

MEDICINE AND THE LAW

An imaginary legal conundrum: A reply to the response by Mahomed, Nöthling-Slabbert and Pepper

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In their original article on the subject of research using human biological material, Mahomed, Nöthling-Slabbert and Pepper advanced the notion that the law regarding ownership of human biological material is uncertain, and proposed that our country's healthcare policy of altruism be changed to mandatory profit-sharing by research participants. In my critique article, I took issue with the notion that the relevant law is uncertain, and suggested that Mahomed *et al.* failed to present a convincing argument in support of the proposed policy change from altruism to profit-sharing. In their response to my critique article, Mahomed *et al.* persist with the notion that the relevant law is uncertain; I suggest that this notion is erroneous, as our common law in this regard is well established, and as the authors base their argument exclusively on foreign case law. The authors further fail to make use of the opportunity to augment their argument in support of their proposed policy change from altruism to profit-sharing – in fact, they contradict themselves by disavowing their proposed policy change.

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I am disappointed by the aggressive tone adopted by Mahomed, Nöthling-Slabbert and Pepper in their letter to the editor^[1] and in their response article.^[2] I am also disappointed that they make a number of vague allegations against me, such as that I misinterpret the issues, and that my conclusions are not reasonable, without substantiating these allegations with any specific examples. Suffice it to say that there is no merit in these vague allegations. The reader is invited to read the original article by Mahomed *et al.*^[3] and my critique article,^[4] and to be the judge.

In this response, I will briefly address the following main themes: (i) the issue of ownership of human biological material; (ii) profit-sharing by research participants; and (iii) terminology.

The issue of ownership of human biological material

Our law provides that human biological material cannot be owned,^[5,6] with the exception of gametes and embryos *in vitro*.^[7] However, Mahomed *et al.* persist in their argument that there are no firm rules, and that each situation will have to be determined on its own facts. In support of their argument that there is uncertainty regarding ownership of human biological material, Mahomed *et al.* in their response article refer extensively to foreign case law. However, cases in foreign jurisdictions do not change South African (SA) law, or make SA law uncertain. Accordingly, the argument made by Mahomed *et al.* that there is uncertainty regarding ownership of human biological material, and that such uncertainty calls for legislative amendment, does not hold water.

Ownership is a species of proprietary rights. In both their original article and their response article, Mahomed *et al.* use the concept 'proprietary right' interchangeably with 'proprietary interest'. This is incorrect and confusing, as a 'right' is not the same as an 'interest' in our law. In their original article, Mahomed *et al.* propose the following definition of 'proprietary rights': 'Proprietary rights are property rights of an owner of proprietary information

that may be protected under law.' In a footnote reference, they rely on BusinessDictionary.com as the source of this definition of 'proprietary rights'. The BusinessDictionary.com definition is manifestly incorrect. In our law, proprietary rights encompass not only rights that have information as object, but a whole array of rights that have a patrimonial element, such as personal rights to performance in terms of a contract, and real rights in tangible objects.

In their response article, Mahomed *et al.* express the opinion that there is 'confusion' among 'researchers and academics working in the field' regarding ownership of human biological material and a series of other legal concepts. The two sources cited for such purported 'confusion' are articles co-authored by *inter alia* Pepper and Nöthling-Slabbert on the application of the concept 'genomic sovereignty' to human biological material. In this context, Pepper and Nöthling-Slabbert indeed express the opinion that there is confusion in the law. However, self-referencing to one's own opinion regarding the state of the law cannot logically be generalised to 'confusion' among 'researchers and academics working in the field'.

Profit-sharing by research participants

Our law upholds an altruistic paradigm for participation in research and outlaws any form of remuneration of the research participant over and above reimbursement for reasonable expenses.^[8] In their original article, Mahomed *et al.* clearly challenge the altruistic paradigm and propose profit-sharing by research participants. For instance, they state as follows: 'This [a proprietary interest vested in the research participant] would ensure that the proceeds of any therapy developed from the tissues [biological material] would be distributed, in part, to the subject [research participant]. A mandatory agreement stipulating the terms and conditions of such distribution should be required.' (My emphases.)

I concluded my critique article by suggesting that there is a broad array of ethical and legal ramifications that must be considered if the altruistic paradigm is to be replaced with a new paradigm of benefit-

sharing (which includes profit-sharing) by research participants. Despite having the opportunity to respond, Mahomed *et al.* failed to address any of these ethical and legal ramifications. In my critique article, I also highlighted the absence of a convincing rationale for replacing the altruistic paradigm with a paradigm of benefit-sharing. Again, despite having the opportunity to respond, Mahomed *et al.* failed to attempt to make a case for the paradigm change that they advocate in their original article.

Instead of picking up the gauntlet and defending their proposal of profit-sharing, Mahomed *et al.* attempt to avoid the issue by denying that they proposed that the current altruistic paradigm be replaced with profit-sharing by research participants. However, paradoxically, in the same paragraph of their response article they propose that research participants be afforded a 'proprietary interest' in the human biological material that they contribute to research, in order to ensure that the 'proceeds' of any therapy that is developed through such research would be 'distributed, in part, to the participants'. The distribution of proceeds from commercial research to research participants is plainly a mode of profit-sharing, and a clear departure from the altruistic paradigm of SA's current healthcare policy. Yet, again paradoxically, Mahomed *et al.* in their response article maintain that it was never their intention to challenge current healthcare policy. These self-contradictory avoidance attempts employed by Mahomed *et al.* frustrate proper discourse on the subject.

Lastly, Mahomed *et al.* still fail to give an accurate representation of Truog *et al.*^[9] In their original article, they state that 'Truog *et al.* have suggested that there are three distinct *obligations* that an investigator who seeks access to tissue might have towards an individual whose tissues, upon removal from the body, might have value for biomedical research. These include ... *rights to revenue streams*.' (My emphases.) In their response article, Mahomed *et al.* state as follows: 'The fact that Truog *et al.* do not specifically advocate a profit-sharing model is not a point that the authors of the original article were trying to make.' In fact, Truog *et al.*^[9] specifically argue *against* profit-sharing by research participants. The reader is invited to read the comprehensive arguments by Truog *et al.* against profit-sharing.

Terminology

In their original article, Mahomed *et al.* use the terms 'donor' and 'subject'. In my critique article, I suggested that the term 'research participant' is preferable to 'donor', given that 'donor' has a legal-technical meaning that implies ownership; in contrast, the term 'research participant' is not shackled by a similar implication, and is sufficiently broad to include participation in activities that go beyond allowing biological material to be withdrawn and used in research, but that are also integral to the research project. In their response article, Mahomed *et al.* appear to adopt my suggestion of rather employing the term 'participant'.

The definition of 'research participant' that I proposed in my critique article is based on the first edition of the health ethics guidelines^[10] by the Department of Health. In their response article, Mahomed *et al.* point out that a second edition of the health ethics guidelines^[11] has since been published, and express the opinion that my reference to the first edition's definition is incorrect. While a second edition of the health ethics guidelines has indeed been published, it uses the terms 'donor' and 'research participant' interchangeably, and fails to provide a definition of 'research participant'. Given this omission in the second edition, I suggest that it is reasonable to rely on the definition provided in the first edition, as I did. Accordingly, there is no merit in the opinion of Mahomed *et al.* that my reference to the first edition's definition is 'incorrect'. They fail to provide any detail as to why they take issue with the definition of 'research participant' that I proposed.

Conclusion

Social justice in the context of research using human biological material is an important contemporary legal-ethical issue. The stated purpose of my critique article was to stimulate debate on this important issue. Academic discourse on this issue would have been assisted had Mahomed *et al.* in their response article attempted to appreciate and answer the main points that I made in my critique article. Rather, they attacked my critique article with vague rhetoric and contradicted themselves in an attempt to avoid defending their proposal of profit-sharing. Furthermore, they persisted with legal errors, and relied on self-referencing to aver 'confusion' about ownership of human biological material where there are in fact well-established rules. Accordingly, I suggest that the 'legal conundrum' regarding the ownership of human biological material that Mahomed *et al.* proclaim is sensationalist and not real.

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