

## MEDICINE AND THE LAW

# Social justice and research using human biological material: A response to Mahomed, Nöthling-Slabbert and Pepper

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Social justice in the context of research using human biological material is an important contemporary legal-ethical issue. A question at the heart of this issue is the following: Is it fair to expect a research participant (a person who participates in such research by, among others, making available biological material from his or her body) to participate on an altruistic basis, while the researchers and the investors in the research can gain commercially from the research? In a recent article, Mahomed, Nöthling-Slabbert and Pepper proposed that research participants should be entitled to share in the profits emanating from such research via a proposed new statutory right to the intellectual property emanating from such research. In order to stimulate debate on this important issue of social justice, this article responds to the position of Mahomed *et al.* by focusing on two main points: Firstly, I contend that Mahomed *et al.* fail to make a convincing argument in favour of shifting away from altruism; secondly, I caution against framing the debate in terms of the binary poles of altruism v. profit-sharing, and suggest that should healthcare public policy ever move away from altruism, various non-monetary forms of benefit-sharing by research participants should be considered.

*S Afr Med J* 2016;106(7):678-680. DOI:10.7196/SAMJ.2016.v106i7.10552

The broad theme of this article is social justice in the context of commercial medical research that uses human biological material, such as blood samples or other tissue samples that may have been removed during a medical procedure on a patient. Within this broad theme, the following question is germane: Is it fair that the researchers and the investors in the research can commercially gain from the research, while the research participants – persons who participate in such medical research by, among others, making available biological material from their bodies – are expected to do so altruistically?

Current healthcare public policy answers this question in the affirmative: In March 2012, the South African (SA) Minister of Health made the Regulations Relating to the Use of Human Biological Material<sup>[1]</sup> in terms of the National Health Act.<sup>[2]</sup> These Regulations deal with the use of human biological material for research purposes, and provide that a person from whose body human biological material is withdrawn for research purposes may only be reimbursed for reasonable expenses incurred by him or her.<sup>[1,reg11]</sup> Accordingly, our law as it currently stands upholds an altruistic paradigm for participation in research and effectively outlaws any form of remuneration of the research participant over and above reimbursement for reasonable expenses.

In a recent article, Mahomed *et al.*<sup>[3]</sup> explore the subject of commercial medical research that uses human biological material, and take an opposing position to the current healthcare public policy of altruism, suggesting that research participants should be entitled to share in the profits emanating from the research to which they contributed. As a vehicle for such entitlement, Mahomed *et al.* propose that research participants should have a statutory right regarding the information generated from research to which they contributed; therefore, in effect a new type of intellectual property right.

In an open society, which SA aspires to be, no aspect of public policy should be sacrosanct and beyond critical, rational analysis. As such, the

challenge to the current altruistic paradigm by Mahomed *et al.* should be welcomed. Moreover, I suggest that the issue of social justice in the context of commercial medical research that uses human biological material is an important legal-ethical issue in contemporary society, and deserves more critical analysis. To stimulate academic discourse on this issue, this article briefly responds to the article by Mahomed *et al.* This article is not intended to provide arguments for or against current healthcare public policy, but is intended to highlight the weaknesses in the challenge to current healthcare public policy mounted by Mahomed *et al.* In particular, I contend that the position regarding (non-)ownership of human biological material is not as vague as suggested by Mahomed *et al.*, but is in fact well established. I subsequently highlight that the only purported support that Mahomed *et al.* proffer for their proposed shift away from altruism in fact lends no support to such proposed shift. Lastly, accepting for the sake of argument that healthcare public policy may move away from altruism, I point out that profit-sharing as proposed by Mahomed *et al.* is not the only alternative to altruism, and suggest that other forms of community-based benefit-sharing may be more appropriate alternatives.

## A note on terminology

Mahomed *et al.* employ the terms ‘human tissue’ and ‘tissue donors’. Instead of these terms, I use ‘human biological material’ and ‘research participant’. My reasons are as follows:

The Regulations Relating to the Use of Human Biological Material<sup>[1,reg1]</sup> define ‘biological material’ as:

‘material from a human being including DNA, RNA, blastomeres, polar bodies, cultured cells, embryos, gametes, progenitor stem cells, small tissue biopsies and growth factors from the same.’

I suggest that ‘human biological material’ is therefore a more suitable term than ‘human tissue’ in the context of research using human biological material.

The Regulations Relating to the Use of Human Biological Material<sup>[1]</sup> employ the term 'donor'. However, given that 'donor' has a legal-technical meaning that implies ownership, I suggest that this term may as such cause confusion. I rather employ the term 'research participant'. The term 'research participant' is defined by the Department of Health<sup>[4,p59]</sup> as follows:

'A living individual (or group of living individuals) about whom a researcher conducting research obtains data through intervention or interaction with the person or identifiable private information.'

The term is sufficiently wide to include – and therefore acknowledge – activities by the research participant that go beyond allowing biological material to be withdrawn from her or his body, such as regularly completing questionnaires for the research, participating in the planning and conducting of the research project, and involvement in patient advocacy groups that may play an oversight role regarding the research.

### The issue of ownership of human biological material

Mahomed *et al.* suggest that there are no firm 'rules' regarding ownership of human biological material and, with reference to two landmark US cases, suggest that each situation will have to be determined on its own facts.<sup>[3,p18]</sup> It is against this background of purported legal uncertainty that Mahomed *et al.* propose the legislative intervention to create legal certainty in the form of a new statutory intellectual property right to ensure profit-sharing by research participants.

However, I differ from the position of Mahomed *et al.* that there are no firm 'rules' regarding ownership of human biological material for three reasons:

Firstly, the common law position in SA is clear, namely that the human body is not a proper object of ownership: Grotius,<sup>[5]</sup> a leading Roman-Dutch law authority, defines property as all useful things excluding or external to humans (my translation of: '*Zaken noemen wy hier al wat daer is buiten den mensch, den mensch eenichsints nut zijnde*'); this definition by Grotius must be read with the provision in the *Corpus Iuris Civilis*<sup>[6]</sup> (a codification of Roman Law) that no-one is to be regarded as the owner of his own limbs (my translation of: '*quoniam dominus membrorum suorum nemo videtur*'). As Mahomed *et al.* point out, this general common law rule has been changed through secondary legislation – the Regulations Relating to Artificial Fertilisation of Persons<sup>[7]</sup> – in the specific case of gametes and embryos in the context of artificial reproduction. However, this exception created by these Regulations is specific to gametes and embryos in the context of artificial reproduction, and does not amount to general uncertainty regarding ownership of human biological material that calls for a case-by-case approach. In the absence of more legislation in this field, the courts will apply the rule that human biological material (except gametes and embryos in the context of artificial reproduction) cannot be owned.

Secondly, US case law must be contextualised and cannot simply be applied to the SA context. For instance, one of the US cases discussed by Mahomed *et al.*, *Washington University v Catalona*,<sup>[8]</sup> was decided in the jurisdiction of the state of Missouri, where – in contradistinction from SA – human biological material is a proper object of ownership. In other words, in Missouri ownership of human biological material can contractually be transferred from a research participant as original owner to another person, such as a research institution, that will then become the new legal owner. Such a transaction would be a legal impossibility in SA (arguably with the possible exception of gametes and embryos in the context of artificial reproduction).

Thirdly, I do not agree with the interpretation by Mahomed *et al.* of the other landmark US case that they discuss in their article, *Moore v Regents of the University of California*.<sup>[9]</sup> In particular, Mahomed *et al.* state that the California Supreme Court found that 'an individual has a tangible property right in his or her own tissue.'<sup>[3,p18]</sup> This is incorrect. In *Moore v Regents of the University of California*, the research participant indeed argued that withdrawn human biological material should be legally perceived as a species of tangible personal property, but although a lower court accepted this argument, the majority of the California Supreme Court held the argument to be 'problematic.'<sup>[9]</sup> The majority ruled that withdrawn human biological material is a legal object *sui generis* and that it cannot be assumed that the residual right to control the use of withdrawn human biological material amounts to 'property'.<sup>[9]</sup> The statement by Mahomed *et al.* on this core issue is therefore the exact opposite of what was in fact decided by the California Supreme Court.

Accordingly, the position taken by Mahomed *et al.* that there are no firm 'rules' regarding ownership of human biological material in SA, and that each situation will have to be determined on its own facts, does not hold water. As I state above, the SA common law position is clear, and approximates to the position set out by the California Supreme Court in *Moore v Regents of the University of California*.

### Profit-sharing by research participants

Mahomed *et al.* propose that the current altruistic paradigm be replaced by profit-sharing by research participants.<sup>[3,p19]</sup> The only purported support that Mahomed *et al.* proffer for such a major shift in healthcare public policy is a single article by Truog *et al.*<sup>[10]</sup> However, contrary to the statements by Mahomed *et al.* that they attribute to Truog *et al.*, Truog *et al.* do not propose profit-sharing. In fact, Truog *et al.* conclude their article as follows:

'While the intuition that tissue donors should be financially compensated for their donation is commendable, as a policy matter this approach is ethically and practically problematic. Except in those situations where the tissue's market value can be estimated beforehand, *investigators should adopt a practice of accepting tissue donations only when patients have freely agreed to give the donation as a gift, without expectation of monetary compensation.* However, the altruism of patients to donate tissue to medical research must be met by similar generosity on the part of investigators and institutions. This could be accomplished through legislative mandates that promote the sharing of research findings and products with other scientists, or by voluntary efforts of investigators and institutions to do the same.' (*My emphasis*)

Accordingly, the only purported support that Mahomed *et al.* proffer for their proposed shift away from the current altruistic paradigm, in fact lends no support to such proposed shift.

### Profit-sharing as a species of benefit-sharing

Should society's changing sense of social justice ever demand that research participants can no longer be expected to contribute biological material altruistically to commercial medical research, but are morally entitled to some benefit (beyond reimbursement for costs incurred), such benefit could take various forms, such as immediate payment, free products or healthcare services provided by the research organisation or its affiliates, or community-based benefits, such as building a new clinic or school. Mahomed *et al.* frame the benefit that they propose exclusively in monetary language and make it dependent on the eventual success of both the research and the commercialisation effort. (Mahomed *et al.* refer to the 'distribution'

and ‘apportionment’ of ‘proceeds’ and ‘profit’.<sup>13,pp18-19</sup>) The question should be posed as to whether this is the most appropriate form of benefit-sharing with research participants. Mahomed *et al.* do not provide a rationale for preferring their particular form of profit-sharing over other forms of benefit-sharing. Should our country’s healthcare public policy ever move away from altruism and embrace benefit-sharing with research participants, there is a variety of benefit-sharing options available, and the proponent of one (or a certain combination) would have to put forward convincing reasons for favouring a specific one (or a specific combination) of benefit-sharing options above the rest.

### Conclusion

Truog *et al.* – on whom Mahomed *et al.* purportedly rely – are clearly of the opinion that although not without its practical challenges, social justice can in principle be served within the altruistic paradigm. If Truog *et al.* are wrong, and social justice demands a new paradigm of benefit-sharing by research participants, the following ramifications must be considered: If research participants are entitled to benefit directly from their contribution of human biological material, why not also organ donors and blood donors? Is there a moral difference between having a blood sample taken for purposes of medical research, and

having blood taken for purposes of blood transfusion; and if the answer is affirmative, does such moral difference warrant the right to a benefit in the former case but not the latter? These are just some of the ramifications that require consideration if one intends to mount a challenge to the current altruistic paradigm. In the absence of an exhaustive and convincing rationale for replacing the existing altruistic paradigm with a paradigm of benefit-sharing by research participants, any discussion of benefits for research participants is driftwood in the legal-ethical ocean.

1. Regulations Relating to the Use of Human Biological Material GN R177/2012.
2. National Health Act, No. 61 of 2003.
3. Mahomed S, Nöthling-Slabbert M, Pepper MS. The legal position on the classification of human tissue in South Africa: Can tissues be owned? *S Afr J BL* 2013;6(1):16-20. DOI:10.7196/SAJBL.258
4. National Department of Health, South Africa. Ethics in Health Research: Principles, Structures, and Processes. Pretoria: DoH, 2004.
5. Grotius. Inleidinge tot de Hollandsche Rechts-Geleerdheid. 2.1.3.
6. Digesta 9.2.13 pr.
7. Regulations Relating to Artificial Fertilisation of Persons GN R175/2012.
8. *Washington University v Catalona* 490 F 3d 667 - Court of Appeals, 8th Circuit 2007.
9. *Moore v Regents of the University of California* 51 Cal. 3d 120; 271 Cal. Rptr. 146; 793 P2d 479, 15 U.S.P.Q.2d 1753 (1990).
10. Truog RD, Kesselheim AS, Joffe S. Paying tissue donors: The legacy of Henrietta Lacks. *Science* 2012;337(6090):37-38. DOI:10.1126/science.1216888

Accepted 11 May 2016.