LIFE AND DEATH

A Decade of Biomedical Law Making 2000–2010

This article seeks to provide a survey and broad analysis of the law-making activities of the Singapore legislature in the context of global and national trends in biomedical and healthcare developments from 2000 to 2010 in the following areas: (a) regulation of complementary and alternative medicine; (b) epidemiology, infectious diseases and public health; (c) ethical issues in human organ transplantation; (d) mental capacity, mental health and competence issues; (e) regulation of medical and healthcare professionals; and (f) governance for biomedical research and biosafety.

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I. Introduction

1 In December 2000, the Singapore Bioethics Advisory Committee was established. The ensuing decade, 2000–2010, has witnessed an active Singapore legislature in the area of healthcare and biomedical issues. This article seeks to survey and discuss these legislative changes in the following broad areas:

(a) regulation of complementary and alternative medicine;

(b) epidemiology, infectious diseases and public health;

(c) ethical issues in human organ transplantation;

(d) mental capacity, mental health and competence issues;

(e) regulation of medical and healthcare professionals; and

(f) governance for biomedical research and biosafety.

2 Having regard to the sheer breadth and volume of the legislation generated in the past decade, this article can neither be

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comprehensive nor carry a detailed analysis. What it seeks to do is to provide a survey and broad analysis of the law-making activities of the Singapore legislature in response to global and national developments in biomedical and healthcare issues.

II. Regulation of complementary and alternative medicine

3 As Singapore is a unique Asian country, it is apt that this article begins with the issue of complementary and alternative medicine ("CAM") and in particular Traditional Chinese Medicine or "TCM". In Western culture, alternative medicine is any healing practice "that does not fall within the realm of conventional medicine".[1] It is often opposed to scientific evidence based medicine and encompasses therapies with a historical or cultural, rather than a scientific, basis. Due to the uncertain nature of various alternative therapies and the wide variety of claims different practitioners make, alternative medicine has sparked vigorous debate around the world. In the last decade, complementary and alternative medicine has gained increasing popularity even in Western cultures. This has given rise to ethical implications in terms of preventing harm to potential patients (principle of non-maleficence) as well as the dilemma presented to medical practitioners in integrating alternative therapies with traditional medical treatment and advising their patients on alternative treatments. For example, how does a physician advise a patient who refuses conventional treatment in favour of alternative therapy (principle of patient autonomy and informed consent)? The author of this article recalls that his ENT specialist at a government restructured hospital actually underwent training in the traditional Chinese practice of acupuncture. One can criticise alternative medicine as a failure of ethical principles on the basis that it is entirely without scientific merit. Yet there is arguably ample empirical evidence that certain forms of alternative medicine yield results (principle of beneficience). Some regulatory authorities continue to attempt to strike a regulatory balance. The World Health Organization ("WHO") document, "Guidelines for Clinical Research on Acupuncture",[2] states that "consideration should be given to the different value systems that are involved in human rights such as social, cultural and historical issues" and that "further studies should be conducted in relation to ethical issues involved in clinical research on acupuncture".

4 The most common and most well accepted form of alternative medicine in Singapore is TCM. The health authorities in Singapore

1 Steven Bratman, MD, *The Alternative Medicine Sourcebook* (Lowell House, 1997) at p 7.

2 World Health Organization Regional Office for the Western Pacific, *Guidelines for Clinical Research on Acupuncture* (Manila, Philippines: WHO, 1995).

appear to have been persuaded by the body of evidence supporting the effectiveness of acupuncture therapy in particular. A distinct trend toward the integration of CAM therapies with the practice of conventional medicine is occurring in Singapore as it is elsewhere. The largest government restructured hospitals in Singapore have integrated acupuncture into their traditional health care services. The National University Hospital, Singapore General Hospital and Tan Tock Seng Hospital provide acupuncture services as part of their hospital services.[3] The health authorities in Singapore have not only explored the integrationist options but also embraced them. The application of acupuncture therapy in this context can be said to be complementary rather than alternative medicine.

5 A judge in Singapore's highest court of appeal, Justice Andrew Phang (then a Judicial Commissioner) said in *Tang Kin Hwa v Traditional Chinese Medicine Practitioners Board*:[4]

> Traditional Chinese medicine ("TCM") is becoming increasingly popular and attempts are being sought to integrate it with more conventional methods of medical treatment. This is all to the good. However, the industry is still developing and its operational oversight is still in its relative infancy. It therefore needs to be afforded the maximum latitude to ensure its success – not only for its practitioners or even for the industry as a whole but also, and more importantly, for the overall benefit of Singapore in all its multifarious aspects. However, it is imperative that all this must be achieved within an appropriate legal structure.

6 It is not therefore surprising that Singapore is a leader in introducing legislation regulating TCM. In moving the second reading of the Traditional Chinese Medicine Practitioners Bill on 14 November 2000,[5] then Parliamentary Secretary to the Minister for Health, Chan Soo Sen, cited that TCM enjoys considerable popularity as a complementary form of healthcare. Mr Chan said that it has been estimated that about 45% of the population has consulted a TCM practitioner at some time. About 12% of the daily outpatient attendances opt to see TCM practitioners. Hence, TCM is a significant factor in the healthcare scene in Singapore.

7 As far back as a decade ago, the regulatory approach adopted is one of quasi self-regulation by a board comprising TCM expert

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3 Health Minister Khaw Boon Wan stated in Parliament on 26 April 2010 in answer to a parliamentary question from Indranee Rajah MP on the use of disposable acupuncture needles (*Singapore Parliamentary Debates, Official Report* (26 April 2010) vol 87). Other TCM clinics set up within the premises of restructured hospitals are independent entities and tenants of the hospitals.

4 [2005] 4 SLR(R) 604 at [1].

5 *Singapore Parliament Debates, Official Report* (14 November 2000) vol 72 at col 1128.

practitioners. The Traditional Chinese Medicine Practitioners Act[6] established and vests regulation in a Traditional Chinese Medicine Practitioners Board ("TCM Practitioners Board"). This statutory board registers TCM practitioners (both acupuncturists and TCM physicians), accredits TCM institutions and TCM courses for the purpose of registration and regulates the professional ethics and conduct of registered TCM practitioners. There are two types of registration for TCM practitioners. Full registration allows a TCM practitioner to practise his prescribed area or areas of TCM on his own anywhere in Singapore. Conditional registration allows a TCM practitioner to work in an approved TCM healthcare establishment, under the supervision or charge of a TCM practitioner on full registration. There are as at 31 December 2008, a total of 2,373 registered TCM practitioners with 1,213 registered both as TCM practitioners and acupuncturists, 954 registered as TCM physicians and 206 registered as acupuncturists.[7] In January 2010, the number of registered TCM practitioners in Singapore increased to 2,421.[8]

A. Ethical Code and Ethical Guidelines for TCM Practitioners

8 The "Ethical Code and Ethical Guidelines for TCM Practitioners" published in March 2006[9] represent the fundamental tenets of conduct and behaviour expected of TCM practitioners practising in Singapore and elaborate on their applications. They are intended as a guide to all TCM practitioners as to what the TCM Practitioners Board regards as the minimum standards required of all TCM practitioners in the discharge of their professional duties and responsibilities in the practice of TCM in Singapore.

9 From 2007 to 2009, the TCM Practitioners Board received a total of 23 complaints against registered TCM practitioners: ten in 2007, seven in 2008 and six in 2009. The complaints were mainly related to allegations of professional negligence, misconduct and the misuse of Western medicine.[10] Although the TCM Practitioners Board encourages all registered TCM practitioners to be covered by professional indemnity

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6 Cap 333A, 2001 Rev Ed. Enacted in 2000.

7 Traditional Chinese Medicine Practitioners Board Annual Report 2008 at p 2 (Chairman's report). A list published by the local TCM community in 1997 indicated that there were 1,807 TCM practitioners in Singapore.

8 Reply from the Minister for Health to Parliamentary Question No 290 by Dr Lam Pin Min (12 January 2010). See <http://www.moh.gov.sg/mohcorp/parliamentaryqa.aspx?id=23660> (accessed 15 October 2010).

9 The guidelines are in both English and Chinese versions and can be downloaded at the Ministry of Health website <www.moh.gov.sg> (accessed 15 October 2010).

10 Reply from the Minister for Health to Parliamentary Question No 290 by Dr Lam Pin Min (12 January 2010). See <http://www.moh.gov.sg/mohcorp/parliamentaryqa.aspx?id=23660> (accessed 15 October 2010).

insurance on a voluntary basis, such insurance is not mandatory and there appears to be a gap in protection for patients. On the other hand, TCM practice is generally non-invasive and mandatory insurance might increase costs to patients. A recent case illustrates that the TCM Practitioners Board is an active regulator. On 29 April 2010, the High Court dismissed the appeal of a TCM practitioner, Huang Danmin, against the decision of the TCM Practitioners Board in April 2008 to revoke his registration.[11] In January 2004, Tan Nan Kee, 72, who was suffering from terminal rectal cancer, approached Huang in his Singapore clinic for an alternative treatment. Although he visited the clinic regularly, Tan was told on three occasions to visit Huang's second clinic just across the border in Johor Bahru, Malaysia. In June 2004, Huang told Tan and his family he had an electro-thermal needle machine in the Johor Bahru clinic that might be able to treat Tan's condition. By then, Tan was bedridden, on an intravenous drip and dependent on morphine for pain relief. He was transported to the Johor Bahru clinic in an ambulance. The use of the machine did not relieve Tan's condition but caused more pain. He returned to Singapore on 6 June 2004, and died 15 days later. One possible reason why Huang's doubtful electro-thermal equipment was situated across the border was to remove it from the jurisdictional reach of Singapore's TCM Practitioners Board. Indeed, Huang's counsel argued at the hearing that the physician's actions outside Singapore should not be held against him. Counsel for the TCM Practitioners Board argued that Tan and his family were consulting Huang as a TCM practitioner registered in Singapore. She added that Huang administered the injections and electro-thermal needle machine treatment despite knowing that they were not established TCM practices. The facts of this case also illustrate the ethical dangers of acceptance of TCM therapies that have no or little evidence of medical benefit.

10 Another case illustrates the seriousness with which the TCM Practitioners Board views its statutory duties. In *PP v Zhong Zhi Li*,[12] the accused, Zhong, was convicted after a trial on four charges under s 26(*a*) of the Traditional Chinese Medicine Practitioners Act.[13] The four charges were in substance for procuring registration from the TCM Practitioners Board as an acupuncturist by knowingly producing a false certificate from the Guangzhou TCM University (formerly known as Guangzhou TCM College). The accused, Zhong, was sentenced to two weeks' imprisonment *per* charge and two of the sentences were to run consecutively for a total of four weeks' imprisonment. This case is an illustration of the stringent standards and checks imposed by the Board.

11 "Appeal against High Court unsuccessful for TCM physician" *Today* (30 April 2010).

12 [2007] SGDC 126.

13 Cap 333A, 2001 Rev Ed.

It is interesting that although Guangzhou TCM University informed the Board that they were unable to send a representative to Singapore to testify concerning the authenticity of the accused's certificate, the Board went to the extent of sending its officer, Mrs Chuo-Ng, to Guangzhou TCM University in March 2007 to inspect the University's records. Mrs Chuo-Ng testified that she inspected the relevant records in the University and made photocopies of them. The records were retrieved for her inspection by the Deputy Director of the Educational Affairs Department of the University. The Deputy Director also briefed Mrs Chuo-Ng on the reasons why they were certain that Zhong's certificate was forged and provided a letter explaining this. In addition, a lawyer in China witnessed and certified that Mrs Chuo-Ng had scrutinised the original documents.

11 Although the TCM Practitioners Board took its regulatory duties seriously, the High Court recently reminded the TCM Practitioners Board and in general the governing bodies of regulatory, professional and other organisations that they should ensure that they act in accordance with their power and duties under law. If they fail to do so, they should be prepared to acknowledge the fact. Woo Bih Li J's remarks were made in *Yip Kok Seng v Traditional Chinese Medicine Practitioners Board*,[14] where Yip, a registered acupuncturist with the TCM Practitioners Board and not a full TCM physician, sought certain declaratory reliefs from the Singapore High Court with regard to investigations conducted by the TCM Practitioners Board pursuant to complaints made by a patient, B.[15] On 2 May 2008, B complained to the Board that Yip had checked her private parts during her second appointment with him, without the presence of a female nurse, and that he had molested her. The Inquiry Committee had not yet adjudicated on the matter. Woo J accepted the general principle stated in *Wong Keng Leong Rayney v Law Society of Singapore*[16] that it should be for the Inquiry Committee to decide in the first instance whether it has the jurisdiction to adjudicate on the matter brought before it. However, Woo J held that the scope of the power of the TCM Practitioners Board's officer to investigate under s 30(1) of the Act is circumscribed by that provision and it did not empower the investigator to inspect medical records. A parting note that although TCM is recognised and

14 [2010] SGHC 226.

15 Yip had two primary complaints. The first was that the TCM Practitioners Board had acted *ultra vires* its powers when it acted on a complaint made by B on 2 May 2008 which was not supported by a statutory declaration as required by reg 3(2) of the Traditional Chinese Medicine Practitioners (Investigation of Complaints) Regulations (Cap 333A, Rg 4, 2002 Rev Ed). The second was that the Board lacked jurisdiction to investigate a second complaint dated 2 June 2008 by B because the conduct complained of was not performed in the course of a healing session under TCM methods.

16 [2006] 4 SLR(R) 934.

regulated in Singapore, the practice by medical practitioners of other forms of alternative medicine may constitute unethical conduct. A medical practitioner, Dr Erwin Kay, was fined $5,000 and censured by the Singapore Medical Council's disciplinary committee for using a bioresonance machine to treat patients. Dr Kay pleaded guilty on 20 September 2010 to the charge of professional misconduct for failing to treat his patients according to generally accepted methods of treatment.[17]

III. Epidemiology, infectious diseases and public health

12 Epidemiology[18] rose to the forefront of public consciousness in Singapore in the last decade with the emergence of challenges to public health caused by infectious diseases such as SARS and H1N1 and the increase in HIV infections. This was reflected in the global situation with the WHO reacting and some say overreacting (in the case of N1N1) to these public health threats. The multiple global threats of infectious diseases are now widely recognised because diseases spread through international air travel. Instantaneous blow by blow accounts through globalised media news has heightened global fears of pandemics. The economic and societal burden, actual and potential, imposed by infectious diseases is so heavy that Enemark argues that governments might choose to frame them as threats to national security.[19] Responses to potential pandemics might necessitate restrictions to individual liberty and movement. Enemark correctly identifies that the threshold upon which threats to public health can be framed as threats to national security is one for political judgment. At the same time, it raises the ethical issue as to the extent to which limitations on individual liberty is justified by such threats. Article 13(2) of the Singapore Constitution[20] relating to freedom of movement and residence is subject to laws relating to the security of Singapore, public order and *public health*. Article 14 on freedom of speech, assembly and association is, however, not expressly subject to laws relating to *public*

17 Poon Chian Hui, "Doctor fined and rapped for alternative treatment" *The Straits Times* (30 October 2010).

18 For the benefit of lawyers, "epidemiology" is the study of factors affecting the health and illness of populations, and serves as the foundation and logic of interventions made in the interest of public health and preventive medicine. In the study of communicable and non-communicable diseases, the work of epidemiologists ranges from outbreak investigation to study design, data collection and analysis including the development of statistical models to test hypotheses and the documentation of results for submission to peer-reviewed journals.

19 Christian Enemark, *Infectious Diseases, Security and Ethics*, Abstract for 10th World Congress of Bioethics, Singapore, 29 July 2010. See also Christian Enemark, *Disease and security: natural plagues and biological weapons in East Asia* (New York: Routledge, 2007).

20 Constitution of the Republic of Singapore (1999 Rev Ed).

health. Although data protection and privacy are not fundamental liberties entrenched in the Singapore Constitution, the tension exists between public health measures and data protection and privacy of the patient. The unique circumstances of Singapore, as a densely populated city-state and an international air transport hub, would, in this author's view, justify a lower threshold and earlier and wider limitations on individual liberty to effectively contain any potential pandemic threat. It is submitted that this is consistent with the ethical principle of cultural diversity.

A. SARS 2003

13 In March 2003, the whole nation was gripped by fear when the deadly Severe Acute Respiratory Syndrome ("SARS") arrived in Singapore. The then Minister for Health, Lim Hng Kiang, explained the severity of the crisis in the following words:[21]

> We are faced today with an unprecedented public health crisis. This crisis has been caused by the outbreak of Severe Acute Respiratory Syndrome or SARS. Several senior doctors told me that they have not experienced anything like this in the last 40–50 years. The SARS outbreak can destroy the capability of our national healthcare system if it is not contained. It can have wide and severe repercussions on many sectors of our economy.

14 A professor of medicine from Guangzhou fell ill while in Hong Kong. He stayed at a hotel in Hong Kong on 21 and 22 February. He infected seven persons at the hotel, including three Singaporeans. The three Singaporeans returned on 25 February 2003 and they were well at that time. Between 1 and 3 March, they fell ill and they were admitted to our hospitals as cases of pneumonia. On 6 March, the WHO issued an alert that healthcare workers in Hanoi, who had treated an American who had come from Hong Kong, were falling ill. When the WHO issued this alert, the Ministry of Health instructed hospitals to isolate the three patients and to implement stringent isolation measures.[22] The crisis ended when Singapore was declared SARS free by the WHO on 31 May 2003. In the meanwhile, 32 persons had succumbed to the deadly disease. International medical officials praised Singapore's handling of the outbreak and its prompt and open reporting of cases, saying other countries could learn from its example. Dr David Heymann, Executive Director for Communicable Diseases at the WHO said: "From the start,

21 Second reading speech for the Infectious Diseases (Amendment No 2) Bill, *Singapore Parliamentary Debates, Official Report* (25 April 2003) vol 76 at cols 2173–2250.

22 Brief history of SARS recounted by then Minister of State for Health (Dr Balaji Sadasivan) in moving second reading of the Infectious (Diseases) Amendment Bill 2003 on 21 March 2003.

Singapore's handling of its SARS outbreak has been exemplary. This is an inspiring victory that should make all of us optimistic that SARS can be contained everywhere."[23] Singapore carried out thermal-imaging of all air passengers to see if anyone had high temperatures, and quarantined those with symptoms – drafting in the army to enforce the containment.

15 The outbreak of SARS called for an immediate legislative response. The Infectious Diseases Act[24] was enacted in 1976 to prevent the introduction and spread of all infectious diseases in Singapore. The Infectious Diseases (Amendment No 2) Bill[25] was introduced in Parliament on 24 April 2003 on a certificate of urgency under Standing Order 84 and passed by Parliament on the next day, 25 April 2003. A certificate of urgency is rarely invoked in Singapore as it does not allow sufficient time for members of Parliament to study the provisions of the Bill before debate. It is interesting to note that just a month earlier, on 21 March 2003, an earlier amendment Bill[26] to the Infectious Diseases Act had just been debated. Although the Minister of State for Health recounted the origin of SARS at the parliamentary debate, this set of amendments[27] did not specifically address SARS. A probable reason for this was because SARS cases were discovered in mid-March 2003, just days before the introduction of the Bill. The swift legislative response to SARS underlined the political will to take "draconian" measures to contain SARS. The sometimes irrational fear of fatal infection had taken a toll on the economy and businesses as people avoided unnecessary contact and leisure activities. Even the constantly busy shopping district of Orchard Road was deathly quiet. The main provisions introduced to deal with the SARS crisis covered five key areas: home quarantine orders, the quarantine of premises, the prevention of persons from irresponsible actions which could cause the infectious disease to spread, compliance with disease control measures and the handling of bodies of deceased persons who are suspected to have SARS. As there was no cure for SARS, the measures focused on containment and prevention. Bearing in mind the context, we can understand the widespread public acceptance of the need for the "draconian measures" and why proportional inroads into the patient's individual liberty, autonomy and protection of personal data were

23 "Singapore Success Against SARS" BBC News, posted 31 May 2003, at <http://news.bbc.co.uk/2/hi/americas/2951508.stm> (accessed 15 October 2010)).

24 Cap 137, 1985 Rev Ed.

25 Bill No 10/2003.

26 Infectious (Diseases) Amendment Bill 2003.

27 These amendments sought to enable the transfer of the existing medical related functions required for the prevention and control of infectious diseases from the Ministry of the Environment to the Ministry of Health, to expand the definitions of infectious disease, and to enhance the Minister for Health's authority to order mandatory vaccinations.

necessary for the "public good". This author submits that it is a question of fine balancing and akin to key hole surgery, ensuring that the "invasive surgery" of the patient's rights is minimised.

16 The parliamentary debate itself was a vivid illustration of the home quarantine, voluntary or mandatory, in place at that time. The current Health Minister, Khaw Boon Wan,[28] made his speech remotely through video facility. He had earlier in the week visited Tan Tock Seng Hospital, Intensive Care Unit, where SARS patients were being cared for. Although he had been properly protected and there was no risk of his having been infected, he decided to stay away from Parliament in order to allay any anxiety. Members of Parliament, Dr Ng Eng Hen, Tan Cheng Bock and Dr Balaji Sadasivan also made their speeches through video link.

17 The Ministry of Health was not content to rest on its laurels. It made further amendments in 2008 in anticipation of new public health threats that could be more severe than SARS. The Health Minister explained that a virus might surface which is more contagious than SARS and not easily identifiable or an infected person can be infectious yet without showing any physical signs. The Minister cited one such threat of a global influenza pandemic could be the mutation of the bird flu into human-to-human transmission. Unlike SARS, those infected may develop no or very mild symptoms, yet they are infectious. So contact tracing and quarantine may not be totally effective. In such a scenario, the Minister explained[29] that the option is to restrict and reduce social interactions through "social distancing" measures. This means prohibiting mass gathering in order to slow the spread of the disease in the community. Social distancing will buy valuable time until an effective vaccine becomes available and also reduce the peak of the pandemic.

18 Before 2008, the Infectious Diseases Act[30] already empowered the Ministry to prohibit specific meetings, gatherings and public entertainments when the holding of such events is judged to increase the spread of any infectious disease. But individual prohibition orders would have to be issued to prohibit each meeting or each gathering. This would be too slow in a major crisis like the flu pandemic. The Infectious Diseases (Amendment) Act 2008[31] was thus enacted to close this gap by

28 He was then Senior Minister of State for Transport and Information, Communications and the Arts.

29 *Singapore Parliamentary Debates, Official Report* (22 April 2008) vol 84 at cols 2661–2712

30 Cap 137, 2003 Rev Ed.

31 Act 10 of 2008.

empowering the Ministry to impose social distancing measures speedily in response to a potential severe public health emergency.

B. H1N1

19 Six years after SARS in 2009, the world (and not just Singapore) was again seized by fear at the spectre of the Influenza A (H1N1-2009) (also described as 2009 Influenza A (H1N1), and previously referred to as the "new strain of swine flu") which is a new strain of influenza virus that spreads from human to human. The novel influenza A (H1N1) outbreak was officially declared a pandemic by the WHO on 11 June 2009. The first local imported case of H1N1-2009, a Singaporean who had returned from New York City, was detected on 26 May 2009. The first unlinked case (*ie*, a case with no epidemiological links to previous cases) was detected on 18 June 2009 – the first indication that community transmission of H1N1-2009 had begun locally. By 9 July 2009, there were 1,301 laboratory-confirmed cases of H1N1.[32] Historically, influenza pandemics have encircled the globe in two, sometimes three, waves. The 1918 pandemic (or "Spanish Flu"), the most deadly of them all, began in a mild wave and then returned in a far more deadly one. The pandemic of 1957 (or "Asian Flu") began with a mild phase which was followed, in several countries, by a second wave with higher fatality. The pandemic of 1968 (or "Hong Kong Flu") remained, in most countries, comparatively mild in both its first and second waves. No legislative response was required as the legislative framework had been put in place in response to SARS. Although the WHO was criticised for being unduly alarmist, the threat demonstrated that Singapore had in place the legislative and public health infrastructure, on a "whole of government"[33] perspective, to deal with the threatened pandemic. This was buttressed by the 2008 amendments to the Infectious Diseases Act.[34] In the absence of complete information, Tay, Ng, Cutter and James have argued that good risk management requires that control measures err on the side of caution. No doubt, valuable but costly lessons had been learnt from the 2003 SARS epidemic. Tay, Ng, Cutter and James also argue that Singapore's ability to respond to public health threats has improved significantly, because of its experience in managing the SARS epidemic, and its "whole of government" approach in preparing for a pandemic over the past five

32 Joanne Tay, Yeuk Fan Ng, Jeffery Cutter & Lyn James, "Pandemic in Singapore – Public Health Control Measures Implemented and Lessons Learnt" Ann Acad Med Singapore 2010 (April); 39(4): 313–324.

33 The "whole of government" initiative encourages public servants to work and think in terms of the whole of government rather than in individual silos within their own ministries or departments.

34 Cap 137, 2003 Rev Ed.

years.[35] The co-ordinated and collaborative efforts of government agencies, the healthcare sector, businesses, and members of the public were essential in ensuring that the measures to control the spread of H1N1-2009 were implemented efficiently and effectively. As in the SARS epidemic, there was widespread public acceptance and support for these preventive measures for the "public good". The H1N1 pandemic that started in the spring of 2009 was officially declared to have "largely run its course" by WHO Director Margaret Chan on 10 August 2010 and she explained that "we are now moving into the post-pandemic period".[36]

C. HIV

20 AIDS, which is caused by the Human Immunodeficiency Virus ("HIV"), became a notifiable disease under the Infectious Diseases Act[37] a quarter of a century ago in 1985. In 1992, this Act was amended to include provisions to tighten the control of the spread of AIDS and to provide for the confidentiality of infected persons. The Health Minister explained[38] in 2008 that HIV remains a problem in Singapore. The number of new cases continued to grow. In 2001, there were 237 newly notified HIV cases. In 2007, that number had almost doubled to 422. The main mode of transmission of HIV in Singapore is through unprotected sex with an HIV-infected person. Section 23 of the Infectious Diseases Act pre-amendment provides that before sexual intercourse, a person who knows of his HIV status is required to inform his sexual partner of the risk of contracting HIV from him. If the partner willingly accepts the risk, no offence is committed. Doctors regularly inform HIV patients about this law at the point of diagnosis. Section 23 is, however, effective only when a person has actual knowledge that he or she is HIV positive. Despite the easy access to testing in Singapore, it is estimated that for every known HIV case, there could be another one to two cases who are infected but remain undiagnosed, until the symptoms appear. The latter group may continue transmitting HIV unknowingly to their partners for many years during the asymptomatic period. The Infectious Diseases (Amendment) Act 2008 thus amended s 23 to shift greater responsibility to individuals whose sexual behaviour, for example, puts their spouses

35 Joanne Tay, Yeuk Fan Ng, Jeffery Cutter & Lyn James, "Pandemic in Singapore – Public Health Control Measures Implemented and Lessons Learnt" Ann Acad Med Singapore 2010 (April); 39(4): 313–324, at 324.

36 Martin Enserink, "WHO Declares Official End to H1N1 'Swine Flu' Pandemic" Science Insider (10 August 2010) <http://news.sciencemag.org/scienceinsider/2010/08/who-declares-official-end-to-h1n1-pandemic.html?rss=1> (accessed 15 October 2010).

37 Cap 137, 2003 Rev Ed.

38 Minister Khaw when moving the Infectious Diseases (Amendment) Bill 2008. *Singapore Parliamentary Debates, Official Report* (22 April 2008) vol 84 at cols 2661–2712.

and partners at risk of contracting AIDS. A person who has reason to believe that he has been exposed to a significant risk of contracting AIDS must take reasonable precautions to protect his sexual partner, *eg*, by protected sex, even if he is ignorant of his HIV positive status. Alternatively, he can opt for an HIV test to confirm that he is HIV-negative. Otherwise, he must inform his partner of the risk of contracting HIV from him, leaving the partner to voluntarily accept the risk, if he or she so wishes. The objective of this amendment appears to be to promote the use of condoms and regular HIV testing. The Minister gave the assurance that it was not the intention to enforce the law against every HIV-infected person. Enforcement will be triggered by a complaint from an aggrieved victim, and only after a thorough investigation to establish the facts. The penalties for HIV/AIDS related offences were also increased to reflect the seriousness with which society views such offences and as a deterrent measure.

21 Shortly after the 2008 amendments to the Infectious Diseases Act[39] came into force, a 43-year-old man pleaded guilty on 14 July 2008 to a charge under s 23(2) of the Infectious Diseases Act of performing an act of fellatio in a public toilet on another male aged 16 years without informing him of the risk of contracting HIV Infection and without obtaining his prior voluntary agreement to accept that risk (*PP v Chan Mun Chiong*).[40] The accused, Chan, had actual knowledge that he was suffering from HIV Infection. Although the conviction took place after the 2008 amendments came into force on 10 June 2008, the offence took place prior to that date. The District Court sentenced the accused to 12 months' imprisonment after taking into account that the victim had not been infected with HIV. The District Judge added a warning to future offenders that the punishment had since 10 June 2008 been enhanced from a maximum of two-year imprisonment term and $10,000 fine to a maximum of $50,000 fine or imprisonment for a term not exceeding ten years or both.

D. Public health and smoking

22 Tobacco contains more than 60 chemicals that are known to cause at least 20 forms of cancer. Tobacco use is the leading cause of preventable death, killing more than five million people every year worldwide. To different degrees of success, countries have tried to stem the tobacco epidemic. Singapore was a world pioneer in tobacco control. It was the first country in Asia to ban tobacco advertising in 1971. In 2004, it was again the first country in Asia to mandate the use of graphic warnings on cigarette packs to deter smokers from lighting up. On

39 Cap 137, 2003 Rev Ed.
40 [2008] SGDC 189.

efforts to get smokers to quit, the WHO recognised only nine countries, including Singapore, for their nationwide network of smoking cessation services. As a result of these proactive efforts, the smoking prevalence, at below 14%, is among the lowest in the world.

23 In 2003, the WHO developed the Framework Cooperation on Tobacco Control ("FCTC") for the purpose of compelling its Member States to adopt strategies and best practices aimed at reducing the demand for tobacco and regulating its supply. Singapore signed the FCTC in 2004. Two FCTC obligations, (a) imposing a comprehensive ban on tobacco advertising, promotion and sponsorship; and (b) extending health warning labels to the outer packaging, and prohibiting false and misleading packaging and labelling of tobacco products, were fulfilled by the Smoking (Control of Advertisements and Sale of Tobacco) (Amendment) Act 2010. Due to fundamental changes in the scope of the Smoking (Control of Advertisements and Sale of Tobacco) Act,[41] this Act will be renamed the Tobacco (Control of Advertisements and Sale) Act.

24 Apart from the FCTC amendments, innovative and alternative tobacco products will be prohibited by an interesting amendment to s 15 of the Tobacco (Control of Advertisements and Sale) Act.[42] Section 15 will cover future variations of emerging products by regulation-making powers to prohibit future innovative products if they do not fit within the current categories of banned tobacco products such as smokeless chewing tobacco. The proposed prohibitions are in line with bans already imposed in several countries including Australia, Canada, and the European Union. The Health Minister explained[43] the concern over the emergence of new and alternative tobacco products. As far back as 1993, the WHO had already expressed concern over new and emerging harmful tobacco products. Since then tobacco companies have become even more aggressive and innovative. Unconventional tobacco products come in various forms – smoked tobacco such as flavoured cigarettes, smokeless tobacco such as tobacco gels, dissolvable tobacco which resembles candy and tobacco substitutes such as e-cigarettes and even drinks like nicotine water. These new and emerging products are being marketed as safer alternatives to cigarettes but they are not. Although these new products have not yet reached Singapore, the legislature has taken the bold pre-emptive step to ban them.

41 Cap 309, 2003 Rev Ed.

42 Cap 309, 2003 Rev Ed.

43 Minister Khaw in moving the second reading of the Smoking (Control of Advertisements and Sale of Tobacco) (Amendment) Bill 2010, *Singapore Parliament Debates, Official Report* (19 July 2010) vol 87.

IV. Ethics of human organ transplantation

25 In the past decade, the issue of international trade in human biological materials and the so-called "transplant tourism" has been widely discussed in many bioethics conferences and forums.[44] There is widespread global consensus that "transplant tourism" and the "commodification" of the human body is ethically wrong. What is not so clear is the extent to which the donor can be compensated or reimbursed for the loss he had incurred for an altruistic act. The Istanbul Declaration permits "comprehensive reimbursement".

26 In the first prosecution and conviction in Singapore involving the illegal purchase of a human organ (kidney), *PP v Tang Wee Sung*,[45] the District Court sentenced retail magnate Tang Wee Sung on 3 September 2008 to a fine of $7,000 under the Human Organ Transplant Act[46] and to one day's imprisonment and a $10,000 fine under the Oaths and Declarations Act.[47] Tang was suffering from end-stage renal failure. His case sparked public debate as over a thousand people face organ failure. Ironically, he received a kidney transplant in January 2009 from an undisclosed donor.[48] Singapore's legislation on human organ transplants can be broadly categorised into opt-in and opt-out legislation. Back in 1972, Singapore had like most other countries an opt-in system. The Medical (Therapy, Education and Research) Act[49] ("MTERA") enacted in 1972 is an opt-in system, which allows anyone at least 18 years old to donate their organs and tissues to be used for transplant, education or research after their death. A gift of all or any part of a body may be made by the donor either in writing at any time or orally in the presence of two or more witnesses during a last illness. A pledge can only be revoked by the person who made the pledge. Upon death, the person's decision will be respected, and his family members will not be able to revoke his pledge. Under the MTERA, one can choose to donate all his or her organs and tissues or specify those he or she wishes to donate. Relatives may also donate the organs of a brain-dead patient who has not made this pledge.

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44 For example, it featured as a major topic in the 9th World Congress of Bioethics, 3–8 September 2008, Rijeka and Opatija, Croatia, and at the 10th World Congress of Bioethics, 28–31 July 2010, Singapore.

45 [2008] SGDC 262.

46 Cap 131A, 2005 Rev Ed.

47 Cap 211, 2001 Rev Ed.

48 *The Straits Times* on 10 January 2009 reported its belief that the kidney came from former triad leader Tan Chor Jin, who gunned down a nightclub owner in 2006. The gangster, dubbed the "One-Eyed Dragon", was sentenced to death and executed at Changi Prison on the same morning of Tang's transplant. Tan's mistress confirmed that his organs were donated.

49 Cap 175, 1985 Rev Ed.

27 In 1987, Singapore was one of the first few countries in the world to switch to the opt-out system by enactment of the Human Organ Transplant Act[50] ("HOTA"). The HOTA allows the kidneys, liver, heart and corneas to be recovered in the event of death[51] in a hospital from any cause for the purpose of transplantation unless the deceased person had earlier opted out of this system. The HOTA applies to all Singapore citizens and permanent residents between 21 and 60 years of age before the 2009 amendments (which removed the upper age limit). Spain has a similar system. Elsewhere in Europe, former British Prime Minister Gordon Brown said in 2009 that: "Organ donation could still be made automatic." A British Private Member introduced in 2009 the Organ Donation (Presumed Consent) Bill 2009 but it was not passed due to lack of parliamentary time.

28 Muslims have been included under the HOTA[52] since 1 August 2008. Before that, Muslims who wished to donate their organs had to opt-in under the MTERA.[53] The HOTA also does not apply to those of unsound mind. Those who do not opt-out under the HOTA will not only have the chance to help others, but will also have higher priority on the waiting lists for organ transplant.

A. Addressing cultural and religious sensitivities

29 It was a deliberate decision in 1987 to exclude Muslims from the HOTA[54] because a *Fatwa* (Islamic legal ruling) then required the consent of two *waris* (paternal next-of-kin, according to Islamic hierarchy) for organ donation. As actual consent is required, presumed consent was excluded. Even so, the Singapore Islamic religious authority known as the Majlis Ugama Islam Singapura ("MUIS") made it clear that organ donation to save lives was permissible under Muslim law. Muslims who wished to donate their organs could do so by making a pledge under the MTERA.[55] In accordance with the ethical principle of fairness and reciprocity, Muslims who did not opt in were accorded a lower priority

50 Cap 131A, 2005 Rev Ed.

51 The Interpretation Act (Cap 1, 2002 Rev Ed) was amended in 1998 to introduce criteria for determining "death" (s 2A) as cardiac death or brain death. Cardiac death is defined as the irreversible cessation of blood and respiration in the body. Brain death is defined as the total and irreversible cessation of all functions of the brain. The certification of brain death for Human Organ Transplant Act (Cap 131A, 2005 Rev Ed) organ removal must be by two independent medical practitioners with prescribed postgraduate medical qualifications (s 2A(6) of the Interpretation Act). The criteria for brain death and the postgraduate qualifications are prescribed in Interpretation (Determination and Certification of Death) Regulations (Cap 1, Rg 1, 2000 Rev Ed).

52 Human Organ Transplant Act (Cap 131A, 2005 Rev Ed).

53 Medical (Therapy, Education and Research) Act (Cap 175, 1985 Rev Ed).

54 Human Organ Transplant Act (Cap 131A, 2005 Rev Ed).

55 Medical (Therapy, Education and Research) Act (Cap 175, 1985 Rev Ed).

than non-Muslims who did not opt out. However, Muslims who opted in under the MTERA were accorded the same priority as non-Muslims who did not opt out under the HOTA.

30 This legislative approach is justifiable under Art 15(3)(*a*) of the Singapore Constitution[56] which preserves the right of Muslims (as a religious group) to manage their own religious affairs and Art 153 of the Constitution which empowers Parliament to "by law make provision for regulating Muslim religious affairs". In 2006, the Fatwa Committee of the Islamic Religious Council of Singapore (MUIS) launched a review of the *Fatwa* on organ donation. While there were concerns on practical aspects of transplantation, the Muslim community generally voiced acceptance of organ donation and supported the MUIS move to increase the number of Muslim donors. Full equality was achieved when the legislative amendments in 2008 included Muslims after the Fatwa Committee issued in July 2007 a new *Fatwa* making it permissible for Muslims to be covered under the HOTA.[57] MUIS identified the need for organ donation among Muslims and advances in medical sciences and technology as reasons underlying the change.[58]

B. First human organ trading case

31 As mentioned above, in the first case in Singapore involving the illegal purchase of a human organ (kidney), *PP v Tang Wee Sung*,[59] the District Court sentenced retail magnate Tang Wee Sung on 3 September 2008 to a $7,000 fine under the HOTA[60] and to one day's imprisonment and a $10,000 fine for making a false statutory declaration. In *PP v Sulaiman Damanik*,[61] Sulaiman Damanik, 26, who agreed to sell his kidney to Tang, was sentenced to two weeks imprisonment and fined

56 Constitution of the Republic of Singapore (1999 Rev Ed).

57 Human Organ Transplant Act (Cap 131A, 2005 Rev Ed).

58 Health Minister Khaw Boon Wan announced in Parliament on 10 February 2009 that the number of Muslim patients who received organ transplants had doubled to 38 in the span of just five months since the Human Organ Transplant Act (Cap 131A, 2005 Rev Ed) was amended (1 August 2008) to cover the community. The number was just 19 for the whole of 2007. In terms of percentage of all patients receiving transplants, Muslim recipients had increased their proportion from 11% in the past to 19% in 2008. Since 1 August 2008, four Muslim donors had donated eight kidneys, three livers and four corneas, giving 15 persons a new lease of life. The Health Minister also explained non-legislative measures to take care of the cultural and religious sensitivities of Muslims. For example, the hospitals are sensitive to the need of relatives to take the bodies of their loved ones as soon as possible for religious rites. Adequate washing facilities in hospitals and a second sitting for coroner's cases are also now available to reduce possible delays. See *Singapore Parliamentary Debates, Official Report* (10 February 2009) vol 85.

59 [2008] SGDC 262.

60 Human Organ Transplant Act (Cap 131A, 2005 Rev Ed).

61 [2008] SGDC 175.

$1,000. As he could not pay the fine, he was imprisoned for another one week. Sulaiman's compatriot, Toni, who was a runner for an organ-trafficking syndicate and had sold his kidney to an Indonesian woman, Juliana Soh, was sentenced to three months imprisonment and fined $2,000. In *PP v Wang Chin Sing*,[62] Wang Chin Sing, the middleman who received $300,000 from Tang for brokering the illegal kidney-for-sale transaction, was sentenced to a 14-month imprisonment term.

C. Aftermath of Tang Wee Sung

32 *Tang Wee Sung*'s case sparked public debate over organ transplantation as over a thousand people face organ failure. The public consultation exercise conducted by the Ministry of Health from 14 November to 15 December 2008 sought feedback on proposed amendments to the HOTA.[63] The responses received from the public, medical profession and non-governmental organisations showed that Singaporeans were supportive of the proposed amendments. The Minister for Health explained at the second reading of the HOTA amendment Bill that:[64] "Our current legislation, pretending that donors need not be compensated, is one extreme."

33 The public consultation revealed that more than 85% of respondents[65] were in support of the four changes introduced by the Bill. Some reservations from the public feedback were expressed on use of the word "compensation" because it could be misunderstood as payment for the organ and that it could amount to an inducement to donate the organ, and discourage altruistic organ donation. Many, however, agreed with reimbursing and defraying the costs incurred by living donors to cover direct expenses (*eg*, transport and accommodation), indirect losses (*eg*, loss of time and earnings) and future expenses (*eg*, anticipated costs of medical follow-up).

34 The HOTA (Amendment) Bill 2009 was tabled on 19 January 2009 and passed on 24 March 2009. In recognition of the sensitivities, the Whip was lifted and at least one People's Action Party ("PAP")

62 [2008] SGDC 268.

63 Human Organ Transplant Act (Cap 131A, 2005 Rev Ed).

64 *Singapore Parliamentary Debates, Official Report* (24 March 2009) vol 85 at cols 3524–3604.

65 The support levels were:

(a) Lifting the upper age limit for cadaveric organ donation (93%).

(b) Allowing donor-recipient paired matching for exchanges of organs (96%).

(c) Increasing penalties for organ trading syndicates and middlemen (96%).

(d) Some form of payment to living organ donors (86%).

Member of Parliament ("MP") (Christopher De Souza) voted against the Bill. The Minister explained that:[66]

> This is a Bill about fairness, being fair to donors who do suffer financial consequences as a result of their act of donation. The current law short changes them.

35 The amendment Act introduced four main changes. First, to widen the pool of organ donors by removing the prohibition against harvesting the organs of a dead person above 60 years old (prohibition in s 5(2)(*d*) repealed). Second, to expressly allow paired living donor organ transplant arrangements and to remove doubt that such arrangements do not constitute inducement. Third, to allow the comprehensive reimbursement of costs and expenses incurred by a living organ donor. Fourth, to enhance the penalties for intermediaries in organ trading.

D. Lifting age limit

36 The intention behind lifting the age limit of 60 years was to widen the pool of organ donors by removing the prohibition against harvesting the organs of a dead person above 60 years old (prohibition in s 5(2)(*d*) repealed) (cl 2). This age limit was set many years ago as a proxy indicator of a person's health in relation to his suitability as a donor. In practice, whether an organ can be used for transplant depends on the organ's condition and not the age of the donor. The Minister estimated that this could increase the number of cadaveric organ donors by ten to 12 each year. On the flip side, lifting the age limit would also increase the number of older persons on the waiting list.[67]

E. Allow paired matching

37 The amendment Act expressly allows paired living donor organ transplant arrangements so as to remove any doubt that such arrangements do not constitute inducement. So, for example, Angela Heckman received a kidney from a stranger, and then her mother,

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66 *Singapore Parliamentary Debates, Official Report* (24 March 2009) vol 85 at cols 3524–3604.

67 In relation to the effect on the waiting list, the Minister said at the parliamentary debate on 24 March 2009: "Dr Lim Wee Kiak asked what would happen to the waiting list once we lifted the age limit. Dr Loo Choon Yong has mentioned the figure of 563 … once we lift the HOTA age limit, we must by reciprocity also allow seniors above 60 to remain on the waiting list. Our preliminary projection is that the list will then surge beyond 1,000. But that has to be the case because once we lift the age limit, we must expect that more seniors will be able to benefit from the amendment." See *Singapore Parliamentary Debates, Official Report* (24 March 2009) vol 85 at cols 3524–3604.

Laurie Sarvo, whose kidney did not match her daughter, donated her kidney to another stranger in a successful chain of transplants facilitated by Dr Michael Rees in Toledo, Ohio.

38 Professor Thio Li-ann, NMP posed the interesting question:[68]

> …what measures will be taken to ensure that no one backs out of this sort of arrangement? I understand in other jurisdictions that such operations are done simultaneously, requiring four operating rooms, to ensure the recipients that both will receive their donated kidneys.

39 The Minister replied in the affirmative. But he added that although the Ministry of Health can achieve such an outcome administratively, his Ministry will study if there is a need for an explicit regulation. He said:

> Indeed, this will be the requirement for paired matching, that the surgeries will all be done simultaneously. Our Bill includes provisions for subsidiary legislation to be made to regulate organ transplant arrangements, including mandating that paired transplants be simultaneously performed, if it is necessary. We can achieve such an outcome administratively … but we will study if there is a need for an explicit regulation.

F. Allow comprehensive reimbursement

40 In view of the negative feedback, the word "compensation" was removed. Instead, "comprehensive reimbursement" is permitted, in money or money's worth, of costs, expenses and loss of earnings reasonably incurred by altruistic living organ donors. Such reimbursements include the costs of travel, accommodation costs, domestic help, and child care necessary as a consequence of organ donation. As the Minister explained succinctly:[69]

> First, there was concern over the use of the term 'compensation'. We used that term in the original draft Bill. Some Singaporeans felt that it might be misconstrued as the legalisation of organ trading. We have thus removed the term 'compensation' and instead used the words 'defraying' and 'reimbursing' to refer to the payment to cover the costs or expenses that a donor incurs as a result of his donation. Hospital transplant ethics committees will continue to screen living donor transplants to weed out organ trading.

41 While all MPs supported the good intention to reduce financial losses incurred by donors through reasonable payment, many MPs were

68 See *Singapore Parliamentary Debates, Official Report* (24 March 2009) vol 85 at cols 3524–3604.

69 See *Singapore Parliamentary Debates, Official Report* (24 March 2009) vol 85 at cols 3524–3604.

concerned that it might lead to organ trading, and Singapore becoming a regional organ trading hub. MPs (*eg*, PAP MP Christopher de Souza and opposition Workers Party MP Sylvia Lim) were concerned that the coverage of reimbursement under the Bill was so wide that it could be a backdoor for organ trading. The Minister reiterated that this Bill does not legalise organ trading.

G. International norms – Istanbul Declaration 2008

42 Are the HOTA amendments in accordance with international norms? The Declaration of Istanbul on Organ Trafficking and Transplant Tourism ("Istanbul Declaration") was made on 2 May 2008. Clause 6 of the 2008 Istanbul Declaration provides that: "Comprehensive reimbursement of the actual, documented costs of donating an organ does not constitute a payment for an organ but is rather part of the legitimate costs of treating the recipient."

43 Clause 7 further provides that legitimate expenses that may be reimbursed when documented include the following:

> (a) costs incurred in arranging and effecting the preoperative, perioperative, and postoperative phases of the donation process (*eg*, long-distance telephone calls, travel, accommodation, and subsistence expenses);
>
> (b) medical expenses incurred for post discharge care of the donor; and
>
> (c) lost income in relation to donation (consistent with national norms).

44 The HOTA amendments also include provision of the reasonable costs or expenses of short-term or long-term medical care or insurance protection which is or may reasonably be necessary as a result of the donation of the organ by an altruistic living donor. Clause 5 of the Istanbul Declaration states that:

> Provision of care includes medical and psychosocial care at the time of donation and for any short- and long-term consequences related to organ donation. In jurisdictions and countries that lack universal health insurance, the provision of disability, life, and health insurance related to the donation event is a necessary requirement in providing care for the donor. In those jurisdictions that have universal health insurance, governmental services should ensure donors have access to appropriate medical care related to the donation event. Health and/or life insurance coverage and employment opportunities of persons who donate organs should not be compromised.

H. International norms – WHO

45 The recent WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation were endorsed by the 63rd World Health Assembly in May 2010, in Resolution WHA63.22. Guiding Principle 5 states that the prohibition on sale or purchase of cells, tissues and organs does not preclude reimbursing reasonable and verifiable expenses incurred by the donor, including loss of income, or paying the costs of recovering, processing, preserving and supplying human cells, tissues or organs for transplantation.[70]

I. Enhancing penalties against organ traders/brokers

46 In *Wang Chin Sing v PP*,[71] the High Court dismissed the organ broker Wang's appeal to reduce his 14 months' imprisonment sentence. In his judgment, V K Rajah JA said the sentence was "amply justified" and sent a clear message that organ trafficking would not be tolerated in Singapore.[72] Rajah JA said: "The appellant has peddled deceit, trafficked in organs and profiteered from misery." Rajah JA highlighted the role of "shady middlemen" who exploit desperately ill buyers and financially disadvantaged sellers, usually inspired by "unbridled avarice to maximise their financial returns" from each transaction.[73] As a strong stand against organ trading, a specific offence of commercial dealings in organs by intermediaries (middlemen) was created with enhanced penalties of a maximum $100,000 fine or maximum ten years' imprisonment or both.

V. Mental capacity and mental health

47 The Mental Capacity Act 2008[74] reforms and updates the law where decisions need to be made on behalf of persons lacking capacity

70 The World Health Organization's explanation to Guiding Principle 5 explains that this Principle permits compensation for the costs of making donations (including medical expenses and lost earnings for live donors), lest they operate as a disincentive to donation. The need to cover legitimate costs of procurement and of ensuring the safety, quality and efficacy of human cell and tissue products and organs for transplantation is also accepted as long as the human body and its parts as such are not a source of financial gain. Incentives that encompass essential items which donors would otherwise be unable to afford, such as medical care or health insurance coverage, raise concerns. Access to the highest attainable standard of health is a fundamental right, not something to be purchased in exchange for body parts. However, free periodic medical assessments related to the donation and insurance for death or complications that arise from the donation may legitimately be provided to living donors.

71 [2009] 1 SLR(R) 870.

72 *Wang Chin Sing v PP* [2009] 1 SLR(R) 870 at [6].

73 *Wang Chin Sing v PP* [2009] 1 SLR(R) 870 at [1] and [3].

74 Cap 177A, 2010 Rev Ed.

in two situations: (a) where they lose mental capacity at some point in their lives (*eg*, as a result of dementia or brain injury) and (b) where the incapacitating condition has been present since birth. The Act came into operation on 1 March 2010. A new statutory form of power of attorney known as the lasting power of attorney has been created. The donor is enabled to confer on the donee authority to make decisions about the donor's personal welfare, property and affairs when the donor no longer has capacity to make such decisions. Excluded decisions include consent to marriage, adopting or renouncing a religion, making or revoking a Central Provident Fund nomination and registering or withdrawing an objection to human organ transplantation. This reform is long overdue as the repealed Mental Disorders and Treatment Act was widely criticised as being archaic, cumbersome and out of synch with modern medical concepts of mental capacity. For example, the concept of unsound mind has been jettisoned in favour of the concept of mental capacity. The introduction of the lasting power of attorney was a quantum leap for Singapore in that, unlike the UK, Singapore did not have the "enduring power of attorney"[75] which was the predecessor in UK to the "lasting power of attorney". Unlike the UK, the Singapore lasting power of attorney cannot apply to the refusal of life sustaining treatment. This has to be left to the Advance Medical Directives Act.[76] The Health Ministry has indicated in 2008 that it is reviewing the Advance Medical Directive Act to encourage more Singaporeans to make such directives.[77]

48 The Mental Health (Care and Treatment) Act 2008[78] enhanced the safeguards for the protection of the interests of patients who are compulsorily admitted into psychiatric institutions. Provisions regulating the admission and detention of persons of unsound mind in mental hospitals which were previously set out in the Mental Disorders and Treatment Act were repealed and re-enacted under the new Act.

VI. Regulation of health care professionals

49 Ethical standards of medical practitioners and allied healthcare professionals are maintained through regulatory legislation and disciplinary processes. The decade saw the introduction of legislation to regulate optometrists and opticians in 2007.[79] Substantial amendments were made to the legislation regulating the profession closest to medical

75 Introduced by the UK Enduring Powers of Attorney Act 1985 (c 29), which was in turn repealed by the UK Mental Capacity Act 2005 (c 9) with effect from 2007.

76 Cap 4A, 1997 Rev Ed.

77 Imelda Saad, "More 'die-logues' expected as govt considers changes to AMD" *Channel NewsAsia* (17 November 2008).

78 Act 21 of 2008.

79 Optometrists and Opticians Act (Cap 213A, 2008 Rev Ed).

practitioners, namely, dentists. The Dentists (Amendment) Act 2007 revised and renamed the Dentists Act to become the Dental Registration Act.[80] An Allied Health Professionals Bill 2010 was released for public consultation by the Ministry of Health in September 2010. The proposed omnibus legislation will seek to regulate all allied health professions in Singapore for the protection of the public. Apart from establishing a regulatory body under the Ministry of Health for the registration of allied health professionals, the proposed legislation will also establish a regime for complaints management, inquiry, investigation and discipline of cases involving registered persons. For a start, only occupational therapists, physiotherapists and speech therapists will be regulated. As regards the primary health professionals, *viz* doctors, a major overhaul of the Medical Registration Act[81] was enacted in 2009 after lengthy consultations.

A. Medical practitioners – Doctors

50 The Medical Registration (Amendment) Act 2010 was the culmination of a major review of the Medical Registration Act[82] to address new issues that have arisen in the areas of professional conduct and standards of health care, and to provide for mechanisms to ensure that medical practitioners are competent and fit to practise medicine. Moving the second reading of the Bill in Parliament, Health Minister Khaw Boon Wan noted that Singapore has enjoyed high standards of medical practice.[83] But despite this, he added that there is still a need to tighten the Singapore Medical Council's ("SMC") disciplinary processes. Minister Khaw said the number of complaints against doctors has gone up, from 66 in 2003 to 96 in 2009 – partly due to the increase in the number of doctors. There were over 9,000 doctors in 2008, compared to 6,300 in 2003. This works out to about 11 complaints *per* 1,000 doctors a year. The Minister explained that though not alarming, the Council's capacity to cope with the rising number of complaints has not changed. The new legislation aims to address this problem by speeding up the disciplinary process. The delay in the process was candidly explained by the Health Minister:

> Last year, for example, a simple complaint took about three months to conclude, and a complex case actually took more than five years. As a result of long delay, there have been instances where the complainant who was dissatisfied with the outcome of the disciplinary process, was unable to initiate civil proceedings against the doctor. The

80 Cap 76, 2009 Rev Ed.
81 Cap 174, 2004 Rev Ed.
82 Cap 174, 2004 Rev Ed.
83 *Singapore Parliamentary Debates, Official Report* (11 January 2010) vol 86 at col 1895–1962.

> complainant also has no recourse for appeal against the Disciplinary Committee's decision under the current Act. This is unsatisfactory.

51 One deficiency in the regime was that absent from the composition of the Disciplinary Committee ("DC") was a lawyer. Given the quasi-judicial nature of the disciplinary proceedings and the common law requirement that the standard of proof is that of beyond a reasonable doubt, it is not surprising that persons who are not legally trained would face difficulty handling the proceedings and adversarial counsel correctly and appropriately. This deficiency was highlighted in an appeal to the High Court comprising three judges in *Gobinathan Devathasan v Singapore Medical Council*[84] ("*Gobinathan*"). Justice V K Rajah JA in *Gobinathan* made the following general observations soon after the Bill was passed by Parliament:

> 77 In closing, we find it necessary to express our concern that the DC's failure to understand the nature of the charge against Dr Devathasan and the evidence required to prove the same left much to be desired. The proceedings against Dr Devathasan, beginning with the framing of the original charges, to the amendment of the same very late in the day, to the relevancy of the evidence that was adduced to prove the charge, and finally the legal reasoning leading to the finding of guilt against Dr Devathasan on the Second Charge, could have been better handled.

52 Rajah JA was unequivocal in his criticism of the DC in somewhat harsh terms:[85]

> In the present case, the DC tied itself up in a confusing pattern of intricate legal knots which we have found impossible to unravel without having to set aside the conviction.

53 The proposal to allow a senior lawyer or former judge to chair the DC was met with stiff resistance from the medical fraternity who felt that it was an affront to their profession for their disciplinary proceedings to be presided over by a lawyer and not a doctor. On the other hand, V K Rajah JA in *Gobinathan* welcomed this approach:[86]

> In this connection, it is just as well that the Act has been recently amended to allow the appointment of a legally trained person (be it an ex-Judge or ex-Judicial Commissioner of the Supreme Court, an advocate or solicitor of at least 15 years' standing, or a legal officer from the Singapore Legal Service with at least 15 years' experience) to sit as one of the members in the SMC's Disciplinary Committees. Unlike the external legal assessor who only advises on issues referred to him or her, we believe that having a legally trained member as part

84 [2010] 2 SLR 926 at [77].
85 *Gobinathan Devathasan v Singapore Medical Council* [2010] 2 SLR 926 at [77].
86 *Gobinathan Devathasan v Singapore Medical Council* [2010] 2 SLR 926 at [77].

of a Disciplinary Committee would ensure due process and a fuller appreciation of the nature of the proceedings against alleged errant doctors.

54 One innovative change is that a medical practitioner who is aware of his own disability or inability to perform competently can voluntarily request the SMC to remove his name from the register or suspend him without the stigma of going through the disciplinary process. Previously, the appeal process was one-sided in favour of the physician but the SMC is now empowered to appeal to the High Court against the tribunal's decision. An aggrieved complainant cannot appeal directly but he is enabled to apply to a Review Committee appointed by the Minister which can require the SMC to file such appeal to the High Court. This mechanism will save the complainant from having to incur legal fees and operates as a filtering process against frivolous appeals.

55 Recognition of family physicians was accorded by the establishment of a Register of Family Physicians ("RFP") and a Family Physicians Accreditation Board ("FPAB"). Physicians who have been certified by the FPAB as sufficiently qualified in family medicine may be registered in the RFP as a family physician, subject to any conditions or restrictions that the SMC may impose. The FPAB may determine the training programmes to be recognised for persons applying to be registered as family physicians as well as continuing medical education for persons who are so registered. The Specialists Accreditation Board was also empowered to define areas of sub-specialties within specialties.

VII. Governance for biomedical research and biosafety

56 Dolly the sheep became a scientific sensation when her birth was announced in 1997. Her relatively early death in February 2003 fuels the debate about the ethics of cloning research and the long-term health of clones. In 2000, the Bioethics Advisory Committee ("BAC") was created to examine the ethical, legal and social issues arising from biomedical research and to recommend policies. The BAC's first report issued on 21 June 2002 was entitled "Ethical, Legal and Social Issues in Human Stem Cell Research, Reproductive and Therapeutic Cloning".[87] The BAC recognised that it is crucial to set up a comprehensive legislative and regulatory framework to control human stem cell research, and proposed the setting up of a regulatory body to license, control and monitor human stem cell research in Singapore. As for reproductive cloning, the BAC took the view that the creation of a

87 Available at <http://www.bioethics-singapore.org/> (accessed 15 October 2010). See Knoppers, Kirby & Isasi, "Genetics and Stem Cell Research: Models of International Policy-making" in *Bioethics in Singapore, the Ethical Microcosm* (Elliott, Ho & Lim eds) (World Scientific, 2010).

human being by any cell nuclear replacement techniques or any other method should be prohibited as the public policy reasons against this are overwhelming. The Singapore legislature responded in 2004 by banning human reproductive cloning through the enactment of the Human Cloning and Other Prohibited Practices Act 2004.[88] It also prohibits the import and export of any human embryo clone into and out of Singapore and the commercial trading of human eggs, sperm and embryos. The Act also prohibits the practices associated with reproductive cloning such as prohibiting the development of human embryos outside of the body of a woman for a period of more than 14 days. The policy framework established by the BAC is reinforced by the Directives for Private Healthcare Institutions Providing Assisted Reproduction Services issued by the Ministry of Health. These Directives established the regulatory framework for all research involving human embryos and oocytes.[89]

57 It was reported in the media on 1 February 2007 that the Singapore Health Ministry was studying legislation on biomedical research, particularly on the import of human eggs and embryo for research.[90] One lacuna is that there is no legislative prohibition against a scientist working in Singapore from importing human eggs and embryos less than 14 days old for his research. In Singapore, only doctors can harvest human eggs and embryos, and these medical professionals are well-regulated under the Medical Registration Act[91] and the SMC's Ethical Code and Ethical Guidelines. But a scientist who procures human eggs and embryos from sources outside Singapore is not covered by the Medical Registration Act.[92] As mentioned above, under the Directives for Private Healthcare Institutions Providing Assisted Reproduction Services, research on or using human embryos which are more than 14 days old from the time of creation is prohibited. But the Act does not cover the import of embryos under 14 days old, eggs and other biological tissues. Interestingly, the Ministry of Health had on 10 November 2003 conducted a public consultation exercise on the draft Regulation of Biomedical Research Bill. A total of 319 responses on the draft Bill were received from various professional organisations, religious groups, members of the general public and the scientific research community. Respondents generally agreed that

88 Cap 131B, 2005 Rev Ed.

89 Private Hospitals and Medical Clinics Regulations (Cap 248, Rg 1, 2002 Rev Ed) reg 4 mandates compliance with the Directives. Cited in Knoppers, Kirby & Isasi, "Genetics and Stem Cell Research: Models of International Policy-making" in *Bioethics in Singapore, the Ethical Microcosm* (Elliott, Ho & Lim eds) (World Scientific, 2010).

90 Hasnita A Majid "Health Ministry considering legislation on biomedical research" (1 February 2007) <channelnewsasia.com>.

91 Cap 174, 2004 Rev Ed.

92 Cap 174, 2004 Rev Ed.

biomedical research should be conducted in an ethical manner, and supported the Ministry's efforts to regulate biomedical research through a legislative framework. This Regulation of Biomedical Research Bill was not, however, introduced in Parliament. The Ministry explained on its website that after carefully considering the feedback that was received, it decided "to adopt a step-by-step approach to regulating biomedical research activities".[93] As a first step, it proposed to enact the Human Cloning and Other Prohibited Practices Act[94] to prohibit human reproductive cloning, as this is the issue associated with the greatest ethical concerns. On hindsight, this author agrees that this minimalist and light-touch pragmatic approach by the Ministry may well have contributed to the thriving biomedical research environment over the past decade. Highly prescriptive regulatory legislation may actually hinder research in unforeseen ways and give rise to satellite litigation. Scientific advancements might render the statutory definitions of technical terms obsolete. On 27 September 2010, the Ministry of Health issued a public statement[95] accepting the BAC's recommendations on human-animal combinations ("HAC") in stem cell research. The BAC released its report earlier on 22 September 2010 entitled "Human-Animal Combinations in Stem Cell Research".[96] The BAC report supported only two types of HAC research: (a) the creation of cytoplasmic hybrids; and (b) the introduction of human stem cells into animals, in view of their potential scientific value and likely importance to Singapore. The BAC report used the phrase "strong scientific merit in, and potential medical benefit from, such research". The BAC also recommended that a single national body, which must include lay members of the public, should be established to review and monitor all stem cell research involving human pluripotent stem cells or human-animal combinations conducted in Singapore. This body should also be empowered to determine the kinds of research that need not undergo its review.

58 The Ministry agreed with the BAC that stem cell research involving these two types of HAC and with clear therapeutic potential, should be supported provided it is strictly regulated. The Ministry also announced that it will set up a robust regulatory framework to ensure that such research operates within boundaries acceptable to society. The Ministry will draft a new Bill to regulate research involving cytoplasmic hybrids and the introduction of human pluripotent stem cells into animals. The recommendations of BAC will be fully incorporated in this

93 See <www.moh.gov.sg> at Legislation E-Consultation (accessed 15 October 2010).
94 Cap 131B, 2005 Rev Ed.
95 "MOH accepts Bioethics Advisory Committee's recommendations on Human-Animal Combinations in Stem Cell Research" MOH Press Release (27 September 2010), available at <www.moh.gov.sg> (accessed 15 October 2010).
96 Available at <http://www.bioethics-singapore.org/> (accessed 15 October 2010).

Bill. MOH will also work with the Ministry of National Development and the Agri-Food and Veterinary Authority to establish a robust enforcement framework to ensure compliance with BAC's recommendations. The Ministry also revealed that in developing the Bill by 2011, it will study best practices from overseas.

59 A biological agent accident occurred at Singapore's Environmental Health Institute ("EHI") in 2003, when a National University of Singapore researcher was infected with SARS there. The EHI, which stopped its high-safety-level research after the SARS case, resumed such research in 2005 when it moved to new premises at the biomedical hub, Biopolis, in Buona Vista. The highest safety-level labs in Singapore work on the stringent biosafety level ("BSL") 3 standards, which are needed for research on SARS, West Nile virus and Japanese encephalitis. Most other laboratories in Singapore, which deal with less dangerous agents, follow the lower BSL 2 standards.

60 In 2005, the Biological Agents and Toxins Act[97] was enacted to impose criminal penalties on the operators of laboratories that handle biological agents and toxins if they fail to obtain regulatory approval to possess or transfer such materials. The most severe penalty – a fine of $1m and/or life imprisonment – will be imposed on a person found using or possessing a biological agent for biological warfare or non-peaceful purposes.[98] The provisions of the Act cover facilities, agents and transport controls. Laboratory operators are required to set up biosafety committees and appoint co-ordinators. They will also have to ensure that their facilities and equipment are safe and in working condition, and that no biological material, including waste, is discharged into the environment.

61 "There has been an increase in the number of institutions working with high-risk biological agents and toxins in Singapore," said Professor K Satku, director of medical services at the Ministry of Health, which is the lead agency for the Biological Agents and Toxins Act.[99] "Hence, it is necessary that operators of high-containment laboratories put in place the management structure, engineering control as well as work procedures and practices to protect the laboratory workers, the general public and the environment from exposure to high-risk biological agents and toxins."[100]

97 Cap 24A, 2006 Rev Ed.

98 See Biological Agents and Toxins Act (Cap 24A, 2006 Rev Ed) s 5(2).

99 Cap 24A, 2006 Rev Ed.

100 Jean Chua, "Stiff penalties for those who flout biomedical safety" *Business Times* (12 April 2005).

A. Protection of data in medical research

62 In moving the National Registry of Diseases Bill on 12 November 2007, Health Minister Khaw Boon Wan recounted historical attempts at registering diseases:[101]

> Formal attempts at registering diseases date back to 1728, the year of London's first General Census of Cancer. This was followed by attempts in the Netherlands, Spain, Portugal, Sweden, Hungary, among other countries. Most of these attempts failed due to incompleteness of data, as the reporting was voluntary. The breakthrough came from the United States where a regulation was enacted in 1939, requiring reporting of all cancer cases diagnosed in New York State. Since then, the US has made cancer reporting mandatory in most of its states. Similar laws have been passed over the last 50 years in Canada, Australia, New Zealand, Denmark, Norway, Finland and Germany, just to name a few. We have studied their legislation and drawn on relevant features when drafting our own Bill.

63 The National Registry of Diseases Act was enacted in 2007 to establish the National Registry of Diseases and impose mandatory obligations[102] on healthcare institutions to submit relevant epidemiological data to the National Registry of Diseases for public policy and planning purposes.[103] The Minister conceded that the Act commits the Ministry to responsible stewardship in the storage and disclosure of registry data by ensuring that patient confidentiality is observed by all persons who maintain and use the data. The registry is already subject to stringent governance standards in securing the information collected and protecting patient confidentiality. The Act articulates these practices and provides for powers of enforcement.

64 Of ethical importance is the fact that the patient's consent for the disclosure is not required but the *quid pro quo* are the safeguards imposed on the registry as custodian of the confidentiality of such patient information. Minister Khaw explained that the National Registry of Diseases Act[104] drew upon the recommendations of the BAC in its

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101 *Singapore Parliamentary Debates, Official Report* (12 November 2007) vol 83 at cols 2532–2574.

102 The National Registry of Diseases Act (Cap 201B, 2008 Rev Ed) (s 6) imposes on the manager of a healthcare institution the duty to notify the Registrar of cases in which a person has been diagnosed with or undergoing treatment for a reportable disease at the healthcare institution. The Act (s 7) empowers the Registrar or an authorised registry officer to collect prescribed additional information from the manager of a healthcare institution who has made such a notification.

103 The long title of the National Registry of Diseases Act (Cap 201B, 2008 Rev Ed) explains it as "to provide for the compilation of information on the incidence of certain diseases for use as a basis for the direction of programmes for disease prevention and control".

104 Cap 201B, 2008 Rev Ed.

2007 report, "Personal Information in Biomedical Research"[105] after an extensive public consultation among doctors, members of the public, experts in ethics and international scientists. Among other things, the BAC concluded that it is "ethically proper for medical information to be disclosed by physicians to national disease registries without patients' consent, provided that adequate privacy and other ethical safeguards are in place and patients are appropriately informed".

65 The National Registry of Diseases Act[106] clearly lays down the rules as to whom, and for what purpose, and in what form, the information can be released. In addition to its primary use by the Ministry of Health for healthcare policy planning, it was anticipated that the public, doctors, academics and researchers will want to know key statistics about the chronic diseases. The registry will therefore publish reports of analysed data in simplified form on a regular basis. Such reports will be made publicly available. The Registrar of the National Registry of Diseases is also empowered to release de-identified or anonymised data for research of significant public health importance that has undergone rigorous scientific, ethical and regulatory scrutiny. There is persuasive UK authority that disclosure of anonymised patient information does not breach confidentiality. The UK Court of Appeal in *R v Department of Health, ex parte Source Informatics Ltd*[107] held, *inter alia*, that where a patient's identity was protected, it would not be a breach of confidence for general practitioners and pharmacists to disclose to a third party, without the patient's consent. Source Informatics operated a scheme whereby patient drug prescription information was obtained from general practitioners and pharmacists. The information came from prescription forms each of which contained the doctor's name, the patient's name, the date of prescription, the product prescribed and the quantity prescribed. Pharmacists, for their own purposes, entered all that information on to their computer database together with specific details of the drug dispensed and the date of dispensing. All the information on the prescription forms, except for the patient's identity, was passed on to the applicants by means of specially designed computer software. The anonymised information was sold by the applicants to pharmaceutical companies who used it for marketing purposes. The UK Department of Health issued a policy document advising that the anonymisation of such information would not remove the duty of confidence owed to patients. Source Informatics brought judicial review proceedings against the Department seeking a declaration that the policy guidance was wrong.

105 Available at <http://www.bioethics-singapore.org/> (accessed 15 October 2010).
106 Cap 201B, 2008 Rev Ed.
107 [2001] QB 424.

66 The national registry of diseases[108] is a centralised, disease-specific database that can be used to study disease trends, outcomes and impact of national disease prevention and control policies. The diseases covered in the national registry are cancer, end-stage renal diseases, acute myocardial infraction (heart failure) and stroke. The cancer registry was the first to be established in Singapore in 2001.

67 Identifiable patient information may be disclosed under the National Registry of Diseases Act[109] for the purposes of national public health programmes. Such disclosure will require the approval of the Director of Medical Services. In deciding whether to give his approval, the Director of Medical Services will, amongst other things, consider the aims and objectives of the proposed programme, and whether it has any public health benefits for Singapore. He must be satisfied that the programme cannot be carried out using anonymised data. In addition, the Director of Medical Services must also be convinced that adequate measures will be put in place to protect the individually-identifiable information from unauthorised disclosure. The consent of the patient is not required.

68 The National Registry of Diseases Act[110] also permits identifiable patient information to be disclosed for the purposes of medical treatment or for public health research. In contradistinction with disclosure for national public health programmes, disclosure for these purposes will only be permitted if the person to whom the identifiable information relates has given the requisite consent. National Registry of Diseases data will not be released for other purposes, for instance, to employers or insurance companies.

VIII. Conclusion – Directions for next decade

69 What direction is the Singapore legislature likely to head in the next decade? We have had glimpses into a new Allied Health Professionals Bill, a review of the Advance Medical Directives Act[111] as well as the forthcoming comprehensive legislation on biomedical research. It is highly likely that legislative directions will be responses to future bioethical issues over the horizon. John Elliott bravely addressed the issue of how future bioethical issues will engage Singapore.[112] In

108 Maintained by the National Registry of Diseases Office of the Health Promotion Board. See www.nrdo.gov.sg (accessed 15 October 2010).

109 Cap 201B, 2008 Rev Ed.

110 Cap 201B, 2008 Rev Ed.

111 Cap 4A, 1997 Rev Ed.

112 John M Elliott, "How Will Future Bioethical Issues Engage Singapore?" in *Bioethics in Singapore, the Ethical Microcosm* (Elliott, Ho & Lim eds) (World Scientific, 2010).

exploring the ethical future, Elliott identified the future issues of enhancement, primate disease models and artificial intelligence and synthetic biology. Enhancement is going beyond curative or restorative power of medicine to enhance and engineer desired outcomes that exceed nature. For example, by producing genetically modified "designer babies". A second issue is the potential use of non-human primates as disease and treatment models. The risk of humanisation of a primate in the use of disease models for treatments is one example of possible ethical concerns in this area. Thirdly, the creation of synthetic life or life-like entities in both biological and cognitive domains might be a possibility. The scenarios depicted in the "Matrix" and "Terminator" movie serials where robots become sentient and intelligent beings might not be just science fiction fantasy.