

# LEGISLATIVE BRIEF

## Transplantation of Human Organs and Tissues Bill, 2007

*The Bill was introduced in the National Assembly on August 17, 2007 and was referred to the National Assembly Standing Committee on Health the same day*

*This Legislative Brief is a part of the PILDAT Legislative Development Programme and is authored by Dr. Sania Nishtar S.I. FRCP PhD, Founder and President, 'Heartfile' at the request of Pakistan Institute of Legislative Development And Transparency PILDAT conforming to the format set by PILDAT. The objective of the Brief is to assist the parliamentarians to understand the context, objective and the issues relating to the legislation and to enable them to participate in a more informed debate and take well considered position on the subject. The Brief is also intended to enhance awareness of the Citizens and Media in general so that they may also participate in the process as informed stake holders and communicate their views to the public representatives accordingly. A broad objective is to make the legislative process more open and participatory*

**August 24, 2007**

### Highlights of the Bill

The objective of the law is to build ethical safeguards and curb unethical and illegal practices in organ trade. The highlights of the law include:

- *Stipulating* norms for donation of organs or tissues by living or deceased persons;
- *Legalizing* cadaver (dead body) organ donation and devising a system for people to will their organs for transplantation after their death;
- *Mandating* the creation of Evaluation Committees in all institutions and hospitals where transplants are carried out and outlining the constitution of membership and prerogatives of the Evaluation Committees;
- *Building safeguards* in the process of transplantation by ensuring procedural clarity and incorporating consent and disclosure-related clauses;
- *Mandating* the creation of a Monitoring Authority, defining its roles, responsibilities and prerogatives and relations with other stakeholders and agencies;
- *Outlining* penalties and punishments in cases of violation of the law.

### Executive Summary

The Transplantation of Human Organs and Tissues Bill, 2007 is **aimed at** regulating the removal, storage, sale and transplantation of human organs and tissues in end stage diseases. The Bill is **envisaged to impact** and curb the widely prevalent unethical and illegal practices in human organ trade. Pakistan has one of the highest rates of unrelated<sup>1</sup> commercial transplantations in the world; the process of organized organ brokerage has been institutionalized in the country with the help of the unethical community of health care providers and a range of vendors. As a result, poor patients in desperate need of money are exploited for meager sums. The determinants of this pattern include an unregulated private sector, absence of quality assurance institutional mechanisms and lack of policy and legislative arrangements to check unethical practices. Pakistan is the only country in the region as of this date without a law on organ transplantation and therefore this Bill is aimed to set standards and ensure compliance with these standards.

In terms of its **Status**, the legislation was previously under heavy criticism with concerns being expressed that the trade can get legal sanctions through the legislation. On August 1, 2007 the Federal Cabinet mandated an inter-ministerial committee to address these concerns with specific recommendations to modify the law, albeit while approving the law in principle. However in an unexpected move, while the legislation was being processed as an Ordinance, a Bill was moved on the floor of the National Assembly on August 17, 2007. The objective of this move is a subject of active debate. Notwithstanding this controversy, it is important that the National Assembly Standing Committee on Health should now convene a meeting soon to deliberate on this matter given that the Assembly will be completing its term on November 15, 2007. However, it must also be recognized that the revised version of the law still has many limitations. Although the previously controversial Clause 3(2) does not endorse compensation anymore, it also does not regard doing so illegal, by virtue of which the Clause may still remain exploitable. In addition, this brief also outlines many other gaps in the law which have not received due attention and must be addressed during parliamentary deliberations.

1. Donation by a persons who is not related to the person receiving the transplant

## Background and Context

The Transplantation of Human Organs and Tissues Bill, 2007 is aimed at regulating the removal, storage, sale and transplantation of human organs and tissues in end stage diseases. Of the several transplantation procedures established globally, kidney transplantation is widely practiced in Pakistan with an estimated 2000 transplants being performed annually<sup>2</sup>. However, it must be recognized that due to paucity of donors, kidney transplants can only be performed in 5% of the total number of patients who actually require the procedure.

There are two prevailing modes of kidney transplantation. The *ethical* mode involves cadaver donations and altruistic donations from live related donors, which reflect a donor's motivation to save a life. The *unethical* mode involves donations from live unrelated donors and is generally based on putting a price on human body parts. Due to scarcity of human organs, the latter option has greatly increased over the years in resource challenged countries with poor regulations where the poor are willing to trade a kidney for incentives as they realize that one kidney is sufficient for a good quality of life. Analysis of kidney transplantation trends in Pakistan is indicative of this pattern. In the 1990's unrelated commercial transplantations constituted 25% of all the transplantations carried out in Pakistan; by 2004, this had risen to 80% of all transplants<sup>3</sup>. The existence of an unregulated private sector has greatly facilitated the institutionalization of this trade in Pakistan, as has the absence of legislation on organ transplantation. Presently, the trade has an estimated turnover of Pak Rs. 1 Billion in Pakistan according to conservative estimates. More than 80% of the transplants are currently being performed in private hospitals, which openly offer 'transplant packages' to clients both within and outside the country. As a result of these practices, Pakistan is unfortunately being ranked amongst the few countries of the world where transplant related-tourism is burgeoning.

## The Evolution of the Bill

The evolution of the present Bill dates back to March 2004 when it was tabled in the Senate as a private members bill by Dr. Shahzad Waseem however after being on the agenda of the Cabinet in October 2006, it was deferred. Shortly thereafter, in November 2006, the Chief Justice of Pakistan took *suo moto* action based on a complaint in the Yazman case,<sup>4</sup> which related to the coercive and illegal removal of a poor man's kidney without his knowledge. The Supreme Court also directed the Ministry of Health to pursue legislation; in addition, the Deputy Attorney General of Pakistan suggested that an Ordinance be pursued in the interest of expediency a suggestion also endorsed by the Ministry of Law. In January 2007, the Ministry of Health submitted the Ordinance's first draft to the Cabinet Division, based on which inputs were officially solicited from the Federal Law Minister and the Prime Minister's Senior Advisor on Law, Justice and Parliamentary Affairs. In tandem, a request was also sent by Secretary Health to the Prime Minister requesting him to exercise his authority under Rule-16 (2) of the Rules of Business of Pakistan 1973, so that the Federal Cabinet could be bypassed and an advice could be sent to the President directly to promulgate the ordinance expeditiously. However it was ultimately decided to seek the Cabinet's approval on the draft Ordinance, which resulted in some delay as the item was awaiting its turn to be placed on the Cabinet's agenda. The Supreme Court took notice of this delay and on July 26, 2007 directed the Cabinet Division to accord high priority to the matter in the next Cabinet meeting; the case was adjourned to the first week of September 2007. Subsequently, the matter was discussed in the Cabinet on August 1, and the law was approved in principle; however, the matter was referred to an inter-ministerial committee with recommendations, based on which several changes were made to the law. These include changes in the membership of the Evaluation Committee (Clause 5),<sup>5</sup> and Monitoring Authority (Clause 8);<sup>6</sup> the use of fund established as a statutory entity (Clause 8 [5]);<sup>7</sup> the term of imprisonment (Clause 10)<sup>8</sup> and modification of Clause 3(2), which was the most controversial of all the Clauses. These changes were made as a response to the extensive criticism on the earlier draft of law by the professional community both internationally as well as within the country. The extent to which these amendments are likely to influence the true spirit of the bill

2. Kidney transplantation is the definitive treatment for end stage renal failure. There are two types of treatments for such patients; one involves regular dialysis an expensive tertiary hospital-based process in which the entire blood is filtered artificially on a regular basis whereas the other involves transplanting a kidney
3. A gift for life: World Donation Day. [http://www.fairtransplant.org/downloads/Transpl\\_Society\\_Report\\_Wdtd.pdf](http://www.fairtransplant.org/downloads/Transpl_Society_Report_Wdtd.pdf) (accessed August 18, 2007)
4. Application by Muhammad Asghar Son of Mukhtar Ahmed case Arian Resident of Chak No 42/DB, Tehsil Yazman, District Bahawalpur. HRC no: 2926/2006
5. Membership has been broadened to include two notables
6. Membership of the Society of transplant Physicians and Surgeons of Pakistan was canceled
7. The law now stipulates that the fund will be used to benefit post-transplant patients
8. Increased from five to ten years

has been referred to in a subsequent section of this brief. However, from a process-related perspective, it is interesting to note that the legislation was not processed further as an Ordinance but in an unexpected move, was tabled as a Bill on the floor of the National Assembly on August 17, 2007 in the absence of the key parliamentary representatives on health (Federal Minister of Health, Minister of State for Health and the Parliamentary Secretary for Health). The bill was referred to the National Assembly Standing Committee on Health the same day; however the Assembly session was also prorogued indefinitely the same day. The objective of this move is a subject of active debate. Clearly, with the National Assembly in session the law could not have been processed as an Ordinance; one school of thought therefore, is of the opinion that this move is in response to that constraint. The other school of thought regards it as a strategy to further delay the promulgation of the law.

In view of these circumstances, the National Assembly Standing Committee on Health should now convene a meeting at the earliest to deliberate on this matter and forward its report to the National Assembly. In order to assist the parliamentarians, citizens and media in this task, a review is presented on the strengths, weaknesses and limitations of the law. These have been based on a comparison of the law with internationally recognized ideal attributes of a law, which draw on the principles of international guidelines published by the World Health Organization. These guidelines aim to ensure protection against exploitative and unethical practices that can allow people to sell their organs and specify that procuring human organs in lieu of monetary payment is unethical.

## Technical review of the Bill

**Strengths of the law:** The law is consistent with some international standards and not with others. With respect to its strengths, it does set regulations for obtaining organs from deceased persons and adequately highlights the consent related issues in this regard. It also consolidates specific measures in the regulation aimed at protecting minors. The law also specifies the creation of national registries with surveillance functions and inventorying potential recipients in addition to indicating that international collaborations will be established for a range of purposes. All of these are positive steps indeed. The updated version of the law will also address one of the earlier weaknesses of law, which related to its lack of organizing donor care and donor follow up by earmarking the use of the Fund created under the aegis of this law for post transplant care of patients.<sup>9</sup> Moreover the oversight role of Evaluation Committees in the few public sector hospitals involved with legitimate organ donation efforts is envisaged to be positive; however this cannot be generalized to the *non-bona fide* private sector.

**Weaknesses of the law:** in terms of its weaknesses, the most controversial clause of the law and the one that received attention the most was Clause 3(2). In its earlier version, it mandated Evaluation Committees to allow donation by a live non-blood relative or non-relative and made provision for compensation '*as may be prescribed*'. The Clause left a lot to the discretion of the Evaluation Committees and it was therefore envisaged that this Clause would be used to allow organ trade to flourish on the plea that 'there is a threat to life'. As a result of severe criticism by the professional community, individual experts in the field as well as apex professional associations, this Clause has been revisited. Presently it allows transplantations from *non-'close blood relatives'*, but does not endorse compensation. However it must be noted that it does not regard doing so illegal, by virtue of which the Clause still remains exploitable. The Clause should clearly forbid compensation and allow it only in the circumstance as outlined in the WHO guideline, which permits it for '*covering the costs of reasonable and verifiable expenses incurred by the donor, including costs of income, or the payment of other expenses relating to the costs of recovering, processing, preserving and supplying human cells, tissues and organs for transplantation*'. In order to ensure that this guidance is not exploitable, the legislative language must specify 'income' in terms of loss of income from the diagnostic to the full recovery phase and payment of 'other expenses' as pertaining to actual expenses of operation upto complete recovery and such like other related expenses so that there is a clear separation between expenses and compensation. To a certain extent, the

9. Refer to the earlier section on the Cabinets decision in its August 1, 2007 meeting

definition of payment in Clause 2(g) is consistent with this definition. However in order to reinforce this point, a clarification may be desirable in Clause 3(2). Experts in the field were also of the opinion that the law should make it mandatory for the Evaluation Committees to ensure that certain prerequisites are met prior to approval of *non close blood relative donor* such as proof that the donor has altruistic relationship with the recipient for over a period of ten years and proof of financial and social compatibility between the recipient and the donor. These have not been included in the updated version of the Clause.

Furthermore, the law also has a number of other weaknesses, upon which attention has not focused to date.

*First*, it does not explicitly state that donations from the deceased should be preferred or that altruistic donations by means of public appeal or advertisement should be encouraged. Although its reference to '*non close blood relative*' in the context of '*unavailability of donors in other categories*', implicitly implies that the latter are preferred, the law does not emphasize this explicitly.

*Secondly*, the law also does not lay out specific measures to protect legally incompetent persons (people with mental retardation or learning disabilities who cannot make valid decisions or patients with severe psychiatric illnesses who cannot decipher the implications of their decisions) as it does for minors.

*Thirdly*, the law does not stipulate safeguards against tourism for the purpose of seeking renal transplants. In fact, the law's reference to 'tourism' in Clause 7 (1) is in fact contradictory to the principles, which underscore the need for promoting donations from the deceased and altruistic donations.

In the *fourth* place, the law does not make provision for preventing conflict of interest by not allowing those involved in tissue and organ removal from deceased donors to have any link with transplantation procedures one of the guiding principles stipulated by WHO in relation to organ transplantation.

In the *fifth* place, Clause 4 states that the '*cases of unclaimed brain dead hospitalized patients shall be presented to the Evaluation Committee for transplantation after an intensive search for their relatives within 24 hours*'; this time frame may be too short given the logistics and administrative ability of hospitals to track next of kin.

In addition to these omissions, there are other limitations of the law in terms of the institutional capacity of the system to implement the law. In theory, the law also requires that donations should be '*voluntary, genuinely motivated and without duress or coercion*'<sup>10</sup> and that live donors should be given a detailed explanation about the '*effects, complications and hazards connected with organ removal*'.<sup>11</sup> In addition in Clauses 9 and 10 it also prohibits all possible stakeholders from engaging in transplantation of human organs without ethical authority and makes doing so a punishable offence.

However the implementation of these clauses would be problematic because of limited institutional regulatory capacity of state health agencies the Federal Ministry of Health and provincial departments of health. The country does not have a law on setting standards or regulating the private sector *per se* where most of the unscrupulous practices in transplantation are known to take place. In the absence of overarching regulation of practices of the private sector and institutional mechanisms of quality assurance, there is limited impact that a dedicated Monitoring Authority created under the aegis of this law will have even if it is statutorily mandated to '*hold enquires and conduct inspections on quality*', as is the case.

Preserving a high level of quality of care, safety and efficacy of procedures can only be done through the implementation of quality systems. Clearly the health system in Pakistan lacks the ability to ensure that outcome.

10. Clause 3 (b)

11. Clause 7 (2)

To summarize therefore, there should be no disagreement on the need for curbing Pakistan's thriving organ market and the potential that it has to exploit the financial vulnerable of the poor. However, it must be recognized that as an instrument of policy and regulation, a law should not create the space for exploitation. The updated version of the law is an improvement from the earlier version; however it still needs substantial improvement. As the Bill goes to the Parliamentary Committees, these limitations and weaknesses must be a subject of debate not only to improve the present law but also to strengthen the institutional mechanisms that implement it. It is also important that this Bill be given priority by the Assembly, given that it will be completing its term on November 15, 2007. With other important items coming up on the agenda of the Assembly, there is a danger that this Bill may get shelved with the completion of the term. If that happens, it would be truly tragic given that it is after decades of advocacy and many years of institutional deliberations and work that legislation on this subject has come to this stage.

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