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Response: Direct to consumer genetic testing and the libertarian right to test

ABSTRACT:

Loi recently proposed a libertarian right to direct to consumer genetic testing (DTCGT) – independent of autonomy or utility – accruing to the individual derived from Cohen’s work on self-ownership and Hohfeld’s model of jural relations. Loi argued that the burden of justification lies on those seeking regulation which interferes with the individual’s exercise of that right, rather than on individuals seeking to exercise the right. Circumstances justifying interference with the right identified by Loi include ‘conflict with other people’s rights’, ‘aggressive’ use of the genome by the individual; and ‘harming others’.

The distinction between ‘aggressive’ and ‘non-aggressive’ use of the genome, which according to Loi may justify regulatory interference with the proposed libertarian right to test, is, therefore, unclear, as each of the above criteria has different implications and, potentially, affects a different range of rights holders. Further compounding the complexity is that Loi (and Cohen) espoused a model of libertarianism dealing principally with self-ownership of the physical body, which Loi’s model adequately accounts for. However DNA is also an informational substrate, which is highly conserved within families, creating a subpopulation of people with informational interests in an individual’s genomic DNA extends beyond those affected by purely physical dealings with an individual’s genome. Harms potentially experienced by this subpopulation as a result of a related individual’s exercise of a right to test include breach of genetic privacy, violation of their right to determine when, and if, they undertake genetic testing, and discrimination. Such harms may justify regulatory intervention, in the event they are recognised; however without clarification around what types of harm justify regulation, or what the motivation of individuals causing harm are that would justify regulation, translation of Loi’s model from the theoretical into the practical is unachievable. :

INTRODUCTION:

How – and indeed if – direct to consumer genetic testing (DTCGT) should be regulated has preoccupied commentators, consumers, and policymakers since emergence of the sector in the mid-2000's. DTC businesses have strenuously resisted calls for regulation, amid controversy over notions of informed consent, regulatory arbitrage, provision of population-scale genomic data to drug companies and other partners of DTC enterprises, and disagreement about a 'right not to know' and a 'right to be tested', the latter more aptly construed as a right to exploit data. Regulators have appeared perplexed about how – and what – they should regulate. Consumer views have similarly been complex. Pragmatic concerns about protection of genetic information, and validity and utility of test results, have been juxtaposed against an ethical discourse grounded on the individual's rights to access tests (ie overriding regulatory restrictions in jurisdictions such as Australia) and to access information derived from those tests. Arguments in that discourse are frequently reliant on philosophical concepts such as autonomy and utility. [1,2]

In a recent article, Loi proposed a libertarian right of the individual to access DTCGT, based on self-ownership. Loi distinguished his model from other 'libertarian' arguments opposing 'tight' regulation of DTCGT on the basis that those arguments perceive regulation as an interference with the individual's autonomy, specifically his or her right to access information which could be of use to them: those models require a *prima facie* demonstration of the utility of DTCGT by the individual before the individual's right to DTCGT is recognised. In this way, such models are applicable only to DTCGT with utility, ie an outcome that may provide 'useful' information or outcomes.

Loi's model, in contrast, is based on the premise that if one owns oneself, and the genome is part of oneself, then one has a *prima facie* right to use their genome as they wish- including DTCGT – regardless of the utility or otherwise of the DTCGT in question. Accordingly under Loi's model, the 'right to test' is independent of any 'right to know'.

Loi's model draws authority from a number of sources, but particularly Cohen's work on self-ownership, and Hohfeld's work on the incidents of property.

Loi's model: a broad libertarian 'right to test', derived from Cohen

Loi [7] identifies four premises which summarise the libertarian argument for the 'right to test':

1. "Each person is the rightful owner of her person and powers. Consequently, each is free to use her person and these powers as she wishes, provided that she does not use them aggressively against others.

2. A person's genome is part of what a person is.

From these two premises, one infers that:

3. Each person is the rightful moral owner of his or her genome; consequently, each is free to use her genome as she wishes, provided that she does not use her own person and powers aggressively against others.
4. Each person is free to have tests performed on her genome as long as the test providers (legitimate owners of the resources for performing the test) are not forced to perform those tests by aggressive means."

In discussing the second premise, Loi states the following, identifying it as 'a matter of fact': 'my genome, no less than my arm or my brain, is just part of who I am...my genome... is a part of my body, since the beginning of my existence, and I am the only person having a moral right of ownership over it.'

Libertarianism, self-ownership, and the paradoxical nature of DNA

Loi conceptualises the 'right' to test as 'distinctively libertarian', derived from a 'moral concept of self-ownership'. He cites Cohen's example of an organ lottery, in which Cohen argued egalitarian denial of self-ownership must necessarily result in support for conscripted donation of kidneys or eyes in support of that concept of self-ownership.[6]

Cohen found that libertarian self-ownership [7], was 'at least as plausible as any other fundamental ethical belief'. [6] However although Cohen found self-ownership was plausible when considered against other ethical beliefs, he nonetheless rejected it on the grounds that it 'threatens autonomy, and provides no guarantee against a utilitarian use of people'. While acknowledging that did not amount to a strict refutation of self-ownership, Cohen nonetheless questioned why anyone would continue to adhere to it.[6]

Despite Cohen ultimately rejecting his own model of libertarian self-ownership, it nonetheless remains '... as plausible as any other fundamental ethical belief', at least with respect to tangible parts of the body. The model's adoption by Loi in the context of the genome, however, is made more complicated by the peculiarly dual nature of DNA.

From one perspective, DNA is little more than a chemical substance capable of isolation from the body, capable of being regarded in the same way as plasma, or other bodily fluids or samples, or even solid tissues or organs. From this perspective, Loi's application of Cohen's model is entirely defensible.

An alternate perspective, of equal validity, focuses instead on DNA as an informational storage medium, where the 'value' of the DNA - including genomic DNA - lies not in its chemical composition, but rather in the data yielded by the molecular sequence those chemicals are arranged in. It is in its informational rather than physical form, that genomic DNA sits less well within the confines of Cohen's model.

Loi's model begins to recognise some of the complexity arising from the duality of DNA. He observes that sharing a qualitatively similar genome is insufficient to establish 'individual identity', citing the case of monozygotic twins; and also notes that genomic identity is not a necessary condition for 'individual identity', in the context of mutation within an individual's genome during their lifespan not undermining their identity.

However he only approaches the issue from the pole of identity, and disregards the implications of DNA's dual nature when viewed from the opposite pole of commonality: for while Loi states that sharing genomic DNA does not make monozygotic twins individually identical, he fails to recognise that, despite not being identical, those monozygotic twins are nonetheless substantially similar, as a consequence of the extent to which their genomic DNA is shared. While DNA is by no means all there is to establishing identity, it is nonetheless a significant part of it. However the commonality perspective doesn't only apply to monozygotic twins: it extends to varying degrees to others who are related to the genome-bearer in question, typically in proportion to the degree of relatedness. So while my sibling and I are not genomically identical, a significant proportion of each of our respective genomes will be common between us; smaller proportions will be shared between us and our cousins; and so on.

So while each individual generally has a physical copy of the genome contained within each of the cells of the body, to which Cohen's model of self-ownership might apply, self-ownership does not necessarily logically extend to the commonly-held information derived from those physical copies. By analogy- ownership of a physical copy of a book, for example, does not give you exclusive rights over the information contained within the book, derived by reading it. It is here that Loi's model of a libertarian right to test requires some refinement.

Loi's model invites consideration of the interests, rights and responsibilities of two clear entities: 'A'- the individual seeking to engage in DTCGT – and another, who we shall label 'not A', ie, everyone else including, potentially, the state and/or regulators. When the dual nature of DNA is considered from the commonality perspective as well as the individual one, however, it becomes apparent that there is at least one other entity requiring separate consideration - 'B'- consisting of individuals who are not 'A', but are related to A sufficiently closely as to share a greater degree of commonality between their genome and the genome of 'A' due to relatedness than does the general 'not A' population and 'A' It is to the interests of 'B' that we now turn our attention.

What about 'B'? The silent partner in Hohfeld's incidents of ownership

Loi characterises the 'right to test' as both a negative right, and a broad one. It is negative in the sense that it requires non-interference on the part of others, rather than creates an obligation for others to support its exercise through provision of testing services. It is broad in the sense that it encompasses use of the genome for any purpose, regardless of the value

(if any) of any knowledge obtained from the use. In this way, the 'right to test' is independent of a 'right to know'.

Loi [5] discusses the content of the right by reference to Hohfeld's incidents of ownership [8], finding that the:

1. 'liberty right' (privilege-right) means the individual 'has no duty *not* to test her genome';
2. 'liberty right' (privilege right) means the individual 'has no duty to test her genome';
3. 'claim-right' which prevents others from interfering with the individual's right to test (or, presumably, not test);
4. 'power-right' to 'transfer' rights, ie authorise others to test on the individual's behalf;
5. 'immunity right', which 'confers protection from the above rights being modified by others'.

In each of the examples above, Loi's individual is characterised as 'A'; the 'others', by contextual inference, are 'not A'. No mention of the group we designate 'B' appears.

Yet we would argue that while the liberty (privilege) right of A to test (1) applies to DNA if it is viewed purely as a physical body part, Loi's assumed corresponding lack of duty *not* to test is problematic in light of the informational commonality between A's genome and B's. Furthermore, in exercising the right to test (or argued lack of duty not to test) A is interfering with two rights of B's: B's immunity right conferring protection on their rights from interference by others (ie A) (5); and B's liberty/privilege right not to have their genome tested (2). While it could be argued that A's exercise of their right to test doesn't interfere with B's rights regarding B's physical copy of B's genome, or force B to exercise B's right to test B's physical copy of B's genome, A's exercising of their right to test nonetheless will reveal, or open to inference, the informational content of B's physical copy of B's genome: if, for example, my sister exercises her 'right' to test, and discovers that she is a carrier of a particular genetic variant rendering her susceptible to breast cancer, my status as a carrier of that variant is either revealed, or at the very least susceptible to inference, notwithstanding that the majority of our genomes may not consist of common genomic DNA. In this way, A's exercise of their right to test their genome necessarily interferes with B's right not to have their rights modified (2) ie characteristics of their genome previously unknown are now known, or at least susceptible to inference, in addition to B's right not to test their genome (2).

Loi states that the libertarian right to test is only a prima facie right, that can be defeated by other interests; however it is not clear to us why A's right to test is the prima facie starting point for consideration, rather than B's right not to test, noting that the rights of both A and B must necessarily rely on the same moral authority, in this case derived from Cohen's model of self ownership. Consequently, Loi's proposition that proponents of regulatory

intervention should demonstrate why that intervention is justified, rather than the onus lying on consumers to show why they should be allowed unrestricted access to DTCGT, becomes problematic: given that 'B' may not be aware of A's intention to engage in DTCGT prior to them doing so, there is a compelling argument that the interests of B in their shared genetic information should be protected. We would, however, argue that rather than prohibition of DTCGT, an appropriate mechanism for protection in this context is adequate privacy safeguards designed to limit dissemination of A's genetic information commonly held with B, including from B herself, in the event B so desires.

When is regulatory interference justified?

According to Loi, Cohen's theory of self-ownership extends to ownership of the genome, and includes a right to 'use' the genome, as the only person with a moral right of ownership over it. That right is not indefeasible: Loi emphasises that the right might be defeated by 'conflict with the rights of others' - however he does not identify what those rights are, or who may hold them.

Elsewhere, he states that, 'One is morally authorised to use her genome in ways that do not harm others', leaving the moral status of use which does harm others unclear - is regulatory intervention always justified if use of the genome causes harm to others, or only sometimes justified? And what 'harms' justify regulatory intervention? Is it restricted to financial harms, such as failing to pay a DTCGT provider? Or does it extend to informational harms, such as making someone's genomic sequence publicly available, and consequently also revealing information about the genomic sequence of their children, or parents, or siblings, who may not have consented?

Loi also proposes that 'aggressive' use of person or power is inconsistent with 'free' use of the genome by the individual, which is otherwise attributable to the individual as the rightful moral owner of the genome. Examples of 'aggressive' use presumably include financial, physical, or psychological coercion being applied to providers of testing services, or other genome holders, to test or restrain from testing. What is not clear, however, is whether aggression requires an intention to harm the interests of others generally, or if only harm to specific interests will be recognised as harmed; or whether inadvertently, or recklessly, harming the interests of others will justify regulatory intervention? Nonetheless, Loi proposes that the recognition of a prima facie libertarian right to test necessarily shifts the onus onto supporters of regulation to demonstrate why intervention to restrict access to DTCGT is justified, away from requiring consumers to show why they should be allowed to exercise that right.

A critical component of any regulatory system is identification of the objectives of regulation. In the case of DTCGT, it remains unclear whose interests are served by regulation: is its purpose consumer protection, ie those who are providing DNA samples for testing against unscrupulous DTCGT providers?; is it intended to protect DTCGT providers

from defaulting consumers?; is it intended to protect the community, through for example ensuring standards of ethical testing are upheld?; or is it, as we would propose, vital in protecting the interests of people whose genetic information is revealed indirectly, as a consequence of their relatives' choice to participate in DTCGT? Any or all of those may be legitimate regulator objectives. For Loi's proposed model of a prima facie libertarian right to test being defeasible only on justification of regulation, identification of whom the regulation is directed against is a critical first step, a step which is currently unachievable under Loi's model.

Loi's article considers the financial harm to DTCGT providers of 'aggressive' use of the genome, which might justify interference; similarly, forcing individuals to participate in DTCGT, through physical or psychological coercion, are other obvious examples where use of a genome is characterised by aggression. Less obvious is the harm resulting from an individual's use of the genome that harms the informational interests of the individual's relatives who share common genetic information. It is those informational interests, and the effect of their recognition on the burden of justification, that is the focus of this response.

Conclusion

Loi's model makes a valuable contribution to the debate about access to, and regulation of, the burgeoning DTCGT industry, a debate which has to date suffered from a lack of theorisation. The model adequately accounts for genomic DNA if DNA is viewed solely as a physical object. However DNA is inherently more complex than that: it is not merely a physical or tangible substrate, similar to other body parts, but is also an informational substrate, more closely aligned to binary code. Furthermore, that information may be common to multiple members of the same family, as a consequence of the phenomenon of heritability: while genomic sequence may be isolated from a DNA sample obtained from a single individual, it will also reveal genetic information about that individual's relatives.

Furthermore, the model provides a starting point for when regulatory intervention may be justified, but is sufficiently lacking in detail that it raises more questions than it resolves, including questions that are fundamental to the purpose and objectives of regulation of DTCGT.

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