DTCGT without appropriate pre-market review, unlike other medical devices. As the running regulatory system being enforced by the UK's Medicines and Healthcare Products Regulatory Agency (MHRA) – the EU *In Vitro* Diagnostic Devices (IVD) directive (98/79/EC) – is predicated on risk-classification, genetic tests fall as 'low-risk' and are, therefore, exempt from pre-market review (Hogarth et al., 2008, Hogarth et al., 2007,

House of Lords, 2009). Although they can be used to guide serious clinical decisions, such as treatment for inherited cancers, there are usually neither confirmatory tests nor pre- and post-test counselling with the DTC approach, which sponsors the need to enhance their risk-classification (Hogarth et al., 2008, Hogarth et al., 2007). Nevertheless, regulators understand that subjecting those tests to greater scrutiny, as for other medical devices, might discourage the diagnostic industry from developing new tests. These actions might consequently diminish people's access to better predictive tools, further minimising the potentialities for personal genomics to attend its desired public health purposes in terms of prevention and early diagnosis (HGC, 2007, Hogarth et al., 2008, Hogarth et al., 2007, House of Lords, 2009, Patch et al., 2009b).

Interestingly, given our experience with both the development and implementation of a clinically and scientifically proven cost-effective genetic screening and follow-up *modus operandi* for an inherited type of cancer syndrome in Brazil – the Brazilian Consortium for Medullary Endocrine Neoplasia Type 2 (MEN2), BRASMEN (Álvares Da Silva et al., 2003, Camacho et al., 2008, Germano-Neto et al., 2012, Lindsey et al., 2012, Signorini et al., 2014, Tamanaha et al., 2009, Valente et al., 2013) – we have also observed the rise of: personalised/precision medicine, patient/consumers and different levels of (bio)citizenship, from a developing country scenario (Sousa et al., 2015, Sousa and Maciel, 2015).

In this sense, we contended over the question: what is the current regulatory context for personalised/precision medicine in Brazil, and if and/or how policy-makers outside Euro-North American societies should proceed – i.e. which paradigms to consider – since developed countries have adopted opposing regulatory approaches on the DTCGT matter? Ultimately, we aimed to observe what Brazilian regulators could learn from the UK's (lack of) formal regulation on DTCGT. Although the UK's NHS is advanced and richer in resources when compared to the Brazilian Unified Health System (*Sistema Único de Saúde*, SUS), which has been historically supplemented by a large private health sector due to its shortcomings (Paim et al., 2011), both offer universal health coverage.

2. Methodology

Using an approach inspired by grounded theory (Strauss, 1990, Strauss, 2003), we developed a case study triangulation with: a) participant observation fieldwork notes from three centres (São Paulo, Ceará and Espírito Santo) of the Brazilian consortium for research, development and implementation of a genetic testing and follow-up *modus operandi* for MEN2 (BRASMEN); and b) critical discourse analysis of: I) first-person narratives from all social actors who hold an interest in (personalised) genomics clinical assistance for this inherited type of cancer syndrome in Brazil: MEN2 families and BRASMEN health professionals, besides national regulators, providers and users from both public and private health sectors; and II) transcripts from interviews with key informants on the regulatory context of DTCGT in the UK.

2.1. Participants and Recruitment

After a first encounter with health professionals at the BRASMEN centre in São Paulo and with a key-informant in London, snowball sampling was deployed and interviewees comprised four sample groups:

- Sixteen users (eight patients, seven family members with MEN2 from Ceará, Espírito Santo and São Paulo; one DTCGT user from São Paulo);
- Twenty-one health professionals (eight endocrinologists, four head and neck surgeons, six key Brazilian researchers in the field of MEN2 and two laboratory technicians; all from Ceará, Espírito Santo, Minas Gerais, Rio de Janeiro, São Paulo and Rio Grande do Sul; one private diagnostic laboratory representative from São Paulo);
- Four regulators (representatives from: Brazilian Society of Clinical Pathology – SBPC in Rio de Janeiro; Health Technology Products Section at National Health Surveillance Agency – ANVISA in Brasília; Healthcare Regulation and Products License Section at National Regulatory Agency for Private Health Insurance and Plans – ANS in Rio de Janeiro; National Commission for the Incorporation of Technologies – CONITEC in Brasília)

- Four UK experts: two bioethics/policy researchers; two policy-makers with experience in Clinical Genetics, who played major roles in the running DTCGT recommendations for the UK.

For the Brazilian interviews, inclusion criteria were: health professionals and researchers involved with MEN2 in Brazil, patients and relatives from the BRASMEN research consortium, users and providers of DTCGT and representatives from governmental agencies involved with genetic tests' regulation in Brazil; exclusion criteria were failure to: agree with informed consent, respond to invitation contact after two trials, and validate narrative after interview; and response to invitation was 78.85% (41/52) and 100% for narrative validation. For the UK interviews, inclusion criteria were: UK-based bioethics experts and/or policy-makers whose field of work encompassed DTCGT regulation, working at the UK's Higher Education System or NHS; response to invitation was 100%.

Brazilian users' group encompassed families: from São Paulo who belonged to all socioeconomic and cultural strata and whose children underwent preventive surgery in São Paulo; from Ceará who belonged to lower socioeconomic and cultural strata, and presented high levels of consanguinity (i.e. several first-cousins' marriages), whose family members were in the early/preventive stages of clinical assistance (diagnosis and preventive/curative surgery); from Espírito Santo who belonged to all socioeconomic and cultural strata, and whose majority of family members were in all stages of clinical assistance (genetic diagnosis, preventive/curative surgery, post-surgical follow-up and IVF-family planning), relying both on public and supplementary private healthcare for assistance – some underwent genetic screening, surgical and post-operative follow-up treatment; others only genetic screening; and several remain undiagnosed. Specific profile characterisation of participants has been summarised at Supplementary Table 1.

2.2. Data Collection and Analysis

Participant observation notes (Denzin and Lincoln, 1994, Geertz, 1988) derived from fieldwork during clinical consultations at three BRASMEN centres where users, health professionals and regulators were interviewed during the whole year of 2012 (São Paulo, Ceará and Espírito Santo). The four UK interviews occurred during June-July/2011 in London. Following ethical approval (Federal

University of São Paulo REC 0468/10; King's College London REC 10-11_591) and given participants' informed consent, all interviews lasted between one to two hours, were audio-recorded and transcribed. Brazilian interview transcripts were 'transcreated' into oral life history narratives before analysis (Gallian, 2009, Gallian et al., 2009, Meihy and Holanda, 2007, Meihy and Ribeiro, 2011). All interviews were conducted as a series of in-depth semi-structured open-ended questions meant to introduce interviewees to talk about their experience with the subject and from which following questions derived.

For the analysis, we used an approach inspired on grounded theory, as both personalised/precision medicine and its regulation are complex and requires conceptually dense theory emanating from actual data, and this methodological approach can account for a great deal of variation in the phenomena studied (Strauss, 1990, Strauss, 2003). All data was coded, according to raising and/or approached themes during and across policy documents, fieldwork notes, transcripts and narratives systematic analysis (Strauss, 1990, Strauss, 2003). Since we were interested in how not only users but also experts interpreted their experiences with this field, the triangulation with critical discourse analysis was considered a valuable analytical framework as it can illuminate how issues are evaluated and how beliefs and values can be discussed (Chouliaraki and Fairclough, 1999).

As a contextual analysis of the rhetoric used and the possible ways that others interpreted such experiences (Brown and Yule, 1983, Chouliaraki and Fairclough, 1999), our case study did not attempt any in-depth linguistic evaluations, but used instead the more interpretative analysis. On this score, we were more interested in the participants' capacity to project futures that can have effects, than in the 'truth-value' of their accounts. Quotes drawn on are representative, illustrating saturated themes. Anonymity was guaranteed for all interviewees. Narratives underwent respondent validation for internal validity of data collected (Mays and Pope, 2000). Finally, it is important to outline that we simply focused on the debates themselves, observing how they were structured within the UK's and Brazilian sociocultural and political economic contexts, respectively.

3. Case Study Findings

First, we present our main findings on the underlying socio-ethical, cultural and political economic consequences from the (virtual) rising demand for clinical usership of genetic tests as diagnostic tools in Brazil and the UK. Then we outline the policy and regulatory gaps found by our BRASMEN respondents. Finally, we present our main findings on how the UK policy-makers have closed such gaps, illuminating ways for Brazilian policy-makers and regulators to compare and contrast with the ongoing complex regulatory context for personalised/precision medicine in Brazil today, as respondents discussed it.

3.1. Patient Consumerism in Brazil: no genetic exceptionalism

Regarding the DTC availability of genetic tests, we observed that the rising demand for clinical usership of genetic tests and personal genetic data in Brazil is partially due to the changing socioeconomic context and increasing international commercial interest in the Brazilian expanding market for healthcare products (Landim et al., 2013, Sousa and Maciel, 2015). Our fieldwork findings showed that the majority of diagnostic laboratories in Brazil already offer genetic screening for one or more of the following: *BRCA1/BRCA2*, other biomarkers for various cancer types including MEN2, monogenic disorders, nutritional and athlete-performance enhancement purposes. In fact, these genetic services can be accompanied or not by genetic counselling also at spin-off companies under the Brazilian 'health industry complex' or at private diagnostic laboratories, especially around São Paulo (Sousa and Maciel, 2015).

When it comes to consumption of information, biotechnologies and expertise in the realm of biomedicine, it seems that it does not matter whether it is genetic, biochemical, clinical or another type of medically-relevant information, product or service – genetic exceptionalism looses authority to simply health exceptionalism in both the UK and Brazil. The majority of our Brazilian respondents and ¾ UK experts, manifested their concerns about the consequences of such direct availability. We observed that the majority of the health professionals and regulators in Brazil (n = 23/25) showed negative views about DTCGT, mainly about the potentiality for misuse and misinterpretation of potentially harmful information.

> [T]oday, there are people in Brazil who can access this type of information and who can understand it, mainly about risk prevention not only for chronic non-communicable diseases, but also for health promotion… Although this group is small, there are others who can also buy these tests but will not understand it. What will we do with these patient-consumers exposed to such types of information within our health system? […] We hear about 'functional illiteracy' in Brazil, so can you imagine this type of person reading the instructions of a genetic test to perform at home? Besides, there is the television marketing to convince people to use it. (SBPC Regulator)

One of the UK bioethics experts as well as two Brazilian head and neck surgeons showed more optimistic views about the DTC approach. However, all respondents restated the importance of expertise in the field, as a by-product of individual interest, in order to render reliable information resource and governance skills.

> I think that the personal genomics field is very interesting because the layperson does not exist anymore. Usually, people who spend time on those sites know more about this than many GPs and medical professionals. So, who is lay and who is expert is not that clear cut, I think. […] Of course people can always misunderstand things, [for example] that this would tell you what you will suffer from when you are fifty [years old. However,] this is very unlikely that people would get that so often. Maybe they will underestimate a little what people would value, or overestimate, but the same can happen to professionals. (Bioethics Expert I)

In this sense, patient/consumers, health professionals and regulators want to rely on scientifically sound information, providing clear and trustworthy evidence of the biotechnology's novelty, utility, safety and efficiency. According to the Brazilian regulators and UK policy-makers,

> *We are not making science, at this moment: we want to use scientific results!* We would like to 'buy' a good result for the money that will be spent. (CONITEC Regulator; *emphasis* from interviewee)

Discussing the autonomy exerted by patient/consumers, one of the UK respondents pointed that the move to privatisation and self-healthcare that has recently been instilled by the UK government

(Janssens et al., 2008, Lupton, 1997, Salter, 2002, Webster, 2007) was not the sole reason for such empowerment process.

> [S]ociologists are very keen on the idea that we have entered a post-paternalist era […] But, I think […] two things about this particular kind of arguments in Sociology of Medicine, Sociology in Health and Illness. The first one is that it over-exaggerates how much patients were disempowered prior to the 1960's, 70's and 80's, whenever you can demise a [certain] paternalism. Secondly, I think it probably over-exaggerates the degrees in which we have lessened our lives on doctors […] [P]atients have probably always greatly operated, into some degree, a pluralistic market place. We have always been able to buy OTC medicines for common ailments; we have treated common ailments at home. The first act of diagnosis [is done] by your mother […] A huge amount of medical care has always happened at home and historically, if you look at the 19th, 18th century, we see huge amount of interest in self-medication, visiting spa's [...] So I think we have over-exaggerated the novelty of our kind of modern biosociety. (Bioethics Expert II)

The justification for such statement was aggravated by British governmental initiatives, which instilled that "healthcare is also represented as 'just like any other commodity'. [In this way,] [p]atients *qua* consumers are urged to refuse to accept paternalism or 'medical dominance' on the part of the doctor, to 'shop around', to actively evaluate doctors' services and go elsewhere should the 'commodity' be found unsatisfactory" (Lupton, 1997, p. 373, Janssens et al., 2008). Therefore, "[a]s [bio]citizens come to see themselves as active consumers of healthcare, rather than the passive recipients of authoritative clinical decisions, so they are in effect redefining their welfare citizenship, their health-care rights, their expectations and the political demands they place upon the polity" (Salter, 2002, p. 62).

On this specific issue, the Brazilian private health sector (ANS) regulator reverberated such views about the consumerist approach we observed in the Brazilian patients' engagement with health care and technologies during fieldwork. They aim a healthy status, which is perceived as a desirable 'good' that can and should be purchased. In this sense, as recently discussed for the US (Jauhar, 2014), we observed the 'buffet' effect on people's consumerist approach to healthcare. Jauhar (2014) discussed

that as patients become aware of healthcare expenditure for procedures, they spent 14% less than those who remained unaware. On the other hand,

> In Brazil, generally, we have a mix of the UK's NHS – our SUS – and 'Medicaid' – the US private health insurance plans' companies. However, our SUS is inefficient and lacking resources unlike the NHS […] Today, differently from other countries, we do not have many studies about this because *we use all technologies badly… Extremely bad!* Besides, our health indicators are *awful…* If we used a lot of technologies and did something useful with it, great! […] We must incorporate novel technologies with a guideline; otherwise people use it unreasonably because we have this 'pro-technology' culture. (ANS Regulator; *emphasis* from interviewee)

During fieldwork around BRASMEN centres, health professionals mentioned that priority to access under the biomedical 'hidden innovation system' (Sousa et al., 2015) was granted to those who relied exclusively on the public service for clinical assistance – i.e. SUS – as a way of balancing social inequalities. We also observed that half of the genetic test users interviewed (n = 8/16) – those who could afford private health insurance plans, from very simple to all-inclusive coverage – willingly committed to out-of-pocket expenditure in order to access certain types of high-density health technologies, follow-up care and/or surgical treatments at private hospitals that were not included in the BRASMEN research consortium *modus operandi*. The majority of the health professionals and regulators (n = 19/25) mentioned that the Brazilian consumerist approach to 'anything health-related', given persuasive marketing and fashionable trends, pertained to most of patients and families assisted, despite sociocultural and economic differences.

> Sometimes, these preventive medicine policies that institute prophylaxis make us rather anxious. This is an anxiety also created due to the greater and facilitated availability to these tests as, nowadays, there are laboratory tests for almost everything being offered on the Internet by labs like '23andMe'… These 'early adopters' of genetic tests are the so-called 'lay experts': it is the individual who has money to buy […] full-body MRI, whole genome mapping and so on… This is why I am not sure if these non-directed tests that people buy out of curiosity, for leisure, or due to

anxiety are a good idea… Many times, it is *hypochondria*! The person wants to '*nit-pick*'! (Endocrinologist Researcher from São Paulo; *emphasis* from interviewee)

Echoing this more consumerist approach to health observed in Brazil, the private diagnostic laboratory representative illuminated how the manner Brazilian patient/consumers engage with health products and services is more similar to the US, when analysing the private health sector.

> In a global context, I think we are going towards a more US than the British model, or that of any other European country… Mainly because, here in Brazil, we already have a lot of US influence anyway. Perhaps, this influence lies on how easy it is for you to get what you want […] If I need to do something, which is available and standardised, that I have confidence in using it… If I want to pay for it, I will buy it! […] Why would I remain stuck with a physician to get this evaluation? Well, this is what I believe, but I do not see our Medicine this way, because people abuse. We had to prohibit people from buying antibiotics without prescription… We had to forbid controlled anti-inflammatory… What I mean is: *either we prohibit those things so no one can do them or, maybe, a cost-effectiveness analysis will find evidence and the government will say: 'Only those who have familial syndromes will access it'... Then, yes! If it is established by law, maybe, the British model will fit here.* If we do not have such statutory intervention, meaning that, if you pay, you get a result… This would be the US model that we have seen happen here more frequently. (*Emphasis* from interviewee)

In this sense, we argue whether this enhanced sense of responsibility for health self-management we observed during fieldwork – the various levels of (bio)citizenship (Sousa et al., 2015) – could be partially explained by the fact that those societies whose relationship with health care and expertise is based more on consumer ethics, instead of that from citizenship and legal rights or professional ethics. As discussed by Downie and colleagues (Downie and Randall, 2008, Downie et al., 2000), our findings illuminated how consumerism in medicine can and have transformed health professionals as service and/or goods providers, especially in the private health sector. This was the view of all our health professionals and regulators interviewed in Brazil.

> Do we really have a cultural background to support such autonomy, as it happens in the US, Norway, Sweden, Finland and opt to undergo such tests, aware of all consequences of knowing

> the result? I have great doubt if, as society, we have such culture for this in Brazil. I mean culture in the sense of 'way of thinking', attitude of our people, not as lack of education, because many people could understand such information with the help of a physician, a genetic counsellor, someone explaining this information available on the Internet… Culturally, we deal with death in a very specific manner, we deal with disease in a very specific manner… My perception is we still do not have a cultural background for this type of national attitude of prevention in health, of assuming the responsibility for all factors involved in such personal genetic data analysis. (ANS Regulator)

As genetic testing providers, the BRASMEN health professionals showed their concerns about the abuse potentialities that DTCGT matter poses for professional ethics and, therefore, requested pre-emptive local regulation.

> I think that, even in Brazil, we need some initiative in terms of regulating this better at the federal government level soon. My view is it would not be precipitate as *tests are here, patients are here… It is all here, so, until when will we wait?* We cannot wait for this to happen to then chase after it… Exactly because [it] will grow a lot! It already has […] It is much easier: you enter the website, pay and get it. (Private Diagnostic Laboratory Representative; *emphasis* from interviewee)

Reverberating such concerns as personal genomics has also reached Brazil, how can the UK's regulatory decision inform policy-makers and regulators about the personalised/precision medicine market?

3.2. Health Information Governance in Brazil and the UK: a matter of trust and shared-decision making

Firstly, as pointed by one of the UK respondents,

> [W]hat people say and what they do are two different things […] in the early days, when they [NHS] were doing research and [thought] they should offer Huntington's disease testing to people […] they went to the Huntington's disease patient community and said 'do you want testing?' and they said 'yes!' And then they offered testing, and did people have it? No! Ok. So,

> then, if you look at the consumer market, which is what we are talking here, that what people say in focus groups about 'oh, yes! I am interested in that. I am interested in this' is not actually what they go and do. (Bioethics Expert II)

According to another respondent, letting the DTCGT field be self-regulated and driven by free-market could be an even greater mistake in the UK, because

> [U]ndoubtedly, if it was cheap enough some people would do it. And some people would do it without any thought. I gave a talk once and an epidemiologist came to me and said: 'Look, if it is £50, I would do it. Just for curiosity. Just for a bit of fun'… But that does not mean that the NHS should pay for that. (Policy-Maker I)

This point illuminates an argument mentioned by all UK and Brazilian interviewees: DTCGT still remains a luxury item; a niche market. In this sense, it is noteworthy that the private health sector in Brazil covers 50.6 million citizens (ANS, 2014) – a population that prefers the more equipped and faster services provided by private insurance plans than those from SUS. Consequently, from the 190 million citizens assisted by SUS, 140 million depends exclusively on the public health services. As pointed by the BRASMEN health professionals outside the southeast-south axis of technology and expertise concentration (in our case study, Ceará and Minas Gerais), their patients tend to portray conformism, mainly searching for treatment, not prevention. Nevertheless, the private sector covers a growing and already considerably large population who willingly want to commit to heightened (financial and/or social) responsibilities to actively pursue a healthier lifestyle.

Hence, for now, as the NHS will not willingly pay for patients to undergo tests that have no clinical utility, our data suggests that SUS should proceed similarly. On the other hand, genetic test with clear clinical utility and validity such as for MEN2 diagnosis should be made available for free under the SUS' remit to all potentially affected. In this sense, we observed growing demand not only for clearer regulations to guide availability and access also via the private health sector, but especially for genetic testing itself, as reported by the BRASMEN health professionals interviewed who received patient/consumers of DTCGT in Brazil. Following this reasoning behind the Brazilian health professionals and regulators interviewed, we observed how governmental policy inertia explains how

"much [of the] contemporary public and individual dissatisfaction with doctors arises precisely because patients still rely on them so heavily for expert guidance and care" (Hogarth, 2010, p. 323).

According to three UK respondents, "the State [...] still quite heavily rely on doctors, and doctors continue to be extremely powerful" (Bioethics Expert II). Therefore,

> [A]t the moment, most people that search for healthcare do through the NHS and, actually, that is the biggest driver against the [DTCGT] uptake. People do not tend to shop for healthcare [in the UK]. A few people do, but if they do shop for healthcare, they shop through doctors […] [T]here is not a big market in the UK at the moment while the NHS exists. (Policy-Maker I)

Interestingly, this is a convergence point we observed in our data: both Brazilian and UK patient/consumers rely on their physicians to consume health products and services while searching for healthier lifestyles. Therefore, both systems establish health professionals as gatekeepers of access to health care and technologies via different rationales. However, according to the private diagnostic laboratory representative and the SBPC regulator, the regulatory context of diagnostic testing is complex in Brazil, holding gaps and contrasting assumptions that leave space for the DTC approach. ANVISA resolution RDC N˚206 from 2006 (ANVISA, 2011) establishes a risk-classification in Brazil, whereby DTCGT would be classified as 'IIIa' – medium risk – for 'auto-test'. Within this risk class, obligatory user instructions must explain that 'auto-tests' are only indicative of the type of disease that the test was used, without any diagnostic purposes. In this sense, any type of additional information must be sought via medical orientation. The ANVISA regulator explained more of the current regulatory incongruences.

> In Brazil, it is not allowed to send tests via post, today, as the diagnosis is a medical responsibility. As far as the sanitary vigilance is concerned, there is no specific term saying 'genetic test is prohibited'… Or: 'It is prohibited to send via post'. Law N˚6.360 from 1976, which deals with the commercialisation of products, states it must be done at services authorised by the sanitary vigilance. These are the institutions that posses an 'operation license' – the competence to commercialise the product and that will be held responsible, in case something happens to that product. […] *My view is this will hardly change in the coming years…"* (*Emphasis* from interviewee)

This finding illuminates how the Brazilian government deployed complex regulatory inertia as a way of driving public and individual dissatisfaction towards health professionals, distancing themselves from tis citizens. In this sense, our finding shows another convergence point in our data: most Brazilian and UK patient/consumers rely on clinical expertise for access to and clarification of the information received from genetic screening tests. Three clinical researchers mentioned receiving patients who underwent DTCGT and specifically searched for them on the Internet to request further genetic counselling (Sousa et al., 2015). They observed that Brazilian patients still quite heavily rely on the public health sector's professional expertise for trustworthy medical guidance, illuminating one of the main reasons why most people are still not interested in DTCGT in Brazil this far. The UK presents a similar scenario.

> The companies will not publish their activity data. When talking to patients, […] most of them would say 'look, if we needed genetic tests, we know that the NHS would do them, so why should we pay?' The only people I have seen here who had DTCGT and wanted help in understanding their results were a few journalists. […] But other patients generally come and take advice as to which genetic tests could be relevant and help them prevent diseases, and which tests have been organised to be provided by the NHS for the most amount of people. (Policy-Maker II)

According to Salter (2002, p. 61), "the view of many citizens that medical regulation is no longer delivering its part of the contract, no longer providing citizens with what they expect in terms of the quality of clinical care they receive" may not be entirely true in the realm of DTCGT in the UK, as opposed to our data for the Brazilian case study. However, "[w]hat no state wants to do is to reduce, rather than restore, the public's faith in the profession by adopting an over-aggressive stance towards doctors, since this would limit medicine's ability to implement official policy. Nor, if it is wise, does a state wish to assume direct responsibility for the governance of medicine since it, rather than the profession, would then become the immediate target for citizen discontent with the standards of healthcare. The advantage of self-regulation to any government is the distance it places between itself and its citizens" (Salter, 2002, p. 63). However, whether the DTCGT should be self-regulated in Brazil remains a worry, mainly for the private health sector (ANS) regulator.

Our respondents' views allied with the above theoretical reasoning for the (patient) autonomy *versus* (physician) paternalism struggle, weighing at times on patient/consumers and others on health professionals, resonates the UK's HGC's principle 2.5 that states that genetic tests should only happen in an appropriate clinical environment – "[i]nformation about tests which are available only in the context of a consultation with a health professional, or are only provided to consumers with both individualised pre- and post-test counselling should make it clear that tests are available only in that context" (HGC, 2010, p. 6).

Considering our BRASMEN health professionals' experience with this type of technology, the majority argued for genetic tests to be centralised under the regulation of reference centres, while the DTCGT remains incipient in Brazil, as it is far more cost-effective for SUS that has already invested in these excellence institutions and guides the use of only those diagnostic tests with clear evidence of clinical utility, safety and efficiency. Interestingly, the Brazilian early adopter interviewed explained his perspective on the incipient DTCGT market, globally (Rabinow and Rose, 2006, Rose and Novas, 2002).

> It is a limited market even in the US… Besides, it is an expensive business for the information you receive and whose utility is questionable. Obviously, people can produce misleading propaganda stating this will be important, but the fact is that very little can be changed to improve your health status for what you pay. (*Emphasis* from interviewee)

On the UK side, respondents supported the view that, while the NHS exists, the DTCGT market seems to remain quite small.

> In the UK, the government made a decision over five years ago to make statins, cholesterol-lowering drug, an OTC medicine, so you can buy without a prescription. […] What they wanted to do was to encourage everyone in the country over a certain age to consider taking statins, because they are so effective in lowering cholesterol and that would dramatically lower the rate of heart diseases. […] Basically, nobody bought them. Anyone who thought they would need statins would go and see their doctor to get them on prescription and be managed by their doctor. This is what I mean about we have over-exaggerated the idea that we live in a post-

paternalist era. The government gets us to buy statins OTC and we just said 'No, thank you! (Bioethics Expert II)

Reverberating such views, one experienced clinical researcher in this field of DTCGT, at both public and private realms in São Paulo, illuminated another issue that has maintained the DTCGT as a niche market, besides regulatory complexity and high prices: the patient-physician relationship.

> It does not matter if the person understands […] everything, he will always ask the physician: 'So, what should I do?' […] It is a *gigantic* problem we have nowadays: it is the price we pay to drop the paternalism and reach more freedom of choice. […] Regarding the utilitarian paternalism on the researchers' behalf, and the *'naïvité'* on the patients' side… I believe the issue is about understanding both attitudes. I would say that one of the main problems in Brazil is culture *sensu lato!* People are ignorant… As you have a culture like ours, whoever has the knowledge is more arrogant! […] However, in Sweden, for example, the other side – the patient – is not as fragile and the arrogant here – the health professional – *knows he is not so fragile*; so, their attitudes are more balanced. In Brazil, since we have such a *monumental* gap of humanistic culture as a whole, we have this tendency to portray a more paternalist attitude […] [T]his is the reason why equilibrium must come from both sides; it is not only one side that is wrong – it is both! For this reason, maybe, it is essential for us to have *an intermediary – to level this!* (*Emphasis* from interviewee)

On the other hand, as discussed by one of the UK bioethics experts, this field of personalised/precision medicine has incorporated lay expertise into the patient-physician relationship. One BRASMEN health professional explained how this incorporation has also happened in Brazil.

> Nowadays, it is very rare for someone to come searching for information primarily with me. It is rare because, today, the information is very easily available. I have patients who come with a *highlighted copy of the American guideline protocol for medullary thyroid carcinoma, filled with questions, doubts*… The patient comes with 'Dr. Google', normally, or with some information that might be wrong. Many times, what I do is open the computer and ask where he found that information so, from that, I base where I will start the clinical approach,

individually, *case-by-case.* (Endocrinologist Researcher from Minas Gerais; *emphasis* from interviewee)

One of the BRASMEN family members explained feeling more comfortable when sharing the decision-making process.

> I looked at the Internet, but *I trusted [the health professionals] a lot.* […] If I had only considered what I read, the tests' results, maybe I would not have chosen the prophylactic surgery for my son. *When you talk with a professional, a person who opens a range of options in front of you and explains it until you understand it… Sometimes, even disclosing that they have children and, if this happened in their family, they would do it… You feel safer, more protected*. So *I followed this more humane side they showed… It helped me a lot!* (*Emphasis* from interviewee)

Summarising this expertise issue also for the UK scenario, one respondent discussed:

> Certainly the idea of 'your doctor knows best' is more or less gone. It is about shared decision-making, but that does not mean that people do not expect expertise… Otherwise people would just diagnose themselves. They do expect and want expertise. They expect the healthcare system to have expertise. I see families all the time with very rare syndromes and they do not want to be the expert each time they go to a doctor. In that sense, they want the healthcare system to be able to contain their needs and do it. (Policy-Maker II)

Further substantiating the fact that both Brazilian and UK governments still heavily relies on their healthcare system professionals to deliver patient/consumers' demands for trusted expertise on diagnostic genetic testing, the next subsection will present our main findings on how the UK experience can better inform the Brazilian policy-makers in regulators on the DTCGT matter, given the various levels of (bio)citizenship observed in our BRASMEN case study (Sousa et al., 2015).

3.3. Statutory Oversight versus Self-Regulation: the best option for Brazil

Due to the struggle patient/consumers face, as they have to move from relying on health professionals' expertise, given the historical trust-based patient-physician relationship, to exert their

empowered (bio)citizenship rights instilled by governmental initiatives for self-healthcare, UK stakeholders also struggle on the best way to regulate DTCGT services. They feel "it is a battle not worth starting" (Policy-Maker I). Manifesting divergent opinions around specific regulation patterns, one respondent was extremely keen on self-regulation, giving free-market justifications.

> [B]ecause it is such a fast moving field […] if there are websites which point out the standards that should be maintained by the companies, the type of information that should be disclosed and the policies that are seen as good and bad practice; then, it would be a good, very effective tool of governance, which is not strictly speaking self-regulation […] Then companies will comply with those. Many of them actually want to comply with good standards, because they do not want trouble. Their reputation is a very valuable asset. I do not think companies would like to be named as particularly irresponsible and horrible enterprises. (Bioethics Expert I)

Conversely, another respondent echoed other experts' concerned views (Andermann et al., 2011, Andermann et al., 2010, Hogarth, 2010, Patch et al., 2009b), precisely because it is such a fast-moving field, thus pointing the need for pre-market evaluation.

> [T]here are people who would say 'well, in the UK, we have been much more sophisticated and we are going to use self-regulation'. Indeed, when the guiding principles came out, the HGC was making noises like that. But in fact, the HGC has not changed its position from Genes Direct, and More Genes Direct reiterated what was stated in the original report, which is that tests should be treated as medical devices and subject to pre-market review by the relevant authority (Bioethics Expert II).

In this sense, according to the ANVISA resolution RDC N˚50 from 2002, all diagnostic tests must undergo pre- and post-market evaluations, during the registration process by this national sanitary vigilance agency. Further on the issue of enforcement, post-market evaluations must be notified to the sanitary vigilance agency via the Technical Vigilance Notification System (NOTIVISA). Nevertheless, the ANVISA regulator explained one of the problems of tracking sanitary control over genetic tests, which was pointed to require new regulation.

> [T]here is one important detail at this differentiation between a medical device from a medicine: if we stop commercialisation of a medicine, theoretically, we halt the problem; whereas that, *in the case of a health product, depending on the type of product, if it is an implant, for example, we must track those people who use it to know who has that product that presented the problem.* [Because] the implant is with people. Transposing this issue to the clinical genetics situation, there is one differential point: the diagnosis induced a whole treatment process that might have been mistaken, in other words, *the consequences are worse because they are not always predictable*. (*Emphasis* from interviewee)

Furthermore, concerns over useful scientific developments ceasing due to excessively bureaucratic and stringent control over genetic tests might partially explain the lack of a formal regulatory system specifically designed for personal genomics in the UK

> [R]egulation always costs. *It is all cost-effectiveness.* This is the downside of the direct cycle of innovation, putting even more delays. We do not have good systems in the healthcare for introducing technologies at work quickly. And potentially introducing more delays is not a good thing. […] [T]he rare diseases are where you cannot get the level of evidence that might be required if you have a very rigid system to introduce things. So, it would just possibly add another spam of work for not much gain in safety. But, if it became that companies were selling so well that they would overwhelm the healthcare system, then it is a different matter (Policy-Maker I).

Following a similar rationale, the private sector regulator added the Brazilian perspective on the introduction of novel biotechnologies into the market.

> There is interest, at ANS, to implement access to genetic tests even if we still cannot grant full access to more basic tests, because we cannot halt technology development! We have only to guide that whatever is good and, preferably, cost-effective is implemented for use. We cannot say: "No! We already do badly with the rest, we will not incorporate what is new"… We have discussed a lot about how to do this and I believe Brazil will still change a lot in this sense. (ANS Regulator)

Such findings illuminate which points where the UK's more austere attitude towards a mixed approach amongst self-regulation and market-driven demands for statutory oversight might be considered the best option for the personal genomics field also in Brazil. In this sense, the HGC discussed the UK's more balanced approach for regulating DTCGT, placing them as a trendsetter in the field of personal genomics regulation. According to the European public consultation for the IVD directive revision, "extensive reference was made to the HGC's 'Common Framework of Principles'" in respondents' reviews (HGC, 2011, p. 10). Similarly, on 18 January 2011, US president Barack Obama also urged the UK's light-approach towards 'increased flexibility' for reviewing regulation on DTCGT, "to reduce regulatory burdens on small business in order to help restore the US economy, jobs and its international competitiveness" (HGC, 2011, p. 6 – 7).

Pondering, therefore, whether this might be an economical instead of an ethical matter, given that there is a body of regulatory authorities in the UK (MHRA, UK Genetic Tests Network – UKGTN – and EuroGentest) responsible for enforcing control over DTCGT services, our respondents explained why the UK's government opted to restrain from formally regulating the personal genomics industry. When questioned about future perspectives for the DTCGT market, UK experts mentioned this is a matter of misplaced myths, misconceptions and misdirected precautions (Hogarth, 2010, Prainsack et al., 2008, Hogarth et al., 2008).

> [W]e need systems that work to adopt tests within the healthcare system. So, it is regulation by payer. We do have it for genetic testing, the UKGTN. There are structures in place to validate […] [but] I am not sure that regulation by saying 'these things are only available through a doctor' necessarily answers the problem, because doctors often sell their services and they will offer. […] I do not think regulation is the answer. I cannot be persuaded that the risks are so great that we need to introduce regulation, because regulation always has unintended economical consequences and I know that this particular administration is so off it. It is a battle not worth starting. (Policy-Maker I)

While we found that this more effective system for introducing new diagnostic tests in the healthcare system is also the case for our Brazilian case study (Sousa and Maciel, 2015), all our Brazilian health professionals and interviewees showed concerned views about the complete lack of

statutory oversight, as discussed. In this sense, another UK expert on DTCGT detailed her concerned views on self-regulation for the UK market.

> We have had a change in government since the 'Principles' were written, and the government we have now is probably even *less* likely to go for formal regulation than the previous one. They are more likely to say 'let it be self-regulated'. In theory, I am concerned about the lack of regulation, […] I do not feel comfortable with the idea of self-regulation, because the regulation will only be as good as the company regulating itself and some of the companies are sometimes more scrupulous than others. Some of them just want to make money. But in practice, I cannot say that I can identify patients who had access to tests results and have come to harm. That may be because they do not exist, or maybe because they do exist but we have not heard about them. So, maybe it is ok as it is been at the moment. (Policy-Maker II, *emphasis* from interviewee).

On this specific issue of abuse of patients' genetic information by third parties – i.e. employers and private health insurance companies – as well as social discrimination and stigma, our UK stakeholders explained that the current economical stagnation has contributed to the small market on personal genomics in the UK. Hence, since no significant evidence was found to support the potentiality for ethical, social and legal implications regarding DTCGT services so far, the lack of a formal regulatory system seems acceptable for the UK scenario. Conversely, for the Brazilian case study, our findings enumerated not only various cases of stigmatisation for those MEN2 families based in Espírito Santo, but also three cases of discrimination by private health insurance companies for patients in São Paulo and Espírito Santo (Sousa et al., 2015).

Our findings give substance to the health professionals and regulators claims for statutory oversight on the issue of personal genetic data confidentiality. So far, not only this issue but also genetic testing and counselling activities remain unregulated, despite previous governmental efforts from Ministerial Ordinance N°81 (Brazil, 2009, Zenker, 2009). Other than this document, Brazil only formally comply the UNESCO's Universal Declaration on the Human Genome and Human Rights from 1997 (UNESCO, 1997). Regarding the genetic counselling activity, all health professionals and the genetic test users interviewed mentioned two policy-making and/or regulatory opportunities.

Firstly, the majority of the Brazilian health professionals are not prepared to deal with a DTCGT result, due to lack of adequate medical education on clinical genetics and genetic tests' uses as diagnostic tools. Second, such activity should be performed, ideally, by a group of adequately trained health professionals, opening more career opportunities for other health professionals, besides physicians – i.e. clinical geneticists.

> I am always concerned if our genetic counselling is non-directive, because we have many patients with such huge fright of undergoing surgery… We never know if they postponed it due to lack of better guidance, if it is due to *depression that overpowers in such cases*, or if it is simply due to the lack of well organised logistics at SUS […] In the end, those who perform the role of social workers and psychologists are the physicians because, *theoretically, there should be other professionals talking to patients about everything that is parallel to the clinical issues!* (Laboratory Technician from São Paulo; *emphasis* from interviewee)

4. Concluding Remarks

Although "there is little understanding of the consumption of healthcare *qua* commodity as a dynamic and intersubjective sociocultural process rather than as an outcome of an individualized calculation" (Lupton, 1997, p. 374), this study helped illuminate how UK experts in personalised/precision medicine regulation did not see a particular need for statutory oversight on the UK's DTCGT market. Since the degree of trust put in the NHS gives the UK an insulation packaging that, so far, cannot be seen in other Euro/North-American countries, according to our respondents' justified opinions, the UK regulatory inertia seems to be, in fact, driven by economical matters. In this sense, as genetic tests moved from the bench to the bedside or, in this case, also to the Internet, our analysis showed that their implementation has challenged the UK's market uptake. In this sense, the trust-based patient-physician relationship still surpasses public interest in the consumerism of scientific innovations. It further challenged the UK's government ability to support scientific innovations' development, while warranting patient/consumers protection from further economical exploitations.

Asking ourselves how this UK's scenario could inform the rising personalised/precision medicine market we observed in our Brazilian case study (Sousa et al., 2015, Sousa and Maciel, 2015), the present work illuminated the ways in which this developing country scenario differs and/or present similarities with the British analysis. Regarding the similarities, our data showed how important the trust-based patient-physician relationships also are for both Brazilian patient/consumers and health professionals, who act as gatekeepers of health information products and services. In this sense, not only the UK but also the Brazilian government still heavily rely on their health professionals' clinical and scientific expertise to attend the public health's demands. We also observed that this fact is not exclusive for this field of diagnostic genetic tests; it pertains to healthcare in general. Hence, we found no genetic exceptionalism when it comes to patients' reliance on their doctors when looking for expert advice during their health decision-making processes.

Regarding the disparities, we found that Brazilian patient/consumers tend to establish a more consumerist relationship with health care, information and technologies than the UK population, who still heavily relies on their advanced and rich in resources NHS. Consequently, the supplementary private health sector in Brazil is much larger than the British one, covering around 50 million citizens who shop for healthcare through their doctors, deeming a healthy status as a desirable commodity. Brazilian patient/consumers present heightened demands to their physicians and willingly commit to co-payment or out-of pocket expenditure in order to access the tools to help them actively shape their life courses through acts of choice – the various levels of biocitizenship manifestation we observed in Brazil (Sousa et al., 2015). As all health professionals mentioned, we also observed a series of ethical, social and legal implications regarding the DTCGT services so far, due to the also observed lack of a clearer regulatory context to guide use and availability to protect Brazilian patient/consumers genetic information confidentiality

In this sense, inspired by the analysis we performed on all these social actors' narratives in an 'open debate' (Hoare, 2010, Rorty, 1989), as means by which we could observe if and/or how the UK's regulatory context could better inform the Brazilian regulatory gap on DTCGT, our findings summarised a couple of policy and regulatory opportunities in Brazil in order to pre-emptively legislate on this also blooming field in a developing country scenario. The first opportunity our

findings' discussion enumerated was the need for Brazilian policy-makers to find an indigenous solution amongst the current complex statutory oversight for genetic testing and counselling with a dose of self-regulation from those laboratories who already started offering such tests, under a clinical environment, being necessarily accompanied by pre- and post-testing counselling. This solution should suffice health professionals' and regulators' concerns over misinterpretation and misuse of genetic tests' results.

The second opportunity lies on the need to formally regulate the confidentiality of personal genetic data in Brazil. Our data, here and elsewhere (Sousa et al., 2015), illuminated many ways by which patient/consumers have suffered legal and social abuse due to this regulatory gap in Brazil today. In this sense, we argued that our findings also illuminate that the various levels of (bio)citizenship observed in our case study might partially operate in the sense of these patients acting like consumers and, therefore, demanding respect for their consumers' right, as discussed by Downie and colleagues (Downie and Randall, 2008, Downie et al., 2000), rather than basing themselves strictly on the enhanced sense of responsibility for health self-management, as discussed by Rose and colleagues (Rabinow and Rose, 2006, Rose and Novas, 2002).

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