

Enactment of Chapter 8 of the National Health Act and regulations thereto

To the Editor: Legislation pertaining to human tissues is complex. In addition to an ever-changing landscape where advances in science and medicine need to be accommodated, a high degree of technical expertise is required to ensure that the legislation is accurate, appropriate and unambiguous. It is generally accepted that, where human tissue legislation is concerned, the law does not keep pace with advances in science and technology. In this regard, the National Health Act 61 of 2003 (hereafter NHA), assented to by the President on 18 July 2004, came into force on 2 May 2005. At that time, however, Chapter 8 of the NHA, entitled 'Control of use of Blood, Blood Products, Tissue and Gametes in Humans', was not enacted, and matters pertaining to human tissues were legislated under the Human Tissue Act 65 of 1983 (hereafter HTA). The HTA was drafted at a time when many of the cutting-edge scientific and medical practices that have become part of routine medical practice today, were still in their infancy or barely envisaged. These include, for example, much of assisted reproductive technology, cell-based therapy and tissue banks. Many of the advances in blood transfusion, transplantation and genetic services that occurred subsequently were likewise not provided for in the HTA.

All of the sections of Chapter 8 have now been enacted: section 53 came into force on 30 June 2008; sections 55, 56 and 68 on 17 May 2012; and, most recently, on 1 March 2012, the remaining sections 54 and 57 - 67 were enacted. Several sets of regulations pertinent to Chapter 8 were published on 2 March 2012.

Legislation that now partially fills a regulatory vacuum that has been in existence for many years in this domain is indeed wel-

come. However, much work still needs to be done to bring the legislation up to date with national requirements and international trends. In particular, the area of cell-based therapy (including stem cells), which is the author's field of interest, has not been adequately covered. Stem cell tourism and the selling of inadequately validated treatments is a global problem where emotionally vulnerable patients are exploited by unscrupulous individuals whose monetary motives exceed consideration for patients' wellbeing. South Africa has regrettably not been spared in this regard, and it will be important to see whether the newly enacted legislation will have any effect on curbing this scourge.

In a field that holds great hope for patients with a variety of disorders, it is important to recall in these heady days of exciting discovery that, from the patient's perspective, any form of therapy that is not established or is experimental in nature will need to go through clinical trials that must be scrutinised by an ethics committee and require the blessing of the Medicines Control Council (or its equivalent when this has been revised). In addition, patients should not be expected to pay for therapies that are unproven and are not part of current clinical practice.

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