OPINION

The battle against stem cell hype: Are we doing enough? Can the medical and scientific community do more to support regulatory boards in advocating ethical evidence-based medicine?

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This article highlights the current controversies around stem cell research and its application in clinical medicine. It aims to discuss the ethical concerns around how corporate involvement is corrupting the ethical progression in this field of research. The author appeals to medical and scientific communities to take cognisance of current practices and to facilitate the regulation of new stem cell therapies being advertised to the public.

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It is human nature to believe in hope and the possibility of a better outcome no matter what the circumstances. In many degenerative disorders, the affected persons are desperately seeking such hope to bring them the strength to face their lifelong suffering. This desire has led many to view the 'new' stem cell therapies as the solution, with the conviction of their beliefs often blinding them to accepting the limitations. The vulnerability of these patients is totally understood, acknowledged and accepted by the broader medical community. Yet, in spite of this realisation, some medical scientists and doctors have adopted a more entrepreneurial approach, seeking profit from this established business opportunity.[1]

The focus of this article is on the continuation of caution regarding the stem cell hype.[2-5] Its purpose is to highlight the current ethical controversies around the way in which the corporate mindset is corrupting sound and ethical science. This topic of discussion needs refreshing so that all may be reminded of how past bad practices sometimes still prevail today.

Before dealing with the stem cell controversy directly, it may be important to review how global medicine has reached the point whereby corporate interest is manipulating proper scientific rigour. The concept of translational research has come to the forefront where there remains a desperate need to transform scientific discovery into clinical results; thereby bridging the so-called 'valley of death' between basic bench research and appropriate clinical application.[6]

The idea of translational medicine is not without its own flaws, and in his published appeal in the prestigious journal *Nature*, Prof. P Bianco from the University of Rome (2013) cautions the scientific community to address these shortcomings.[7] The most pertinent of such limitations is undoubtedly the length of time needed to complete the 'translation' process. Biotechnology companies have therefore opted to do 'translational medicine in reverse',[7] with corporate interest advertising as the expected benefit of therapies before conclusive scientific evidence can be found to support them, giving an inaccurate impression of current scientific understanding.[8]

This is not an unfamiliar ploy, as over the years the pharmaceutical industry has led the way in shaping unethical, profit-orientated medical science in pursuit of its own benefit.[9] In recent times, the baton has been passed to the various private companies offering 'revolutionary' therapies, with stem cell research being one of the more publicised examples of such hype v hope controversies.[10]

The past decade has seen both the media and the medical world broadcast the unfolding of the stem cell saga. Some preach its wonder, while others desperately try to instil reality and caution. Even though stem cell research has evolved significantly, crossing vast technological and ethical barriers, it is well known that such therapy is largely unproven and still a long way away from clinical trials. There therefore remains a need to distinguish the 'should I' from the 'can I' approach, as introduced by Liao.[11]

With the ever-multiplying number of stem cell therapy distributors – or 'hope providers' – rushing into the market around the globe, medical control boards have recently been put under pressure to implement some form of regulation. While embarking on their quest to purge unethical practice, their greatest opponent is not the providers of the services but their customers.

It would appear that the public are refusing to take note and accusing the regulatory boards of withholding potentially 'life-changing' therapies that they believe they are entitled to. Cyranoski's[1] article in *Nature,* entitled 'Stem cells in Texas: Cowboy culture' depicts such a battle between the Food and Drug Administration (FDA) and the 'revolutionary' company Celltex, which has left many of the Texas population starting to question the motives of the FDA, which is mandated to protect them.

Referring back to the original ethical controversies around stem cell research prior to the induced pluripotent stem cell era,[4] it is interesting to observe the initial reaction of the public to the introduction of such technology. There was a huge uproar when the harvesting of embryonic stem cells was announced, and many voiced their moral objections and interrogated the ethical reasoning behind this technology. Where has such passion for ethical consideration gone? In the light of what is currently happening, it appears that bioethics has fallen to its knees in the face of corporate investment, with many of the medical community bowing in submission to this allure – a distressing reality.

These points inevitably lead to the question of whether the medical and scientific community is doing enough to support regulatory boards in upholding ethical, evidence-based medicine. The consequences of involvement in this ethically cavalier behaviour do not provide the necessary disincentive. It may now be the time to instil harsher punishments to ensure that medical 'cowboys' are held accountable for 'playing with' the idea of stem cell therapy without prior experience or qualification. After all, is it not within the Consumer Protection Act in South Africa (SA) that companies provide approved and truthful services?

There is no doubt that a novel regulation system needs to be implemented to help control corporate involvement in science before things proceed further down the path of ethical neglect. Many scientists in SA are probably familiar with the life science and diagnostic activity monitoring initiative proposed by the Academy of Science of South Africa (ASSAf).[12] Such a notion has the potential to identify and 'police' scientifically unjust diagnostic and therapeutic services before they are advertised via the media. This may provide a much-needed solution to current stem cell abuse and could initiate further advances in the regulation of these therapies in SA.

The public looks to medical scientists and healthcare workers in the belief that as professionals, they have profound competency in their calling. Although some may abuse this in pursuit of fame, fortune and excessive financial gain, it remains the duty of the remainder to fight the good fight.

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