"Let's pull these technologies out of the ivory tower": The politics, ethos, and ironies of participant-driven genomic research

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This manuscript is comprised of original material that is not under review elsewhere, and the study on which the research is based was approved by the Institutional Review Board at McGill University's Faculty of Medicine. No authors of this manuscript have any competing interests – intellectual or financial – in the research detailed in the manuscript.

Acknowledgements: This research was collected as part of a grant funded by the National Institutes of Health (R01 HG005277-10). We would also like to thank Michael Flatt, Roselle Ponsaran, and Timothy Ottusch for their research assistance in collecting these data.

Abstract

This paper investigates how groups of "citizen scientists" in non-traditional settings and largely online networks claim to be challenging conventional genomic research processes and norms. Although these groups are highly diverse, they all distinguish their efforts from traditional university- or industry-based genomic research as being "participant-driven" in one way or another. Participant-driven genomic research (PDGR) groups often work from "labs" that consist of servers and computing devices as much as wet lab apparatus, relying on information-processing software for data-driven, discovery-based analysis rather than hypothesis-driven experimentation. We interviewed individuals from a variety of efforts across the expanding ecosystem of PDGR, including academic groups, start-ups, activists, hobbyists, and hackers, in order to compare and contrast how they relate their stated objectives, practices, and political and

moral stances to institutions of expert scientific knowledge production. Results reveal that these groups, despite their diversity, share commitments to promoting alternative modes of housing, conducting, and funding genomic research and, ultimately, sharing knowledge. In doing so, PDGR discourses challenge existing approaches to research governance as well, especially the regulation, ethics, and oversight of human genomic information management. Interestingly, the reaction of the traditional genomics research community to this revolutionary challenge has not been negative: in fact, the community seems to be embracing the ethos espoused by PDGR, at the highest levels of science policy. As conventional genomic research assimilates the ethos of PDGR, the movement's "democratizing" views on research governance are likely to become normalized as well, creating new tensions for science policy and research ethics.

Keywords: genomic research, crowdsourcing, citizen science, patient advocacy, democratizing science, research ethics

Introduction

The field of human genome research provoked controversy at its inception as an example of "Big Science" in biology. Human geneticists and cell biologists worried about sacrificing the intellectual creativity of their "investigator-initiated," local academic lab-based research culture to the research needs of the Human Genome Project for centralized planning, data-pooling, and methodological standardization (Cook-Deegan, 1994, Authors, 2014). Government agencies were called upon to repurpose the Cold War's national physical science laboratories, establish national databases, and launch dedicated federal funding programs to create the infrastructure that genomics research required. Twenty-five years later, a generation of genome scientists has prospered from these platforms, in both academic and commercial settings. Most have come to value the "translational" efficiencies that a more institutionalized genomic research environment affords, and collaborate in and promote the Human Genome Project's even more consolidated

progeny, such as the SNP Consortium, the International HapMap Project, the eMERGE Consortium, ENGAGE, H3Africa, and now the White House Precision Medicine Initiative (Authors, 2014, White House, 2015, Authors, 2016a). Meanwhile, the landscape of genomic research is changing again, in ways that challenge the professional culture of science from a distinctly different direction. The intermingling of academic and commercial genomic research platforms, political patient advocacy, advances in Web 2.0 technologies, "citizen science," electronic personal health monitoring, open access and open source cultures – all within an age of social networking and the corporate university (Delfanti, 2011, Kelty, 2010, Levina, 2010) – has given rise to new forms of translational genomic research. While researchers in these domains often cite the same translational efficiencies, communitarian values, and civic virtues espoused by contemporary genome science, they do so to support efforts to liberate and deinstitutionalize genomic research from the conventional scientific community altogether, and place it into the hands of consumers, patients, and citizens to promote the design and conduct of genomic research through the use of interactive, dynamic, and web-based tools to enroll participants, gather, manage, and analyze data, and distribute findings. This constellation of novel approaches to genomic research have been called public participation, citizen-driven, crowd-sourced, participant-led, participant-centric, and participant-driven genomic research, but despite variable nomenclature and dimensions of participation across initiatives, all have a common emphasis on involving non-experts in genomic research practices (Eriksson et al., 2010, Vayena and Tasioulas, 2013a, Kelty and Panofsky, 2014). For our purposes, we will utilize the terminology of participant-driven genomic research (PDGR), as evocative of their common core emphasis on direct lay involvement in genomic information management.

Drawing on data from interviews with leading figures from across the PDGR landscape, we explore how their organizations seek to challenge traditional approaches to genomic research. We begin with a background section that provides a context for the main themes raised by the participants we interviewed, including Health 2.0 and self-tracking technologies, the rise of internet-based citizen science projects, and the perceived value of crowdsourcing knowledge. Although these groups often have distinct philosophies, practices, and goals from each other, they share rhetorical commitments to individual empowerment (that is, enabling control over one's own genetic information) and the democratization of genomic research (that is, making it possible for everyone to access data and participate in the research process). We describe their objectives in promoting this vision for genomic research, their scientific practices, and the political and moral principles that inform their work. We conclude by suggesting how this ethos might challenge conventional views of genomic expertise, research funding, and participant engagement, especially if it is embraced by the genomic research "establishment" to which it claims to provide an alternative.

Background

Calculable selves, predictable futures

One of the most powerful cultural shifts accompanying the rise in PDGR relates to a rise in social expectations that individuals should monitor and manage their own health. This expectation undergirds terms such as "participatory medicine", "Health 2.0", "Medicine 2.0", or "Health 2050" (Harris et al., 2013, Hughes et al., 2008, Kaye et al., 2012, Swan, 2012). The communities that have devised and promoted these terms are committed to the idea that people

are no longer 'patients' but are instead 'participants' and instigators of their own health management. More precisely, the expectation is that individuals participate proactively in health monitoring processes that enable them to pre-emptively identify and manage disease risks or factors and to maintain or enhance health and wellbeing (Authors, 2012). These might be accomplished, for example, through the optimization of sleep, diet, physical activity, and cognitive performance.

Technology is key to this optimization, including an array of products such as increasingly low-cost smartphones, wearable gadgets, biosensors and cloud-based services that track, store and aggregate data about an individual's genome, microbiome, biophysical functioning, and physical environment. Data derived via these technologies are not only quantitative but also qualitative. The aforementioned metrics can be coupled with self-reported data on one's symptoms, mood, sociability, or stress. Self-tracking thus leads to the collection of information that is 'actionable' in that it enables feedback loops for behavior changes that are intended to foster better or different outcomes (Swan, 2013).

Genomic research beyond the traditional laboratory

The expectation that individuals track health-related information and manage their health – and be empowered to do so – has also led to changes in how genomic research is conducted (Wyatt et al., 2013). Perhaps the most important of these changes has been to harness Health 2.0 technological and cultural developments in attempts to overcome the methodological challenges of underpowered and proprietary genomic research studies. PDGR groups have a heavy online presence and capitalize on the interactive nature of the Internet to gather and present genetic data to large communities of web-based research participants and consumers of direct-to-consumer (DTC) genomic technologies (MacArthur, 2009). This research paradigm not only improves

statistical power for studies of genetic risk variants and environmental risk factors, but it also means that genomic research increasingly takes place outside the bounds of the traditional research laboratory.

Citizen genomics

The activities of these organizations frequently reflect the ethos and practices tied to the growing movement of 'citizen science' and public participation in scientific knowledge production (Lengwiler, 2008, Kelty and Panofsky, 2014). The citizen science movement aspires to open the sphere of scientific expertise by drawing on the energy and capacities of large and widely distributed communities and by involving the participation of 'lay scientists' in research design and funding, and in collecting, analyzing, applying, and disseminating data (Irwin, 1995, Prainsack, 2013). This activity has largely been driven by grassroots organizations and community-based organizing related to environmental (in)justice, and has involved attempts to collect data to demonstrate the disproportionate and damaging effects of environmental exposures of some groups and neighborhoods (e.g., (Allen, 2003, Brown and Mikkelsen, 1997, Brown et al., 2011, Author, 2000, Ottinger, 2013). In recent years, the term "citizen science" has also been used in other contexts to describe web-based science projects that use "lay citizens" as data collectors—but without its earlier political dimensions or commitments. Exemplars of contemporary citizen science projects relate to large-scale ornithology, astronomy and conservation (Citizen Science Alliance, 2014, Trumbull et al., 2000). Recent biomedical projects within and outside of traditional research contexts have also been advanced through citizen science strategies.

These projects and the organizations that have propelled them reflect the ethos of the open science movement, which rejects the corporate privatization and patenting of scientific

data, knowledge and biological processes in favor of cooperative research and the free sharing of data and knowledge (Delfanti, 2011, Kelty and Panofsky, 2014, Vayena et al., 2015). PDGR groups have actively taken up the ethos of citizen science and 'democratic science', with many online communities employing open source computer programming, collaborative learning, and the language of empowerment (especially regarding the rights of participants to access, share, and own their data) to expand the notion of scientific 'expertise' and participation in research beyond universities, hospitals, and companies.

Crowdsourcing – a method borne out of the Internet's capacity to recruit large numbers of people – allows for the accelerated and inclusive gathering of data. Wikipedia is the most well-known example of this type of data collection. It is based on a belief about the "wisdom of crowds": the power of numbers will lead to greater accuracy and more complete information (Surowiecki, 2005). The perspective is that when all people are permitted to participate, the resulting information is at once richer and more accurate. This method has been adopted in biomedical research, for example, through the web-based submission of biological data gathered through kits or questionnaire data on genetic, phenotypic or lifestyle matters. Within the arena of Health 2.0, the most prominent example of this thinking is Patients Like Me. Patients Like me began as an online repository for ALS patients and their caregivers to document the effectiveness and side effects of medications. However, this soon grew to a broad-based website for "patients" to report their symptoms and symptom relief from a myriad of health conditions, ranging from fibromyalgia and depression to epilepsy and Parkinson's Disease. Anyone (with or without a medical diagnosis) is welcome to participate by adding her own personal information. This resulting data have already been used in publications (e.g., Wicks et al., 2011) and is available for use by pharmaceutical companies and other researchers who partner with Patients Like Me

via individual contracts.

Crowdsourcing has facilitated large-scale data collection for a wide range of PDGR-labeled projects and organizations. The logic of harnessing wisdom, talent, and free labour through the Internet is very appealing as it has created new opportunities for businesses and researchers, and for engaging people with and without formal expertise (Howe, 2006). For example, DIYgenomics, an organization for crowdsourced health research, aims to increase participant-led collaborative research in order to build large biobanks whose information can accelerate advances in health management and preventive medicine (DIYgenomics, 2015b). Users are invited to upload individual data gathered from smartphone applications to contribute to projects ranging from studies of vitamin deficiencies to telomerase activation and social intelligence (DIYgenomics, 2015a). In capitalizing on social media technology and the growing imperative to share information about oneself with online communities, PDGR is constructing new niches for active biological citizenship, a means of finding political, social, and other affinities with others on the basis of shared biological characteristics (e.g., genetic, disease status) (Levina, 2010, Rose and Novas, 2005).

By challenging professionally-mediated access to genomic information PDGR resembles the wave of commercialized DTC genomic testing companies, such as 23andMe, that disrupted traditional clinical gatekeeping on the risk assessment side of PGM. Customers of 23andMe can directly order test kits online at increasingly low cost, provide saliva samples, and then gain online access to a set of personalized disease risks, phenotypic traits and ancestry-related data based on a scan of around 500,000 single nucleotide polymorphisms across the genome (Authors, 2010). A research arm of 23andMe calls for customers to contribute their data to larger research studies. It has been a forerunner in maximizing the capabilities of crowdsourcing, a key

tool in the emergent field of PDGR. Yet, we did not include this company in our sample, as consumer-participants have a low-degree of control over agenda setting and resource control (Kelty and Panofsky 2014)— it is not itself "participant-driven," but a for-profit company with "participatory" dimensions.

Present Study

This study draws on interviews with a diverse array of organizations and individuals that contribute to the expanding ecosystem of "PDGR" – including academic groups, start-ups, activists, hobbyists and hackers – in order to compare and contrast how they relate their stated objectives, practices, and political and moral stances to institutions of expert scientific knowledge production.

This study developed as part of our on-going research on the emergence of personalized genomic medicine, specifically, on early users' motivations for engaging with direct-to-consumer (DTC) personal genome testing, a technology born of genomic research, the Internet age, and commercial entrepreneurialism (Authors, 2010). Misha Angrist (2009) refers to early adopters of this technology as utilizing "citizen science", and Barbara Prainsack (2014: 155) has documented how the leading commercial provider of personal genome testing "fits into the bigger picture of citizen science." We have argued elsewhere that DTC personal genomic testing rearticulated the relationship between biomedical and information technologies through its co-constitution by developers and users (Authors, 2010), and this led us to question whether and how PDGR rearticulates the relationship between biomedical research and information technologies. This nascent intersection of participant-driven citizen science and genomics led us to further explore this phenomenon among non-commercial entities in order to assess the goals, values, practices and future visions among organizational leaders involved in PDGR, with a

particular focus on notions of knowledge producers, research questions and settings, research funding, and research ethics.

Kelty and Panofsky (2014, 2) have argued that "traditionally, scientists and medical researchers have preferred research subjects to remain 'subject' to their direction and control, not 'subjects' in the sense of people who 'talk back' to experts and insist on representing or pursuing their own interests." We use the term "participant-driven genomic research" purposefully, as an umbrella term to describe commitments that each of the organizations we interviewed share that challenge the traditional scientist/subject relationship: involving non-traditional "participants" (e.g., "lay" people, consumers, patients, scientists in non-academic or commercial settings) in the multidimensional aspects of genomic research, including design, funding, conduct, analysis, and/or distribution of findings. While this is not necessarily a term that each organization would ascribe to themselves, it adequately captures the organizational features that we will be highlighting in our analysis.

Methods

Sampling strategy

We first learned of the existence of PDGR organizations through conducting research with early users of DTC personal genome testing (e.g., DIY Genomics and SNPedia). The aims and approach of this earlier project provided us with a census of stakeholders, including a growing community of enthusiasts pursuing what we call "participant-driven genomic research" (PDGR). Through this research we were became aware of groups like bioCURIOUS, Genomes Unzipped, and Personal Genome Project. These interviews sensitized us to a new development

within genomic research: the emergence of groups like these that exist outside of mainstream academia and conventional genomic companies. We did not initially label these groups, but sought to identify groups that expanded our sample to include other organizations conducting genomic "research" very broadly construed in an effort to recognize the broader array of emergent groups concerned and invested in public participation in research to inform personalized medicine. This approach follows from our methodological framework of Social Worlds and Arenas Theory (Clarke, 2005, Clarke and Star, 2007), which requires that we map and ascertain the perspectives of all actors within a social arena that has a "going concern" with the phenomenon in question (Hughes, 1971, see also Fujimura, 1996, Clarke, 1998).

In addition to sampling leaders of organizations we encountered in the course of our empirical research, we also conducted a web-based literature review using Google Scholar and PubMed, combining the search terms "online", "genomics" and "citizen science" to assess the online presence and activity of PDGR. Through this approach we identified two additional organizations: DIYbio and My Daughter's DNA.

We also employed a snowball sampling approach to reach leaders of organizations suggested by interviewees recruited using the strategies above. As new organizations were suggested through snowball sampling, we compiled information through review of websites and reports to ensure its relevance to a) genomics and b) fit with the aim of the project on "participant-driven research". This led to the inclusion of five additional organizations: Foldit, HiveBio, Indie Biotech, OpenPCR, and American Gut Project. While we did not purposely choose North American organizations exclusively, all but one of the people we interviewed were based in the United States, which shapes our analysis considerably (see Keulartz and van den Belt, 2016). Table 1 provides a complete list of the 12 organizations included in the final sample.

[Table 1 about here]

We do not mean to imply that there is uniformity or even cohesion across these groups: they vary considerably in terms of their approaches, activities, organizational structures, and dimensions of participation (Kelty and Panofsky 2014). We sampled, interviewed, and analysed these organizations together because they each explicitly identified themselves as engaging a range of actors that would not typically be considered experts in scientific knowledge production in the design, conduct, and distribution of genomic research and attendant technologies.

Recruitment

We contacted the executive directors, founders or active spokespeople from each organization with a personalized email or phone call in order to describe our research interest in their organization. Recruitment occurred between April and September 2013. We contacted leaders from 23 organizations, and successfully recruited key informants from 12 organizations. We interviewed a single informant from seven organizations, two informants each from four organizations, and three informants from one organization, for a total of 17 interviews with 18 individuals. Informed consent was secured in writing and verbally at the start of each interview, at which point interviewees also indicated whether they wished to have their name associated with their responses. SC and MM conducted the interviews via Skype or by phone using a semi-structured interview guide developed by the research team. The interview guide contained questions pertaining to the role of the interviewee in the organization; the goals, values, funding and research priorities of their organization; beliefs about impacts of PDGR on healthcare and medical practice; ethical, legal and social challenges of PDGR; and their visions of the future of the field. Questions were asked flexibly so that interviewers could respond appropriately, probe answers as necessary, and collect consistent information across participants. Interviews lasted 45

to 75 minutes and were recorded using Audacity 2.0.3 software.

Data analysis

Following standard strategies in the social sciences, interviews were transcribed verbatim, reviewed for quality control, and coded using a codebook with precise definitions for thematic analysis. In order to ensure reliability, the research team first coded a batch of initial interviews together to develop the codebook and establish guidelines for applying codes. The research assistants charged with coding all of the interviews then coded each interview using Atlas.ti 6 qualitative data analysis software. The research team drafted summaries of coded data, working across summaries to identify major themes (Merriam, 2009, Braun and Clarke, 2006). In this paper, we rely on thematic analysis of codes that captured the goals and ethos of the various groups, descriptions of their methods and practices, and asserted uses of technology. We used these codes to characterize the organizations involved in PDGR and to distinguish their particular objectives vis-à-vis mainstream genomic research, moral and political principles and any tensions therein.

Results

Our analysis enabled us to articulate the ethical and research commitments of these communities. Although the groups draw on some similar research methods, and share certain goals, they have differing emphases in their overall approaches and ethos, as well as distinct organizational structures and research priorities. Amongst the goals that these groups espouse, we have identified and analyzed their varied (and not necessarily unanimous) commitments to (1) rare disease patient advocacy, (2) democratizing access to genomic information, (3) deinstitutionalizing scientific practices, education, and outreach, (4) increasing the affordability

of technologies, and (5) re-envisioning research participation and funding. We discuss each of these below, explaining the differences across organizations and analyzing these goals vis-à-vis the ideological commitments and ethos of PDGR's participants.

Rare disease patient advocacy

PDGR has increased patient advocacy on the web related to rare diseases (Kelty and Panofsky, 2014). A prominent example is MyDaughtersDNA.org, led by Hugh Reinhoff, who developed a website as he sequenced a portion of his daughter's DNA to investigate the genetic basis of her undiagnosed condition. In our interview, Reinhoff noted that his perception of unmet needs in the rare disease research sector and medical system drove him to establish his own website to conduct research on his daughter's undiagnosed condition. He explained his efforts: "If we really wanted to know, I had to spearhead the effort myself, and the first step in that was really getting a thorough inventory of her chronicle phenotype." Reinhoff characterized his site as a forum for altruists and social activists aiming to increase awareness and raise funds for understudied genetic diseases. He has been lauded by others in the patient advocacy world as a trailblazer in inspiring patients and parents of children with rare diseases to create and participate in online communities in order to discuss and investigate complicated diagnoses (Maher, 2013).

Efforts like My Daughter's DNA benefit from the availability and popularization of web-based social networking platforms and crowdsourcing to engage patients and their families in collecting and analyzing data (Vayena and Tasioulas, 2013b). Because rare disease communities have historically been marginalized by academic, commercial, and federally-funded science (Novas, 2015), PDGR aims to develop new health measures, disseminate research to large numbers of participants, and generate results faster than the time frames associated with traditional approaches to genomic research.

However, rare disease patient advocacy, especially in the genetics arena, pre-existed this most recent incarnation. Throughout the 1980s and 90s, groups emerged to provide support for those with rare diseases (Rabeharisoa and Callon, 1998). During this time, patient groups' involvement with disease research went beyond advocacy to develop 'partnerships' with scientists (Rabeharisoa, 2003). As has been detailed elsewhere, patient groups have turned to "evidence-based" activism to strengthen their cause, developing their own networks of knowledge production that become indispensable to scientists as a way to become "insiders" in scientific research (Rabeharisoa et al., 2014). Genetic Alliance is the paradigmatic and most prominent example of these types of advocacy organizations. With time, Genetic Alliance also began to advocate for genetic research and, moreover, to place the findings and potential benefits of research directly in the hands of affected individuals (rather than through traditional healthcare, academic, or research-based organizations) (Lambertson and Terry, 2014). Arguably, organizations like Genetic Alliance have led the way for other disease-based and data-driven PDGR movements in the United States.

Democratizing access to genomic information

The perceived value of taking data into one's own hands is, of course, not restricted to rare disease advocacy. Indeed, all of the individuals and organizations in the participant-driven genomics space are, by definition, founded on this principle. As Kristina Hathaway of DIY Genomics explained:

> One of the nice things about participant-led genomics is it allows you to get data on an underserved population or on an unmet need. So you know really rare genetic disorders and conditions that just, they don't make sense to research commercially, right? […] I

> think that that's a really important priority for participant-led genomics … I think that we as a nation are not serving our populous when we make it so difficult to get that information …I think it's the regulatory environment, and I think it's continuing to look at this new information through an old lens that no longer serves and no longer fits. It's like trying to look at the sun with a microscope.

Hathaway's quote is particularly salient in the realm of rare disease advocacy, which intends not only to hasten the pace of traditional genomic research, but it is also committed to challenging the research regulation and clinical trial paradigm that demands that research generate generalizable knowledge (and therefore applicable to wide populations) rather than personally relevant knowledge (and applicable to very narrow populations).

Through attempts to take genomic research "into one's own hands," PGDR advocates challenge the notion that genomic research needs be motivated by the potential for profit or return on investment. Indie Biotech's Cathal Garvey explained:

> The environment in biomedical science is completely corrupted where any work you could do which is of any consequence will never reach a patient because the only people with the money to bring it to market are those with a direct incentive, market incentive, not to cure people. So it's just, it's a waste of time.

One point that is pertinent to rare-disease advocacy is that research is characterized as underfunded through traditional research mechanisms. This makes more pressing for them the need to take data—and moreover funding—into their own hands. Hugh Reinhoff's self-funded My Daughter's DNA drew upon strong professional connections to the commercial genomic research industry to help him sequence his daughter's DNA outside of the academic and

commercial sectors, epitomizing Chris Kelty's (2010) figure of the Victorian gentleman scientist with the means and connections to conduct amateur research in his salon. While clearly pulling on the same purse strings as traditional research alliances, My Daughter's DNA demonstrates the still-requisite need for significant social and market capital.

The commitment of the leaders of PDGR organizations we interviewed to open-source principles and data explicitly attempts to challenge the for-profit orientation and traditional revenue streams of commercially-driven genomic science. Some organizations we studied, including SNPedia – a Wiki-style site for sharing one's own genetic information and researching "risk information" related to SNPs – approach this through an emphasis on open access to genomic data. These organizations have benefited from the access policies of private companies such as 23andMe – the most widely-used and privately owned platform for PDGR (23andMe, 2014) – to share raw data with its customers. SNPedia, for example, uses the freeware program Promethease to gauge personal information about the propensity to diseases through comparisons with the information in the database, which is curated by a community of anonymous participants. Open participation, open source computing, and open access to data are fundamental principles of SNPedia as they simultaneously strive to share genetic information with users based on traditional evidence published in scientific literature. As Greg Lennon of SNPedia explained:

> We ought to be doing more for ourselves and the world than just publishing things in journals that only other scientists read. You know there has to be some translational mechanism […] There has to be some way so that we can discuss and make available to at least those who are interested to non-scientists, as well as scientists [...]Well it seems that if you put billions of dollars into sequencing and trying to understand the

point of the genome, then there ought to be numerous ways (SNPedia is one of them) to make it matter to people.

Effectively, the site additionally functions to fulfill the founders' goals of meeting the translational imperative of genomic research, providing a direct link between institutional science and lay concerns about genomics and fostering the translation of genomic research to the public. However, despite rejecting private ownership of genomic information, SNPedia is not completely disentangled from corporate interests. This group purchases inexpensive server space from Amazon.com to store data uploaded to SNPedia, which raises questions about the implications of shift from private ownership to private storage of genomic data. Furthermore, using the site also requires a certain amount of genetic literacy and knowledge that SNPedia itself does not provide.

Deinstitutionalizing science: practices, education, and outreach

Groups organized around self-tracking, self-experimentation, and participant-driven approaches in genomics are not solely, or even primarily, focused on concerns about personally relevant hereditary disorders. Self-ascribed as 'health hackers,' 'biohackers' or 'biopunk' hobbyists, these groups constitute movements of people organized as social networks, and include latter day Victorian amateur scientists (often graduate students and hobbyists), artists, hackers and software specialists who are guided by a set of goals that are compatible with but an extension of "citizen science" movements and principles (Keulartz and van den Belt, 2016).

Their engagement in genomic research, both online and in physical spaces outside of traditional research institutions, is driven by the wish to be liberated from traditional relationships between research, universities, and the market. They seek to redefine genomic 'expertise' and the ownership of data, and to conduct research in deinstitutionalized spaces and

develop or access low-cost and shared apparatus and laboratory resources and software (freeware). Their goals are manifold: to engage the public in science, to promote the use of open source software, to transpose hacking practices into the realm of genomics and synthetic biology, to de-institutionalize research, and to develop innovative solutions to scientific problems or simply matters of curiosity (Delfanti, 2012).

Self-styled and publicly portrayed as being 'outside the system', 'hipsters', 'geeks' and 'for the people', these groups have garnered intense attention from the popular and scientific media for their unconventional approaches to scientific research (Kelty, 2010, Bennett et al., 2009). As Eri Gentry, one of the founders of bioCURIOUS, a California-based DIY citizen science organization, explained:

> I don't really want or need somebody else to tell me how to (1) do my research or (2) live my life, or whatever it is. Like different sorts of fundamentals, and whatever the belief is or whatever your personal reason is, there are some like shared aspects of these cultures. Like a dedication to transparency, to open source, to lowering the cost of access, freedom of data. So you know if you looked across the forums of DIYbio and Quantified Self, as well as like the computer hacking (hacking in positive way) communities, you're gonna see those threads appear again and again.

One of the groups mentioned by Gentry – DIYbio – was intentionally organized (in 2008) to become a home for 'outlaw' biologists functioning primarily outside the academy and industry and working to demystify scientific systems and protocols (Kelty, 2010). DIYbio (whose logo is a fist with a pipette) (www.diybio.org) embodies the 'biopunk' spirit in that it uses community spaces – from garages to kitchens, closets and schools – to provide lay biologists and engineers with the know-how and tools to conduct genomic research cheaply,

investigate their own questions, share data with peers and form communities around the values of openness in knowledge production (Ledford, 2010b, Ledford, 2010a, Keulartz and van den Belt, 2016).

Indeed, in our interviews, founders of bioCURIOUS similarly characterized their approach as a commitment to "radical openness" – from passing a hat at meetings to raise the funds to buy software, to designing a community-based laboratory space, to delineating democratic procedures for storing equipment and materials – which is meant to disrupt the traditional hierarchy of knowledge production, organization, and control in the laboratory. As Raymond Macauley from bioCURIOUS describes:

> ….and the lab by literally architectural design is open where they are no walls between work spaces. All of the storage is transparent, literally these clear plastic tops. We ripped the doors off of a storage cabinet so you can see what's in there, and mostly that's just to make things easier to find, but it's also…to promote sort of a radical openness that it's such a different lab design because you don't have one person in charge of it saying 'This is what you will do and won't do and we'll organize it this way and that way.

We see here the metaphorical and literal use of "openness," where the open lab space design and shared ownership of equipment reflects the underlying ideological commitments to deinstitutionalizing science— a commitment to doing science differently once it is wrested away from academic and other institutions and put in the hands of a community. Whether this architecture is largely symbolic or materially transformative is an open question, but this was a conscious decision to disrupt materially conventional ways of 'doing science.'

These groups also wish to disrupt conventions related to the control of data by academic

'experts' and as well as the monopoly of big corporations over genomic information. Bergen McMurray of HiveBio explained this commitment:

> As people become more informed and are less dependent on a small handful of experts to tell them about their own bodies […] I mean I think that anything in medicine and biology should definitely be expert-driven, but I think there's room for a lot more experts in the world than there are now.

This marks an important difference in their demarcation of 'experts' and the definition of 'expertise' not being confined to or contained within academia or even those with advanced academic degrees. Importantly, educational outreach is at the core of DIYbio groups: they see it as a moral imperative to reach out to, and inform, lay amateurs about genomic science methods and ethics, to help them take science 'into their own hands' in asking and answering questions about their health, and to encourage them to contribute their data to large scale studies on health and disease outside of universities and companies. In describing their mission this way, they challenge the idea that science must be conducted, and decisions determined, inside the 'ivory tower' by 'elite' experts. As Raymond Macauley of bioCURIOUS articulated:

> There's part of that that's sort of a distrust of authority or you know 'Let's pull these technologies out of the ivory tower', but I would say it's not even so much a reaction against authority as it is a belief in grassroots, a belief in you know 'I'm the best monitor of my own health. I'm the best judge of what I should do about it, and I don't necessarily want to go to someone who sits in a big chair with a fancy degree to tell me what to do. I want to know and understand and take that action myself.'

These practices have elicited anxiety among governments and regulatory bodies (e.g., FBI and the Presidential Commission on Bioethics) due to concerns about biosecurity and safety

(Bennett et al., 2009, Whalen, 2009). However, these groups countered with the argument that their practices foster much-needed public education on genetics and scientific citizenship (Delfanti, 2012). In our interviews, spokespeople for DIYbio describe their spaces as hubs to engage lay people in the skills and familiarity to understand genomic science, debate its implications, and equip them with the tools to participate in everyday decision-making in our technoscientific societies. For example, the group in Los Angeles offers courses on basics of polymerase chain reactions (PCR), teaching participants to sequence their own DNA from cheek swabs and discover predispositions to illnesses; the New York City group, called Genspace (Genspace, 2014), has a "PCR and Pizza" night and "Biohacker Bootcamp", and the Brooklyn group has a storytelling evening (a cross between biotech and sci-fi class).

Increasing affordability of technology

Democratizing genomics through low-cost and open source technologies are core philosophies of like-minded PDGR organizations. As Cathal Garvey of Indie Biotech explained:

> I was very heartened recently to get an email from a guy in West Africa saying […] 'Where I live, genetic testing is beyond our means. We can't afford it' […] and he was asking me give him the price of my lab […] saying 'I saw how much it took you to set up your lab, and it seems you might be able to do this […] I'm going to reply to him this evening saying 'I'm not in a position to do genetic testing, but I would be eager to help you set up your own genetic testing lab.' And that is validating for me. […] There are people out there who want to do this, who are trying to do this already, and as soon as I can come up with a tool kit that self-replicates, I will have to get back to them saying 'For now it'll be difficult.'[But soon] I'll be able to say 'Here you go. Take this. Run away.'

Garvey's eagerness to help represents his and others' belief that wresting genetic technologies away from traditional manufacturing, and moreover, commercial patenting, will revolutionize global access to genetic testing in a way that obviates the need for traditional experts or traditional labs. While some may see this as a naïve reading of global science and global marketing, there is no reason to doubt his sincerity in wanting to make this happen.

Similarly oriented, openpcr.org is a web-based company that sells DIY kits for building thermocyclers to run PCR for DNA sequencing at considerably cheaper prices than those sold to universities and biotech companies. As co-founder Josh Perfetto explained:

> Initially we were actually just going to make an open source design and not even sell kits, but then I saw that if we didn't sell a kit, it would be too hard for everybody to build or nobody would build it. So it was designed for these makers, DIYbio biohackers, and what's really interesting is today I would say about 90% of the sales are actually going to institutions […] biotech companies, educational labs […] I think that partly also it's just kind of the economics of the thing. I mean, if you're a biotech company, $600 is nothing. I mean that's what [they spend] every day for reagents, whereas if you're a home hacker that's still quite a bit of money. And there's not honestly that many biohackers out there today [but] there's a lot of biotech companies, but I was surprised by their acceptance of this kit, because there is a machine you have, and then we sell the kit. You have to build it yourself, and I didn't think that too many people in a professional environment would be interested in that and I was surprised to learn that that's not true actually. I mean some people, or quite a few of them actually, have a genuine interest in kind of building things themselves and doing DIY-ish things, even if they're in a professional setting, and then

for others they're just, you know it's such a cost-conscious setting that if it takes three extra hours to build it, that's fine given the cost savings.

Openpcr.org illustrates what Delfanti (2012) characterized as a notable contradiction in the values of many of these groups. In this case, on one hand, the 'hack' was to undercut PCR machines on the market, and to make them open source and relatively cheap. On the other hand, the very biotechnology companies and research institutions that members of openpcr.org initially aimed to subvert are now buying their low-cost PCR kits. The politics of these groups are therefore often paradoxical: they aim to undermine intellectual property rights and monopolies of capital and power in biotechnology, yet these organizations are often simultaneously eager to establish small start-ups which will compete with the big biotechnology companies, and maybe even become one of them. Macauley characterized the receptiveness of bioCURIOUS – a Silicon Valley-based biotech hackerspace – to such eventualities as reflective of its open-science ethos: "We care to be fairly radically open science. People come in, and if somebody wants to work on something and commercialize it, they're free to do that."

The spirit of bioCURIOUS, DIYbio, openpcr, SNPedia, and biohackers is therefore both subversive and entrepreneurial: biohackers draw from the mythologies associated with the start-up success of Silicon Valley – Google, Apple, etc. – while simultaneously critiquing the hierarchy and profit incentives of universities and corporations (Delfanti, 2012, Wohlsen, 2008). Like their Silicon Valley heroes, they embrace open information sharing, non-competitive collaboration, and market-deflating 'hacking', but only until there is money to made. At that point, their libertarian spirit equally easily justifies joining the market to capitalize on their work for financial profit. In this way, their political economy operates very much like traditional genome science, where data pooling and the free flow of ideas is endorsed right up until the

intellectual property involved begins to show signs of scientific value.

Re-envisioning research participation and funding

While many of the PDGR groups discussed thus far explicitly position themselves outside of mainstream scientific channels and in opposition to the elitism of university research departments, other groups operate in partnership or as part of academic science. These groups largely engage PDGR through re-imagining what it means to be a research participant in an academic setting, and challenging traditional research funding paradigms.

The open-data Personal Genome Project (Personal Genome Project: Harvard, 2014), for example, has been a forerunner in participatory genomic research, with participants being described as "co-drivers of the project" (Angrist, 2009). Initiated in 2005 by Professor George Church, the aim of the project is to collect genotypic and phenotypic data of 100,000 people in the U.S., Canada and UK who consent to making their personal genomic information publicly available as a research resource. Church described how the Personal Genome Project (PGP) re-envisions the traditional researcher-subject relationship as a partnership:

> You need people that are providing infrastructure and making decisions with the IRB and so forth. So I would say PGP is slightly more on the researchers leading more than the participants, but it's intended to be a partnership where the leaders in a certain sense are doing work for and in a way are employees of the participants, but we're not providing a service, so then it's much more of a partnership.

The project, whose first ten participants ("PGP-10") famously donated samples for analysis between 2006 and 2007 (Harmon, 2008), has been influential in guiding debates about the ethical and legal aspects of sharing genomic information. In particular, the PGP has challenged guidelines and regulations governing human subjects research that have held dear the

exceptionalism of personal genomic information and importance of individual genetic privacy. To enroll, participants must provide open consent - foregoing privacy protections in favor of full disclosure of personal genomic information - which makes it impossible to guarantee participant anonymity because of the potential to re-identify individuals through their DNA sequence (Angrist, 2009). Interestingly, several students and researchers who were associated with Church's Harvard laboratory have gone on to become active figures in the domain of DIYbio.

Another individual involved with the Church lab and PGP, Dan Vorhaus, established his own website, www.genomesunzipped.org, designed to educate the public about legal aspects of ownership of genomic data and research. In describing the drive to re-envision the researcher-participant relationship in genomics, Vorhaus explained:

> I still today get frustrated with the strains of paternalism that I see sometimes in scientific and medical research where there are still studies that are structured in a way and still I think advocates of a kind of research model that would shield individuals and shield participants from knowing certain things, from being able to access certain information, whether on the front end when they're deciding to participate or not, or on the back end when they are being offered the chance to learn about the research in which they've participated. I think that ultimately that kind of model, the limited knowledge or the limited access model, may be desirable, may be appropriate for many people, but I think they should have the opportunity to choose. I think it should not be imposed upon them.

This is both a statement about how PDGR challenges research ethics and policy, as well as aspirations for how research epistemologies may be reshaped through participant-driven research efforts. Our informants did not view the reimagining of the researcher-participant relationship as novel. Rather, it was framed as a necessary step in addressing previously

unanswerable and 'unfundable' research questions.

In fusing traditional research with non-academic entities and methods, the American Gut Project is a paradigmatic illustration of the hybrid nature of recent large-scale PDGR projects meant to remediate some of these problems (Human Food Project, 2015, Costandi, 2013). Using crowdsourcing and crowdfunding strategies to collect and analyze individuals' gut microbiota, the American Gut Project was conceived by academic researchers, including Rob Knight at the University of Colorado at Boulder and Jack Gilbert at the University of Chicago. Knight explained their need to depart from traditional approaches to microbiome research:

> One ongoing frustration with typical studies of the microbiome, either funded by the government or funded by private foundations, is there's very little way for the public to participate because typically for any given project we have a very carefully defined set of exclusion criteria and most people are going to be excluded by those criteria. So, for example, the Human Microbiome Project wound up being primarily a study of medical students in their 20s at Wash U and Baylor. […] We knew for sure that the microbiome changes with age, with health status and with population and a lot of those factors just weren't being covered in the amount of time and the amount of expenditure […] in the context of a traditional grant application process. It was gonna be far off into the future.

In this sense, the American Gut Project styles itself as departing from traditional, exclusionary approaches to research that limit eligibility to college students, and as shaping the 'future' of biomedical research by expanding recruitment processes and enlarging the conception of the 'eligible' research subject. This, in turn, aims to diversify results and their generalizability, and ultimately increase the robustness of knowledge production.

To appeal to more traditional funders, this project utilized an approach to sourcing the

materials and funding that can simultaneously be characterized as more democratic and more entrepreneurial than the typical university-based genomic research project. Research samples are processed at the University of Colorado, but the project itself has been crowdsourced and crowdfunded by the general public (especially by participants who have volunteered to join and provide specimens) as well as private biotech companies. Gilbert described how the power of crowdsourcing genomic research relies on the accessibility of personal computing and digital technologies:

> Without the democratized use of computing, there's no way we would be able to simulate the knowledge that we can gain from this kind of investigation. So without the Internet, without web-based tools, without technological advances in access routes to knowledge and information, there's no way this project could ever transform into the potential we hope it will have, but you know I guess, yeah, in light of that, this kind of discovery-driven science has real transformative potential because of the technological advancements in data access and accessibility have really enabled people to be able to equip themselves with the knowledge that they need at a given time point. This I guess opens up more avenues whereby people may be interested in this research providing us with a bigger population, a bigger sample size to access.

A significant need and subsequent benefit of participant-driven research is the availability of large volumes of 'big data'. Academic research groups have also taken advantage of this method to tap anonymous participants' 'brain power' through online games (Good and Su, 2011). For example, researchers at the Departments of Biochemistry and Game Science at the University of Washington developed an online protein folding game in 2008 (Foldit, 2014, Khatib et al., 2011). With over 240,000 registered players, participants' pattern recognition and

puzzle solving skills provide steps towards solutions for the design of protein structures relevant to drug development for diseases including HIV, Alzheimer's, and cancer.

These rapidly expanding and highly publicized projects reflect changes to academic research in structural genomics rather than emerging primarily from PDGR groups themselves: these studies employ discovery and data-driven methodologies, rather than more traditional hypothesis-driven approaches, and nontraditional strategies for sampling, funding and knowledge transfer. Firas Khatib of Foldit illustrated how these new collaborations pose both opportunities and challenges to traditional conceptualizations of credit sharing in academic research:

> There are three players that solved the monkey virus protein and we were sure they they'd want to be co-authors on our paper and we offered that to them and they said 'Oh no. No, thanks. That's okay. If you like, we'd love it if our Foldit team name (they're on a big team with like 20 players), if that could be a co-author on the paper', and so that's how we published the paper [...] and it was you know really very nobly and kind of un-academic, I'd say.

The implicit internal critique embedded here is that traditional models of academic credit with individual authors jockeying for position lacks nobility. The ethics and notions of credit-sharing within participatory projects like Foldit encourage what Khatib and others see as humble and commendable behaviors. Notably, the idea of "group" credit is possible for those who are outside academia and whose livelihoods are not dependent on the economy of manuscript authorship and credit.

These hybrid practices are built on new interdependencies between research departments, private investors, and individuals – and they bring new regulatory questions related to research

practice, credit-sharing, and ownership over products and findings, and the need for researchers to be both calculating and entrepreneurial in framing their research approaches (Rajan, 2006).

Discussion

An overarching theme to emerge from our interview data was the respondents' hope that PDGR engendered alternative possibilities for biomedical research, which challenge traditional modes of investigation, funding, and dissemination associated with mainstream academic and commercial research laboratories. Though participants did not present a singular understanding of the establishment or the traditional scientific research enterprise – with critiques being levelled against universities, the biotechnology industry, funding agencies, the academic publishing industry, and regulatory bodies – they were unified in their critique of the 'status quo.' Interviewees across the range of organizations lauded the opportunities presented by their attempts to disrupt the boundaries between experts and amateurs, funders and researchers, institutions and scientists through participant-driven approaches to genomics and by employing alternative research paradigms. These distinctions from mainstream research tended to underpin the politics of each organization, and were often defined in terms of moral imperatives to diverge from mainstream approaches in view of existing shortcomings. Interestingly, we noted certain contradictions, or ironies, which revealed entanglements between the values and resources of organizations and the institutions interviewees claim to subvert. These political agendas, moral imperatives, and occasional ironies emerged throughout the themes described below.

First and foremost, PDGR rhetoric represents a critique of conventional goals and approaches to genomic research. This is evident in our informants' vocal disillusionment with traditional funding priorities and mechanisms for genomic research, which tend to be hypothesis-driven and focused on questions pertaining to generalizable knowledge about population health

(while at the same time creating exclusionary parameters that limit participation in ways that curtail what can be known about the population in all its diversity). Vayena and colleagues (2015) argue that the goal of participant-led research is to produce generalizable health knowledge. Yet, this did not appear to be an orienting goal among most of the organizations' leaders that we interviewed, despite the emphasis on enrolling as many new participants as possible, with the stark exception of the research projects tied to academic research institutions, where their deployment of PDGR techniques seemed partially driven by their ability to attract a large and broad swathe of "research participants", many of whom would have otherwise never participated in (or had access to) a genomic study. However, the majority of the organizations we spoke with were more concerned with producing or analysing personally-relevant genomic research questions or information that they saw as posing a direct challenge to the established hierarchy of knowledge, opening opportunities to participate in (and benefit from) genomic research on their own terms. Our findings are more in line with Rabeharisoa et al. (2014) who found that the epidemiologic-based goal of "generalizability" did not resonate with members of rare disease patient advocacy groups. Instead they were motivated by what the authors label as a "politics of singularisation," which allows them to share the specificities of their situations while still joining together collectively and in fact wishes to capitalize on those experiences rather follow a logic of numbers, where research benefits are only accrued based on sufficient sample sizes. This was also true for the PDGR groups we interviewed who were focused on rare diseases. However, for other groups we interviewed, the motivation for disrupting conventional research norms and standards was less about producing *either* generalizable or singular knowledge via genomics and more about creating an alternative technical-knowledge infrastructure for genomic research and knowledge production that operated outside of the

traditional modes. Some went so far as to use these alternatives to challenge the distribution of power in the sciences by rejecting the accepted notions of genomic expertise and designated spaces for genomic research (see also Delfanti, 2012). In fact, the research establishment's focus on generalizability was, for some, one of the sacred cows that PDGR could dismantle, along with traditional ideas about other goals of modern science. In fact, as Rabeharisoa et al. (2014) also demonstrate in their research of four patient advocacy organizations, PDGR research highlights one of the paradoxes of genomic research as the bridge to "personalized medicine" in that it claims to create generalizable findings that are also simultaneously individualized.

Second, by disrupting the hierarchy of scientific knowledge production and spaces, PDGR also purports to challenge the ways in which genomic research has historically been housed, conducted, and funded. Rather than relying on traditional sources, settings, and timeframes for conducting genomic research, PDGR organizations have been entrepreneurial in their approaches to seeking funding and sometimes capitalist in orientation. The ethos of funding PDGR is far from homogenous, with a mix of self-funding, community-funding, crowd-funding, commercialization, and innovative cost-management strategies. What these organizations do have in common though is a rejection of reliance on institutional, governmental, and corporate sponsorship to legitimize their research practices. Ironically though, some of the approaches these researchers have used to support their research efforts are not known for their inclusivity or an adherence to the open source ethos they espouse, specifically when organizations have relied upon or benefited from commercialization of their efforts.

Embedded in participant-driven genomic researchers' calls for individual and marginalized groups' rights to set genomic research agendas, access to genomic information, and data are ideologies of radical individualism and populism. Delfanti (2011) has characterized this

as a biohacker ethos, a blend between two ethics: individualist open-source, anti-establishment science and communal peer-production and democratization, infused with the entrepreneurial spirit of capitalism in the information society. He argues that this ethos reflects the mythology of contemporary economic dynamics of Silicon Valley, in which academic research is rejected in favor of corporate possibility. However, just as Delfanti has described biohackers, there are internal inconsistencies in the ethics and allegiances among our interviewees. For instance, while some organizational leaders explicitly named their distrust in the authority of academic and commercial research enterprise, funders, and institutional review boards, others expressed ambivalence about their relationship to Big Bio, and relied on elements of this infrastructure to support their own research agendas. Keulartz and van den Belt (2016) similarly identified this ambivalent relationship with Big Bio in their in-depth analysis of DIYbio. This, Kelty (2010: 2) has argued, is why we should recognize that "outlaw biology" does not exist "outside of Big Bio but within it – it depends on it, thrives on it and wouldn't exist without it." Specifically, he points to the information, tools, and technologies generated by the Human Genome Project, as enabling the development of participatory genomics. Similarly, we can point to the reliance on academic and commercial research infrastructure and tools upon which many of our interviewees rely, and or modify for their own purposes.

Third, PDGR proponents wish to challenge traditional approaches to research ethics, specifically in terms of the regulation and oversight of genomic research involving humans. Historically, genomic research and information has been proprietary and carefully guarded for privacy consideration by "responsible" investigators. Advocates of PDGR reject these ideas about research protection and paternalism by disavowing private ownership of genomic information and embracing an explicit commitment to an open, accessible, grassroots approach

to genomic research. In some cases this extends to upending what constitutes an 'investigator,' opening up new questions regarding who is conducting the research, ownership of collected data, and how credit and responsibility for outcomes should be distributed. In this way PDGR's organizational leaders illustrate the multidimensionality of the promise of citizen science research participation described by Kelty and Panofsky (2014), where the virtues of participation are in part their inherent educative intentions, of shared control and ownership of resources, and of voluntariness.

Hence, these groups' ethics often run counter to conventional research ethics, which were developed specifically for traditional academic research (Vayena et al., 2015), and engage larger principles about the purpose and orientation of contemporary scientific research. Some ethicists argue for the establishment of a new social contract to govern participant-led research (Vayena et al., 2015). While this may be a valuable undertaking in the sense of revisiting research regulations that have become outdated or ill-fitting, the heterogeneity and multidimensionality of the participant-driven research approaches described by our participants point to the challenges of developing a singular code of ethics that would encompass the manifold values and goals that these kinds of organizations bring to their research activities, as these organizations are often fiercely dedicated to self-governance. For instance, one cannot assume that producing generalizable knowledge is a goal for all PDGR. In our view, one can account for the epistemological break from standard biomedical and scientific research by the points of entry of these groups into PDGR, whether it is from genomic science/medicine or from biohacking. Those who came to PDGR through more traditional channels of scientific and genomic research were more likely to have toeholds in these worlds, relying more heavily on the infrastructure that has supported and nurtured the burgeoning field of genomic research, while problematizing and

re-envisioning aspects of research question prioritization, funding, and participation. However, those who came to genomics through the "biohacking" realm were more likely to rely on the Silicon Valley ethos described above, with a more democratic, libertarian, and entrepreneurial spirit underlying their efforts. Hence, there are at least two alternative – though not mutually exclusive – moral frameworks at work governing PDGR.

Conclusion

Most revolutionary movements expect resistance from the established authorities they seek to dethrone. One of the interesting features of PDGR, however, has been the fact that its rhetoric seems to have been endorsed by much of the mainstream genomics research community as a compatible extension of its own efforts. There are even tentative, but high profile, signs of assimilation, as we discuss below. Some prominent genome scientists, like George Church, who is not incidentally on faculty at the revered and staid Harvard University, seem to relish the role of a professional renegade in support of lay science efforts, and even the most institutionally-entrenched professional science venues revel in the "pro-science" stance PDGR endorses (see e.g., NIH Citizen Science Working Group, 2013). Governmental agencies and Big Bio projects need ever-larger numbers of people to pursue their population genomic goals, and are happy to trade on the ideals of solidarity and volunteerism that "citizen science" celebrates to meet those needs (Authors 2016b). In addition, PDGR's interest in personally relevant and practical results rather than more basic science is wholly consistent with public policy imperatives for federally funded science to be more "translational." And, while they may argue over where the proper locus of responsibility lies for the ethical oversight of science, both conventional genome scientists and the biomedical research regulatory community agree that the current oversight system is "broken" and requires reform (e.g., Collins and Varmus, 2015). To the extent that these

shared commitments encourage the assimilation of the PGDR ethos by Big Bio, the inherent challenges that ethos entails will also become important to the future course of genomic research.

Whether or not PDGR organizations' challenges have effectively changed the course of usual genomics science remains an open question and one that our data cannot effectively address. However, recent trends in mainstream genomic research demonstrate a recognition of the appeal and need for the rhetoric of participant-driven research endeavours for their success. For example, the emerging White House Precision Medicine Initiative (PMI), has been framed as an effort "change the way we do research. Participants will be partners in research, *not subjects*, and will have access to a wide range of study results (Collins 2015). Its foundational "Principles of Participant Privacy and Trust" borrow liberally from the PGDR ethos, as do its implementation recommendations from its major planning group and the solicitations it has issued to the wider scientific community to advance its cause (White House 2015). For example, one recommendation in the PMI Working Group's report is that "research participants and their advocates should be central partners in the governance, design, conduct, oversight, dissemination, and evaluation activities of the PMI-CP" (Precision Medicine Initiative Working Group 2015).

It is not yet clear, however, how the PMI's PGDR-oriented aspirations can be realized for a large, centrally organized national research initiative, since, at first glance, the PMI seems exactly the model of science that PGDR advocates would reject. The architects of PDGR - with their varied commitments to patient advocacy, democratizing access and deinstitutionalizing science, increasing the affordability of technologies, and re-envisioning research participation and funding - are not likely to be happy if PDGR simply becomes a recruitment tool for a national genomic research initiative managed from the top by the mainstream genomics

community. On the other hand, if the PMI attempts to live up to the participatory rhetoric of its "Principles of Privacy and Trust," the stakeholders invested in traditional approaches to genomic research regulation, ethics, and oversight are going to have to take seriously both the mandate to give their volunteers more "editorial" control over the science it facilitates than they ever have in the past and the challenges to scientific integrity, public oversight, and the responsible conduct of research that this mandate creates. In the end, it may be that the most significant challenges that the scientific community will face if it embraces and assimilates PGDR approaches will not be in the mechanics of research recruitment, funding, and dissemination, but in sacrificing its privilege to self-regulate by its own internal values. Eliminating this level of governance shifts society's scientific safety mechanisms to the law, public policy and the market: instruments that could just as easily cut against the public interest as secure it.

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