Source: www.goprocurement.com/news.php?id=104

Over the past four to five years, misinformation about stem cell therapies and products in Thailand has created a storm. Advertisements have made claims which have had no technical basis, and thus have had the potential to cause serious health problems. The problem has been so extreme that the American Medical Association has come out claiming Thailand has deceptive and exaggerated advertisements on unethical stem cell services and treatments.

9 Stem Cell Law: Ethics and Progress

Life to Life

A stem cell is a young cell that is ready to grow and divide into cells. It has the ability to renew itself and grow into a diverse range of specialized cell types which can be tissues and/or organs. Stem cells can be classified into two categories based on the cell origin;[1]

1. Embryonic stem cell derived from the inner cell mass of humans or animals at an early gestational stage

2. Tissue-specific stem cell or adult stem cell found in bone marrow, blood, tissues, primary teeth, etc.

Generally, stem cells from adult stem cells will generate tissues or certain organs. Embryonic stem cells, on the other hand, have the capacity to generate more cells, tissues and organs, and even whole bodies.[2]

Researchers, particularly those outside of Thailand, have based their research mostly on adult stem cells. In early 2009, the US President Barack Obama revoked the previous administration's restrictions on federal funding for human embryonic stem cell research. Therefore, it is expected that more research on embryonic stem cells will be implemented.

Based on articles in Thai newspaper in 2009, it is clear that extensive efforts to use stem cells for medical purposes have been made in Thailand.[3] They include an attempt to develop stem cells by using baby skin instead of embryonic stem cells, the discovery of leukaemia stem cells that could lead to treatment methods for a complete cure for this disease and the attempt to use stem cells to grow a part of a jawbone in the lab to treat temporomandibular joint disorder. Further, there have been attempts at artificial blood production from stem cells for those with insufficient blood supply and sepsis, the use of the umbilical cord stem cell transplant to treat opacity of cornea and the transplantation of artificial bones using stem cells from the blood of the patient which was conducted by researchers from Chulalongkorn University.

Nevertheless, some research projects are criticized for being unnatural and unethical, namely the production of egg and sperm using embryonic stem cells for sterilized people or those effected by cancer treatments and the injection of embryonic stem cells to treat the paralysis of the lower part of the body, which was the first embryonic stem cell test in humans. However, most of the above mentioned research-studies will take around five to ten years before results are known.

As reported by Dr. Pipat Yingseree, Secretary General, Food and Drug Administration (FDA), the accepted stem cell treatment around the world are for bone marrow transplants and rheumatologic diseases such as leukaemia and genetic blood diseases. Stem cells can treat patients whose bone marrow is damaged by cancer medicines. However, these patients' recovery is only temporary, as a complete cure is still unavailable. Further, side effects occur as the safety of the treatment has not been proved yet.[4]

The limited success of stem cell treatment indicates that **stem cell treatments other than for rheumatologic diseases and bone marrow transplant are misleading and deceptive, with the potential of causing serious harm to individuals.**

Exaggerated Claims

Over 8,000 websites and web boards in Thai, advertise "placenta stem cells" from sheep, deer and even from infants. There are empty boasts about imported products with very high prices. Their qualities are exaggerated, as if to be an "elixir" that can be injected, eaten or applied. They will give you beautiful clear, clean, white and young baby like skin, replacing old wrinkly and damaged skin. Some brands even boast that they can slow ageing, build up immune, stimulate the nerve system, develop new hair, make our sleep better and so on, as if our bodies will return back to our youthful forms.[5]

Private clinics and hospitals have been using stem cell transplants for a while. They claim they treat diabetes, renal diseases, heart diseases, Alzheimer's and Parkinson's disease. A couple of years ago, stem cell therapies were "extremely popular", making huge profits. They were called the "rising star service" as the treatment was costly and limited to wealthy people.[6]

Advertisements for stem cells can be classified into two groups;[7]

(1) Stem cells made by order: This is to extract stem cells from the patient to treat heart disease and for cosmetic surgery and anti-aging. They are blood stem cells, vessel stem cells and fat stem cells which are widely used in hospitals and private clinics. However this made-to-order process is not popular because it is complex and time-consuming.

(2) Stem cell products, which are products made from stem cells or related to stem cells. They come as a liquid, powder or cream and can be injected, eaten or applied. These products are highly popular throughout the country.

In his article "Everything about stem cells",[8] Dr. Tanom Bunaprasert, **Director of the Innovative Cell-Tissue Engineering and Organ Synthesis Centre, Chulalongkorn University,** tries to determine why stem cell research has been so popular in Thailand, even though this research is in its infancy, with only a few universities undertaking studies in the last few years. He also tries to determine if the advertisement claims being made about stem cell treatment were true or not.

American research indicates that using stem cells for treatment is possible (See picture P. 72). However, what is possible as indicated by this American medical research is completely different from what is advertised in Thailand; stem cell advertisements in Thailand are exaggerated, lack accuracy and deceive people by playing on their dreams of finding a magical cure.

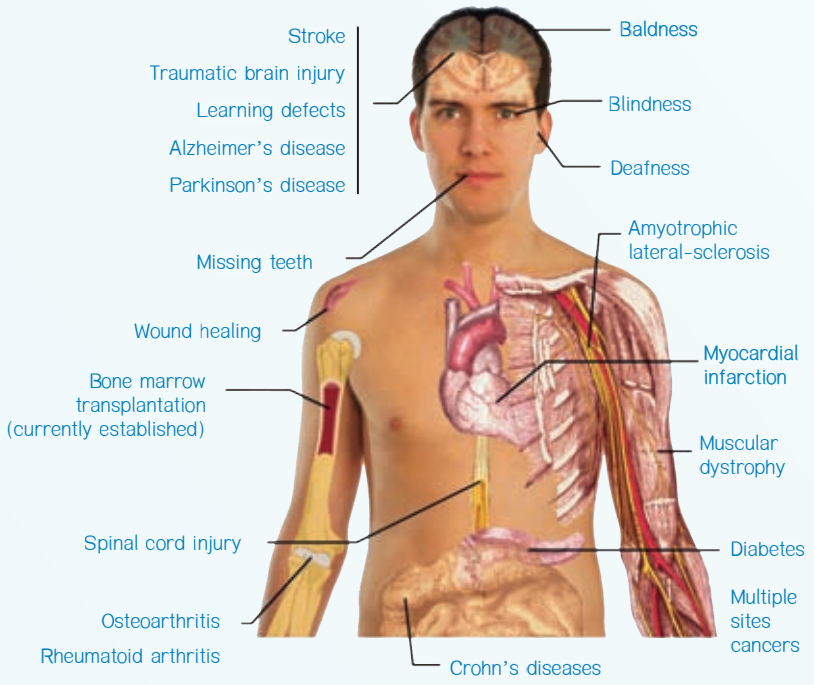
Dr. Theerawat Hemajutha, Director of the Neurology Operation Centre, Chulalongkorn Hospital, indicated that the American Medical Association has conducted a survey showing which countries unethically using stem cells and Thailand was categorized as having deceptive and exaggerated advertisement practises about stem cell services and therapies. Therefore, it is time for Thailand to have a law specifically to control stem cell research and promotion.[9]

Medical Council's Tough Regulation to Control Stem Cell

Drug companies selling stem cell products in Thailand have been able to charge inflated prices and have used numerous methods to deceive customers, which has been possible in part because of the ease that these products can be used.

On March 27, 2009, the FDA tried to overcome these problems, by using a provision of the Drug Act B.E. 2510 and by announcing the Control and Supervision of Drugs and Products from Stem Cell (Amendment). These laws require any stem cell use,

Ongoing Potential Uses of Stem Cells



Remark: Until 2009, only bone marrow transplants could be treated by stem cells. Other diseases or illness, as in the picture, were still in the experimental process (from 13 research studies cited in http://en.wikipedia.org/wiki/Stem_cell, March 9, 2010).

including the sale, research and registration, to be approved by FDA. Failure to do so would result in a prison sentence or fine, or both.

Despite the new laws, problems associated with stem cells have continued. Dr. Somsak Lohlekha, Chairman of the Medical Council of Thailand, indicated there have been many public complaints that the Council has investigated. They found many private clinics providing stem cell injection services at huge sums of money. However, they could not be charged as there was no law against this. All that could be done was to provide a warning and if problems continued, to suspend or withdraw the clinics license.

Using other laws against stem cell treatments has also proven to be infective, due to gaps in the law. Any drugs produced for an individual do not require FDA approval; most stem cell treatments are based on individual therapies.[10]

Finally, Thailand gained a law designed specifically to control the abuse of fake stem cell treatments. Dr. Somsak Lohlekha, Council's Chairman, signed the Medical Council's Regulation on Medical Ethics Regarding Stem Cell Research for Human Treatment B.E. 2552 on November 23, 2009. The law became effective on January 11, 2010.

The regulation requires all studies on stem cells to be approved and controls the use of stem cell treatments in all medical schools, private hospitals and clinics. The regulation authorizes the Medical Registration Division and the Food and Drug Association to penalise any health care provider failing to abide the law. Key points in the regulation are summarized as follows:[11]

(1) Controlling the treatment and research according to standards: The law excludes stem cell transplants for blood and bone marrow diseases, such as thalassemia, which is already accepted and controlled by law. Treatments for other disease treatments must be approved.

(2) Establishing a National Committee: The Committee is obliged to review all stem cell research and treatments. Prior to the Committee's review, they must be reviewed by their ethical review board. Failing to do so will result in ethical punishment, from a warning to a withdrawal of medical license of the doctor providing the service. The Committee is made up of experts from the Medical Council of Thailand, Ministry of Public Health, academics, doctors, lawyers,

representatives from the Supreme Court, the Lawyers Council of Thailand, and civil society. For transparency and to avoid any conflict of interest, the names of the committee members will be announced to the public.

(3) Registering persons who conduct stem cell research or persons who use stem cells for disease treatments should take place within 60 days after the law is effective. The objective of this is to check and prevent persons who are not capable and have not undergone the proper training from performing stem cell treatments.

Will the Regulations Hit the Right Spot?

Before introducing this tough law, the Medical Council's Board undertook many rounds of discussion before proposing the law to the Public Health Minister. All concerned parties agreed that the law would systematize stem cell use, ensuring that they meet Thai ethical practices and academic accuracy.

This process was time consuming as some people were against the law. The law was perceived by some as an obstruction to stem cell research. Some researchers wondered if the law scratched "the wrong spot". The penalty was another worrisome problem to researchers. Never before has a penalty been so harsh, with the suspension and withdrawal of medical licenses.

Researchers felt discouraged. Assoc. Prof. Pisamai Laupattarakasem from Khon Kean University said she would stop doing her research as the new regulations would result in too many reviews from many different committees. She felt that the slow process of reviews would result in Thai research lagging behind other countries. Another researcher said with irony that she would continue her research but in another country, such as Laos, Cambodia or Singapore, where they would be more open and supportive compared to Thailand.[12]

Stem cell companies or entrepreneurs are another group that felt discouraged. They worried that the Council's new regulation might make investment in biotechnology business riskier. Private hospitals with huge profits from stem cell services were definitely impacted from the regulation. Prof. Sawang Boonchalermvipas, Director of the Health Laws and Ethics Centre, Faculty of Law, Thammasat University, a member of the Siriraj Institutional Review Board said that:

"Private health care places have no right to conduct any human research because their duty is to treat, not to do academic work. The problem is that here are no laws to control this and these private clinics will try to undertake this work so that the can earn money from the treatment of other diseases about from haematological".[13]

Dr. Somsak Lohlekha, Medical Council's Chairman and the host of regulating bodies, said there is no intention or desire to impede stem cell studies, but a desire to promote quality and acceptable studies with standards and accuracy. After being effective on January 11, 2010, the law requires researchers working on stem cells to submit their research reports and previous research to the Council within 120 days. After this time, any clinic or hospital conducting stem cell work that has not submitted the paper work for approval will be prosecuted, resulting in the withdrawal of their medical licenses.[14]

The enforcement of this tough law will prove whether it is "scratching the wrong spot" as criticized. Amendments maybe necessary to enable it to "scratch the correct spot" as recommended by experts, for example having "a system to control research on commercial product development"[15] which is taken care by the FDA and using a guideline to control stem cell therapies in accordance with the stem cell decree of the international association and of the U.S. Food and Drug Administration. The guideline would help regulate stem cell use of Thailand to meet international standards.[16]

All recommendations are meant to balance between "ethics and progress" that matter to the country and people.