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NATIONAL ADVISORY COUNCIL ON INNOVATION

National Biotechnology Advisory Committee (NBAC)

Position statement on Stem Cell Regulations in South Africa

An increasing number of current therapeutic applications and the future potential of cell-based therapy have moved stem cells centre stage in the hope that is provided by modern medicine. The spotlight is also on controversial issues such as regenerative medicine, the ethics of cloning, and the use of embryonic stem cells, to name but a few.

It is critical that therapeutic and other activities involving stem cells must be governed by appropriate regulations. Several important reasons follow:

1. Work involving material that will be (re)introduced into patients must be conducted under strictly controlled and accredited conditions of sterility to ensure that the unintended transfer to patients of harmful material (infectious and otherwise) is avoided.
2. The absence of regulations dissuades the transfer of stem cell intellectual property and foreign investment into South Africa because of the fear of an unknown legislative environment that may impact negatively on activities that take considerable time and resources to establish.
3. The absence of regulations also permits (and even encourages) the emergence of medically-unsound and unethical practices involving stem cells that may be associated with exploitation of emotionally vulnerable patients.

An important distinction needs to be made between activities that involve altruistic donation of human material and those that result in commercial gain. Any commercial activity directly involving human material (including stem cells) that is provided on an altruistic basis by a voluntary donor must be run on a not-for-profit basis with publicly accessible accountability of how resources are managed. All other activities that involve human stem cells directly or indirectly and that are not based on the principle of an altruistic donation should be permitted to run on a for-profit basis. This includes, but is not limited to, manipulation and storage¹ of stem cells for individuals who pay for the service on a fee-for-service basis, as well as all related activities including but not limited to the development and manufacture of tissue culture reagents (including growth factors) and medical devices (including those required for stem cell harvesting and purification).

The NBAC wishes to bring to the attention of the relevant authorities the precarious situation that our country finds itself in by perpetuating an unregulated environment with regard to stem cells. There is an urgent need to stimulate an open consultation between all relevant stakeholders leading to the rapid establishment and promulgation of Stem Cell Regulations in South Africa.

¹In accordance with the National Health Act (No. 61 of 2003), stem cells may not be sold or traded privately. Payment in respect of the acquisition, supply, importation or export of stem cells may only be received by an authorized institution.