



CrossMark

The right to know and genetic testing

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This issue of the journal contains three sets of papers clustered around three issues: organs, genetic testing and moral enhancement. Michael Hauskeller has written a guest editorial on the issue of moral enhancement (*see page 289*) and linked to the Author Meets Critics section of the issue (*see pages 338–352*). In what follows I will make a few remarks on the issue of genetic testing.

Two sets of questions occupy the authors writing on genetic testing in this issue. The first of these surrounds the ways in which, in the context of direct to consumer testing (DTC), the autonomy of the patient/consumer is respected, enhanced or undermined. The second issue involves how we think of the value of the genetic test itself: should we care mostly about clinical utility in this context or can a notion of personal utility play a role in the justification and permissibility of genetic testing.

Effy Vayena argues that if we use understand autonomy in the way that Joseph Raz has articulated it, we are in a better position to be clear about the acceptability or otherwise of direct to consumer genetic testing (*see page 310*). She argues that it is important to consider the nature of the options that are provided in the choice and that when we do we can see that it is a mistake only to consider the extent to which these genetic results can be understood to clinically relevant.

In her commentary on Vayena's paper, Eline Bunnick suggests that it is unlikely that the broader conception of the options included in the Razian account of autonomy will help in defending the claim that DTC genetic tests promote autonomy (*see page 315*). Instead, referring to her second paper in this issue, Bunnick claims that the broader personal value of genetic testing will necessarily "generate valuable life-shaping options". In an important step back to questions of utility, Bunnick suggests that what matters is not perceived utility but actual utility and that actual utility is more closely associated with clinical rather than personal utility.

Perhaps a useful way to understand this debate is in terms of the very familiar debate about paternalism and autonomy. That is, the question here is whether our decisions about the value of genetic testing (and correspondingly how it is

regulated) should be determined (i) by the clinical view of what is best (or what has utility according to some 'external' or 'objective' standard) or (ii) by the agent themselves as the locus of what is of value to them. This is not a dispute about who is correct about what is best (or who is the better judge). It is fundamentally a decision about whether it is right to privilege a notion of betterness over one of rightness.

THE RIGHT TO KNOW

One fundamental argument regarding genetic information crucially that is only briefly touched on in these papers (it is explicitly mentioned by Bunnick (*see page 322*)) involves the claim that an individual has a right to possess (and know) information about themselves and hence has a right to access or to attempt to access that information. This might be taken to be a fairly fundamental and uncontroversial moral right with the main questions surrounding it involving when, if ever, the harms involved in not having access outweigh the individual's desire to have it. Importantly this is not about the utility of associated with the desire.

There are several ways in which we might ground this right. Perhaps most obviously, we might see personal information and personal knowledge as a key element of respect for autonomy—personal or self-knowledge is likely to be an important factor in the business of self-governance and if we respect this ability then we arguably should protect the individual's interest in obtaining such knowledge. Alternatively we might ground this right in terms of interests or welfare. Knowing about oneself is likely to be importantly connected to protecting my key interests or welfare—I may wish to adjust my lifestyle or goals on the basis of what I come to know. Although they would be operating in a very different way—here to ground a right to access, the discussion of Razian autonomy and personal utility could well be put to good use here.

A plausible construal of the right in question here is as a negative right and this is, I take it, slightly a different tack to the discussion in the pages below. As a negative right, the obligation falls on others generally *not to prevent* individuals

from accessing personal information. For example, it is accepted that an individual need not justify their need for access to personal information, but there should be an obligation on the state to justify why such access should not be permitted. This seems to be a more workable conception of the right in question—on most plausible understandings of rights the right to possess or have access to personal information would be unlikely to come out as a positive right and this also fits well with more liberal conceptions of the state.

The right of individuals to possess information about themselves is a basic one that is only overridden in the face of serious harms to themselves or others. Indeed those who would regulate the DTC genetic testing industry do not usually deny this as a *prima facie* right. Instead their position often rests on a combination of worries about the accuracy of the information that the DTC genetic testing companies provide and the harms associated with choices made on the basis of genetic information.

REGULATING DTC GENETIC TESTS

The key question is not whether there should be regulation but at what level of interference. So what makes DTC markets different from others? Why should they be regulated beyond the claims of manufacturers of functional foods, herbal remedies or indeed used car salesmen, all of whom will, in the peddling of their wares seek to convince potential consumers that they should enter into a bargain? In all these cases, the claims made by the potential vendors will be subject to the scrutiny of consumer protection regulation: false or misleading claims could justify actionable claims by the consumer. Providers of DTC genetic tests will be no different in this regard.

When it comes to access to genetic information, it seems reasonable to accept that some of the harms associated with choices made on the basis of such information can be significant, but it is unclear that these harms are significant enough to warrant overriding the right of individuals to have access to it. Similarly, there are valid questions concerning the accuracy of information about, for example, susceptibilities that can be interpreted from genetic information. But it does not follow that these

perceived inaccuracies warrant anything more than the usual provisos and safeguards given in a consumer context. In other words, DTC genetic testing should certainly not escape the existing regulatory reach that protects consumers; but this does not mean that they should be subject to further, bespoke forms of regulation.

The difficulty in this debate looks to rest on the quantification and level of (dis) value placed on the relevant harms—one side claims that there are not many harms and that they do not matter as much as the rights violation while the other claims that there are many harms and they matter more than the right of access. Even if the empirical, quantification question could be answered this would not address the difference in relative valuing of the harms as compared to the right of access. This argumentative stalemate is what justifies both ours and our opponents' argumentative strategy: the central claim at issue then is that this industry/market, whether because of the nature of the information being provided or the medical nature of the practice, is importantly different from other industries/markets and so should be regulated differently.

There is no unified call for an outright prohibition of legitimate DTC genetic tests. Instead the suggested regulation/oversight is about, for example,

controlling the kinds of tests and the standards of those tests as well as requiring healthcare or medical professional involvement. Thus the question is about how to structure 'gatekeeping' and who should have the authority to decide.

When we adopt a market 'model,' what tests/services are offered by the industry and the individual companies is determined by the individual companies presumably according to their assessment of the market forces/trends. In this sense the companies are the gatekeepers. So the question is not whether there should be gatekeepers or not, but who should be the gatekeepers. A better way of putting this is in terms of the guiding or overarching ethical norms that should govern gatekeeping. On the one hand these norms should be determined according to the norms of the market. On the other they should be determined more according to the norms of healthcare.

CLINICAL AND RESEARCH TESTING

The final piece of this puzzle is provided by Nina Hallowell and colleagues (*see page 317*, Editor's choice). They examine ethical issues that arise in the context of whole-genome and whole-exome sequencing in both clinical and research settings. The central focus in their paper is the return of findings, both intentional and

incidental, to participants in these settings.

These issues take us further in this debate and allow us to consider not only the question of who should judge what is of value and how valuable it is but the distinction between the clinical and research contexts. The fundamental observation seems exactly right: clinicians have an obligation to inform and to deal with findings of any sort when it comes to their patients, whereas it is far from clear that researchers have anything like this obligation. Indeed it is hard to see what would ground such an obligation unless it was a straightforward mapping across from the clinical context.

The distinction between these contexts seems clear to me—clinicians and researchers are not embarking on the same project and relate to patients and participants in very different ways. To fail to see this is to misunderstand the variety of researcher/participant relationships. This distinction however is only the beginning and while being clear about purposes and functions is one step, it might not always help the embedded clinician researcher who is at once caring for a patient and learning from a participant, nor will it always help the researcher who could provide important clinical help to a participant.