



MEDICINE AND THE LAW

Ownership and human tissue – the legal conundrum: A response to Jordaan's critique

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The debate over whether there should be a property or non-property approach with regard to human tissue is only the tip of the iceberg, because the issues involved are very complex, reflecting profound considerations on the nature of the self and the structuring of society; the balance of power between the citizen, the government and commercial interests; and human beings' perceptions of themselves and their bodies. This article responds to a publication by Donrich Jordaan titled 'Social justice and research using human biological material: A response to Mahomed, Nöthling-Slabbert and Pepper' in the July 2016 SAMJ. The original article to which Jordaan's critique refers and that provides the source for his response appeared in the *South African Journal of Bioethics and Law* in 2013, titled 'The legal position on the classification of human tissue in South Africa: Can tissues be owned?'. It is our contention that Jordaan's critique is based on a misinterpretation of the issues raised relating to the ownership of human tissue, an issue extensively debated in the academic sphere for many years. Jordaan's critique focuses on selected aspects of the original article and draws unjustifiable inferences from these. The purpose of this article is to contextualise Jordaan's critique and reaffirm the validity of the arguments made in the original article in 2013. There are, however, certain aspects of Jordaan's critique that we as authors of the original article acknowledge and appreciate in the spirit of academic discourse.

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This article has been written in response to a publication by Donrich Jordaan titled 'Social justice and research using human biological material: A response to Mahomed, Nöthling-Slabbert and Pepper'^[1] in the July 2016 SAMJ (hereinafter referred to as Jordaan's critique). The original article to which Jordaan's critique refers and that provides the source for his response appeared in the *South African Journal of Bioethics and Law* in 2013, titled 'The legal position on the classification of human tissue in South Africa: Can tissues be owned?'^[2] (hereinafter referred to as the original article).

Jordaan's critique^[1] mainly attempts to highlight weaknesses in the original article's purported challenge to current healthcare public policy; contend that the original article's conclusion regarding the legal ambivalence characterising ownership of human biological materials is incorrect; indicate that the original article's alleged shift away from altruism lends no support to such shift; and purport that profit-sharing is not the only alternative to altruism. It is our contention that Jordaan's critique is based on a misinterpretation of the issues raised relating to the ownership of human tissue, an issue extensively debated in the academic sphere for many years. Jordaan's critique focuses on selected aspects of the original article and draws unjustifiable inferences from these. The purpose of this article is to contextualise Jordaan's critique and reaffirm the validity of the arguments made in the original article in 2013. There are, however, certain aspects of Jordaan's critique that we as authors of the original article acknowledge and appreciate in the spirit of academic discourse.

The original article's alleged challenge to current healthcare public policy

It was never the intention of the original article to challenge current healthcare policy, as Jordaan suggests. The intention was to provide an outline of the legislative framework regarding the ownership of human tissue in South Africa (SA) and to comment broadly on whether it provides sufficient and consistent guidance in this regard. The purpose was to highlight further, by analysing relevant international case law (as the position remains untested in SA courts), differing views on ownership of human tissue, with specific emphasis on medical research. In addition, the original article argues that the use of the word 'ownership' as referred to in the Regulations to the National Health Act 61 of 2003 (hereinafter referred to as the NHA) is problematic and that it should be substituted with a 'proprietary interest', which denotes something different from the legal understanding of ownership.^[2] It is trite that conclusion validity *inter alia* requires scientific conclusions to be reasonable, which, with regard to Jordaan's observations, appears to fall short of this requirement, as his critique selectively analyses certain issues in the original article, without regard to the entire context thereof. This, in our view as authors of the original article, has created confusion and misperception which this article aims to address. The legal principles highlighted in this article relate to the ownership of removed human tissue or human biological materials for medical research, therapeutics or diagnostic purposes. Human tissue and human biological materials are used interchangeably.

One should not overlook the fact that advances in medicine, ranging from transplant surgery to *in vitro* fertilisation, nanotechnology and neuroscience, have radically changed the way in which human bodies are perceived. There are abundant examples in law showing the law's uneasiness in making sense of the human body in the context of ownership and property, as the notion of owning oneself (and one's tissues) implies that persons are able to objectify their selves, and in the process become susceptible to objectification by others.^[2] Furthermore, the question of the human body as property involves complicated ethical and philosophical dimensions that cannot be dealt with exhaustively within the scope of a legislative framework. There are very real issues with regard to who owns human tissue, especially in the research context.

Terminology

Jordaan criticises the original article's reference to the terms 'human tissue' and 'tissue donors' and suggests that 'human biological material' and 'research participant' are more appropriate terms for the SA context. The original article draws attention to the fact that, owing to inconsistencies and contradictions between the definitions relating to human tissue,^[3] human biological material,^[4] tissue,^[5] substance^[6] and body specimen^[7] in the NHA and the different sets of Regulations thereto, ambiguity should be avoided as these terms essentially relate to one another. The original article also argues that the NHA and its Regulations do not provide for a *legal* classification of human tissue, and to this end cause imprecision and uncertainty. Jordaan's critique, in fact, incorrectly references definitions from the first edition of the National Department of Health's ethics guidelines,^[8] these having subsequently been updated by the publication of a second edition^[9] in 2015.

Is ownership of human tissue certain?

The original article contends that there are currently no firm rules *per se* in respect of ownership of human biological materials, as far as medical research is concerned. This is particularly relevant when secondary uses of materials and third-party transfers relevant to biobank research are considered. Jordaan's differing opinion and argument in support of such opinion hinges on the original article's perceived misunderstanding of the common law position in SA, misguidance in respect of the interpretation of legislation, and relevance of foreign case law alluded to.

The original article's interpretation of the common law understanding of the human body is in fact similar to the position expressed in Jordaan's critique. The human body and its parts are traditionally classified as *res extra commercium* (things outside the commercial sphere). Separated bodily materials present a problematic category, as the law has traditionally regarded separated bodily materials as *res nullius*, belonging to no one, until brought under the control of the first person who obtains possession of the separated human tissue.^[2,10] The universal legal prohibition on the sale or trade of human tissue, embodied globally, and various statutory regulations on the use of human tissue, are equally ambiguous, as these statutory prohibitions paradoxically reinforce a construction of the human body as a commodity (property), subject to regulation. It is unfortunate that Jordaan, in taking exception to the original article's reference to the NHA Regulations Relating to Artificial Fertilisation,^[11] selects one paragraph specific to the ownership of gametes, without considering the original article's position that underlines the ambiguity created in respect of the operational definitions of an embryo in the NHA and the 2012 Regulations.^[6] The original article emphasises that current legislation does not provide any guidance on whether an embryo may fulfil the requirements to

be categorised as property. In contradiction to Jordaan's assumption that the original article relies on one specific set of Regulations^[11] to further a general position regarding uncertainty of ownership of human biological material, its intent in this instance was to highlight that the exact characterisation of an embryo in SA law remains unknown and will have to be dealt with on a case-by-case basis, taking into consideration all relevant factors.^[2]

Jordaan's critique questions the relevance in the original article of *Washington University v Catalonia*.^[12] This specific case was selected to highlight how courts have struggled to reconcile legal tradition and precedent with novel ethical and legal challenges arising from the use of human tissue in the biotechnology era. This case illustrates that even though samples were donated to the university for the purpose of cancer research, the institution could not use the samples as they pleased without any regard to the rights of the participants. It is not uncommon for international case law to be cited in instances where domestic law is untested, silent or ambiguous with regard to a specific legal issue. Even though, as Jordaan points out, human biological materials are a proper object of ownership in Missouri, the participants in this case still retained rights as to how their tissues would be used and were provided with the opportunity to disallow the use of their tissues for future research purposes, despite the fact that the institution was regarded as the owner of the tissues.^[13]

We agree, in part, with Jordaan's interpretation of the California Supreme Court judgment in *Moore v Regents of the University of California*.^[14] However, the California Supreme Court in *Moore* cautioned that 'we do not purport to hold that excised cells can never be property for any purpose whatsoever ...'.^[14] The settlement between the members of the Havasupai tribe and Arizona State University^[15] suggests that the defendants and their counsel in this matter applied the qualifying language as set out in *Moore* seriously.^[16] The Havasupai tribe alleged that researchers from Arizona State University had collected blood samples to study the prevalence of diabetes in their tribe; however, subsequently and without their permission, the researchers used the blood samples to study genetic markers for other disorders, including schizophrenia and alcoholism.^[16] In order to remedy the problematic situation, Arizona State University agreed to compensate members of the tribe monetarily, return the blood samples and provide other forms of assistance to the disadvantaged Havasupai. The significance of this settlement highlights that the rights of participants can indeed be violated when they are not fully informed about how their samples, in this case blood samples, *might* be used. By questioning the honesty of researchers from Arizona State University and probing whether they had been involved in exploiting a vulnerable population, this case cast a negative image on the university, which portrayed itself as a respectable institution for American Indian studies.^[15] Genetics experts and civil rights advocates assert that the continuous and growing debate over a researcher's responsibility to communicate the range of personal information that may be sourced from DNA at the time it is initially collected may be further fuelled by the outcomes of this case.^[15]

We may only speculate on the outcome of this matter, had it been litigated in court. The university's decision to settle, however, possibly indicates apprehension on the part of the university that litigation would have been successful. In a 2014 Canadian judgment, the Ontario Superior Court of Justice decided, as a preliminary issue, that tissue removed from a body for diagnostic medical tests is 'personal property' belonging to the hospital where the procedure was performed.^[17] This case involved an action of medical negligence instituted by the estate of a deceased patient against two doctors for failing to diagnose colorectal cancer of the deceased, who died in

2011. The doctors requested to have access to the liver tissue biopsied from the deceased. Before considering whether the defendant doctors had a right to access the liver tissue to determine whether the deceased patient had hereditary non-polyposis colorectal cancer, the court had to address the issue of ownership of the relevant tissue.

An earlier UK judgment that has made reference to ownership of male gametes is *Yearworth v North Bristol NHS Trust*,^[18] which involved the negligent destruction of the sperm of six men that had been stored prior to their cancer treatment. In this case, the Court of Appeal for England and Wales held that, for the purposes of the negligence claim, the men 'owned' their sperm as the sperm was deposited solely for their own benefit. 'Ownership' of human tissue or human biological materials, although possible in certain circumstances, is therefore not as clear cut as Jordaan proposes. What these cases may point to is that although the position that all human biological material is not property remains the status quo, some courts seem willing to deal with novel cases on an ad hoc basis, which over time may extend the circumstances under which human biological material could be viewed as legal property. This supports the contention in the original article that there may be some instances where a case-by-case approach is more appropriate, as the specific facts of a matter do have significant bearing on the outcomes, as seen above.^[2]

The original article's alleged shift away from altruism towards a model of profit-sharing

Contrary to Jordaan's critique, which suggests that the original article proposes that the current altruistic research paradigm be replaced by profit-sharing by participants, the original article introduces the proposition of compensation for research participants as a means to benefit the most vulnerable in society. In fact, the 'altruistic paradigm' to which Jordaan refers is in itself questionable, as the historical exploitation of research participants in Africa is a glaring reality.^[19-21] The fact that Troug *et al.*^[22] do not specifically advocate a profit-sharing model is not a point that the authors of the original article were trying to make. Truog *et al.*^[22] recommend, in light of the *Moore* decision^[14] and other legal precedents, that individuals do not retain property ownership over removed tissues:^[2] 'a plausible rationale for justifying such payments is that they are made in exchange for the performance of a service, rather than for the transfer of property'.^[22] Furthermore, if human tissues are afforded a proprietary interest, they would be protected from unauthorised use. The holders of the proprietary right (i.e. the research subject) would have to consent to any use of their tissue in the research phase and any subsequent future use thereof. This would also ensure that the proceeds of any therapy developed from the tissue would be distributed, in part, to the participants.^[2] A mandatory agreement stipulating the terms and conditions of such distribution should be enforced. In this way, unscrupulous activities could be minimised and vulnerable individuals, in particular, could benefit from the use of their tissues.^[2] The authors of the original article did not claim that this is the only form of 'benefit sharing', as Jordaan's critique asserts.^[1] The original article merely suggests that monetary compensation should not be overlooked.

Jordaan's critique furthermore contends that '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] It is prudent to note that the original article does not advance the view that one model be replaced with another. The recommendation of profit-sharing in no way

precludes other possible or viable benefit-sharing mechanisms from being considered.

Conclusion

It is imperative that legislation in SA relating to the regulation of human tissue be amended to provide a clear and consistent message regarding any proprietary claims in respect of human tissue.^[2] In the present context, researchers and academics working in the field of human tissue frequently express their confusion regarding the meaning and practical implications of possession, custodianship, ownership, database rights and intellectual property.^[23,24] The conflicting descriptions in statute and regulations relating to the regulation of human tissues add to this confusion.^[25] In light of the above, we stand by the arguments developed in our original article and assert that to apply a blanket 'no property rights' rule to all cases in which removed human tissue is involved would amount to a careless and reckless application. In fact, as Goold *et al.*^[26] correctly observe, the debate over whether there should be a property or non-property approach with regard to human tissue is only the tip of the iceberg, because the issues involved are very complex, reflecting profound debates on the nature of the self and the structuring of society; the balance of power between the citizen, the government and commercial interests; and human beings' perceptions of themselves and their bodies.

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