Sender's Fax: 6533 5700
Sender's DID: 6530 0231
Sender's Email: represent@lawsoc.org.sg

Our Ref: LS/84[PUBCONSULT-GEN]/08/KG
Your Ref: MH 78:18

THE LAW SOCIETY OF SINGAPORE

39 South Bridge Road
Singapore 058673
Tel: 6538 2500
Fax: 6533 5700
Email: lawsoc@lawsoc.org.sg
Website: www.lawsociety.org.sg

PRO BONO SERVICES OFFICE
1 Havelock Square Level 5
Subordinate Courts Complex
Singapore 059724
Tel : 6536 0650
Tel : 6534 1564 (CLAS)
Fax: 6534 5237
Email: ProBonoServices@lawsoc.org.sg
Email: CLAS@lawsoc.org.sg

17 December 2008

Feedback on Proposed Amendments to HOTA
Ministry of Health
College of Medicine Building
16 College Road
Singapore 169854

BY E-MAIL AND POST
E-mail: MOH_HOTA@moh.gov.sg
No. Of pages: 7 page(s)
(including this page0

Attn: Dr Arthur Chern
Director (Health Regulation)

Dear Sir

PUBLIC CONSULTATION ON THE PROPOSED AMENDMENTS TO THE HUMAN ORGAN TRANSPLANT ACT

We refer to your letter dated 14 November 2008 inviting the Law Society to give our views and feedback on the proposed amendments as set out in the Public Consultation Paper 2008 entitled "Proposed Amendments to the Human Organ Transplant Act".

The matter was referred to our committee for views. The members of the committee are-

1. Ms Kuah Boon Theng
2. Ms Mak Wei Munn
3. Ms Audrey Chiang
4. Mr Charles Lin

We are pleased to enclose the committee's views on the matter.

Yours faithfully

Kenneth Goh
Director, Representation and Law Reform

PUBLIC CONSULTATION ON THE PROPOSED AMENDMENTS TO THE HUMAN ORGAN TRANSPLANT ACT

The Law Society has been invited to give its feedback on the Amendments to the Human Organ Transplant Act ("HOTA") proposed by the Ministry of Health ("the Proposed Amendments"). By way of background, the 4-member Committee tasked by the Law Society to discuss and deliberate on the proposed amendments and to submit its draft feedback to the Society are all lawyers who advise healthcare professionals and institutions on a regular basis as part of their professional practice.

The Proposed Amendments are as follows:

a. Increase the number of cadaveric donors by lifting the upper age limit for cadaveric organ donation;
b. Facilitate living donor transplants by allowing donor-recipient paired matching for exchanges of organs;
c. Support the welfare of living donors by allowing them to be compensated according to accepted international practices;
d. Protect donors and recipients from exploitation by middlemen by increasing the penalties for syndicated organ trading.

Before we proceed to state our views on the Proposed Amendments, it is worth observing that from the legal perspective, the healthcare professionals and the various stakeholders in the healthcare industry owe a *duty of care* not just towards an intended organ recipient, who invariably would already be a patient under the care of a medical professional, but the duty of care must also be owed to the intended donor as well. When the subject of organ transplantation is being discussed with the intended recipient, the doctor and patient relationship would likely have already been established for some time. In contrast, the intended donor is likely to be an otherwise healthy individual not previously under the care of the doctor, and whom the doctor may not know much about.

The duty of care requires a doctor to act in the *best interests of the patient.* While it may be in the best interests of the intended recipient for the living donor transplant to be facilitated, it is usually more difficult to say the same for the intended donor. This is because from the point of view of the health interests of the intended donor, it is never the case that losing one normal functioning kidney would be in one's best interests. That the intended donor would nevertheless be willing to donate a kidney in the first place, would usually require some other compelling motivation valued by the intended donor, such as an act of sacrifice in order to save a loved one, or an act of altruism to help another person.

There are various situations in healthcare where a person may willingly put himself or herself at some health risk without any real expectation of benefit in return. One obvious example is in the area of clinical research. Subjects in clinical research have the benefit of the patient safety oversight of Institutional Research Boards who *inter alia* review the consent documentation and remind researchers of the need to practice high standards of informed consent taking so that clinical research subjects are given adequate information before making the decision to take part in the clinical research study. We are of the view that there must be no less a need to ensure that intended living donors are properly counseled about the risks of donation and are capable of giving informed consent, before they are ever accepted as organ donors.

The Ministry has stated that the aim of the Proposed Amendments is "to increase the organ transplantation rate and save more lives". Increasing the organ transplantation rate must certainly start with the boosting of Singapore's present numbers of cadaveric organ transplants, which we believe are not as good as they should be, bearing in mind that we have adopted an opt-out system under HOTA. Experience shows that there are still social religious and other factors at play that may often cause families to object strenuously to the harvesting the organs of their loved ones even when they are brain dead. Many people may think of organ donation as a good thing in general, and yet resolutely refuse to contemplate this where it involves their loved ones. These very factors that may now be causing the reluctance and objections in potential cadaveric donations, may also lead to a situation where once we have managed to enlarge the pool of living non-related donors by allowing accepted forms of "compensation" or other payment, we may inadvertently shrink the numbers of living related donations because family members may prefer not to have their close relations donate to them, preferring instead to make the payment to a stranger in the hopes of getting a kidney. At the end of the day, the extent to which the Proposed Amendments will actually boost our organ transplantation rates and save more lives, is something that will probably need to be carefully studied and monitored in time to come.

Proposed Amendment (a)

With this in mind, we would support Proposed Amendment (a), which seeks to remove the categorical maximum age limit of 60 for organ procurement under the current HOTA.

We agree that the expected increase in numbers of available organs, and the fact that suitable patients of more than 60 years of age may now benefit from such transplants, would be a welcome development. We note from the proposed amendment to section 5(2)(d) of the HOTA on page 14 of the Consultation Paper that the lifting of the upper age limit refers to it being removed, not raised. We

agree that there is no need for a categorical maximum age limit as the relevant considerations should relate to the person's health rather than age.

The issue of medical suitability would be best assessed by medical specialists on a case-by-case basis. However we recognize that with the removal of the categorical maximum age limit, it would become even more important to have a general consensus on the accepted organ exclusion criteria for cases of more elderly recipients wanting a transplant, so as to ensure a just and consistent approach. In this regard, we note from paragraph 13 of the Consultation Paper that that the MOH Transplant Advisory Committee will refine its organ allocation criteria to ensure maximum benefits to patients on the waiting list. We hope that the revised organ allocation criteria would be transparent in both its formulation and application, in order to promote public confidence that organ allocation under the new HOTA regime will be made equitably.

Proposed Amendment (b)

We would also support Proposed Amendment (b), as we see no legal objection in principle to allowing paired matching of living donors, which can increase the number of medically compatible matched donations as well as potentially improve transplant outcomes.

However, the proposed amendment to section 14(7) of the HOTA appears to be drafted wider than the stated aim in the Consultation Paper of allowing living-donor paired matching. The proposed section 14(7)(a) refers to the "donation of an organ from *another donor*", which could include a cadaveric donor. For clarity, we suggest that section 14(7)(a) be revised to refer to the "donation of an organ from another *living* donor".

Proposed Amendment (c)

With respect to Proposed Amendment (c), we fully agree that the welfare of living donors should be and must be supported. The potential controversies have always arisen in *how* the interests and welfare of living donors are to be supported, and where legally and ethically the lines need to be drawn. We are glad to see that the Ministry is advocating that any payment to the donors be made in accordance with accepted international practices, and we note the principles stated in the WHO Guiding Principles as well as the Declaration of Istanbul, which prohibit financial inducements that could result in the poor and economically disadvantaged being pressurized to "sell" a kidney for money.

We are however of the opinion that the terminology for payments that may be allowed should be clarified and made consistent. The Ministry has referred to the National Medical Ethics Committee's support of the payment of comprehensive reimbursement of costs of donating a kidney, so that the donor is not left to bear the burden of costs that he or she would otherwise not have incurred but for the

transplant. This is based on the NMEC's view that disincentives to organ donation should as far as possible be removed, so that donors who are already acting out of altruism are not left to do so by having to carry a heavy personal burden. However the NMEC has consistently steered clear of referring to such reimbursements as "compensation", which from a legal viewpoint could be interpreted to include other payments such as payment on account of the pain and suffering and loss of amenities associated with losing a kidney, which neither accepted international practices nor the NMEC endorses. Since the Ministry is supporting the recommendations of the international community and the NMEC, the term "compensation" whether in the amendment at section 14(3)(c)(ii) of the HOTA, or in other statements, is probably best dropped in favour of, for example, "comprehensive reimbursement of costs and expenses related to the organ donation and transplant", as being more precise in stating the actual boundaries of such payments.

Again drawing parallels to the situation in clinical research, we also considered that in clinical research scenarios, the subject is often given the assurance that in the event of any injury sustained as a result of participating in the research, the hospital will treat the injury at no cost to the research subject. In many drug trials, the subjects may also be assured of clinical trial compensation such as those recommended by the Association of the British Pharmaceutical Industry. Institutions in Singapore that conduct clinical research are also covered by clinical trial insurance under insurance policies issued to the institution by established insurers and underwriters.

We are of the view that living organ donors should similarly have access to such coverage for their treatment related expenses as well as medical insurance for their future healthcare needs occasioned by their organ donation, and that the authorities should look into making available such insurance coverage for organ donors. It would be unfair if a living donor were to become ineligible for medical insurance coverage, because he only has one kidney as a result of him previously donating the other to save someone else, and then himself loses the means to pay for his own medical treatment in the future should his health deteriorate.

Although the Ministry has referred to the various expenses and costs that would be included for reimbursement (including loss of earnings and time) as well as the payment of the costs and expenses of making adequate provision for the short-term and long-term medical care of the donor which may be reasonably necessary as a consequence of his organ donation, what is not clear thus far is how such adequate provision is to be computed and whether the total amount to be reimbursed or paid will be a pre-determined amount or whether it will be assessed on a case-by-case basis depending on the circumstances of the individual. Obviously a pre-determined amount would be administratively easier to manage. However, if a pre-determined sum were to be paid for all cases, there are risks that it may fall short of removing the actual disincentives to an

individual donating in some cases, and in other cases (for example where the intended donor is unemployed or in very difficult financial circumstances), it may inadvertently constitute a strong financial inducement to the donor to donate a kidney for money.

This brings us to the issue of whether such comprehensive reimbursements should be made available to foreigners who want to donate a kidney here. If a pre-determined sum were to be paid on account of comprehensive reimbursements, then there is a definite possibility that what may not otherwise constitute a financial inducement to the average Singaporean, may well be seen as a very attractive "price" to a foreigner living in poverty. The 1992 Law Reform Commission of Canada's Working Paper 66 on *Procurement and Transfer of Human Tissues and Organs* noted at page 60 that "social reality indicates that what counts as an incentive depends as much upon the situation of the potential recipient as it does upon the amount and spirit of the offering". We are therefore strongly of the view that if we were to include foreign donors for the purposes of reimbursement, then the payment of a pre-determined sum would be undesirable. At the same time, we acknowledge that it can be difficult to estimate what the real future costs of medical care are for such a foreign donor. In some situations, the intended donor is living in such poor financial circumstances that he may not have the kind of access to medical care that Singaporeans enjoy under our healthcare system. In these cases, paying the donor to cover what we in Singapore would consider necessary and reasonable follow up care may have the unintended consequence of encouraging the donor to treat this as "extra payment" and hence constitute a financial inducement.

Hence we are of the view that before we include foreign donors and allow them to receive any form of payment whenever they donate a kidney here, we should ensure that we are truly in a position to protect the interests of such foreign donors, some of whom may be regarded as "vulnerable persons" that may be more at risk of exploitation and financial inducement. We also believe that the NMEC has similarly advocated such a cautious approach to foreign donors.

Proposed Amendment (d)

We agree that the penalties for those involved in syndicated organ trading, and middlemen profiting or seeking to profit from the organ trading transactions should be increased, so as to send a strong signal to such individuals who prey on the plight of sellers and the (often) desperate circumstances of buyers for their own personal gains.

We do however note that what is proposed is a ten-fold increase in sentencing maxima. While we acknowledge that increased sentences will have a deterrent effect, we are of the view that the level of increase in the sentence for organ trading offences under the HOTA should be justified by principled comparisons to similar criminal offences under the Penal Code or other criminal statutes to ensure consistency in the criminal justice regime.

We would like to add that in situations involving living organ donation, it would be preferable that the rules provide for donor and donee to be advised and be treated by separate doctors, in order to avoid any conflict of interests.

Dated 17 December 2008

Members: Ms Mak Wei Munn

Ms Audrey Chiang

Ms Kuah Boon Theng

Mr Charles Lin