

To

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Subject: Comments and Suggestions on the Assisted Reproductive Technology (Regulation) Bill and Rules-2008 (Draft) and request to incorporate suggestions.

Sir,

The Assisted Reproductive Technology (Regulation) Bill and Rules-2008 (Draft) is a document being awaited for almost a decade. It is a welcome step by the Ministry of Health and Family Welfare (MOHFW) and Indian Council of Medical Research (ICMR). Women and Health rights activists have been looking forward to the drafting of the ART (Regulation) Bill & Rules in light of the unregulated practice of these technologies and the increasing commercialization and commodification of women's reproductive tissues.

We acknowledge the initiative of the MOHFW and the ICMR for making sincere efforts in coming up with this document. The various Consent Forms are an important step towards minimizing exploitation of people who seek these technologies. Also, the clauses regarding prohibition of advertising by Assisted Reproductive Technology (ART) clinics, making breach of surrogacy contracts punitive, prohibition of unapproved research on embryos, cloning and other such strict clauses are indicators of a good legislation.

Although the Draft Bill attempts to incorporate many issues related to Assisted Reproductive Technologies (ARTs), it unfortunately carries on the vestiges of the drawbacks present in the National Guidelines on Accreditation, Regulation and Supervision of ART Clinics in India. When the title of the Bill mentions the term 'regulation', it is expected that such a Bill will regulate the providers of the technology and safeguard the rights and interests of the users, in this case women, and incorporate provisions to prevent misuse and malpractice, thereby making the providers accountable to the women/couples and the laws of the land. However, through the various clauses, the Draft Bill tends to promote the interest of the private sector providers of these technologies rather than regulate them and comes across as inadequate in protecting and ensuring the health and wellbeing of women and children.

In light of our experiences and field level interactions with the users and providers of these technologies, we have observed certain perturbing areas in this Draft Bill and we,

as members of a Women and Health Group<sup>1</sup>, are writing to you to convey our concerns and suggestions with regard to the Draft Bill.

The critique of the Draft Bill, as presented below, consists of general comments on certain aspects of the Draft Bill, and is not a clause wise or chapter wise analysis. The points have been articulated under various subheads according to the issue they deal with.

### **Need for Preamble**

A clear preamble outlining the fundamental approach to the Bill emerging from the government's own perspective within the context of pre-existing policies on population and health is seriously lacking in the Bill. There is a need to locate the current legislation on ARTs within the framework of the country's health policy, population policy and other relevant policies. This is important in order to understand the perspective and the motivation with which these technologies are being regulated.

### **Contradictions within the document**

The document lacks clarity at many levels and uses ambiguous language, which makes effective implementation of the Bill challenging. Moreover, different parts of the Draft Bill contradict each other leaving certain critical questions unanswered. Given below are some of the examples of such contradictions as illustrations. Other such points have been mentioned under their respective sections.

Firstly, regarding the issue of making payment to the surrogate, Clause 26 (6) of the Draft Bill states that

*“A semen bank may advertise for gamete donors and surrogates, who may be compensated financially by the bank. But according to Clause 34(2) ‘... the surrogate mother may also receive monetary compensation from the couple or individual, as the case may be, for agreeing to act as such surrogate.”*

Further, the Form of Contract between the Semen Bank and the Surrogate [Form- R2 (4)] mentions that

*“...the consideration for the surrogacy is to be paid by the parent(s) and the Bank will not be responsible for any demand by the surrogate in the form of compensation. The Bank shall not be responsible for payment to the surrogate for any other expenses incurred during the surrogacy period.”*

It is therefore not clear from this, who is actually compensating the surrogate. Is it the Bank or the couple/individual?

Secondly, the Draft Bill is unclear about the venue of the actual oocyte retrieval and screening process – whether it is at the semen bank or the ART clinic. Clause 26 (1) states that

*“The collection, screening, storage, and handling of gametes shall be done by a semen bank ...”*

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<sup>1</sup> Sama - Resource Group for Women and Health

However, Clause 20 (1) mentions that

*“Assisted reproductive technology clinics shall ensure that patients, donors of gametes and surrogate mothers ...have been medically tested for such diseases, sexually transmitted or otherwise, as may be prescribed and all other communicable diseases which may endanger the health of the parents, or any one of them, surrogate or child.”*

It is not clear where the screening and testing of donors would take place. Also, since the semen banks are not equipped to conduct oocyte retrieval, the Draft Bill does not specify how they would equip themselves for the purpose.

According to Clause 20 (10), Surrogacy cannot be considered for “patients for whom it would normally be possible to carry a baby to term”, the Agreement for Surrogacy (Form J) makes the surrogate declare that she agrees to act as host mother for the couple who “who are / is unable (or do not wish to) have a child by any other means.” While on the one hand the Draft Bill makes only those couples eligible for surrogacy who cannot carry a pregnancy to term, on the other, it offers surrogacy as a choice, in case they do not wish to go through pregnancy.

There is ambiguity regarding the minimum age for oocyte donation. Under Clause 26 (3), the minimum age is mentioned as 21 years, but Rule 4.7.1 says that “Donors should be healthy women in the age group of 18-35 years.” The Draft Bill must specify its stand regarding the age.

Another point of contradiction is in the Form of Application for Registration or Renewal of Registration of Semen Bank [Form- A (1)]. In the declaration, while on the one hand the person applying for registration of the bank needs to declare that the bank will operate independently of any ART clinic, in the very following point, he/she must undertake to explain the Act and Rules to all employees of the ART clinic in respect of which the registration is sought. The independence of the semen bank from the ART clinic as envisaged by the Draft Bill comes into question here.

Ambiguity over such crucial points is not expected in a Draft Bill and needs to be rectified. It is also interesting to ponder upon how the law would perceive these contradictory clauses and the way their implementation would be brought about. In cases of such contradictions, which clause would be given precedence?

### **ART Procedures and Research**

The Draft Bill appears narrow in its approach by trying to regulate only a specified number of procedures. For example, the Draft Bill mentions procedures of:

*Artificial Insemination (AIH/AID)*

*Intra Uterine Insemination (IUI-H/ IUI-D)*

*In vitro fertilization and Embryo Transfer (IVF-ET) and associated techniques of Gamete Intrafallopian Tube Transfer (GIFT) or Tubal Embryo Transfer (TET)*

*Intra Cytoplasmic Sperm Injection (ICSI) and ICSI with MESA/PESA/TESA/TESE*

*Oocyte donation or Embryo Donation and Cryopreservation of Semen, Embryos, Oocytes and Ovarian Tissue.*

However, the clinics also offer facilities of assisted hatching, blastocyst culture and transfer, laser hatching, ovarian drilling, in vitro maturation, etc. PGD by PCR/FISH techniques have also been introduced in some of the IVF clinics. The Draft Bill does not mention any of these procedures in the entire draft.

Further, having included a chapter on research on embryos, it is surprising that the Draft Bill does not mention human embryonic stem cell research and the restrictions related to it. Considering the fact that the source of embryonic stem cells is generally the spare embryos developed during IVF, the document should make efforts to regulate this aspect. In not doing so, the legislation is limiting itself to only the ART procedures when the involvement of other aspects is well understood.

Surprisingly, the Department of Bio-Technology's Guidelines on Stem Cell Research also do not properly explain the regulation of spare IVF embryos and oocytes being routed for research. This aspect must be incorporated into the Draft Bill so that at some level at least, the process can be legally regulated. The Bill should make concerted effort to regulate embryonic stem cell research.

Keeping in mind the rapid pace of advancement being made in the field, scope should be left in the legislation for the inclusion of new technologies, researches, and the possible debates ensuing from their potential use.

### **Definition of embryo**

It is surprising to find 'embryo' defined as '*the fertilized ovum that has begun cellular division and continued development up to the blastocyst stage till the end of five days*' [Clause 2(h)]; when the ICMR Guidelines for ART clinics issued in 2005 consider the human organism an embryo till the 56<sup>th</sup> day of development following fertilization or creation. According to the PC&PNDT Act too, the embryonic stage continues till the 56<sup>th</sup> day. It is highly unreasonable that one country can have two separate laws, defining the same term in different ways. The MOHFW/ICMR must explain the reason, if any, for this aberrant definition. Consensus over such technical details is very important for processing other aspects of regulation.

### **Registration and Monitoring of ART Clinics**

The Draft Bill in its present form focuses only on IVF clinics and semen banks, but ignores gynaecologists offering infertility 'treatments' and IUI procedure. The Draft Bill also does not take into consideration other consultancies, organizations, agents, private agencies and travel agencies involved in promoting IVF / ART techniques, egg donation and surrogacy. For example, one such agency, on their website states that,

*"... is the first and only professional organization of its kind in India, providing comprehensive services related to Surrogacy and Egg Donation programs..., we are always with you, like a shadow, supporting you, guiding you through every step of your new journey, may it be parenthood, or becoming a surrogate mother or just donating life through your eggs / sperms."*

The Draft Bill must acknowledge the increasing number of 'players' in the ART 'industry' and take measures to specify their role and status in light of this legislation.

Further, the Draft Bill does not adequately dwell on the regulation and monitoring mechanisms for the public hospitals offering these technologies. Government hospitals are increasingly entering the field of ARTs<sup>2</sup>. Hospitals like Lok Nayak Jai Prakash Hospital (New Delhi)<sup>3</sup>, All India Institute of Medical Sciences (New Delhi)<sup>4</sup> and Post Graduate Institute of Medical Research (Chandigarh)<sup>5</sup> have been in news recently for delivering IVF babies. Public hospitals are mentioned only once as a category in the Form of Application for Registration or Renewal of Registration of an Infertility Clinic [Form A (7)] in Type of institution (Govt. Hospital / Municipal Hospital / Public Hospital / Private Hospital / Private Nursing Home / Private Clinic / Private Laboratory / any other to be stated).

### Advertisements

The Draft Bill allows couples to advertise for surrogates without mentioning ‘*details relating to the caste, ethnic identity or descent of any of the parties*’ and prohibits ART clinics from seeking surrogates for its clients [Clause 34(7)].

However, advertisements for egg donors or surrogates by advertisement agencies, tourism departments, surrogacy agents, women’s magazines, medical tours and travel agencies are not covered in the Draft Bill at all. Advertisements from couples looking for surrogates and women intending to be surrogates can be found regularly in newspapers and magazines like Sarita and Woman’s Era mentioning the desired age, religion, caste and even the skin colour of the donors. For example:

*Wanted fair, good-looking, educated and healthy lady preferably Brahmin of 20-30 years of age in Chennai with good background for egg donation.*

Similarly there are many advertisements by women wanting to be surrogates:

*“Good-looking fair, aged 27 years lady from respected family available for surrogate”.*

However, the Draft Bill only prohibits the clinics from advertising but does not foresee the establishment of newer enterprises that may undertake such advertising.

Another significant omission in the Draft Bill is regulation of the content of the advertisements. Currently many IVF clinics advertise for surrogates and egg donors and generally mention the desired age, religion, caste and even the skin colour of the donors. The promotional advertisements of the ART clinics should also be monitored, for more often than not, they are ridden with false claims, unrealistically high success rates, inaccurate costs and other unethical content aimed to lure couples/individuals into opting for these procedures at their clinic. The Draft Bill needs to specify the kind of information that can and cannot be mentioned in the advertisements.

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<sup>2</sup> IANS, *A Boon for Infertile Couples, Test Tube Baby centre at AIIMS*. Samachar.in February 7 2008

<sup>3</sup> Jaya Shroff Bhalla, *Govt Hospital Rejoices first IVF Babies* Hindustan Times, November 11, 2008

<sup>4</sup> TNN, *AIIMS Gets Its First in-vitro Baby*, Sunday Times of India, May 4 2008

<sup>5</sup> Tribune News Service, *PGI First Government Hospital to Produce Test Tube Babies*, May 20, 2008  
<http://www.tribuneindia.com/2004/20040521/cth1.htm>

## Promoting Eugenics through Donor Matching

According to Clause 20(4),

*“Either of the parties seeking assisted reproductive technology treatment or procedures shall be entitled to specific information in respect of donor of gametes including, but not restricted to, height, weight, ethnicity, skin colour, educational qualifications, medical history of the donor, provided that the identity, name and address of the donor is not made known.”*

Similarly, the couples are entitled to know the ethnicity and educational qualifications of the donor and details like religion, education and monthly income of the donor must be recorded in Form M [Information on Semen Donor (4, 6, 7)].

Form M2 [Information on Surrogate (8, 9)] requires education and occupation of the surrogate and her spouse (if any), religion and monthly income. Moreover, current practices indicate that surrogates and donors are chosen based on their caste, religion, skin colour and attractive physical features. A recent article in Times of India stated that

*“Traits such as Fair skin, Lighter hair, Blue/green or light eyes and High IQ levels are greatly in demand by the Indian couples coming to the fertility clinics”.*<sup>6</sup>

Unfortunately, the Draft Bill too supports these trends by asking for the surrogate’s colour of skin, hair, eyes [Form M2 (34, 35, 36)], which is completely pointless since her oocytes would not be used in the procedures. As she only gestates the child, it is unnecessary to record her genetic characteristics. Giving significance to these characteristics is unnecessary since they do not have a bearing on the genetic composition of a person at all. Revealing particular characteristics of the donor to the intended parents and allowing them to choose donors based on those characteristics ushers in a number of debates. They only encourage eugenic tendencies and lead to discrimination against people belonging to particular religions, castes and with low educational and economic status.

These may promote creation of designer babies and can definitely not be allowed through a national legislation. It must be distinguished whether particular characteristics are being chosen because they match with those of the parents or because they are socially prized. Monitoring of such selection, which has been ignored in the legislation, must be strictly undertaken.

## Rights and Welfare of the Child

The Draft ART Bill states that,

*“A child born to a married couple through the use of assisted reproductive technology shall be presumed to be the legitimate child of the couple, having been born in wedlock, with the consent of both the spouses, and shall have identical legal rights as a legitimate child born through sexual intercourse”* [Clause 35 (1)]

It is unclear as to why there is a separate listing of the legitimacy of a child born through ARTs to married, unmarried and single men and women. Moreover, the definition of legitimacy is premised on the assumption that only children born within wedlock are

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<sup>6</sup> This Sperm Counts, <http://www.outlookindia.com>, accessed on 4.11.2008

legitimate. Such an assumption is problematic firstly because a child should not be accorded legitimacy based on her/his birth within or outside “wedlock”. This essentially violates the right of a child to live a life of dignity and respect.

The Draft Bill makes provision for the child to seek information about donors and surrogates on attaining 18 years of age. But at the same time it excludes information regarding personal identification and only in some cases (medical reasons) allows disclosing the information with prior consent of the donor(s) or surrogate. Clause 36(1) of the Draft Bill states that

*“A child may, upon reaching the age of 18, apply for any information, excluding personal identification, relating to his/her genetic parents or surrogate mother.”*

But, the document does not make it clear where the child needs to apply. Since the Semen Banks, the ART clinics and the central database of the ICMR (where the details of the records will be transferred after expiry of 10 years) will keep the records of the donors and the surrogates, it is not clear where the child should apply. By the time the child is 18 years old, the details would be with the Central Data of ICMR.

The Draft Bill also falls short in the measures taken to ensure the welfare of the children born through ARTs. In fact there is no section in the Draft Bill, which talks about the welfare of the child. The only points mentioned in this regard are those granting legitimacy to the children born through ARTs and the right of the child to have non-identifying information about his/her genetic parents.

Special measures need to be taken to ensure welfare of the child and the Draft Bill must direct the ART providers to take into account the age and health and ensure that the intended parents are of appropriate age and would be able to raise the child till he/she at least reaches adulthood.

### **Adoption**

The Draft Bill does not adequately emphasize on adoption. Considering the fact that these technologies do not ‘treat’ or cure infertility, and keeping the potential risks for the mother and child in mind, a responsible legislation regarding infertility and ARTs must encourage adoption and present it as a course of action as significant as ARTs. Rather, this Draft Bill mentions adoption only twice in the whole document. It also mentions that “...Further treatment for the unresponsive couples will then consist of counselling and an in-depth investigation, leading to the use of ART – failing which, adoption may be the only alternative...” suggesting that adoption is an option if and when ARTs fail for a particular couple. This clearly demonstrates the endorsement of the desire for a ‘biological’ child or ‘genetic make’ in an official document.

### **Oocyte retrieval**

The provisions regarding oocyte retrieval and donation bring up a number of questions and concerns. According to Clause 26 (9) of the Draft Bill,

*“If more than fourteen (14) oocytes are retrieved from the donor at one occasion, they shall not be used for more than two recipients thus ensuring that at least seven oocytes are available for each recipient.”*

Retrieving large number of eggs (like 14), requires hyper stimulating the ovaries by injecting hormonal drugs, which often entails serious medical complications for women. Moreover, the retrieval procedure in itself is highly invasive, and may result in serious damage/harm to the woman undergoing it. Referring to retrieval of such a large number of oocytes only shows the apathy of the Draft Bill towards the women who undergo the procedures and their health. The women generally follow the recommendations of the IVF providers who make them undergo these cycles over and over again, which may be due to the low success rate of these techniques.

The questions that this clause raises include: By what mechanism has the figure 14 been arrived at? How has it been decided that a woman's oocytes can go to two women and not to any number higher? Does this also mean that if less than 14 oocytes are retrieved then they can only be donated to one recipient because if given to a second recipient, she will receive less than 7? The ART Bill needs to give some explanation on these aspects. Also, the fate of the spare oocytes must be spelt out clearly. Fourteen oocytes is a large number and there is a chance that the spare ones may be routed for research or for egg sharing, which should be monitored.

It also raises deeper concerns regarding the number of cycles that a woman can undergo while donating. Though the number of times for which a woman can donate oocytes has been limited to 6, [Clause 26(8)] that

*“No woman shall donate oocytes more than six times in her life, with not less than a three-months interval between the oocyte pick-ups”.*

However, the maximum number of cycles (which may be 6 or more) has not been mentioned. Also the mechanism to record and monitor the number of times a woman is making donations has not been mentioned. The three-month interval between the donations stipulated by the Draft Bill is very inadequate. Three months is too early for a woman to start with the hormonal injections again and undergo another oocyte retrieval. This interval should be increased.

Moreover, the potential of exploitation of women for their eggs is as great as for their wombs. Since the sourcing of both egg donors and surrogates is through semen banks, the risk of commercialization is similar. The flow of payment to the egg donor is not quite clear in the Draft Bill. The clauses of the Draft Bill, which seem to be more harmful to the oocyte donors' health coupled with the complicated payment process, put them in a greater vulnerable position.

Interestingly, the specification regarding number of oocytes to be retrieved is only in case of donors. There must be some specifications for the number of oocytes retrieved from women undergoing IVF or women who agree to share their eggs. In the context of egg-sharing, which is often offered in lieu of a subsidy in the IVF procedure, there are chances that this will encourage the providers to retrieve more oocytes, thus putting women under greater health risks, as larger quantities of ovulation inducing drugs have to be administered on the woman sharing her eggs to maximize the chances of producing 'enough eggs'. In the context of large number of clinics providing the egg-

sharing programme, the Draft Bill should spell out clearly the number of eggs that can be retrieved for egg-sharing.

### **Sperm Donation**

The Draft Bill states that

*“A semen bank shall not supply the sperm of a single donor for use more than seventy-five times”* [Clause 26(7)]

At the same time it explicitly mentions that one sample of semen can be given to only one recipient

*“One sample of semen supplied by a semen bank shall be used by the ART clinic only once on only one recipient”*. [Clause 26(10)]

The rationale behind allowing the sperm of a single donor to be used for seventy-five times is not clear and has not been explained in the Bill. Seventy-five is a considerable figure for a single semen donor's sample to be supplied.

### **Health Risks and Side Effects**

The Draft Bill states that *“ARTs carry small risks both to the mother and the offspring”* (Rules 6.13) and mentions the risks for women which include multiple gestation, ectopic pregnancy, spontaneous abortion and Ovarian Hyper Stimulation Syndrome (OHSS).

It is appalling how the MOHFW/ICMR has described life-threatening risks like multiple gestation, ectopic pregnancy and spontaneous abortion as *‘small risks’*. It only reflects their extent of concern for women's wellbeing in a document that actually seeks to regulate these technologies and ensure their safe delivery. In fact, these risks further entail serious implications, which have not been mentioned in the Draft Bill. For example, multiple gestation pregnancies can lead to toxemia, early labor, placental dysfunction, cesarean sections, increased still birth, late miscarriages, low birth weight babies and perinatal mortality, The other risks include prolonged hospitalization (and the costs associate with it) as premature babies are kept in intensive care for longer periods.

Similarly, while the Draft Bill advises a studied recommendation of foetal reduction for multiple gestation, it does not mention the morbid risks of foetal reduction which include: uterine bleeding, developing infection, premature labour and loss of all fetuses. The Bill should emphasize on keeping the instance of foetal reduction to a minimum, for which the number of oocytes or embryos to be transferred must be restricted to 2 irrespective of the age of the women, the nature of embryos/oocytes (fresh or frozen) etc.

Moreover, the Document states that foetal reduction may be carried out in cases of multiple pregnancy, *“...if so instructed by the patient...”* [Clause 23(5)], thus once again levying the onus of the procedure on the couple that the Draft Bill itself qualifies as problematic in another section.

Risks associated with ectopic pregnancy include internal bleeding, pelvic and abdominal pain, scar tissue formation leading to problems in conception in the future, risk of future ectopic pregnancies, and even shock and death. On the one hand while the Draft Bill

enlists ectopic pregnancies as a 'small risk', on the other, it contradicts itself by mentioning that the risk of an ectopic pregnancy could be as high as 5%, and that of OHSS could range from .2 – 8%. (Rules 6.13.3)

Systematic analysis of the available medical literature reveals that many of the physical side effects of ART are direct by-products of the drugs like Pergonal and Clomiphene that are used to stimulate the ovaries to produce eggs. Severe form of OHSS may lead to renal impairment, liver dysfunction, thromboembolic phenomena and shock. There are also increased risks of pregnancy loss, premature delivery, infant abnormalities, pregnancy-induced hypertension and hemorrhage.

Complications may also occur during egg harvesting procedures. The removal of eggs through an aspirating needle entails a risk of bleeding, infection and damage to the bladder, or a blood vessel and to the bowel.

The document fails to convey the extent to which the drugs used and procedures performed during ARTs may potentially harm the health and well being of the women undergoing the procedures. This attitude is also reflected through the consent forms where adequate information on the implications on OHSS (Form D, Consent form to be signed by the couple for IVF and ICSI) are conspicuous in their absence.

While the document mentions risks for the women, risks to the **offspring** are not mentioned at all. According to a study conducted between May 2001 and April 2004, 7 children between the ages of 5 and 21 months conceived by ART presented with breast development and/or pubic hair and were referred by their pediatricians to the Division of Pediatric Endocrinology at the New York University School of Medicine for evaluation of possible precocious puberty. Patients were evaluated for the possibility of centrally mediated precocious puberty and pseudo precocious puberty, with a possible ovarian or adrenal origin. The clinical presentation in these infants raises awareness that an altered intrauterine hormonal milieu may impact the fetal and infant stages of children conceived by ART.<sup>7</sup>

A recent news item mentions that the risk of birth defects is 2 to 4 times higher in babies born with the help of assisted reproductive technologies.<sup>8</sup>

A recent article announcing the birth of first IVF twins at AIIMS, besides the celebration and the rejoicing, revealed that the woman who gave birth had gone into pre-term labour, underwent an emergency caesarean and that the children weighed only 1.4 kg each<sup>9</sup>. The normal birth weight of twins ranges from 2-2.5 kgs and those born through IVF are clearly underweight. Unexpected complications and low weight at birth are not uncommon in IVF deliveries and definitely have an adverse impact on the health of the off spring.

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<sup>7</sup>Hormonal effects in infants conceived by assisted reproductive technology. Pediatrics. 2005 Jul;116(1):190-4.

<sup>8</sup> Times of India, 19<sup>th</sup> November 2008, Denise Grady, Birth defects tied to fertility techniques

<sup>9</sup> Hindustan Times, AIIMS clinic gets its first IVF twins October 11, 2008

Another research compared around 1.2 million singleton births with 8,229 singletons conceived by ARTs in Norway. It was found that children born by ARTs were around 70% more likely to be premature (born before 37 weeks) and more than twice as likely to be born before 32 weeks. Children born by IVF and other methods were also 26% more likely to be small for their gestational age.<sup>10</sup>

### **Intra-cytoplasmic Sperm Injection (ICSI)**

ICMR should take into consideration the fact that nowadays, some clinics are advocating routine ICSI for all users including those with normal sperm counts, and should stress that pregnancy should be achieved with minimum handling of the gametes outside the body. The Draft Bill must take measures to ensure that ICSI is not resorted to unless the indications specified in the Draft Bill are present.

Moreover, in the entire Draft Bill, the emphasis is on ICSI with MESA/ PESA and TESA/TESE, while other methods using ICSI variations are not mentioned. Though the Consent Form for the procedures of PESA and TESA (Form H) mentions that there is no guarantee of a mentally and physically normal baby; it does not spell out any potential risks or complications involved, nor does it mention that there is a greater risk of genetic abnormalities in the children conceived through ICSI. Although it is seen as a relatively safe and harmless procedure, the most significant drawback is the blind nature of the procedure, often requiring multiple, potentially damaging needle insertions. The delicate, coiled anatomy of the epididymal tubules is easily damaged with such maneuvers. While PESA may be successful for one's first ICSI cycle, future cycles will require repeated procedures and the increased likelihood of progressive epididymal damage. Such potential risks should be clearly stated in the Consent Form.

Even the Consent Form to be signed by the Couple for IVF and ICSI (Form D) does not state any of the risks/complications associated with the procedure. According to few studies, there is a clear increase in sex chromosome abnormalities in the offspring from ICSI, more so in ICSI without PGD. The rate of sex chromosome abnormalities are 1% compared to 0.2% in the general population<sup>11</sup>, i.e., 5 times greater!

The user should be provided with detailed and complete information, as mentioned in the Human Fertilization and Embryology Authority's Code of Practice (6<sup>th</sup> Edition, Part 16-Intra Cytoplasmic Sperm Injection, Factors to be Considered, Pg 134) regarding the following:

- i). risks involved with ICSI
- ii). possible inheritance of genetic and chromosomal abnormalities including
  - (a) inheritance of cystic fibrosis gene mutations
  - (b) sex chromosome defects and the inheritance of sub-fertility
- iii). abnormal numbers or structures of chromosomes

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<sup>10</sup> <http://www.guardian.co.uk/science/2008/jul/31/medicalresearch.health>

<sup>11</sup> Funding in vitro fertilization treatment for persistent sub fertility: the pain and the politics. Fertility and Sterility, Vol 76, no 3, Sept 2001

- iv). novel chromosomal abnormalities
- v). possible developmental and birth defects
- vi). possible risks during pregnancy such as miscarriage

The ART Bill must ensure that ICSI is carried out by qualified practitioners in the ART clinics.

### **Age**

The Draft Bill has left a substantial void in the regulation process by not specifying the maximum permissible age of women for undergoing ART procedures. Considering the serious health implications whose magnitude increases with the age of the women, this lacuna needs to be addressed. There have been cases where women as old as 60 years or above have been made to conceive through ARTs with serious implications to their health. Providers are glad to undertake such 'challenging' cases without analyzing the repercussions and this should be monitored by the MOHFW/ICMR, rather than left to the discretion of the providers. The Draft Bill should specify the maximum age limit for accessing ARTs.

Another important aspect completely missing in the Draft Bill is the number of embryo transfers and oocyte retrievals corresponding with the age of the woman. It states that  
“...not more than three oocytes should be transferred for GIFT and not more than three embryos for IVF-ET at one sitting, excepting under exceptional circumstances (such as elderly women, poor implantation, advanced endometriosis or poor embryo quality).” (Rules 6.13.1)

This may cause problems as it leaves considerable scope to retrieve more eggs and transfer more number of embryos, putting the woman under risk. Moreover, having said that more than 3 embryos may be transferred in cases of older women, the document, on the same page, states that

“Abortion rates rise with increasing age of the mother and in multiple pregnancies, especially with three or more fetuses.” (Rules 6.13.3)

As age has considerable bearing on the number of oocytes retrieved and the embryos to be transferred, it is important that the Draft Bill should take this into consideration.

MOHFW/ICMR should specify the maximum age of the women undergoing ARTs and the number of embryo transfers according to the age of the woman.

### **Semen banks**

The Draft Bill in its current form hands over a substantial part of managing and running the ART process to semen banks without providing any rationale.

According to Clause 26 (1), ‘the collection, screening, storage and handling of gametes will be done by a semen bank’. Moreover, semen banks can also advertise and source surrogates to couples/individuals seeking surrogacy services. It is evident that most semen banks are not currently equipped for carrying out these tasks assigned to them by the MOHFW/ICMR. It is also well known that the process of oocyte retrieval/donation is completely different from sperm donation - it is an invasive procedure requiring ovarian stimulation with hormones and must be conducted in a clinical set up under proper

medical supervision. Without clear directions regarding mandatory equipment and personnel in the semen bank, the Draft Bill does not make itself clear on how they are going to equip themselves for these responsibilities.

More importantly, the Draft Bill does not lay down any clauses specifying who can open and run a semen bank- the qualifications and background of the person and the team necessary to run a semen bank, as has been specified for ART clinics. Keeping in mind the significant duties given to the semen bank, the Draft Bill should make adequate provision for the inspection and monitoring and regulation of semen banks.

While, on the one hand, the attempt made to prevent ART clinics from sourcing the donors and surrogates can be appreciated, by handing over this function to semen banks, the MOHFW/ICMR has just replaced one agency by the other. The issue, however, remains unresolved. Infact, with little explanation in the Draft Bill regarding the operationalization of the whole process, the matter gets more complicated.

Though the Draft Bill envisages separating the semen bank and the ART clinic [Clause 26(2)] to what extent this would be possible is debatable. The Draft Bill anyway appears weak in trying to separate the ART clinic and the semen bank in view of the operational realities and the contradictions within the form for registration of semen banks [Form-A(1)], as has been pointed out before. Though there are both advantages and disadvantages with the segregation, but the main question is whether it would really be possible to implement it. Currently, many ART clinics have their own semen banks and delinking the bank from the clinic may only mean that the bank would be registered separately but continue to function in the same way. Proper protocols, regulatory mechanisms and accreditations are necessary in order to monitor the practice of the semen bank.

The Draft Bill stipulates that the semen bank [Clause 20(3)] should identify a responsible staff member from the semen bank and he/she will take the donor to the clinic who would undertake that they do not disclose the identity of the donor. The purpose of this whole exercise is not clear in the Bill. Would the donor be taken to the clinic only to obtain a written agreement that the clinic shall not reveal the identity of the donor? With every new player being added in the process of donation, the risk of breach of anonymity of the donor keeps getting higher. Moreover, such convoluted procedures only complicate situations where the clarity of roles of the ART clinic and the semen bank gets diffused.

There needs to be a clear cut demarcation of roles of the ART clinic and the semen bank, which is one of the weakest points in this Draft Bill. There is a greater risk of manipulation, entry of intermediaries, breach of anonymity of donors as well as surrogates and thus exploitation of the users as well as donors and surrogates.

### **Screening of the semen**

The modus operandi of the semen bank in the context of screening of semen is somewhere lacking and needs to be thought about. According to the Draft Bill, donor sperm can be used after a quarantine period of six months. Semen donors should

undergo rigorous screening for acquired and genetic diseases including HIV, Hepatitis and other sexually transmitted and infectious diseases. Though a few of the diseases have been mentioned in the Rules, an exhaustive list of all the diseases/conditions/infections for which sperm donors have to be tested must be provided in the Draft Bill.

Moreover, the male partner in a couple commissioning a surrogacy should also be tested in the same way as a sperm donor.

### **Counselling**

The significance of counselling for people who opt for ARTs cannot be emphasized enough, provided the counselling is intended to help them make decisions which are truly 'best' for them. If counselling is done by the ART clinics' own counsellors, one may never be sure in whose interest the counselling is actually being done – the couple or the clinic. It is not difficult to fathom that the clinic may be inclined to further their own commercial interest and may not be able to provide an unbiased and unprejudiced counselling service. This calls for provisions to arrange for counsellors independent of the ART clinic and the Draft Bill must provide the guidance for accessing such independent counselling agencies.

The Draft Bill, while mentioning the educational requirements of a counsellor also states that

*“A member of the staff of an ART clinic who is not engaged in any of other full-time activity in the clinic can act as counsellor.” (Rules 2.4)*

In such a scenario, the quality of counselling would be questionable. Our interactions at various ART clinics across the country show that it is usually the provider who acts as the counsellor. Professional counsellors in ART clinics are rarely employed. This undermines both the quality and the significance of counselling while accessing ART procedures.

There should also be a demarcation between mandatory information to be provided to the users and counselling. While mandatory information should include all the information regarding side effects, systematic break down of costs and essential details of the procedures, counselling should be customized for the particular couple /women according to their age, number of years married, cause of infertility, and other specific details about the couple. Mandatory information should not be camouflaged as counselling.

The following points should be covered as part of information being provided to the users:

- i). all the risks and side effects to the woman and the child, as mentioned in the section on side effects in this critique. )
- ii). cost (hidden and actual, schemes and packages), fees or reimbursements relevant to treatment, donation or storage of gametes or embryos
- iii). information on success rates,

- iv). the availability of embryo freezing facilities and the likelihood of success with embryo freezing, thawing and transfer
- vi). options available in the event of death or mental incapacity of them and/or of a donor and the consent required to fulfill individual's wishes

The Draft Bill should ensure that the ART clinics provide all relevant and correct information to the individuals. All technical terms and details must be explained and all written information must be read out to non-literate persons in a language understood by them.

During the counselling for individuals who are providing gametes or embryos for donation, or wish to store their gametes or embryos, they should be given complete explanations about the medical, scientific, legal, and psychosocial implications of their decision. The couples/individuals should be counselled regarding the other available options for infertility; Possible variations, outcomes and limitations of the procedures (data provided in all relevant patient resources should be the clinic's own most recent live birth rate per treatment cycle and the national live birth rate per treatment cycle); the advantages and disadvantages of continued treatment after failed attempts and the importance of informing the treatment centre about any resulting birth.

In surrogacy cases, the surrogate must be provided with adequate psycho-social counselling, and the implications of her decision on her and her family should be properly explained to her. Directions regarding counselling to the surrogate have not been specified in the Draft Bill. Also, the Draft Bill must clearly specify whether such counselling would be provided by the ART clinic or the semen bank.

Further, the Draft Bill mentions counselling services only within the context of ART clinics, whereas a large proportion of people – the oocyte and sperm donors- would be dealing with the semen bank instead of the ART clinic and should therefore be counselled at the semen bank. The Consent form for Donor of Eggs (Form K) carries an endorsement by the ART clinic saying that the implications of the donation have been explained to the donor (which again raises the confusion whether the oocyte retrieval is taking place at the semen bank or the ART clinic). In case the retrieval is taking place at the semen bank, the bank must have an in-house counsellor to counsel the male and female donors.

The Draft Bill should also mention certain points regarding genetic counselling, since it is one of the services being provided by the clinics. Taking an example from the Human Fertilization and Embryology Authority Code of Practice (6th Edition), 'Centres are expected to a) Have arrangements in place for referral whenever appropriate to specialist genetic counselling services and b) Ensure that whenever individuals are referred for genetic counselling the confidentiality provisions are considered and complied with.'

Genetic counselling is an upcoming field and adequate attention must be given – to understand, regulate and monitor it.

## **Consent Forms**

There are 31 formats (application forms, record sheets, contracts) attached in the end of the Draft Bill, which make up a significant proportion of the document. MOHFW/ICMR's attempt at trying to streamline each and every aspect of the procedures is commendable.

However, in the Consent Form for Freezing of Embryos (Form G), giving the embryos for research (in case of death) is given as one of the options. There is no separate Consent Form for embryo research in the Draft Bill. However, due to increasing interest among scientists in research with embryos, proper consent for research becomes extremely important.

In Form J, (Agreement for Surrogacy) the surrogate needs to declare that she and her husband have not had any extra marital relationship in the last six months. Such provisions are not only unreasonable but also pointless as this impinges on the sexual life of a woman who would be a surrogate. Also there seems to be an assumption in the Draft Bill that HIV can be acquired only through 'extramarital' relationship. Asking for a declaration not only reflects a narrow and stigmatizing attitude towards HIV as a disease but also encroachment on the sexual lives of the individuals. Moreover, she may not be aware of her husband's extramarital relationship, or she may not have a husband at all. It attempts to rule out the inclusion of single women from surrogacy. Surprisingly, there is no mention of the intended parent undergoing any screening tests for HIV or for any other infectious disease.

The various Consent Forms, specially the agreement on surrogacy, stress on spousal consent. Such requirements of 'consent' formally establish and reinforce the heteronormative principle of the 'husband's' right to control the 'wife's' body. This prerequisite appears unreasonable since it takes away the right of the surrogate over her own body. This should be reconsidered by the MOHFW/ICMR.

Moreover, in all procedure and processes, the act of taking Informed Consent should not be restricted to taking a signature of the person concerned, but should be a continuous process of explanation and interaction over a period of time.

## **Database**

Implementing the kind of regulations that the Draft Bill proposes to put in place would be next to impossible without the maintenance of a sound database. For example, it would not be possible to track the number of times a women has acted as surrogate, the number of oocyte retrievals a woman has undergone the number of times a male donor's semen has been used etc. Without the requirement of an updated centralized record keeping, chalking out such rules is futile.

While the Draft Bill mentions a centralized database to be maintained by the ICMR, there is no proposed system to record the number of children born to Indian surrogates being taken out of the country and the number of foreign couples undergoing

ART procedures in India. Serious steps need to be taken to incorporate all these cases into a proper recording system.

Moreover, a database, if properly maintained will be useful in giving a sex-desegregated data (in terms of male and female) with respect to children born through IVF and surrogacy which is not available till now. This would be immensely useful in revealing the extent of sex determination being undertaken during the ART procedures.

It is extremely important that the central database keep a record of:

- Live birth rate/take home baby rate
- No. of implantation Rate
- No of still births
- No. of premature children born
- No. of children born with congenital malformation
- No. of miscarriages
- No. of children born through Cesarean sections
- No. of healthy IVF children born
- No. of male and female children
- No. of maternal deaths

Apart from keeping track of the above data, the ICMR as a premiere medical research body, should undertake research on the health of the women and children born through ARTs to understand the various aspects of the implications of these technologies in the long run. It is the responsibility of the MOHFW/ICMR to establish an authentic success rate of these technologies and establish the potential risks, complications and other health implications as specific to the Indian population to provide the future users of these technologies a more informed choice.

### **Preimplantation Genetic Diagnosis (PGD) and Sex Selection**

The use of PGD for non-medical purposes is very controversial. Many moral and ethical issues are associated with PGD, such as the choice to be able to select the embryos of a particular sex, potential of parents to exercise excessive control over their children's characteristics, costs and availability dependent on the financial status of the parents, safety, accuracy, regulation and monitoring.

The Bill does not carry any Consent form for the procedure of PGD. Even in the Agreement for Surrogacy (Form J) though there is a mention that the surrogate will not be asked to undergo sex determination test for the child, this does not incorporate PGD, which is conducted on the embryo before it is transferred into the surrogate's uterus. Also, the Consent Form for IVF and ICSI (Form D, Pg 81) does not mention anything regarding the prohibition of sex-selection during the procedure.

The use of PGD should be strictly monitored and it should be made clear that PGD will be available only where there is a significant risk of serious genetic condition being present in the embryo. Though prohibition of sex selection has been mentioned in Clause 25 (5) but the Draft Bill should deal with the issue of sex-selection more stringently.

## Eligibility

Though the Bill claims to be liberal by using the phrase married or unmarried couple as eligible for ARTs, it does not include within its ambit people who are not heterosexual and their accessibility to ARTs. The Bill clearly defines “Unmarried Couple” as a man and a woman, both of marriageable age, living together with mutual consent but without getting married [Clause 2(w)] and “Couple”, as persons living together and having a sexual relationship that is legal in the country / countries of which they are citizens or they are living in. [Clause 2(e)]

In fact, ‘Couple’ has been defined in such a way in the Draft Bill that homosexual couples from other countries (where same sex relations are legal) can avail ART services from India, but not Indian homosexuals. Under Section 377 of the Indian Penal Code (IPC), “carnal intercourse against the order of nature”, non procreative sexual acts are criminalized and this law is used to criminalize homosexuality. Therefore, Indians who openly identify as homosexuals are not eligible. Interestingly, some of the clinics are regularly providing these procedures to gay couples from abroad. For example, Rotunda - The Center for Human Reproduction in Mumbai was recently in news for successfully delivering a child for an Israeli gay couple through surrogacy. The centre has seen 40 same sex couples since 2005 and Dr. Gautam Allahabadia of Rotunda says, “We receive frequent requests from same sex couples from France, Spain and Sweden.”<sup>12</sup>

As per both the above-mentioned definitions, only heterosexuals, irrespective of their marital status, are eligible to access these technologies in India. Even the Consent Forms require the signatures of husband and wife, and only at some places does the Draft Bill mention signature of the partner and provide ARTs to heterosexual married couple as a single entity.

The entire document is structured around the heterosexual, married couple. In doing so, the Draft ART Bill provides an articulation of this heteronormative institutional structure and the normative distribution of power therein.

## Surrogacy

Regulation of surrogacy must be preceded by an examination of the context within which it is proliferating in India. Though the practice of surrogacy has been existing from the past, it has become a huge business in recent years, not only nationally, but cutting across national boundaries also. It is estimated that the surrogacy business alone is worth \$445 million in India<sup>13</sup>.

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<sup>12</sup> Times of India, 18 November 2008, Israeli gay couple get a son in India?, by Madhavi Rajadhyaksha

<sup>13</sup> IANS (August 25<sup>th</sup>, 2008) Surrogacy a \$445 mn Business in India’, *The Economic Times*, Mumbai. Retrieved on August 29, 2008 from [http://economictimes.india-times.com/News/News\\_By\\_Industry/Surrogacy\\_a\\_445\\_mn\\_business\\_in\\_India/rssarticleshow/3403841.cm](http://economictimes.india-times.com/News/News_By_Industry/Surrogacy_a_445_mn_business_in_India/rssarticleshow/3403841.cm)

It has become evident through media reports that it is generally the socio-economically marginalized women who agree to act as surrogates due to the financial benefit it entails. This not only puts these already-vulnerable women in situations where their bodies may be exploited for the benefit of other people, but also jeopardizes their physical and mental health, thus making them 'objects of reproduction'.

MOHFW/ICMR should take special measures for safeguarding the rights and health of the surrogates commissioned by foreign couples. It should also be kept in mind that since such agreements cannot be made without employing middlemen, it is simply paving the way for the commercial exploitation of the surrogate. There should be a separate format for the agreement between the surrogate and the foreign couple.

The Draft Bill must prohibit the entry of intermediaries in the process of surrogacy arrangement and clearly prohibit acceptance of consideration for arranging the services of a surrogate or making such offers by making it punitive.

The Draft Bill prohibits the surrogate from being the egg donor [Clause 34 (13)]. Therefore, in case the oocyte of the intended mother is unviable and she is not able to carry a pregnancy to term, the couple would have to seek an egg donor and a surrogate. This also indicates that the surrogate would have to undergo IVF even when her oocytes are viable and she can bear the child through the much simpler IUI technique. Whether this has been stipulated to prevent the surrogate from being the genetic mother (and hence having a greater right over the child) or to promote the financial interests of the ART clinic is not known. Moreover, according to the Reproductive Technologies: Surrogacy, and Eggs and Sperm Donation (from Parliamentary Information and Research Service of Canada), "*Success rates of pregnancy are generally higher for artificial insemination than for IVF, and therefore by extension genetic surrogacy is generally more successful than gestational surrogacy*"<sup>14</sup>. Thus, genetic surrogacy is a more successful and much simpler form of surrogacy.

With these pros and cons in mind, the Draft Bill should permit genetic surrogacy and not restrict itself to the more complicated, expensive and risky gestational surrogacy only.

### **Eligibility & Age**

Whether single women are permitted for surrogacy has been left to the reader's power of deduction. The Draft Bill neither prohibits nor explicitly permits single women for acting as surrogates. Though it permits single women for accessing ARTs in general and also makes statements like

*"In the event that the woman intending to be a surrogate is married, the consent of her spouse shall be required before she may act as such surrogate"* [Clause 34(16)]

It does not clearly mention its stand. The MOHFW/ICMR must take care of such ambiguities.

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<sup>14</sup> Norris, S. 2006, *Reproductive Technologies: Surrogacy, and Eggs and Sperm Donation*, Parliamentary Information and Research Service, Science and Technology Division, Library of Parliament of Canada, <http://www.parl.gc.ca/information/library/PRBpubs/prb0035-e.htm>

The ART Bill mentions that a relative acting as a surrogate must be from the same generation [Clause 34(18)] while restricting the age of the surrogate from 21 to 45 years [Clause 34(5)]. However, there may be cases when the prospective surrogate, mother-in-law for instance, falls within the permitted age group but does not belong to the same generation. The Bill must specify which clause should be adhered to in case the two clash,

### **Contract**

The Draft Bill does not mention the details of administration of the contract between the surrogate and the couple: who makes the contract and monitors that it is not breached? How would the money transaction actually take place? In case the surrogate is directly hired by the couple, how would the semen bank come into the picture and what would be the significance of the surrogate's contract with the semen bank?

There might be cases when the child is unwanted by the intended parent(s) or if the couple splits and there is no-one to take care of the child. The Draft Bill should clearly spell out what happens if such a circumstance arises and any other similar situations.

### **Payment to the surrogate - role of semen bank**

The document does not carry a much-needed elaboration on the money transactions between the surrogate, the commissioning couple and the semen banks - a key problem area. Since the thrust of the regulation is to regularize the commercial angle in the 'ART industry', this aspect is conspicuous in its absence.

Firstly, there is no clarity on the role of the semen banks with regard to financially compensating the surrogate, as has been explained before. Secondly, the Agreement for Surrogacy (Form J) states that "*I have worked out the financial terms and conditions of surrogacy with the couple in writing*" (Pg 92), but does not mention how this would be carried out.

It appears from this statement that the amount will be mutually decided by the couple and the surrogate. But, considering that the surrogate in most of the cases is from a poor socio-economic background, her say in deciding the amount remains questionable. In case the surrogate is not in the capacity to chalk out the financial details by herself, by whom would this process be facilitated? Since the semen bank has a role in sourcing the surrogates, this role may be played by them, which is not a desirable situation either since the semen bank may itself be involved financially in this agreement.

### **Number of cycles/ attempts/ surrogacies**

The Bill mentions that '*No woman shall act as a surrogate for more than 3 successful live births*', ([Clause 34(5)] irrespective of the number of earlier pregnancies although the medical risks of frequent childbirths without adequate spacing are well known. The health risks associated with higher and frequent IVF cycles has been adequately emphasised in an earlier section of this critique.

Restricting surrogacies in terms of successful live births is futile if the number of cycles is not specified. The document allows three successful live births along with permitting 3 ETs for a particular couple. Therefore the surrogate may legally undergo 9 cycles, which

may result in hazardous consequences for her health. Moreover, she may be donating oocytes and may also have had children of her own. These coupled with a lack of record keeping and a subsequent failure to trace a woman's reproductive history may have hazardous consequences on her mental and physical (especially reproductive) health. At the very least, the number of pregnancies that a woman has already had must be considered while restricting the number of surrogacies.

### **Health Insurance and Legal Aid**

The surrogate must be reimbursed all her expenses made owing to the pregnancy including those spent on travel to the doctors, medical check ups, etc. She should also have a medical and life insurance, paid by the intended parents/parent, and assured access to free legal aid in case any conflicts should arise during the surrogacy arrangement.

### **Rights of the Surrogate**

The Draft Bill must ensure that the intended parents understand and agree to the fact that the surrogate has a right to physical integrity and bodily autonomy, i.e. she cannot be forced to abort the foetus, go through foetal reduction or made to follow a certain diet. These decisions are for the surrogate, and no one else, to make. The Medical Termination of Pregnancy (MTP, 1971) Act guarantees women in India the right to abortion, while international human rights legislation guarantees her physical integrity. However, no sex-selection should be allowed even with the consent of the surrogate.

The surrogate's right to privacy and physical integrity should be acknowledged in the Draft Bill. Every human being, without distinction of any kind, has a right to life, health, physical integrity, privacy, and a right to make decisions concerning reproduction free of discrimination, coercion and violence. No antenatal testing, foetal reduction or abortion should be done without the permission of the surrogate. Moreover, the intended parents cannot demand or force her to follow a particular diet, religious rituals or life style during pregnancy. However, it should be ensured that the surrogate behaves responsibly and in the best interest of the unborn child.

### **Screening**

Screening for genetic parents/intended couple has not been emphasized adequately. It has been mentioned in the Contract between the Semen Bank and the Surrogate [Form-R (2)] but has not been listed under the roles and responsibilities of the semen bank. Such provisions in a context where it is the economically weak and the socially marginalized who opt for surrogacy clearly reflect the class and power politics in action. When the Draft Bill makes stringent clauses to screen the surrogate, what is the rationale behind not emphasizing the screening the intended parents to ensure the health and well being of the surrogate?

### **Guardianship**

Clause 34 (19) states that for foreign couples commissioning a surrogacy, a local guardian will be appointed for the surrogate mother. It is highly unacceptable that an adult woman be under the supervision of a guardian, merely because she agrees to carry someone else's child, who can interfere in her daily life by directing what to do and what

not to do. Also, maintenance of the anonymity of the surrogate comes under question with the presence of a local guardian.

While the Bill goes as far as appointing a guardian for the surrogate, it makes no effort in ensuring the safety of the child being taken by the commissioning couple out of the country. There has to be some sort of follow up or reporting back by the couple/individual regarding the child.

### **Birth certificate**

According to Clause 35 (7)

*The birth certificate of a child born through the use of assisted reproductive technology shall contain the name or names of the parent or parents, as the case may be, who sought such use.*

This implies that the name of the couple seeking ART or commissioning the surrogacy will be written on the birth certificate. The MOHFW/ICMR should consider granting a parental status to the surrogate mother. When a woman gives birth to a child, the birth must be officially documented and that woman must be the natural parent of the child born to her. This can be followed by a transfer of parenthood to the intended parents, either through adoption or another system devised for the purpose. Thus the birth certificates must have the name of the genetic/gestational surrogate.

Moreover, the document repeatedly assumes that the intended parents are the genetic parents in surrogacy cases. For example, Clause 34(10) states that “*The birth certificate issued in respect of a baby born through surrogacy shall bear the name(s) of the genetic parents / parent of the baby.*” If the genetic parent of a child born through surrogacy is a donor, then would the birth certificate have the name of the donor?

### **Conclusion**

Apart from inconsistencies in the document, a larger concern emerges from the outlook from which it approaches the issues. The medical approach to address issues rooted in the social context creates more problems than it solves. Moreover, everything that is medically possible should not necessarily be legally permissible. Law is an instrument of social engineering and must be developed with consideration for all sections of society, especially those that are more vulnerable and marginalized, to prevent any kind of exploitation. Since the Draft Bill seems to have been prepared mostly by people from medical fraternity who are practicing ARTs, it appears to aid the growth of the business of ARTs both within and outside the country rather than safeguard the health and interests of the women on whom these technologies are applied.

This document is an effort to point out the limitations in the Draft Bill so that they can be rectified and the suggestions incorporated for the development of a pro-people and pro-women legislation.

Keeping in mind the above mentioned concerns, we urge the MOHFW and ICMR to not rush into finalizing the Draft Bill till a wider debate across the country, at various levels and regions has been conducted and their responses incorporated. We urge the ICMR and MOHFW to organize public hearings in different parts of the country with

active involvement of women's and health movements, and other sections of the civil society. More importantly, the finalization of the Bill should also involve their active participation.

With the experience of working with women on the issue, we urge you to consider our comments and suggestions very seriously and act upon this matter in the larger interest of the health and well being of the women of this country. We hope that sincere attempt would be made to incorporate the points presented in this critique into the Draft Bill on Assisted Reproductive Technologies.

Sincerely,

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