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Sunday, June 19, 2016

To
Mr. Sunil Kumar
Undersecretary to the Government of India
Phone: 011 23061436

Subject: Recommendations and Suggestions to the Draft Bill "The medical treatment of terminally ill patients (Protection of patients and medical practitioners) bill" by the Forum for Medical Ethics Society.

Dear Sir,

The Forum for Medical Ethics Society (FMES) would like to take this opportunity to make suggestions and recommendations to the draft bill titled "The medical treatment of terminally ill patients (Protection of patients and medical practitioners) bill" presented in the Annexure – 2 of the Circular Ref no F.No.S.12011/5/2011-MS(Pt.I) dated May 6, 2016.

FMES has engaged itself with this area of enquiry and the complex debate. We as publisher of the *Indian Journal of Medical Ethics* (IJME) have pursued this topic of enquiry by publishing scholarly debates on various aspects of the topic. We recently published a theme issue on the topic entitled 'Healing and dying with dignity: Ethical issues in palliative care, end-of-life care and euthanasia'. (<http://www.issuesinmedicalethics.org/index.php/ijme/issue/view/137>). The same is attached herewith for your ready reference.

Thanking you

Yours sincerely,

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Recommendations and Suggestions to the Draft Bill entitled

**“THE MEDICAL TREATMENT OF TERMINALLY ILL PATIENTS
(PROTECTION OF PATIENTS AND MEDICAL PRACTITIONERS) BILL”**

Presented as Annexure-2

By

**Drs Sunita Bandewar, Sanjay Nagral and Amar Jesani on behalf of
The Forum for Medical Ethics Society, Mumbai**

General comments

We appreciate the fact that the government has demonstrated its commitment to the cause and has responded to the long drawn debate on the matter relating to end-of-life care and “passive euthanasia”. However, a more robust draft bill was expected after a time lapse of about ten long years since the 196th report of the Law Commission of India published in 2006, debate that was generated by the Public Interest Litigation filed by Pinki Virani in relation to the case of Aruna Shanbaug in March 2011 followed by the Supreme Court’s judgement on the same allowing passive euthanasia in specific situation; and further debate reflected in the 241st report of the Law Commission of India in 2012. **Such a legislation being considered at this juncture in India ought to be premised on the principle of honouring quality death that maintains and respects human dignity; and upholding individual’s right to life (increasingly being interpreted as right to die with dignity) and liberty that is conferred by the Article 21 of the Constitution of India and the Article 4 of the Universal Declaration of Human Rights to which India is a signatory.**

The bill certainly has a number of constraints, gaps, and inconsistencies; and it lacks necessary clarity. Below we offer comments on the draft bill for your consideration.

General recommendations:

- a. The draft bill in the current form should not be processed further without revisions.
- b. The glaring gaps, constraints and internal contradictions should be addressed towards revising the draft bill.
- c. The revised draft bill should again be presented in the public domain for seeking inputs and comments from the wider public.
- d. A preamble to the proposed bill locating it in the broader debate which covers various dimensions - including ethical and medical - of the issue at hand is much needed and should be included in the revised draft bill. The Annexure – 1: Brief on Euthanasia to the aforesaid Circular is inadequate since it doesn’t cover the foundational principles of the proposed bill, the human rights framework, the framework of Indian Constitution and ethics framework.
- e. Needs to revisit the use of ‘passive euthanasia’ since it is being argued against on ethics ground. (Please kindly refer to the IJME theme issue to get brief insights into the current debates on this.).
- f. The draft bill warrants reference to the concept of ‘futility’ and its inclusion in the Annexure -1. The discussion and decision making in a health care setting about ‘futility’ plays out differently in different cases (for example, in case of rich and poor patients). It also plays out differently in government health care settings and in private or corporate hospital settings. We have proposed clinical ethics committees in our suggestions later in this document. These committees will have a seminal role to play to handle ethical issues involved on case to case basis. These ethics consults are important to ensure the two

foundational principles – respecting human dignity and individual autonomy – in end-of-life care are uphold.

Section 2: Definitions

Recommendations:

- a. **Point 2.b** refers to the definition of ‘best interest’. Empirical reality indicates that it is not rare when patients are provided ‘futile’ care which often is intensive care unit based services. This might be due to the insistence of patient and/or families; or could be due to the misleading medical advice. The latter stems from the vested interest of medical practitioners and/or concerned hospitals, often private sector ones. This leads to patients and families incurring huge hospital bills for treatment which don’t contribute to patient’s well-being in anyway. **Against this backdrop, the clause:**

“... are not limited to medical interests of the patients but include ...emotional and other welfare considerations”

Should be replaced with

“... are not limited to medical interests of the patients but include ... emotional, economical, financial, and other welfare considerations”

- b. **Point 2.j** has laid out the definition of ‘minor’ as per the provisions of the Indian Majority Act, 1875 (4 of 1875). This contradicts with Point 2.d which refers to “... ‘incompetent patient’ means a patient who is a minor below the age of 16 years ...”. Also, it is noteworthy that except the recent amendment to the Juvenile Justice Act which allows children between the age of 16 and 18 years to be tried as adults for heinous offences, the age of consent in Indian legal framework is 18 years. These inconsistencies within the draft bill and with the legal age of consent prescribed by other Acts, such as, the Indian Majority Act, 1875 or the Indian Contract Act, 1872 require attention.

It is recommended that either these inconsistencies are explained or the definition of incompetent patient on the parameter of age should be synchronised with the legal age of consent in India which is 18 years. Said simply the concept of ‘minor’ requires to match with the legal age of consent in the legal context of India unless explained otherwise.

- c. **Point 2.m.i** refers to “... untimely...” **which we recommend to delete.**
- d. **Point 2.m.i** refers to “...terminal illness means, such illness, injury or degeneration of physical or mental condition which is causing extreme pain ...”.

This implies that certain ‘mental conditions’ or certain stages of some mental conditions may also be considered as ‘terminal illness’. This leaves too much for interpretation of the clause by medical practitioners and significant others. It can be abused in absence of clarity.

It is recommended that relevant examples are offered to explain this point towards lending crystal clear clarity of what is being proposed.

Section 3: Refusal of medical treatment by a competent patient and its binding nature on medical practitioner

The conditions mentioned in the clause/point 2 in this section lays out the conditions under which the decision of the patient including that of those above the age of 16 years. In that it says that once patient conveys her/his decision regarding withdrawing or withholding of medical treatment to herself or himself, such a decision will be binding on the medical practitioner. However, it is with a caveat that it is binding on the medical practitioner provided s/he is satisfied that the patient is competent and the patient has taken an informed decision.

Depending upon the context and the medical practitioner's approach to patients, their right to decide, and overall the position on end-of-life care and passive euthanasia, this caveat can be interpreted in a very subjective manner impacting adversely patient's autonomy. A number of factors can potentially interfere with medical practitioner's decision making and discretion, such as, her/his religious orientation, if any; and economic stakes, especially in the private health care setting. The latter creates a situation of conflict of interest at least in certain cases. It therefore stands the risk of killing the very spirit of respecting patient's autonomy. This caveat shifts subtly the decision making power to medical practitioners from the patient. Also, practically speaking, often it might be a team of medical practitioners who would be treating a patient. If so, entrusting one single medical practitioner may have pragmatic challenges of its own, as well.

Recommendation:

- a. Because the idea is to offer patient an opportunity to discuss her/his decision and help her/him to view it in perspective; appreciate the consequences including potential pain it might inflict and related matters it is recommended that clinical ethics committees (CECs) are constituted at the hospital level.
- b. Broad guidance for constitution of such CECs to be laid out with required clarity in the draft bill. This should include guidelines for: who should constitute CECs and who and what standard operating procedures it should have, and what should be the composition of these committees.
- c. Such a body needs to be multidisciplinary (such as ethicists, lawyers, representative to bring aboard perspective of common people, medical experts, philosopher and/or social scientist), and should be structured in a manner that it averts situations of conflict of interest.
- d. Provision should be made so that these bodies serve as bridge between medical practitioner/s looking after the patient; and the patient and her/his significant others to make the process of decision making fair, sound, informed, and ensuring that it upholds patient's right to autonomy.
- e. Systematic documentation of these process/ethics consults should be maintained for archiving. (many of these matters can be streamlined and guided via the aforesaid standard operating procedures.)

Section 4: Authority to prepare panel of medical expert

4. Authority to prepare panel of medical experts. (1) The Director-General of Health Services, Central Government and the Director of Medical Services (or officer holding equivalent post) in each State shall, prepare a panel of medical experts for purposes of this Act and more than one panel may be notified to serve the needs of different areas.

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This implies a number of practical constraints. It refers to ‘... prepare a panel of medical experts for the purpose of this Act and more than one panel may be notified to serve the needs of different areas.’. This lacks much needed crystal clear clarity. Most of the states in India have wide geographical areas and/or are characterised by difficult terrains with a number of areas with poor transportation and possibly communication infrastructure. Also, a large number of health care facilities spread across each state imply that a patient in need of seeking passive euthanasia would be located anywhere across a particular state in India. The suggested proposal to constitute one panel (as per “... prepare a panel...”) or may be a few in each state (as per “... more than one panel may be notified...”) needs to be viewed against this empirical reality to understand the inherent challenges involved in this proposal to the extent that these panels after all may remain to be ‘cosmetic elements’ of the proposed Act.

Furthermore it is intriguing to know the silence of the draft bill about the role of these panels “... for the purposes of this Act...”. It is not at all mentioned as to what responsibilities these panels will be entrusted with. It is also unclear as to how these panel will be functioning to meet the needs of patients seeking passive euthanasia and allied needs of families and significant others of the concerned patients regarding consultation with such expert committees. Since the responsibility and role of the said panel of experts is not mentioned, it is difficult to know if it would sufficient to only consider medical experts to serve on these panels. It seems advisable to include members from other fields such as law, ethics, social sciences and representative to offer perspective of patients and families.

Since later in the Bill Section 12 mentions that the Medical Council of India will be entrusted to draw up Guidelines we hoped that it would refer to the responsibility of drawing up modalities and/or standard operating procedures and/or guidelines for functioning of these panels. However, this is not the case. The MCI is expected only to issue guidelines for medical professional confronted with situations of treatment withdrawal or withholding of treatment.

Recommendations:

- a. Explicit guidance must be provided for constituting the said panels of experts.
- b. Explicit roles and obligations of these panels must be laid out.
- c. Explicit guidance must be provided for pathways that hospitals, doctors, patients and their significant others confronted with end-of-life care situations would follow to seek consultations with a panel of experts.
- d. Experts to serve on these panels should be drawn from other relevant fields such as law, ethics, social sciences and humanities. It should also have a representative of patients and families.

Section 6: Palliative care of competent and incompetent patients

6. Palliative care for competent and incompetent patients. – Even though medical treatment has been withheld or withdrawn by the medical practitioner in the case of competent patients and incompetent patients in accordance with the foregoing provisions, such medical practitioner is not debarred from administering palliative care.

Inclusion of this section is an important step forward. However, in the current scenario this may remain only on paper and therefore has bearing on how 'human dignity', which is foundational to this draft bill, would be translated in real world, if at all it could be. This provision although an essential element of the draft bill, given the current scenario of very poor or no access to and availability of palliative care services across the country, it certainly is not a realizable goal.

Against this backdrop, there will be situations of patients being in severe excruciating pain after the implementation of withholding or withdrawing treatment as per the draft bill. Since the above scenario of poor access to and availability of palliative care would be difficult to change in any short time span and bringing out any such changes swiftly may even be considered outside the scope of this bill, it is absolute necessity that patients are provided high-end quality palliative care to honour the foundational principle of and motivation behind this bill of 'dying with dignity'. It should be noted that the notion of palliative care has a much expanded scope now to be comprehensive and inclusive of care beyond pain relief alone.

Also, globally, the significance of access to and availability of palliative care is now underscored drawing upon appropriate UN Conventions and 'utilising the two mutually reinforcing arguments, "lack of access to palliative care is a human rights concern" and "governments' inability to offer pain relief amounts to torture".

Recommendations:

- a. The wording '... such medical practitioner is not debarred from administering palliative care.' should be substituted by '...such medical practitioner should ensure that person has access to and availability of necessary palliative care at no cost.'
- b. It is advisable to explicitly mention in the bill that will allow

Section 9: Permission to be obtained from High Court and the procedure

This section states that relatives and others may approach the High Court for permission in cases of incompetent patients and competent patients whose decision is not an informed decisions as assessed the medical practitioners (as it flows from the Section 3). The proposal in this section has a number of constraints which may defeat the purpose of the proposed legislative reforms. These constraints include:

- a. The volume of these cases might be quite large. This implies that there will substantial burden on the judiciary having to respond to these applications.
- b. From the perspective of patients and their families, it would be most challenging to approach the High Court for a number of obvious reasons.
- c. It is mentioned (Section 9.4) that these would be letters with "... any other expert medical practitioner... And issue appropriate directions for the payment to be made towards the remuneration of the experts.". It is not clear as to who would be paying for these services. This needs to be clarified. If in case, patients and/or their significant others are expected to bear the cost, it would pose as a constraint for a large segment of patients who don't have capacity to pay for care. This may lead a large segment of population to forego their right to die with dignity.
- d. The proposal (Section 9.2) that such applications "... be disposed of by the High Court as far as practicable within a month." seems incongruous in two ways. Firstly, given the current burden of cases and inordinate delays in disposing of cases it seems ambitious to expect such applications to be disposed of within about a month. Secondly, a time span of about a month for a patient for whom a decision is made at her/his and/or family level, it is absurd that the patient would be bearing for this long her/his situation. In most scenarios this would amount to subjecting the patient to "torture" of bearing with

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pain/discomfort. This in turn amounts to violating the UN Convention Against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment, 1984 to which India is a signatory.

Recommendations:

- a. The focus should be shifted to the constitution of Clinical Ethics Committees at the hospital level as recommended earlier in this document in relation to the Section. Only those cases which could not be resolved at this level, the High Court could be approached.
- b. In such situation, full support should be extended to families/significant others of the patient to move the High Court and to not burden them with court related matters.
- c. The government should set up funds for such support.
- d. The stipulated period of 30 days to be amended to 24-48 hours.

Section 11: Advance Medical Directives and Medical Power-of-Attorney to be void

11. Advance Medical Directives as to medical treatment and Medical Powe-of-Attorney to be void and not binding on medical practitioners. – Every advance medical directive (called living will) or medical power-of-attorney executed by a person shall be void and of no effect and shall not be binding on any medical practitioner.

It seems the government has accepted the recommendation in the 196th report of the Law Commission of India, 2006 regarding an advance medical directive without application of logical reasoning for doing so. The aforesaid report mentioned that legalising advance medical directive which would help individuals to exercise their right to refuse medical treatment may lead to unwarranted litigations. This implies that rights are being curtailed or taken away only grounds of the possibility of frequent episodes of moving the courts towards the enforcement of one's rights. Such an approach is difficult to appreciate. The fear of frequent litigation can be circumvented or pre-empted by proposing mechanisms and a robust law.

There are at least three major constraints with this Section. They are:

- a. Firstly, any legislation on end-of-life care and/or passive euthanasia at this juncture will be entirely out-of-sync with the current broader discourse on this topic both in India and the world over in absence of legal recognition to Advance Directive or Living Will.
- b. Secondly, it violates the right conferred to Indian citizens through the Article 21 of the Constitution of India. The Article 21 confers and protects individual's right to life and personal liberty.
- c. Thirdly, it causes obvious, intriguing and unacceptable internal contradiction in this very draft bill. Section 3 and Section 11 stand in contradiction to each other. The former mentions that when a patient, "3.2 ...communicates her or his decision to the medical practitioner, such decision is binding on the medical practitioner,...". However, Section 11 explicitly voids advance medical directive/living will. This also contradicts the current legal framework that lends legal standing to 'wills' relating to finances and properties.

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Recommendations:

- a. Advance Medical Directive or Advance Care Planning or Living Will ought to be legalised.
- b. These ought to be binding on the family members and medical practitioners.
- c. The concept of living will/advance medical directives requires awareness building and necessary support structures to enable easier pathways for any citizens to draft one. The proposed Act mention a mechanism/direction for the government to commitment to this.
- d. The process getting a living will done should be easier. Empanelled lawyers in every tehsil can facilitate this process and such services should available at regulated prices. This also warrants a mention in the draft bill to set up a system for develop necessary skills and knowledge amongst lawyers

Section 12: Medical Council of India to issue Guidelines

12. Medical Council of India to issue Guidelines. – (1) Consistent with the provisions of this Act, the Medical Council of India may prepare and issue guidelines, from time to time for the guidance of medical practitioners in the matter of withholding or withdrawing of medical treatment to competent or incompetent patients suffering from terminal illness.

(2) The Medical Council of India may review and modify the guidelines from time to time.

(3) The guidelines and modifications thereto, if any, shall be published on the website and a press release may be issued to that effect.

Given the current status of MCI against the backdrop of the 92nd report by the Parliamentary Standing Committee (PSC) which is very critical of the current status of affair, it seems odd to entrust additional responsibility to this body.

Recommendations:

- a. Reconsider entrusting MCI with this responsibility. Instead, consider relying more on the clinical ethics committees and constitute National Level Body consisting of experts from various relevant disciplines the secretariat of which could be located in Directorate of Health Services.