

**Handbook on**  
**Pre-Conception & Pre-Natal**  
**Diagnostic Techniques Act, 1994**  
**and Rules with Amendments**



Ministry of Health and Family Welfare  
Government of India  
2006

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## **INTRODUCTION**

The social, cultural and religious fibre of India is pre-dominantly patriarchal contributing extensively to the secondary status to women. The patrilineal social structure based on the foundation that the family line runs through a male makes men a precious commodity that needs to be protected and given a special status. Another important pillar of the patriarchal structure is marriage wherein women are given a subordinate status having no say in the running of their life or any control over their body or bodily integrity. Marriage is also considered as a process whereby the burden of the father is passed on to the husband for a very high price. The dowry or groom price is so staggeringly high irrespective of the class structure that generations may have to toil to repay the debts incurred during marriage. All of this has contributed to a low social status for women in the society to such an extent that even the birth of a girl child in a family is sought to be avoided.

A deleterious fall out of the subjugated position of women is their vulnerability to violence like domestic violence, rape, sexual abuse, dowry harassment, trafficking etc. with little or no mechanisms of combating the same either by way of effective laws and implementation or civil society action. A pernicious form of violence against women in some parts of India has been and still is the elimination of the girl child or female infanticide. Various methods were found to eliminate the girl child after her birth like starving her, crushing her under the bed or giving her poison etc. Pertinently, the responsibility for killing the child was fixed on the woman/mother as she was considered responsible for bringing the girl child into existence.

An examination of the causes for eliminating the girl child indicates that the reasons are similar and different depending upon the geographical location in which female infanticide is practiced. Exorbitant dowry demand is one of the main reasons for female infanticide. Some of the other reasons are the belief that it is only the son who can perform the last rites, lineage and inheritance runs through the male line, sons will look after parents in old age, men are the bread winners etc. Things have come to such a pass that in some villages of Madhya Pradesh, no marriages have taken place for years because there are no girls and the boys are married by buying girls from faraway villages of Bihar for paltry sums. In one district in west Rajasthan, in 1997, the first "baraat" was received after 110 years and in another clan, there are only two female surviving children compared to 400 male children. In some cases parents are prepared to accept the daughter if she happens to be the first child but thereafter they want only sons.

Strong male preference and the consequent elimination of the female child has continued to increase rather than decline with the spread of education. This has been helped by the techniques of elimination of the girl child becoming more scientific with the progress in science and technology. Female infanticide now in most places has been replaced by female foeticide and in fact sadly, female foeticide has made inroads into areas where traditionally there were no instances of female infanticide. The moral guilt attached to elimination of the girl child after she is born is not felt equally if the child is eliminated while still in the womb.

Female foeticide or sex selective abortion is the elimination of the female foetus in the womb itself. However, prior to the elimination, the sex of the foetus has to be determined and it is done by methods like amniocentesis, chorion villus biopsy and now by the most popular technique ultrasonography. Once the sex of the foetus is determined, if it is a female foetus, it is aborted. Apart from the technique and timing varying between female infanticide and female foeticide, for female foeticide the assistance of a third party namely a medical practitioner is required to determine the sex of the foetus. This intervention could have been a great deterrent in effectively countering female foeticide, instead the continuous demand and easy money has led to the medical practitioners colluding with parents and relatives to do sex determination. As a consequence sex determination centres have mushroomed in all parts of the country including small districts and villages. Medical practitioners have overnight changed their discipline to fulfill the never-ending demand for sex determination. In many cases, these centres are manned not by qualified doctors but by only technicians.

The increase in female foeticide has seen the proportionate decrease in female sex ratio which has hit an all time low especially in the 0-6 age group and if this decline is not checked the very delicate equilibrium of nature can be permanently destroyed. Moreover it is not only a problem of numbers. The very status of women and the gains that have been made over the years are at stake. If there are fewer women in society, the violence against women in all its forms would go up and the resultant atmosphere of insecurity would lead to women again being confined within the four walls of the home. The girls would not be allowed to go out to study and women would not be allowed to take up jobs. A time would come when woman would be married off to several men, the manifestations of which are already visible in areas like Dang district of Rajasthan where a woman is living as the wife of eight brothers. Thus the issue of female foeticide is one that needs to be addressed urgently. While it is a social problem requiring changing the mindset of people, yet all possible efforts need to be made at every level. Here law can be used as an effective tool to create fear in the minds of those who resort to sex-determination or those who carry out such techniques.

### **Legal Initiatives**

Female infanticide had been prohibited through legislation in the pre-independence period, however the legislation sadly remained toothless with few or no convictions under the law. Certain provisions were also included in the Indian Penal Code, 1860 punishing causing of miscarriage and other like offences but unfortunately these provisions were rarely resorted to.

With the rise of pre-natal diagnostic techniques especially amniocentesis, the government in 1978 issued a directive banning the misuse of amniocentesis in government hospitals/laboratories. Thereafter due to the relentless efforts of activists, a law to prevent sex determination tests was passed in Maharashtra known as Maharashtra Regulation of Pre-natal Diagnostic Techniques Act, 1988. Finally after intensive public debate all over India the Parliament enacted the Pre-Natal Diagnostic Techniques (Regulation and

Prevention of Misuse) Act on 20<sup>th</sup> September 1994 (hereinafter referred to as the PNDDT Act) to provide for the regulation of:

- the use of pre-natal diagnostic techniques for the purpose of detecting genetic or metabolic disorders or chromosomal abnormalities or certain congenital mal-formations or sex linked disorders;
- for the prevention of the misuse of such techniques for the purpose of pre-natal sex determination leading to female foeticide; and
- for matters connected there with or incidental thereto.

This Act came into force in 1996. By itself it is a comprehensive piece of legislation which defines the terms used therein, lays down when the use of pre-natal diagnostic techniques is prohibited and where it is regulated. It has provisions for bodies which are responsible for policy making under the Act and those which are responsible for the implementation of the Act. The penalties for various offences and how and by whom cognizance of complaints is to be taken, are also elaborated.

#### **Amendments to the Act of 1994**

During the course of the implementation of the said Act, certain inadequacies and practical difficulties in the administration of the Act came to the notice of the Government. At the same time techniques have been developed to select the sex of the child before conception which may further the declining sex-ratio. These developments were also taken note of by the Supreme Court in its various orders in *CEHAT & Ors. V. UOI & Ors.* which is pending before the Court and the Court had also observed that amendments to the PNDDT Act are necessary. After detailed deliberations, the PNDDT Act has been amended with the amended Act having come into force with effect from . The main purpose has been to ban the use of sex-selection techniques before or after conception as well as the misuse of pre-natal diagnostic techniques for sex selective abortions and to regulate such techniques. To make this clear, the long title of the Act has been suitably amended to read:

“An Act to provide for the prohibition of sex selection, before or after conception, and for regulation of pre-natal diagnostic techniques for the purposes of detecting abnormalities or metabolic disorders or chromosomal abnormalities or certain congenital malformations or sex-linked disorders and for the prevention of their misuse for sex determination leading to female foeticide and for matters connected therewith or incidental thereto.”

The title of the Act has also been suitably amended to reflect this and the title of the Act is now to read: “The Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act.”

At the same time certain amendments have also been brought about in the Rules of 1996 to ensure effective implementation of the Act and in view of the observations of the Supreme Court. The amended Rules have come into effect from 14<sup>th</sup> Feb.2003.

The Handbook duly incorporates the amendments that have been made to the PNDT Act and the Rules of 1996 framed thereunder. This compilation puts together a comprehensive set of guidelines elaborating various provisions of the Act and the Rules and their implementation mechanism which clarifies various issues on which the medical practitioners implementing agencies and people at large have varying interpretations to bring in convergence of opinion among all the stake holders.

## CHAPTER II

### DEFINITIONS

#### Techniques

*Pre-natal diagnostic techniques* include all pre-natal diagnostic procedures and pre-natal diagnostic tests.<sup>1</sup>

(A) *Pre-natal diagnostic procedures* mean all gynaecological or obstetrical or medical procedures such as:

- Ultrasonography;
- Foetoscopy;
- Taking or removing samples of:
  - amniotic fluid
  - chorionic villi
  - blood
  - any tissue
  - fluidof a man or a woman before or after conception

for being sent to a Genetic Laboratory or Genetic Clinic for conducting any type of analysis or pre-natal diagnostic tests for selection of sex before or after conception.<sup>2</sup>

(B) *Pre-natal diagnostic test* means:

- Ultrasonography
- Test or analysis of:
  - amniotic fluid
  - chorionic villi
  - blood
  - any tissue
  - fluidof any pregnant woman or conceptus conducted to detect:
  - genetic disorders
  - metabolic disorders
  - chromosomal abnormalities
  - congenital anomalies
  - haemoglobinopathies
  - sex-linked diseases.<sup>3</sup>

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<sup>1</sup> Section 2 (j) of the Act.

<sup>2</sup> Section 2 (i) of the Act.

(C) Sex selection includes:

- Procedure
- Technique
- Test
- Administration
- Prescription
- Provision

of anything for the purpose of ensuring or increasing the probability that an embryo will be of a particular sex.<sup>4</sup>

### **Places**

(A) *Genetic Counselling Centre* means:

- An institute
- Hospital
- Nursing home
- Any place

by whatever name called which provides **genetic counseling to patients.**<sup>5</sup>

(B) *Genetic Clinic* means:

- A clinic
- Institute
- Hospital
- Nursing home
- Any place

by whatever name called which is used for **conducting pre-natal diagnostic procedures.**<sup>6</sup>

By an amendment to the Act of 1994, an explanation has been added to clarify the position of a 'vehicle'. It provides that for the purposes of this clause, a *Genetic Clinic* includes a vehicle, where ultrasound machine or imaging machine or scanner or other equipment capable of determining sex of the foetus or a portable equipment which has the potential for detection of sex during pregnancy or selection of sex before conception, is used.

(C) *Genetic Laboratory* means

- a laboratory; and
- includes a place

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<sup>3</sup> Section 2 (k) of the Act.

<sup>4</sup> Section 2(o) of the Act.

<sup>5</sup> Section 2 (c) of the Act.

<sup>6</sup> Section 2 (d) of the Act.



where facilities are provided for **conducting analysis or tests of samples** received from *Genetic Clinic* for *pre-natal diagnostic test*.<sup>7</sup>

An *explanation* has been added by the amendments of 2002. The explanation provides that “for the purposes of this clause (definition of *Genetic Laboratory*), *Genetic Laboratory* includes a place where ultrasound machine or imaging machine or scanner or other equipment capable of determining sex of the foetus or a portable equipment which has the potential for detection of sex during pregnancy or selection of sex before conception, is used.”

It has been clarified under the amended Rules that every *Genetic Counselling Centre/ Genetic Laboratory/ Genetic Clinic* would include an ultrasound center/ imaging center/ nursing home/ hospital/ institute or any other place, by whatever name called, where any of the machines or equipments capable of selection of sex before or after conception performing or performing any procedure, technique or test for pre-natal detection of sex of foetus is used.<sup>8</sup>

### **Qualified Persons**

(A) *Gynaecologist* means a person who possesses a post-graduate qualification in gynaecology and obstetrics.<sup>9</sup>

The Rules<sup>10</sup> framed under the Act further **qualify** the qualifications by providing additional requirements for a *gynaecologist* when employed by a *genetic counseling center* or a *genetic clinic* but do not necessitate the engagement of a *gynaecologist* by a *genetic laboratory*.

For a *genetic counseling center*, the *gynaecologist* must have

- **6 months experience** in genetic counseling; or
- **4 weeks training** in genetic counseling.<sup>11</sup>

For a *genetic clinic*, the *gynaecologist* should have adequate experience in *pre-natal diagnostic procedures* i.e. should have performed **at least 20 procedures in chorionic villi aspirations per vagina or per abdomen, chorionic villi biopsy, amniocentesis, cordocentesis foetoscopy, foetal skin or organ biopsy or foetal blood sampling etc. under supervision of an experienced gynaecologist in these fields.**<sup>12</sup>

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<sup>7</sup> Section 2 (e) of the Act.

<sup>8</sup> Explanation (1) to Rule 12.

<sup>9</sup> Section 2 (f) of the Act.

<sup>10</sup> The Pre-Natal Diagnostic Techniques (Regulation and Prevention of Misuse) Rules, 1996 which came into force w.e.f. 1.1.1996.

<sup>11</sup> Rule 3 (1) (i) under the PNDT Rules.

<sup>12</sup> Rule 3 (3)(1)(a) under the PNDT Rules.

(B) *Medical Geneticist* includes a person who possesses:

- degree, or
  - diploma
- in genetic science in the fields of *sex selection and pre-natal diagnostic techniques*

or has experience of not less than two years in any of these fields after obtaining-

- any one of the medical qualifications recognized under the Indian Medical Council Act, 1956; or
- a post-graduate degree in biological sciences.<sup>13</sup>

Under the amended definition, possessing a certificate does not make one a qualified *medical geneticist*.

(C) *Paediatrician* means a person who possesses a post-graduate qualification in paediatrics.<sup>14</sup>

The Rules framed under the Act further **qualify** the qualifications by providing additional requirements for a *paediatrician* when employed by a *genetic counseling center*.

For a *genetic counseling center*, the *paediatrician* must have

- **6 months experience** in genetic counseling; or
- **4 weeks training** in genetic counseling.<sup>15</sup>

(D) *Registered Medical Practitioner* means

- a medical practitioner who possesses any recognized medical qualification as defined in clause (h) of Section 2 of the Indian Medical Council Act, 1956; and
- whose name has been entered in a State Medical Register.<sup>16</sup>

The Rules framed under the Act further **qualify** the qualifications by providing additional requirements for a *registered medical practitioner* when employed by a *genetic clinic*. For the purposes of a *genetic clinic* the *registered medical practitioner* should have Post Graduate degree or diploma or six months training or one year experience in sonography or image scanning.<sup>17</sup>

Besides, the Act and the Rules also refer to other types of personnel.

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<sup>13</sup> Section 2 (g) of the Act.

<sup>14</sup> Section 2 (h) of the Act.

<sup>15</sup> Rule 3 (1)(i) under the PNDT Rules.

<sup>16</sup> Section 2 (m) of the Act. In *Prakash Motiram Khobragade v. State of Maharashtra* AIR 2000 Bom. 137, the Bombay High Court has held that persons who are otherwise not qualified for registration under the Medical Practitioner Act, under the Indian Medical Council Act and the State Acts are not entitled to claim any right to practice medicine.

<sup>17</sup> Rule 3 (3) (1) (b) under the PNDT Rules.

(E) For a *genetic laboratory*, there should be a ***laboratory technician***

- having  
B.Sc. degree in Biological Sciences; or  
Degree; or  
Diploma  
in medical laboratory course; and
- at least **one year's experience** in conducting appropriate *pre-natal diagnostic techniques, tests or procedures*.<sup>18</sup>

(F) *Radiologist*<sup>19</sup>

(G) *Sonologist or Imaging Specialist* means a person who possesses-

- any one of the medical qualifications recognized under the Indian Medical Council Act, 1956; or
- a post-graduate qualification in ultrasonography or imaging techniques or radiology.<sup>20</sup>

Certain miscellaneous definitions have been added to clarify concepts used for the first time in the amended Act. These are

(A) *Conceptus* means any product of conception at any stage of development from fertilization until birth including extra embryonic membranes as well as the embryo or foetus.<sup>21</sup>

(B) *Embryo* means a developing human organism after fertilization till the end of eight weeks (fifty-six days).<sup>22</sup>

(C) *Foetus* means a human organism during the period of its development beginning on the fifty-seventh day following fertilization or creation (excluding any time in which its development has been suspended) and ending at the birth.<sup>23</sup>

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<sup>18</sup> Rule 3 (1) and Schedule II under the PNDT Rules.

<sup>19</sup> Rule 3(3)(1)(b) under the PNDT Rules.

<sup>20</sup> Section 2(p) of the Act.

<sup>21</sup> Section 2(ba) of the Act.

<sup>22</sup> Section 2 (bb) of the Act.

<sup>23</sup> Section 2 (bc) of the Act.

### CHAPTER III REGISTRATION

All bodies under the PNDDT Act namely *Genetic Counselling Centre*, *Genetic Laboratory* or *Genetic Clinic* as defined in the preceding chapters cannot function unless registered.<sup>1</sup>

The requirement of registration is mandatory whether the body is government, private, voluntary, honorary, part-time, contractual or consultative. However the PNDDT Act allows registration of these bodies either separately or jointly when a body is for instance both a centre and a clinic.

#### PROCEDURE FOR REGISTRATION

- (A) Every application for registration shall be made:
- to the Chief Medical Officer of the district; or any other medical officer constituted as appropriate authority
  - medical officer constituted as appropriate authority for the sub-district within whose area or jurisdiction the centre, clinic or laboratory is situated.<sup>2</sup>
- (B) Every application shall be made in duplicate in Form A which is appended to the rules.<sup>3</sup>
- (C) Every application shall be duly accompanied by an Affidavit containing-
- an undertaking to the effect that the *Genetic Centre/Laboratory/Clinic/ Ultrasound Clinic/Imaging Centre*/combination thereof, as the case may be, shall not conduct any test or procedure, by whatever name called, for selection of sex before or after conception or for detection of sex of foetus except for diseases specified in Section 4(2) nor shall the sex of foetus be disclosed to any body; and
  - an undertaking to the effect that the *Genetic Centre/Laboratory/Clinic/ combination thereof*, as the case may be, shall display prominently a notice that they do not conduct any technique, test or procedure etc. by whatever name called, for detection of sex of foetus or for selection of sex before or after conception.<sup>4</sup>
- (D) The Appropriate Authority or any authorised person will acknowledge the application in the acknowledgement slip provided at the bottom of Form A on the very same day if personally delivered, otherwise on the next day by post.<sup>5</sup>
- (E) Every application form shall be submitted alongwith an application fee of:

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<sup>1</sup> Section 3 (1) of the Act.

<sup>2</sup> Rule 4 (1) under the PNDDT Rules.

<sup>3</sup> Id.

<sup>4</sup> Id.

<sup>5</sup> Rule 4 (2) under the PNDDT Rules.

- (a) Rs.3000.00 for *Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic* or *Imaging Centre*.
- (b) Rs.4000.00 for an institute, hospital, nursing home, or any place providing jointly the service of a *Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic* or *Imaging Centre* or any combination thereof.<sup>6</sup>

However, if an application for registration has been rejected by the Appropriate Authority, no fee shall be required to be paid on re-submission of the application by the applicant for the same body within 90 days of rejection.

-But every subsequent application shall be accompanied with the prescribed fee. Application fee once paid will not be refunded.<sup>7</sup>

- (F) The application fee shall be paid
  - by way of a demand draft
  - drawn in favour of the Appropriate Authority
  - on any scheduled bank payable at the head quarters of the Appropriate Authority concerned.<sup>8</sup>
- (G) The fees collected by the Appropriate Authority for registration shall be deposited by the Appropriate Authority concerned in a bank account opened in the name of the official designation of the Appropriate Authority concerned.<sup>9</sup>
- (H) The fees so collected by the Appropriate Authority shall be utilized by the Appropriate Authority in connection with the activities connected with implementation of the provisions of the Act and these rules.<sup>10</sup>

### ***MINIMUM REQUIREMENTS FOR REGISTRATION:***

There are different minimum requirements for different bodies as regards minimum qualifications of the employees and the minimum equipment for each of the bodies under the PNDT Act. All the requirements relating to qualifications and equipment are mandatory.<sup>11</sup> Under the amended Rules, the Schedules appended to the earlier Rules have been done away with and the requirements for a *Genetic Counselling Centre, Genetic Laboratory and Genetic Clinic* have been added under Rule 3 itself by redrafting the same though the requirements remain the same, more or less.

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<sup>6</sup> Rule 5(1) under the PNDT Rules.

<sup>7</sup> Proviso to Rule 5 (1) under the PNDT Rules.

<sup>8</sup> Rule 5 (2) under the PNDT Rules.

<sup>9</sup> Rule 5 (2) under the PNDT Rules as amended.

<sup>10</sup> Id.

<sup>11</sup> Rule 3 (1) under the PNDT Rules.

*(A) Genetic Counselling Centre:*

The requirements for a *Genetic Counselling Centre* are enumerated in Rule 3(1) in the amended Rules.

- The center should have adequate space.
- The center should contain educational charts/models/equipments for carrying out genetic counseling.
- The centre must have any one of the following employees namely:
  - a medical geneticist
  - a gynaecologist; or
  - a paediatrician

having such qualifications and experience as mentioned in the **preceding chapter.**

*(B) Genetic Laboratory*

The requirements for a *genetic laboratory* are enumerated in Rule 3(2) in the amended Rules under the PNDT Act.

- The laboratory should have **adequate space** for conducting the tests.
- The laboratory should have or acquire such of the equipments as may be necessary to conduct chromosomal studies, biochemical studies and molecular studies from amongst those enumerated under the amended Rules which has been annexed in the Appendix to this manual.<sup>12</sup>
- The laboratory must have both a **medical geneticist** and a **laboratory technician** in its employment having such qualifications and experience as mentioned in the **preceding chapter.**<sup>13</sup>

*(C) GENETIC CLINIC*

The requirements for a *genetic clinic* are enumerated in Rule 3(3) of the amended Rules under the PNDT Act.

- The center should have adequate space.

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<sup>12</sup> Rule 3(2)(b) under the amended PNDT Rules.

<sup>13</sup> Rule 3(2)(a) under the amended PNDT Rules.

- The clinic/ultrasound clinic/imaging center should have or acquire such of the following equipments, as may be necessary for carrying out the tests or procedures:
  - (a) Equipment and accessories necessary for carrying out clinical examination by an obstetrician /gynaecologist
  - (b) An ultra-sonography machine including mobile ultrasound machine, imaging machine or any other equipment capable of conducting foetal ultrasonography.
  - (c) Appropriate catheters and equipment for carrying out chorionic villi aspirations per vagina or per abdomen.
  - (d) Appropriate sterile needles for amniocentesis or cordocentesis.
  - (e) A suitable foetoscope with appropriate accessories for foetoscopy, foetal skin or organ biopsy or foetal blood sampling shall be optional.
  - (f) Equipment for dry and wet sterilization
  - (g) Equipment for carrying out emergency procedures such as evacuation of uterus or resuscitation in case of need.
  - (h) Genetic Works Station.<sup>14</sup>
  
- The clinic must have gynaecologist or sonologist, imaging specialist, Radiologist or Registered Medical Practitioner or medical geneticist in its employment having such qualifications and experience as mentioned in the **preceding chapter.**<sup>15</sup>

The aforementioned requirements are minimum mandatory and each of these bodies can have more equipment, more number of employees etc. as long as they fulfill the necessary qualifications mentioned in the PNDT Act.

Documentary proof of requisite qualifications and experience as specified under the PNDT Act and rules of persons employed by the facility should be annexed with the application for registration.

The bodies can be owned by any person and he need not have the qualifications required under the Act as long as he has employees that fulfill the minimum qualifications required under the PNDT Act. If an institute, hospital, nursing home or any place provides services jointly of any of these bodies then such a place should fulfill the minimum requirements of both the bodies in order to be registered.

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<sup>14</sup> Rule 3(3)(2) under the amended PNDT Rules.

<sup>15</sup> Rule 3(3)(1) under the amended PNDT Rules.

## PROCESS OF CERTIFICATION<sup>16</sup>

- (a) Every application received by the appropriate authority will firstly be scrutinized by it and an enquiry into whether such body fulfills all the requirements under the PNDDT Act will be done.<sup>17</sup>
- (b) An enquiry by the Appropriate Authority includes an inspection of the premises after giving due notice to the applicant.<sup>18</sup>
- (c) After the appropriate authority is satisfied that the applicant has fulfilled all minimum requirements, the application will be placed before the Advisory Committee. The Advisory Committee shall thereafter scrutinize the application and give its advice on the same to the appropriate authority.
- (d) The Appropriate Authority after considering the advice will grant a certificate of registration.<sup>19</sup>
- (e) The certificate of registration shall be given in duplicate and in the form as prescribed in Form B annexed to the rules under the PNDDT Act and the same is also part of the appendix to this manual. The grant of certificate of registration shall be communicated within 90 days from the date of receipt of application for registration.<sup>20</sup>
- (f) It is mandatory for every body registered under this Act to display the certificate of registration at a conspicuous place in such centre, laboratory or clinic.<sup>21</sup>
- (g) In some cases the appropriate authority depending upon the requirements available at such centre, laboratory or clinic may grant a certificate only to conduct one or more specified pre-natal diagnostic tests or procedures.<sup>22</sup>
- (h) The certificate of registration shall be non-transferable.<sup>23</sup>
- (i) In the event of change of ownership or change of management or when the centre, laboratory or clinic ceases to function as one both copies of certificate of registration shall be surrendered to the Appropriate Authority.<sup>24</sup>

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<sup>16</sup> Section 19 of the Act.

<sup>17</sup> Rule 6 (1) under the PNDDT Rules.

<sup>18</sup> Rule 6 (4) under the PNDDT Rules.

<sup>19</sup> Rule 6 (2) under the PNDDT Rules.

<sup>20</sup> Rule 6 (2) read with Rule 6 (5) under the PNDDT Rules.

<sup>21</sup> Supra n.10.

<sup>22</sup> Proviso to Rule 6(2) under the PNDDT Rules.

<sup>23</sup> Rule 6(6) under the PNDDT Rules.

<sup>24</sup> Id.



- (j) Each new owner or manager of a centre, laboratory or clinic has to apply afresh for grant of certificate of registration.<sup>25</sup>
- (k) All centres, laboratories and clinics registered under the PNDT Act shall give an affidavit affirming that they will not indulge in pre-natal determination of sex as mandated by the Supreme Court in the case of **CEHAT & Ors v. Union of India**.
- (l) The Registration Certificate must mention the *number of ultrasound machines* in the centre. Further the registration certificate must also mention all the portable ultrasound machines in the said centre. In case of registration certificates already issued, the list of ultrasound machines portable or otherwise must be mentioned on another paper and the said paper must also be displayed along with the registration certificate at a conspicuous place in the centre.

### ***REJECTION OF APPLICATION FOR REGISTRATION***

- If after enquiry and after giving an opportunity of hearing to the applicant and after taking advise from the Advisory Committee the Appropriate Authority has come to a conclusion that the applicant has not complied with the requirements of the Act then the said application will be rejected.<sup>26</sup>
- The reasons for the rejection shall be given in writing and as specified in Form C appended to the Rules under PNDT Act.<sup>27</sup>
- The rejection of registration shall be communicated to the applicant within 90 days from the date of the receipt of the registration.<sup>28</sup>

### **CANCELLATION OR SUSPENSION OF REGISTRATION**

The Appropriate Authority can at any time either on its own or on a complaint by anyone issue a show cause notice to the *Genetic Counselling Centre, Genetic Laboratory* or *Genetic Clinic, Ultrasound Clinic* or *Imaging Centre* as to why its registration should not be cancelled or suspended for breach of any of the provisions of the PNDT Act or the rules. The reasons for every such notice should be mentioned in the notice itself.<sup>29</sup>

Thereafter the clinic, laboratory or centre must be given an opportunity to defend itself against the charges. After giving the centre, laboratory or clinic a reasonable opportunity of being heard and after taking into account the advice given by the

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<sup>25</sup> Rule 6(7) under the PNDT Rules.

<sup>26</sup> Rule 6 (3) under the PNDT Rules.

<sup>27</sup>Id.

<sup>28</sup> Rule 6 (5) under the PNDT Rules.

<sup>29</sup> Section 20 (1) of the Act.

Advisory Committee, the Appropriate Authority may either suspend the registration of such a place or cancel the registration depending upon the gravity of the charge. Action can be taken by the Appropriate Authority irrespective of any criminal action that will be taken against such a place.<sup>30</sup>

In certain exceptional cases like in the case of public interest the Appropriate Authority may suspend or cancel registration without issuing a show cause notice. However the reasons for waiving show cause notice have to be given in writing.<sup>31</sup>

## **PROVISION FOR APPEAL<sup>32</sup>**

Any *genetic counselling centre, genetic laboratory or genetic clinic* may appeal against an order of cancellation or suspension of registration within 30 days of the order of cancellation or suspension.

The appeal may be made to:

- the Appropriate Authority at the district level if the order is passed by the Appropriate Authority at sub-district level.<sup>33</sup>
- the Appropriate Authority at the State/UT level if the order is passed by the Appropriate Authority at district level.<sup>34</sup>

Each appeal shall be disposed of by the District Appropriate Authority or by the State/UT Appropriate Authority, as the case may be, within 60 days of its receipt.<sup>35</sup>

Thus a hierarchy of appellate bodies has been provided and further the time limit for disposing of the appeals has been laid down.

Moreover the appeal shall be made to the Central Government if the order is passed by the Central Appropriate Authority.<sup>36</sup>

The appeal shall be made to the State government if the order is passed by the State Appropriate Authority.<sup>37</sup>

If the appeal is not made within the time as prescribed above, the Appropriate Authority may condone the delay in case he/she is satisfied that appellant was prevented for sufficient cause from making such appeal.<sup>38</sup>

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<sup>30</sup> Section 20 (2) of the Act.

<sup>31</sup> Section 20 (3) of the Act.

<sup>32</sup> Section 21 of the Act.

<sup>33</sup> Rule 19(1) under the amended PNDT Rules.

<sup>34</sup> Rule 19(2) under the amended PNDT Rules.

<sup>35</sup> Rule 19(3) under the amended PNDT Rules.

<sup>36</sup> Section 21(i) of the Act.

<sup>37</sup> Section 21(ii) of the Act.

<sup>38</sup> Rule 19(4) under the amended PNDT Rules.

## RENEWAL OF REGISTRATION

(A) Every certificate of registration shall be valid for a period of five years since its issuance.<sup>39</sup>

(B) Thirty days before the date of expiry of the certificate of registration a fresh application for a certificate of Registration should be made.<sup>40</sup>

(C) The application for renewal must be made in duplicate in the prescribed Form A (same as the one prescribed for obtaining the first registration certificate) to the Appropriate Authority.<sup>41</sup>

(D) The Appropriate Authority shall acknowledge the receipt of the application in the acknowledgement slip provided at the bottom of Form A on the very same day if personally delivered otherwise on the next day by post.<sup>42</sup>

(E) Along with the application for renewal of certificate, registration fees of half of what was initially payable will be paid depending upon whether it is for a *genetic counselling centre, genetic laboratory* or *genetic clinic*, ultrasound clinic or imaging centre or for a joint facility.<sup>43</sup>

(F) After the receipt of the application the Appropriate Authority will hold an enquiry including an inspection of the premises after giving due notice into whether the applicant has fulfilled all the requirements necessary under the Act. The Appropriate Authority will also give the applicant a hearing.<sup>44</sup>

(G) After conducting the enquiry and hearing if the Appropriate Authority finds everything satisfactory then it will place the application before the Advisory Committee for its scrutiny.

(H) Thereafter having regard to the advice of the Advisory Committee the Appropriate Authority will renew the certificate of registration in the prescribed Form B (same as the one prescribed for the first registration certificate) for a further period of 5 years starting from the date of expiry of the old certificate.<sup>45</sup>

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<sup>39</sup> Rule 7 under the PNDT Rules.

<sup>40</sup> Rule 8(1) under the PNDT Rules.

<sup>41</sup> Id.

<sup>42</sup> Id.

<sup>43</sup> Rule 8(4) under the PNDT Rules.

<sup>44</sup> Rule 8(2) under the PNDT Rules.

<sup>45</sup> Id.

(I) On the receipt of the renewed certificate of registration in duplicate, the two copies of the earlier certificates will have to be surrendered immediately to the Appropriate Authority.<sup>46</sup>

(J) One copy of the renewed certificate has to be displayed in a conspicuous place of the centre, laboratory or clinic.

(K) If the Appropriate Authority fails to renew the certificate of registration within 90 days of its receiving the application for renewal, it will amount to automatic renewal or deemed renewal.<sup>47</sup>

### ***REJECTION OF APPLICATION FOR RENEWAL***

- After conducting an enquiry into the application for renewal, after hearing the applicant and after taking the advice of the Advisory Committee the Appropriate Authority finds that the applicant has not complied with the requirements of the Act then the appropriate authority can reject the application for renewal.<sup>48</sup>
- Every order of rejection will contain reasons for rejection and it will be communicated in the prescribed Form C.<sup>49</sup> (same as the one prescribed for the initial rejection)
- Once the applicant receives the communication of rejection the applicant must immediately surrender both the copies of the earlier certificate of registration.<sup>50</sup>
- In case the appropriate authority fails to communicate its rejection to the applicant within 90 days of receiving the application for renewal then it amounts to automatic renewal or deemed renewal.<sup>51</sup>

Note: In case of defence establishments, applications for registration have to be submitted to the Appropriate Authorities specifically notified for defence establishments who are otherwise responsible for the implementation of the Act in their areas.

If the machines are lying packed or are not in use, then also registration is mandatory because requirement of registration arises by the very possession of the machines.

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<sup>46</sup> Rule 8(5) under the PNDT Rules.

<sup>47</sup> Rule 8(6) under the PNDT Rules.

<sup>48</sup> Rule 8(3) under the PNDT Rules.

<sup>49</sup> Id.

<sup>50</sup> Rule 8(5) under the PNDT Rules.

<sup>51</sup> Rule 8(6) under the PNDT Rules.

## CHAPTER IV PROHIBITIONS

The PNDT Act is a comprehensive piece of legislation which **prohibits sex selection before or after conception and misuse of pre-natal diagnostic techniques for determination of sex of foetus**, leading to female foeticide as also **advertisements** in relation to such techniques for detection or determination of sex. The Act also specifies the **punishment** for violation of its provisions. Accordingly, the Act imposes the following:

### PROHIBITIONS

#### A) *ON PLACES*

No *genetic counselling centre* or *genetic clinic* or *genetic laboratory* shall

- conduct; or
- associate with; or
- help in conducting *pre-natal diagnostic techniques* unless **registered**.<sup>1</sup>

Moreover the Registration certificate has to be displayed prominently on a board in such place.<sup>2</sup>

- employ or cause to be employed or take services of any person, whether on honorary basis or on payment who does not possess prescribed qualifications.<sup>3</sup>

A qualified person could be:

- *Gynaecologist*
- *Medical Geneticist*
- *Paediatrician*
- *Registered Medical Practitioner*
- *Radiologist*
- *Sonologist*
- *Imaging Specialist*

Who fulfils the requirements laid down under the Act

- conduct or cause to be conducted a *pre-natal diagnostic technique* except for the purposes specified in the Act.

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<sup>1</sup> Section 3 (1) of the Act.

<sup>2</sup> Section 19 (4) of the Act.

<sup>3</sup> Section 3 (2) of the Act.

- **conduct or cause to be conducted a *pre-natal diagnostic technique* including an ultrasonography for the purpose of determining the sex of the foetus.**<sup>4</sup>

Every *genetic counseling centre* or *genetic clinic* or *genetic laboratory* is required to display prominently a notice in English and in the local language or languages that conduct of sex-determination tests/disclosure of sex of the foetus is prohibited.<sup>5</sup>

**B) ON PERSONS**

- No person shall open any *genetic counselling centre, genetic clinic* or *genetic laboratory* including clinic, laboratory or center having ultrasound or imaging machine or scanner or any other technology capable of undertaking determination of sex of foetus and sex selection unless such *centre, clinic* or *laboratory* is duly registered separately or jointly.<sup>6</sup>
- No qualified person shall **conduct** or **aid in conducting** himself or through any other person a *pre-natal diagnostic technique* at any place other than the place registered.<sup>7</sup>

ILLUSTRATION: (A) No one can conduct a pre-natal diagnostic technique at home, unless the facility at home is also registered.

(B) No one can conduct a pre-natal diagnostic technique either on a voluntary basis, or on a charitable basis unless the body is registered after meeting all necessary qualifications of persons, place and equipment.

- No person shall render any services to any facility, after the commencement of the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Amendment Act, 2002 unless such facility is duly registered under the Act.<sup>8</sup>
- No person including a relative or husband of the pregnant woman shall seek or encourage the conduct of any *pre-natal diagnostic techniques* on her except for the purposes specified in clause (2) of Section 4 of the Act.<sup>9</sup>
- No person including a relative or husband of a woman shall seek or encourage the conduct of any sex-selection technique on her or him or both.<sup>10</sup>

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<sup>4</sup> Section 6 (a) of the Act.

<sup>5</sup> Rule 17 (1) under the PNDT Rules.

<sup>6</sup> Section 18 (1) of the Act.

<sup>7</sup> Section 3 (3) of the Act.

<sup>8</sup> Section 18(1) of the Act.

<sup>9</sup> Section 4 (4) of the Act.

<sup>10</sup> Section 4(5) of the Act.

- No person **shall conduct or cause to be conducted** any *pre-natal diagnostic technique* including ultrasonography for purpose of sex determination.<sup>11</sup>

In fact a good doctor should counsel the patient that sex-determination is illegal and should also positively propagate about the girl child. A doctor is highly regarded in the society and any counselling by him/her will have great impact in the implementation of the Act.

- No person, including a specialist or a team of specialists in the field of infertility, shall conduct or cause to be conducted or aid in conducting by himself or by any other person, sex selection on a woman or a man or on both or on any tissue, embryo, conceptus, fluid or gametes derived from either or both of them.<sup>12</sup>
- No person shall, by whatever means, cause or allow to be caused selection of sex before or after conception.<sup>13</sup>
- No person including the person conducting a *pre-natal diagnostic procedures* shall **communicate** to the pregnant woman concerned or her relatives or any other person the sex of the foetus by words, signs or in any other manner whatsoever.<sup>14</sup>

#### ILLUSTRATION:

(A) Dr. Lata tells Ramu it is time to celebrate, give me a packet of sweets. This is illegal as indirectly the Doctor is communicating to the father that it is a baby boy.

(B) Dr.Lama told Geeta, Oh! your shoulders have become heavy now. This is also illegal as the same indirectly conveys the fact that it is baby girl.

(C) Dr Singha used to tell all his patients “You see I have all the latest techniques from America, I can tell the sex of the child within 10 weeks of pregnancy”. In every case the doctor used to tell his patients it was a girl and his wife Mrs. Singha used to conduct the abortions the very next day. Dr.Singha’s actions are in clear violation of the PNDT law. Dr Singha’s actions also amount to misrepresentation and fraud.

(D) Dr.Himmat never told his patients anything, he used raise his left eyebrow when it was a boy and right eyebrow when it was a girl. Dr.Himmat’s actions though creative are also in violation of the PNDT law as the same amount to signs and gestures which is also prohibited.

The Central Supervisory Board has laid down a code of conduct under section 16 (iv) of the Act to be observed by persons working in bodies specified therein and as such the same has to be strictly followed.<sup>15</sup>

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<sup>11</sup> Section 6 (b) of the Act.

<sup>12</sup> Section 3A of the Act.

<sup>13</sup> Section 6(c) of the Act.

<sup>14</sup> Section 5 (2) of the Act.

### C) MISCELLANEOUS

- No person, organization, *Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic*, including clinic, laboratory or center having ultrasound machine or imaging machine or scanner or any other technology capable of undertaking determination of sex of foetus or sex selection shall issue, publish, distribute, communicate or cause to be issued, published, distributed or communicated any advertisement, in any form, including internet, regarding facilities of pre-natal determination of sex or sex selection before conception available at such center, laboratory, clinic or at any other place.<sup>16</sup>

#### ILLUSTRATION:

- (A) “Spend Rs.5000 now and save Rs.5 lakhs later. Contact Dr. Ahmed of Ahmed Diagnostic Center.” This advertisement is illegal as it advertises facilities for sex determination.
- (B) “Urine test now and result known immediately whether boy or girl.” This advertisement is also clearly illegal.
- (C) “Want to know – boy or girl, quick and easy. No surgery required.” This advertisement is clearly illegal.
- No person, organization including *Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic* shall issue, publish, distribute, communicate or cause to be issued, published, distributed or communicated any advertisement, in any manner regarding pre-natal determination or pre-conception selection of sex by any means whatsoever, scientific or otherwise.<sup>17</sup>

#### ILLUSTRATION:

(A) A Magazine published in America but distributed by AB Co in India with office in Delhi carries an advertisement for sex-determination. Such an action on the part of the company in Delhi is in violation of the Act.

Advertisement includes any notice, circular, label, wrapper or other document including advertisement through internet or any other media in electronic or print form and also includes any visible representation made by means of any hoarding, wall-painting, signal, light, sound, smoke or gas.<sup>18</sup>

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<sup>15</sup> The Supreme Court vide its order dated 4.5.2001 has also stressed the formulation of such a code of conduct. The same has now been incorporated under Rule 18 of the amended PNDT Rules.

<sup>16</sup> Section 22 (1) of the Act.

<sup>17</sup> Section 22 (2) of the Act.

<sup>18</sup> Explanation to Section 22 of the Act.



(B)Wrappers of Meera Milk food with a colorful picture of a baby boy—if you want a baby boy contact Meera Diagnostic Center and they will help you, otherwise money back guaranteed. This is clearly illegal.

- No person shall sell, distribute, supply, rent, allow or authorize the use of any ultrasound machine or imaging machine or scanner or any other equipment capable of detecting sex of foetus whether on payment or otherwise to any Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic or any other person or body not registered under the Act.<sup>19</sup>

“Person” includes manufacturer, importer, dealer or supplier of ultrasound machines/imaging machines or any other equipment capable of detecting sex of foetus” as also any organization including a commercial organization.

Further the provider of such machine/equipment to any person/body registered under the Act shall:

a)send to the concerned State/UT Appropriate Authority and to the Central Government, once in three months a list of those to whom the machine/equipment has been provided; and

b)take an affidavit from such body or person purchasing or getting authorization for using such machine/equipment that the machine/equipment shall not be used for detection of sex of foetus or selection of sex before or after conception.<sup>20</sup>

## **PRESCRIPTIONS AND REGULATIONS**

The PNDT law is a prohibitory and regulatory statute; it seeks to put in place a mechanism which prohibits sex selection while preventing the misuse and over-use of the pre-natal diagnostic techniques. At the same time, the Act permits and regulates the use of such techniques for the purpose of detection of specific genetic abnormalities or disorders and for the larger benefit of mankind. The Act further permits the use of such techniques only under certain conditions by the registered bodies. The PNDT Act prohibits the conduct of *pre-natal diagnostic techniques* for determination of the sex of the foetus but allows the conduct of *pre-natal diagnostic techniques* for purposes that have also been specified under the Act. These are for detection of:

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<sup>19</sup> Section 3B of the Act read with Rule 3A under the amended PNDT Rules.

<sup>20</sup> Rule 3A(2) and (3) under the amended PNDT Rules.

- chromosomal abnormalities;
- genetic metabolic diseases;
- haemoglobinopathies;
- sex-linked genetic diseases;
- congenital anomalies;
- other abnormalities or diseases as specified by the Central Supervisory Board.<sup>21</sup>

The Central Supervisory Board has laid down a representative list of indications for ultrasound during pregnancy (see new Form F under the amended Rules which have been annexed to this Handbook).

The conduct of *pre-natal diagnostic techniques* is further permissible if the person qualified is satisfied for reasons to be recorded in writing that any of the following conditions exist:

- age of the pregnant woman is above thirty-five years;
- pregnant woman has undergone two or more spontaneous abortions or foetal loss;
- pregnant woman has been exposed to potentially teratogenic agents such as drugs, radiation, infection or chemicals;
- the pregnant woman or her spouse has a family history of mental retardation or physical deformities such as, spasticity or any other genetic disease;
- any other condition specified by the Central Supervisory Board.<sup>22</sup>

The doctors conducting pre-natal diagnostic techniques should maintain proper documentation. Under the amendments it has been made mandatory that the person conducting ultrasonography on a pregnant woman shall keep complete record thereof in the clinic in such manner, as may be prescribed, and any deficiency or inaccuracy found therein shall amount to contravention of provisions of section 5 or section 6 unless contrary is proved by the person conducting such ultrasonography.<sup>23</sup>

Once the doctor follows all the necessary requirements under the law and does the necessary paperwork as mentioned below, he can have no fear from the law. The woman must not only make sure that her consent is taken in case of invasive procedures but must ask for a copy of every document that she signs. If she does not understand anything she must ask for an explanation and it is her right to be told.

Pre-implantation genetic diagnosis or a *pre-natal diagnostic technique/test/procedure* such as amniocentesis, chorionic villi biopsy, foetoscopy, foetal skin or organ biopsy or cordocentesis can be conducted:

### **ONLY**

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<sup>21</sup> Section 4 (1) of the Act read with Section 4 (2) of the Act.

<sup>22</sup> Section 4 (1) of the Act read with Section 4 (3) of the Act.

<sup>23</sup> Proviso to Section 4(3) of the Act.

- after obtaining the written consent of the woman in the prescribed format in a language which she understands. The format for the written consent is provided in Form G under the Rules.

However, an exception is that where a *Genetic Clinic* has taken a sample of any body tissue or body fluid and sent it to a *Genetic Laboratory* for analysis or test, it shall not be necessary for the *Genetic Laboratory* to obtain a fresh consent in Form G.

- giving her a copy of the same; and
- explaining all known side and after effects of the procedures to the pregnant woman.<sup>24</sup>

Under the amended Rules, a distinction has been made between invasive and non-invasive techniques for the purpose of obtaining consent and the consent is required in the case of invasive techniques. However, in case of ultrasonography, other documentation is now required. Any person conducting ultrasonography/image scanning on a pregnant woman shall give a declaration on each report on ultrasonography/image scanning that he/she has neither detected nor disclosed the sex of foetus of the pregnant woman to any body. The pregnant woman before undergoing ultrasonography/image scanning declare that she does not want to know the sex of her foetus.<sup>25</sup>

It is important to mention that the PNDT Act has an important link with the **Medical Termination of Pregnancy Act, 1971** (hereinafter referred to as the MTP Act). Prior to 1971, abortions were considered illegal in our country and in fact the same could be punishable under the Indian Penal Code. In 1971, the MTP Act was passed which provides for the termination of **certain** pregnancies by registered medical practitioners (as defined under the MTP Act). Thus it is clear that abortion is not provided for in all cases of pregnancy but only in case of certain pregnancies. Under the Act, termination of pregnancy is possible where:

- the length of the pregnancy **does not exceed twelve weeks**;
- the length of the pregnancy **exceeds twelve weeks but does not exceed twenty weeks**: in this case the opinion of two registered medical practitioners in favour of the termination of the pregnancy is essential.<sup>26</sup>

#### ONLY

- i) if the continuance of the pregnancy would involve a risk to the life of the pregnant woman or of grave injury to her physical or mental health<sup>27</sup>; or
- ii) if there is a substantial risk that if the child were born, it would suffer from such physical or mental abnormalities as to be seriously handicapped.<sup>28</sup>

<sup>24</sup> Section 5 of the Act.

<sup>25</sup> Rule 10 (1A) under the amended PNDT Rules.

<sup>26</sup> Section 3 (a) and (b) of the MTP Act.

<sup>27</sup> Section 3 (i) of the MTP Act.

It has been clarified under the Act that where the pregnancy is alleged to have been caused by rape, the anguish caused by such pregnancy **shall** be presumed to constitute a grave injury to the mental health of the pregnant woman.<sup>29</sup> Thus, **pregnancy due to rape can be validly terminated.**

Further, where the pregnancy occurs as a result of failure of any device or method used by any married woman or her husband for the purpose of limiting the number of children, the anguish caused by such unwanted pregnancy **may** be presumed to constitute a grave injury to the mental health of the pregnant woman.<sup>30</sup> Thus, **failure of methods of family planning** could also give rise to a ground for termination of the pregnancy.

While considering whether the continuance of pregnancy would involve risk or injury to the health of the pregnant woman, account may be taken of the pregnant woman's actual or reasonable foreseeable environment.<sup>31</sup>

There is another provision under which the pregnancy can be terminated validly irrespective of the length of the pregnancy and the opinion of two registered medical practitioners. In this case, the registered medical practitioner should be of the opinion, formed in **good faith** that the **termination of the pregnancy is immediately necessary to save the life of the pregnant woman.**<sup>32</sup>

The opinion of the registered medical practitioners should be formed in good faith. Such opinion has to be certified in Form I under the MTP Regulations<sup>33</sup> framed under the Act<sup>34</sup>. Form I is annexed here as **Annexure-I**. In this form the reasons for forming the opinion also have to be stated. Further every registered medical practitioner who terminates any pregnancy is required within three hours from the termination of the pregnancy to certify such termination in the said form<sup>35</sup> where again the reason for terminating the pregnancy has to be specified.

It is clear from what is above mentioned that termination of pregnancy is possible only in certain cases and where the pregnancy is more than 12 weeks old, opinion of two registered medical practitioners as defined under the MTP Act is essential, and then also abortion is possible only upto the twentieth week. Through ultrasonography which is the most commonly used technique for determination of the sex of the foetus, the sex of the foetus can be known only after the 14<sup>th</sup> week. Thus if a woman were to go in for abortion after getting to know the sex of the foetus, since it would be a second trimester pregnancy, opinion of two registered medical practitioners would be essential.

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<sup>28</sup> Section 3 (ii) of the MTP Act.

<sup>29</sup> Explanatory 1 to Section 3 of the MTP Act.

<sup>30</sup> Explanatory 2 to Section 3 of the MTP Act.

<sup>31</sup> Explanatory 3 to Section 3 of the MTP Act.

<sup>32</sup> Section 5 of the MTP Act.

<sup>33</sup> The Medical Termination of Pregnancy Regulations, 1975 published in the *Gazette of India* dated 4.10.75.

<sup>34</sup> Regulation 3 (1) under the MTP Regulations.

<sup>35</sup> Regulation 3 (2) under the MTP Regulations.

The MTP Act further provides that the pregnancy cannot be terminated (except where the woman has not attained the age of 18 years or she has attained the age of 18 years but is a mentally ill person<sup>36</sup> in which case the consent in writing of the guardian is to be taken<sup>37</sup>) except with the consent of the pregnant woman.<sup>38</sup> The form for the consent is provided in Form C under the MTP Rules<sup>39</sup> framed under the MTP Act<sup>40</sup> and is annexed here as **Annexure - II**. The Regulations provide for all the documents i.e. the consent given by a pregnant woman for termination of her pregnancy, the certified opinion recorded under the above provisions and the intimation of termination of pregnancy:

- to be put in a sealed envelope;
- the envelope to be sent by the registered medical practitioner to the head of the hospital or owner of the approved place;
- safe-custody of the same by the latter;
- a weekly statement of cases where medical termination of pregnancy has been done is required to be sent to the Chief Medical Officer by the head of the hospital or the owner of the approved place.<sup>41</sup> This is to be done in Form II under the Regulations and is annexed as **Annexure-III**.
- an admission register is to be maintained for recording therein the admissions of women for the termination of their pregnancies.<sup>42</sup> This is to be done in Form III under the Regulations and is annexed as **Annexure-IV**.

If all these records are duly maintained, with their aid the Appropriate Authorities can monitor the abortions that are being done. For instance, if there are too many cases referred by a particular doctor or the reasons stated are essentially the same, the real reason for the abortion may be traceable to a determination of the sex of the foetus.

The Rules framed under the PNDT Act lay down certain other conditions for analysis or test and *pre-natal diagnostic procedures*. Thus:

- a *Genetic Laboratory* cannot accept for analysis or test any sample, unless referred to it by a *Genetic Clinic*;<sup>43</sup>
- every *pre-natal diagnostic procedure* has to be immediately preceded by locating the foetus and placenta through ultrasonography;<sup>44</sup>

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<sup>36</sup> The word 'lunatic' has been substituted by 'mentally ill person' by an amendment made to the Act in 2002. A 'mentally ill person' means a person who is in need of treatment by reason of any mental disorder other than mental retardation.

<sup>37</sup> Section 3 (4) (a) of the MTP Act.

<sup>38</sup> Section 3 (4) (b) of the MTP Act.

<sup>39</sup> The Medical Termination of Pregnancy Rules, 1975, published in the *Gazette of India*, dated 4.10.75.

<sup>40</sup> Rule 8 under the MTP Rules.

<sup>41</sup> Regulation 4 under the MTP Regulations.

<sup>42</sup> Regulation 5 under the MTP Regulations.

<sup>43</sup> Rule 14 (1) under the MTP Rules.

<sup>44</sup> Rule 14 (2) under the MTP Rules.

- the *pre-natal diagnostic procedure* shall be done under direct ultrasonographic monitoring so as to prevent any damage to the foetus and placenta.<sup>45</sup>

## PENALTIES

### *(A) Offence by persons*

I. If any person acts contrary to the prohibitions listed above including under Sections 22(1) and 22(2) relating to advertisement, he will be liable to be punished with:

- **imprisonment** which may **extend to 3 years**; and
- **fine** which may **extend to Rs.10,000/-**.<sup>46</sup>

Any subsequent conviction entails:

- **imprisonment** which may **extend to 5 years**; and
- **fine** which may extend to Rs.50,000/-.<sup>47</sup>

II. In case of a person seeking the aid of the bodies or persons referred to above for sex selection or for conducting pre-natal diagnostic techniques on any pregnant woman for the purposes other than those specified in Section 4(2), he shall be liable to be punished with:

- imprisonment which may extend to three years; and
- fine which may extend to Rs.50,000/-.

Any subsequent conviction entails:

- imprisonment which may extend to 5 years; and
- fine which may extend to Rs.1 lakh.<sup>48</sup>

III. In case of a registered medical practitioner, his name shall be reported by the Appropriate Authority to the State Medical Council concerned for taking necessary action:

- including suspension of the registration if charges are framed by the court and till the case is disposed of; and
- for the removal of his name from the register of the council on conviction for the period of:

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<sup>45</sup> Ibid.

<sup>46</sup> Sections 22 (3), 23 (1) and 23 (3) of the Act.

<sup>47</sup> Sections 23 (1) of the Act.

<sup>48</sup> Section 23 (3) of the Act.

- five years for the first offence;
- permanently for the subsequent offence.<sup>49</sup>

IV. Husband and relatives of the pregnant woman who undergoes a *pre-natal diagnostic technique* for the purposes other than those specified in sub-section (2) of section 4 shall be:

- presumed to have compelled the woman to undergo the *pre-natal diagnostic technique* **unless the contrary is proved;**<sup>50</sup> and
- liable for abetment of offence under Section 23 (3);<sup>51</sup> and
- punishable for the offence under Section 23 (3).<sup>52</sup>

If the contrary is proved, the woman can also be likewise punished. For the removal of doubts, it has been made clear under the amendments that the provisions of Section 23 (3) shall not apply to the woman who was compelled to undergo such diagnostic techniques or such selection.<sup>53</sup>

V. If any person contravenes any provision of the Act or the Rules made thereunder for which no penalty has been specified, he will be liable to be punished with:

- **imprisonment** which may **extend to three months;** or
- **fine** which may **extend to Rs.1000/-;** or
- with both.<sup>54</sup>

Any subsequent contravention entails an **additional fine** which may extend to Rs.500/- for every day during which such contravention continues after conviction for the first such contravention.

***(B) Offence by a company:***

A company:

- means any body corporate;
- includes a firm or other association of individuals.<sup>55</sup>

In case of offence by a company:

- every person incharge of; and
- every person responsible to

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<sup>49</sup> Section 23 (2) of the Act.

<sup>50</sup> Section 24 of the Act.

<sup>51</sup> Ibid.

<sup>52</sup> Ibid.

<sup>53</sup> Section 23(4) of the Act

<sup>54</sup> Section 25 of the Act.

<sup>55</sup> Explanation (a) to Section 26 of the Act.

the company for the conduct of the business of the company at the time the offence was committed

- the company shall all be deemed to be guilty and accordingly proceeded against and punished.<sup>56</sup>

The aforesaid is subject to the qualification that if any such person proves that the offence was committed without his knowledge or that he had exercise due diligence to prevent the commission of such offence, he may not be so liable.<sup>57</sup>

If consent, connivance of or that it was attributable to any neglect on the part of:

- Director and in relation to a firm, a partner in the firm
- Manager
- Secretary
- Other officer

they shall also be deemed to be guilty and accordingly proceeded against and punished.<sup>58</sup>

The offences under the Act are:

- **cognizable**: This means that for such an offence the police officer may arrest without warrant.
- **non-bailable**: This means that the police cannot grant bail in such a case.
- **non-compoundable**.<sup>59</sup>: This means that the parties to the case cannot settle the case and decide not to prosecute.

#### WHO CAN MAKE A COMPLAINT?

- the Appropriate Authority concerned;<sup>60</sup>
- any officer authorized in this behalf by the Central Government or State Government or the Appropriate Authority;<sup>61</sup>
- a person who has given notice of at least 15 days to the Appropriate Authority of the alleged offence and of his intention to make a complaint in the court i.e. if the Appropriate Authority fails to take action on the complaint made by a person, on the lapse of 15 days, that person can directly approach the court.<sup>62</sup>

Every public spirited person can activate the PNDT law for the violation of the same and he /she can seek the assistance of a lawyer, an NGO and even a group of persons can file a complaint together. Once the complaint is made in the Court the public prosecutor will take on from there and the complainant need not be present on every date of hearing.

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<sup>56</sup> Section 26 (1) of the Act.

<sup>57</sup> Proviso to Section 26 (1) of the Act.

<sup>58</sup> Section 26 (2) of the Act.

<sup>59</sup> Section 27 of the Act.

<sup>60</sup> Section 28 (1) (a) of the Act.

<sup>61</sup> Ibid.

<sup>62</sup> Section 28 (1) (b) of the Act.



Significantly “person” includes a **social organization**.<sup>63</sup>

In such a case, the court, on demand by such person, may direct the Appropriate Authority to make available copies of the relevant records in its possession to such person.<sup>64</sup>

The drafts of complaints that can be made by a public spirited person to the Appropriate Authority are annexed herewith as **Annexure-V**.

The offence under the Act shall be **tried only in a court of the Metropolitan Magistrate or a Judicial Magistrate of the First Class**.<sup>65</sup>

The drafts of complaints that can be filed by the Appropriate Authority in court are annexed herewith as **Annexure-VI**. The reply that can be filed by the Appropriate Authority to an application for anticipatory bail is annexed as **Annexure-VII**.

## **GOOD FAITH**

No suit, prosecution or other legal proceeding shall lie against the Central or State Government or the Appropriate Authority or any officer authorized by them for anything which is in **good faith** done or intended to be done under the Act.<sup>66</sup>

Thus the Appropriate Authority can perform its duties under the Act without any fear of any type of legal proceedings being initiated against him/her.

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<sup>63</sup> Explanation to Section 28 of the Act.

<sup>64</sup> Section 28 (3) of the Act.

<sup>65</sup> Section 28 (2) of the Act.

<sup>66</sup> Section 31 of the Act.

## CHAPTER V INSTRUMENTALITIES FOR IMPLEMENTING THE ACT

### (A) POLICY MAKING BODY

I. A Board is required to be constituted by the Central Government which is known as the **Central Supervisory Board** (hereinafter referred to as the Board).<sup>1</sup> The Act makes provision for inclusion of government officials, specialists as well as representatives of welfare organizations in this Board. Accordingly the Board is to comprise of:

- a) The Minister in charge of the Ministry of Department of Family Welfare who is the Chairman, *ex officio*.
- b) The Secretary to the Government of India in charge of the Department of Family Welfare who is the Vice-Chairman, *ex-officio*.
- c) Three members to be appointed by the Central Government to represent the Ministries of Central Government in charge of Women and Child Development, Department of Legal Affairs or Legislative Department in the Ministry of Law and Justice, and Indian System of Medicine and Homoeopathy, ex officio.
- d) Director General of Health Services of the Central Government, *ex-officio*.
- e) Ten members appointed by the Central Government, two each from amongst-
  1. eminent medical geneticists;
  2. eminent gynaecologists and obstetrician or expert of *stri-roga or prasuti tantra*;
  3. eminent paediatricians;
  4. eminent social scientists; and
  5. representatives of women welfare organizations.
- f) Three women members of Parliament – two elected from Lok Sabha and one from Rajya Sabha.
- g) Four members appointed by the Central Government (on the recommendation of the respective State Government or of Union Territory) by rotation to represent the States and Union Territories.
- h) An officer, not below the rank of Joint Secretary or equivalent of the Central Government, in charge of Family Welfare who is the Member Secretary, *ex-officio*.<sup>2</sup>

The Act also specifies the terms of the various members<sup>3</sup> and prescribes the procedure for the meetings of the Board which is to be further provided for by regulations made by the Board.<sup>4</sup> **It is mandatory for the Board to meet at least once in six months.**<sup>5</sup> Importantly, if a person, in the opinion of the Central Government, has been associated

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<sup>1</sup> Section 7 (1) of the Act.

<sup>2</sup> Section 7 (2) of the Act.

<sup>3</sup> Section 8 of the Act.

<sup>4</sup> Section 9 of the Act.

<sup>5</sup> Proviso to Section 9 (1) of the Act.

with the use or promotion of *pre-natal diagnostic technique for determination of sex* or with any *sex selection technique*, he shall be disqualified from being appointed as a member of the Board.<sup>6</sup>

In the amendments it has been clarified that no member other than an *ex officio* member shall be appointed for more than two consecutive terms.<sup>7</sup>

The functions of the Board as specified under the Act are:

- i) to advise the Central Government on policy matters relating to use of *pre-natal diagnostic techniques*, *sex selection techniques* and against their misuse;
- ii) to review and monitor implementation of the Act and the rules made thereunder and to recommend to the Central Government changes in both;
- iii) to create public awareness against the practice of pre-conception sex selection and pre-natal determination of sex of foetus leading to female foeticide;
- iv) to lay down code of conduct to be observed by persons working at *Genetic Counselling Centres, Genetic Laboratories and Genetic Clinics*;
- v) to oversee the performance of various bodies constituted under the Act and take appropriate steps to ensure its proper and effective implementation.<sup>8</sup>

The Board is also to perform any other functions as may be specified under the Act<sup>9</sup> such as specifying abnormalities or diseases for which *pre-natal diagnostic techniques* can be conducted<sup>10</sup> or the conditions which are necessary to exist before the conduct of these techniques.<sup>11</sup> Thus the Act envisages the Board as the main body which is to make recommendations on policy matters and on amendments that are necessary in the Act.

The Supreme Court vide its order dated 4.5.2001 had also directed the Board to lay down a code of conduct under section 16 (iv) of the Act to be observed by persons working in bodies specified therein and to ensure its publication so that the public at large can know about it. Pursuant to this, the Board has laid down a Code of Conduct to be observed by persons working at any of the facilities. This provides that all persons including the owner, employee or any other persons associated with facilities registered under the Act/the Rules shall-

- (i) not conduct or associate with, or help in carrying out detection or disclosure of sex of foetus in any manner;
- (ii) not employ or cause to be employed any person not possessing qualifications necessary for carrying out pre-natal diagnostic techniques/procedures and tests including ultrasonography;

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<sup>6</sup> Section 14 (f) of the Act.

<sup>7</sup> Proviso to Section 15 of the Act.

<sup>8</sup> Section 16 of the Act.

<sup>9</sup> Section 16 (vi) of the Act.

<sup>10</sup> Section 4 (2) (vi) of the Act.

<sup>11</sup> Section 4 (3) (v) of the Act.

- (iii) not conduct or cause to be conducted or aid in conducting by himself or through any other person any techniques or procedure for selection of sex before or after conception or for detection of sex of foetus except for the purposes specified in sub-section (2) of section 4 of the Act;
- (iv) not conduct or cause to be conducted or aid in conducting by himself or through any other person any techniques or test or procedure under the Act at a place other than a place registered under the Act/the Rules;
- (v) ensure that no provision of the Act and these Rules are violated in any manner;
- (vi) ensure that the person conducting any techniques, test or procedure leading to detection of sex of foetus for purposes not covered under section 4(2) of the Act or selection of sex before or after conception is informed that such procedures lead to violation of the Act and the Rules which are punishable offences;
- (vii) help the law enforcing agencies in bringing to book the violators of the provisions of the Act and the Rules;
- (viii) display his/her name and designation prominently on the dress worn by him/her;
- (ix) write his/her name and designation in full under his/her signature;
- (x) on no account conduct or allow/cause to be conducted female foeticide;
- (xi) not commit any other act of professional misconduct.<sup>12</sup>

II. Under the amended provisions of the Act, a State Supervisory Board or the Union Territory Supervisory Board is required to be constituted by each State and Union Territory having a Legislature. It shall consist of:

- a) the Minister in charge of Health and Family Welfare in the State, who shall be the Chairperson, *ex officio*;
- b) the Secretary in charge of the Department of Health and Family Welfare who shall be the Vice-Chairperson, *ex officio*;
- c) Secretaries or Commissioners in charge of Departments of Women and Child Development, Social Welfare, Law and Indian System of Medicines and Homoeopathy, *ex officio*, or their representatives;
- d) Director of Health and Family Welfare or Indian System of Medicines and Homoeopathy of the State Government, *ex officio*;
- e) Three women members of Legislative Assembly or Legislative Council;
- f) Ten members to be appointed by the State Government out of which two each shall be from the following categories:

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<sup>12</sup> Incorporated as Rule 18 under the amended PNDT Rules.

- i) eminent social scientists and legal experts;
- ii) eminent women activists from non-governmental organizations or otherwise;
- iii) eminent gynaecologists and obstetricians or experts of *stri-roga or prasuti tantra*;
- iv) eminent paediatricians or medical geneticists;
- v) eminent radiologists or sonologists;

g) an officer not below the rank of Joint Director in charge of Family Welfare, who shall be the Member Secretary, *ex officio*.<sup>13</sup>

The Act also specifies the terms of the various members other than *ex officio* members as three years<sup>14</sup>, co-opting of members<sup>15</sup> and procedure for the meetings of the Board.<sup>16</sup> The number of co-opted members cannot exceed one-third of the total strength of the State Board. The co-opted members shall have the same powers and functions as other members, except the right to vote and shall abide by the rules and regulations. It has been clarified that if a member of the Legislative Assembly or member of the Legislative Council who is a member of the State Board, becomes Minister or Speaker or Deputy Speaker of the Legislative Assembly or Chairperson or Deputy Chairperson of the Legislative Council, she shall cease to be a member of the State Board.<sup>17</sup> It is mandatory for the Board to meet at least once in four months<sup>18</sup> and one-third of the total number of members of the State Board shall constitute the quorum.<sup>19</sup>

The functions of the Board as specified are:

- i) to create public awareness against the practice of pre-conception sex selection and pre-natal determination of sex of foetus leading to female foeticide in the State;
  - ii) to review the activities of the Appropriate Authorities functioning in the State and recommend appropriate action against them;
  - iii) to monitor the implementation of provisions of the Act and the rules and make suitable recommendations relating thereto, to the CSB;
  - iv) to send such consolidated reports as may be prescribed in respect of the various activities undertaken in the State under the Act to the Board and the Central Government; and
  - v) any other functions as may be prescribed under the Act.<sup>20</sup>

The Act does not specify the time frame within which such Boards are to be constituted but as the Board has an important role with regard to policy matters and reviewing and

<sup>13</sup> Section 16A (2) of the Act.

<sup>14</sup> Section 16A (4) and (5) of the Act.

<sup>15</sup> Section 16A (8) and (9) of the Act.

<sup>16</sup> Section 16A(10) of the Act.

<sup>17</sup> Section 16A (6) of the Act.

<sup>18</sup> Section 16A (3) of the Act.

<sup>19</sup> Section 16A (7) of the Act.

<sup>20</sup> Section 16A (1) of the Act.

monitoring the work of the other bodies in the State, it would further the implementation of the provisions of the Act if such Boards are set up as expediently as possible.

## **(B) IMPLEMENTING AUTHORITIES**

The role of the implementation of the Act has been assigned to the appropriate authorities. The Appropriate Authorities<sup>21</sup> are to function with the aid and advice of an Advisory Committee. Under the Act:

- the Central Government is required to appoint one or more Appropriate Authorities for each of the Union territories;<sup>22</sup>
- the State Government is required to appoint one or more Appropriate Authorities for the whole or part of the States having regard to the intensity of the problem of pre-natal determination of sex leading to female foeticide;<sup>23</sup>

Under the amendments, a multi-member body has been provided as the State Appropriate Authority (or when appointed for the whole of the Union Territory) consisting of:

- i) an officer of or above the rank of the Joint Director of Health and Family Welfare-Chairperson;
- ii) an eminent woman representing women's organization; and
- iii) an officer of Law Department of the State or the Union Territory concerned.<sup>24</sup>

Such authorities are to be constituted within three months of coming into force of the Amended Act and any vacancy occurring therein is required to be filled within three months of the occurrence.<sup>25</sup>

Under the directions of the Supreme Court, Appropriate Authorities are to be appointed at District and sub-district levels as well. At the District level, the Chief Medical Officers or the Civil Surgeons have been designated as the Appropriate Authorities while at the sub-district level, the practice varies from State to State.

### **Functions of the Appropriate Authority are:**

- to grant, suspend or cancel the registration;
- to enforce the standards for *genetic counselling centre, genetic clinic* and *genetic laboratory*.
- to investigate complaints of breach of provisions of the Act and the Rules;

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<sup>21</sup> Section 17 of the Act.

<sup>22</sup> Section 17 (1) of the Act.

<sup>23</sup> Section 17 (2) of the Act.

<sup>24</sup> Section 17 (3)(a) of the Act.

<sup>25</sup> Proviso to Section 17 (3) (a) of the Act.

- to take the complaints to the court.
- to take appropriate legal action against the use of any sex selection technique by any person at any place, suo motu or brought to its notice and also to initiate independent investigations in such matter;
- to create public awareness against the practice of sex selection or pre-natal determination of sex;
- to supervise the implementation of the provisions of the Act and rules;
- to recommend to the CSB and State Boards modifications required in the rules in accordance with changes in technology or social conditions;
- to take action on the recommendations of the Advisory Committee made after investigation of complaint for suspension or cancellation of registration.<sup>26</sup>

While it is the function of the Appropriate Authority to take a complaint of breach of provisions of the Act and the Rules thereunder to the court, if the Appropriate Authority fails to act on the complaint within **15** days, a public spirited person can take the complaint to the court directly.<sup>27</sup>

Moreover the Appropriate Authority has been invested with the following powers, namely-

- a) summoning of any person who is in possession of any information relating to violation of the provisions of this Act or the rules made thereunder;
- b) production of any document or material object relating to clause (a);
- c) issuing search warrant for any place suspected to be indulging in sex selection techniques or pre-natal sex determination; and
- d) any other matter which may be prescribed.<sup>28</sup>

These provisions are meant to strengthen the hands of the Appropriate Authority while discharging its functions under the Act.

Under the directions of the Supreme Court dated 4.5.2001, all State/Union Territory Appropriate Authorities are required to furnish quarterly returns to the Board giving a report on the implementation and working of the Act. These returns are to cover information, inter alia about:

- i) Survey of bodies specified in Section 3 of the Act;
- ii) Registration of bodies specified in Section 3 of the Act including bodies using ultrasound machines;
- iii) Action taken against non-registered bodies operating in violation of Section 3 of the Act, inclusive of search and seizure of records;
- iv) Complaints received by the Appropriate Authorities under the Act and action taken pursuant thereto;

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<sup>26</sup> Section 17 (4) of the Act.

<sup>27</sup> Section 28 (1) (b) of the Act.

<sup>28</sup> Section 17A of the Act.

- v) Number and nature of awareness campaigns conducted and results flowing therefrom.

The format of the quarterly report that is required to be submitted is annexed herewith as **Annexure-VIII**.

The Act also provides for the appointment of an **Advisory Committee** by the Central or the State Government, as the case may be, to aid and advise the Appropriate Authority in the discharge of its functions.<sup>29</sup> The Advisory Committee is to consist of:

- three medical experts from amongst gynecologists, obstetricians, pediatricians and medical geneticists;
- one legal expert;
- one officer to represent the information and publicity department of the respective government;
- three eminent social workers with at least one being a representative of a women's organization.<sup>30</sup>

A person who has been associated with the use or promotion of *pre-natal diagnostic techniques* for determination of sex or *sex selection* shall be disqualified from appointment as a member of the Advisory Committee.<sup>31</sup>

The intervening period between any two meetings of the Advisory Committee shall not exceed **60 days**<sup>32</sup> whether any application for registration or cancellation of the same is pending or not. At every meeting of the Advisory Committee, four members shall form a quorum. Thus at least four members should be present for the meeting of the Advisory Committee to be held.

Under the Rules specially framed in this behalf, the Appropriate Authority is required to attend the meeting of the Advisory Committee, provide all secretarial and other assistance to the Advisory Committee for the discharge of its functions, though the Appropriate Authority shall not have a right to vote in case of any difference of opinion amongst the members of the Advisory Committee and voting is done.<sup>33</sup>

Moreover the procedure to be followed by the Advisory Committee is to be prescribed by rules and regulations made in this regard. Separate Rules have been framed known as the Pre-Natal Diagnostic Techniques (Regulation and Prevention of Misuse) (Advisory Committee) Rules, 1996 which regulate the procedure to be followed by the Advisory Committees. The same are annexed herewith as **Appendix-III**.

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<sup>29</sup> Section 17 (5) of the Act.

<sup>30</sup> Section 17 (6) of the Act.

<sup>31</sup> Section 17 (7) of the Act.

<sup>32</sup> Rule 4 under the PNDT (Advisory Committee) Rules, 1996.

<sup>33</sup> Rule 9 under the PNDT (Advisory Committee) Rules, 1996.



## CHAPTER VI MAINTENANCE AND PRESERVATION OF RECORDS

The Act and the Rules also deal elaborately with the maintenance and preservation of records. Maintenance of proper records has a dual advantage:

- from the point of view of the **center or clinic or laboratory**, if there is any complaint against them, through the records they can prove that their action was in accordance with the law and the rules.
- from the point of view of the **implementing authorities**, while non-maintenance of proper records can itself give rise to a cause of action, the fact that proper records have not been maintained or that for certain cases no records have been maintained can be indicative of the fact that the center or the clinic or the laboratory is conducting *pre-natal diagnostic techniques* for the purpose of determination of the sex of the foetus or in violation of the Act.

Every *Genetic Counselling Centre, Genetic Clinic or Genetic Laboratory, Ultrasound Clinic and Imaging Centre* is required to maintain certain records:

**Register** showing in serial order:

- names and addresses of men or women given genetic counselling and/or subjected to *pre-natal diagnostic procedure or test*;
- names of their spouses or fathers;
- date on which they first reported for such counselling, procedure or test.<sup>1</sup>

Further,

- Record by every *Genetic Counselling Centre* of each woman counselled is to be as specified in FORM D under the Rules;<sup>2</sup>
- Record by every *Genetic Laboratory* of each man or woman subjected to *pre-natal diagnostic test* is to be as specified in FORM E under the Rules;<sup>3</sup>
- Record by every *Genetic Clinic* of each man or woman subjected to *pre-natal diagnostic procedure* is to be as specified in FORM F under the Rules.<sup>4</sup>

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<sup>1</sup> Rule 9 (1) under the Rules.

<sup>2</sup> Rule 9 (2) under the Rules.

<sup>3</sup> Rule 9 (3) under the Rules.

<sup>4</sup> Rule 9 (4) under the Rules.

The other kinds of records include:

- Case records
- Forms of consent
- Laboratory results
- Microscopic pictures
- Sonographic plates or slides
- Recommendations and letters

A person conducting ultrasonography on a pregnant woman shall keep complete record thereof in the clinic in such manner, as may be prescribed, and if any deficiency or accuracy is found in the same, that would be treated as a contravention of provisions of section 5 or section 6 unless contrary is proved by the person conducting the ultrasonography.<sup>5</sup>

Moreover every Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centre shall send a complete report in respect of all pre-conception or pregnancy related procedures/techniques/tests conducted by them in respect of each month by 5<sup>th</sup> day of the following month to the concerned Appropriate Authority.<sup>6</sup>

These records are required to be maintained for a **period of 2 years**<sup>7</sup> from the date of completion of counseling, *pre-natal diagnostic procedure* or *pre-natal diagnostic test* or in the event of any legal proceeding, till **the final disposal of the legal proceeding**.<sup>8</sup>

In case the records are maintained on computer or other electronic equipment, a printed copy of the record is required to be taken and preserved after authentication by a person responsible for such record.<sup>9</sup>

Records, at all reasonable times are to be made available for inspection to Appropriate Authority or person authorized by the Appropriate Authority in this behalf.<sup>10</sup>

The Appropriate Authority is to maintain a **permanent** record of:

- applications for grant of certificate of registration;
- applications for renewal of certificate of registration as specified in Form H under the Rules;
- letters of intimation of every change of employee, place, address and equipment installed.<sup>11</sup>

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<sup>5</sup> Proviso to Section 4 (3) of the Act.

<sup>6</sup> Rule 9(8) under the amended PNDT Rules.

<sup>7</sup> Section 29 (1) of the Act.

<sup>8</sup> Proviso to Section 29 (1) of the Act read with Rule 6 under the Rules.

<sup>9</sup> Rule 9 (7) under the Rules.

<sup>10</sup> Section 29 (2) of the Act.

<sup>11</sup> Rule 9 (5) under the Rules.

## **CHAPTER VII**

### **SEARCH AND SEIZURE**

A search is an integral step in a criminal investigation. Whenever an appropriate authority or any other authorised officer has reason to believe that an offence under the Act has been or is being committed, he may search a *genetic counseling centre, a genetic laboratory or genetic clinic or any other place which is suspected of conducting pre-natal diagnostic techniques.*

The scope of the powers of the appropriate authority to search and seize is very wide and it includes the power to:

- Enter freely into the place of search.<sup>1</sup>
- Search at all reasonable times.<sup>2</sup>
- Examine and inspect all documents like:
  - i. Registers
  - ii. Records including consent forms, referral slips, charts, laboratory results, microscopic pictures
  - iii .Forms
  - iv.Books
  - v. Pamphlets
  - vi. Advertisements
  - vii. Material objects like sonographic plates or slides
  - viii. Equipment like ultrasonography machines, needles, foetoscope etc.<sup>3</sup>
- Seize and seal any document, record, material object or equipment etc. if there is reason to believe that it may furnish evidence of commission of an offence punishable under the Act.<sup>4</sup>

It has been clarified that ‘material object’ would include records, machines and equipments; and ‘seize’ and ‘seizure’ would include ‘seal’ and ‘sealing’ respectively.

Under the amended Rules, it has been provided that every Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic, Imaging Centre, nursing home, hospital, institute or any other place where any of the machines or equipments capable of performing any procedure, technique or pre-natal determination of sex or selection of sex before or after conception is used, shall afford all reasonable facilities for inspection of the place, equipment and records to the Appropriate Authority in this behalf for registration of such institutions, by whatever name called, under the Act, or for detection of misuse of such facilities or advertisement therefore, or for selection of sex before or after conception, or for detection/disclosure of sex of foetus or for detection of cases of violation of the provisions of the Act in any other manner.

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<sup>1</sup> Section 30(1) of the Act read with Rule 12 (1) under the PNDDT Rules.

<sup>2</sup> Id.

<sup>3</sup> Section 30 (1) of the Act.

<sup>4</sup> Id.

Further the Appropriate Authority may seal and seize any offending equipment if the facility has not registered itself.<sup>5</sup>

The Act<sup>6</sup> has to be read in conjunction with the rules<sup>7</sup> under the Act and the Code of Criminal Procedure<sup>8</sup> to ensure that the search and seizure is done in a fair and non-arbitrary manner.<sup>9</sup>

There are certain **safeguards or prerequisites** to be followed during the search and seizure to ensure the aforementioned objective namely:

### **SEARCH AND WITNESSES:**

- (A) During the search at least two independent witnesses of the locality should be present;<sup>10</sup>
- (B) If no such persons are available or willing to be witness to the search, then two such persons of another locality should be present;
- (C) The search should be made in the presence of the two or more independent witnesses;<sup>11</sup>
- (D) The witnesses are to be selected by the appropriate authority or the officer duly authorised to conduct search;
- (E) The witnesses so selected should be unprejudiced and uninterested as the object of the section is to ensure fair dealing and a feeling of confidence and security amongst public;
- (F) The witnesses may be summoned by Court to appear as witnesses.
- (G) Any person suspected of having any object on his person may also be searched. However, if such person, is a woman than, the search can be done only by a female officer.

### **SEIZURE AND PREPARATION OF LIST:**

- (A) A list of documents, records, material objects etc. seized during the search should be prepared in duplicate and both copies of such list shall be signed on every page by the appropriate authority or the officer authorised and the witnesses to the seizure;<sup>12</sup>
- (B) Assistance of your office staff can always be taken during the process of search and seizure;
- (C) The list should be prepared at the place affecting the seizure and if it is not practicable to do so at the place affecting the seizure then for reasons to be

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<sup>5</sup> Rule 11 under the PNDT Rules.

<sup>6</sup> Section 30 of the Act.

<sup>7</sup> Rule 12 under the PNDT Rules.

<sup>8</sup> Sections 99-105 of the Cr.P.C.

<sup>9</sup> Section 30(2) of the Act.

<sup>10</sup> Rule 12(1) under the PNDT Rules.

<sup>11</sup> Proviso to Rule 12(2) under the PNDT Rules.

<sup>12</sup> Rule 12(2) under the PNDT Rules.

recorded in writing it can be done in any other place but it has to be in the presence of the witnesses;

- (D) A copy of the list prepared must be handed over to the person from whose custody the document, record or material object etc. is being seized or his representative under acknowledgment or sent by registered post to him if he is not available at the place of effecting the seizure;<sup>13</sup>
- (E) The person from whose custody the document, record or material object etc. is being seized or his representative should be permitted to attend during the search and seizure;
- (F) The appropriate authority or the officer duly authorised in this behalf may seize any document, material object, record or equipment and take the same into safe custody;
- (G) It is preferable that along with the preparation of list of objects seized, a slip is made and pasted on each object seized along with the date, time and the signature of the witnesses;
- (H) After a list of seizure is prepared the same must be sent to the Magistrate having jurisdiction or incharge of the case within 24 hours of the seizure by the appropriate authority or officer duly authorised. Permission to retain the seized objects should be obtained from the Court. The owner of the seized object may make an application to the court for the release of the same. The court may do so after imposing conditions for custody and taking a bond to the effect that, the objects must not be misused for conducting sex-determination tests and that the objects must be produced in Court as and when required etc.
- (I) Police aid can be taken if the appropriate authority apprehends a law and order problem during the process of search and seizure.

#### **SEALING:**

- (A) If any material object seized is perishable in nature then arrangements shall be made promptly by the appropriate authority or officer duly authorised for sealing, identification and preservation of the same and send the same to a facility for test if so required;<sup>14</sup>
- (B) And till such arrangements for safe removal are made the refrigerator or other equipment used by the Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic for preservation of such material object seized shall be sealed; In case of such sealing it is important to mention the same in the list of seizure prepared;<sup>15</sup>
- (C) If the search and seizure is not completed in a day then the appropriate authority or officer duly authorised may either seal the premises or mount a guard for safe keeping to prevent any tampering of the documents, records, material objects etc;<sup>16</sup>

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<sup>13</sup> Rule 12 (3) under the PNDR Rules and the proviso to the same.

<sup>14</sup> Rule 12 (4) under the PNDR Rules.

<sup>15</sup> Proviso to Rule 12 (4) under the PNDR Rules.

<sup>16</sup> Rule 12 (5) under the PNDR Rules.

- (D) After seizure the seized objects can be removed to your own premises or may be left in the custody of a respectable person of the locality. If it is not possible to remove the seized objects, they may be retained where they are found after taking a bond from the owner that the same would be produced before the court as and when required.

The machines of the facility that are seized and sealed may be released if such organization pays penalty equal to five times of the registration fee to the Appropriate Authority concerned and gives an undertaking that it shall not undertake detection of sex of foetus.<sup>17</sup>

The appropriate authority is duty bound to maintain systematic records of the search and seizure and the same would also safeguard the appropriate authority against any allegations of abuse.

### ***COLLECTION OF EVIDENCE:***

The evidence that needs to be collected in order to make out a case under the PNDDT Act varies depending upon the nature of the violation and in some cases the pieces of evidence can overlap.

#### **I. Illegal Advertisement**

In case any *genetic counselling centre, genetic laboratory, genetic clinic, ultrasound clinic or imaging centre* advertises the facilities for pre-natal determination of sex or sex selection before or after conception, the advertiser, the distributor, the person or centre who issues or causes to be issued an advertisement for the aforementioned purpose will all be equally liable under the PNDDT Act.

#### ***The documentary evidence will include:***

- (A) the paper cutting of the advertisement, the name of the newspaper or magazine or any other document which carries the advertisement, the date of the issuance of the advertisement;
- (B) the name of the advertiser, his place of business;
- (C) the name of the owner of the clinic, centre or laboratory issuing such advertisement, the address of the said centre, laboratory or clinic;
- (D) the name of the distributor, his place of business ;
- (E) the photograph of the advertisement, the photograph of the hoarding, board, wall on which the advertisement is present etc.
- (F) the letters heads, memorandum of association, annual reports, statements showing organizational structure and ownership of the news paper, or

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<sup>17</sup> Rule 11(2) under the amended PNDDT Rules.

distributorship, or the centre. This information has to be collected in order to link the person to the violation.

The aforementioned list is not exhaustive but merely illustrative.

## **II. In case of conducting a test for determination of sex or communication of the sex of the foetus:**

The investigation of cases of this nature is difficult because of the collusion between the doctor and the persons wanting the test. Nevertheless there are ways and means to collect evidence in such cases as well:

### ***The documentary evidence will include***

- (1) referral slips
- (2) consent forms
- (3) laboratory results
- (4) microscopic pictures
- (5) sonographic plates or slides
- (6) registers containing names and addresses of patients and their families
- (7) case history of the patient
- (8) records of clients maintained on the computer or other electronic equipment can be taken on a floppy or a printed copy of the same
- (9) floppy or printed copy of the ultrasound image of the foetus
- (10) Receipt of fee paid for the test, details of cheque payment etc.

### ***Oral and other evidence***

Apart from documentary evidence, decoy witnesses namely pregnant women can also be sent to suspected centres to find out if pre-natal determination of sex is done. If it is found that such centres are conducting the tests the statements of such witnesses can be recorded by the appropriate authority. That hidden tape recorder or cameras can also be used to record the conversation between the decoy witness and the doctor. When decoy witnesses are sent for getting the tests done then the Chief Medical Officer can at the same time raid the premises or inspect the premises and collect the evidence on the spot. As and when decoy witnesses are used their statement should be taken on affidavit that they are getting the tests done on humanitarian and on the grounds of public interest in order to assist the appropriate authority.

In some cases women may themselves complain that they were forced to get the sex of the foetus determined. Then that woman's statement can be recorded and she can also be called as a witness to depose about the doctor, the centre and the family members who forced her to get the test done.

## **III. In case of non-registration, cancellation or suspension of registration:**

The collection of evidence in these cases is not very difficult as most of the records are available with the appropriate authority itself.

***The documentary and oral evidence will include***

- (a) Copy of the registration certificate
- (b) Copy of the affidavit given by the owner that he will not conduct pre-natal determination of sex.
- (c) Copy of the particulars given about the qualifications of the employees while registration
- (d) Documents collected from the MCI, the degree certificate of the medical practitioners (employees of the centre) etc.
- (e) Statements of decoy witnesses
- (f) The tape and video recording
- (g) Other materials collected as evidence in case of conducting tests.

***The complete evidence to be submitted before the Magistrate would include:***

1. A copy of the complaint
2. A statement showing the list of witnesses both witnesses of the search and seizure and decoy witnesses
3. The report of the search and seizure or commonly called Panchnamah
4. A copy of the all the documents collected.
5. Statements of witnesses if any.
6. Most essential would be the complete address of the *genetic counselling centre, genetic clinic or genetic laboratory.*



ANNEXURE-I

FORM I (under the MTP Regulations)  
(See Regulation 3)

.....  
(Name and qualification of the Registered Medical Practitioner in block letters)

.....  
(Full address of the Registered Medical Practitioner)

I, .....  
(Name and qualification of the Registered Medical Practitioner in block letters)

.....  
(Full address of the Registered Medical Practitioner) hereby certify that  
\*I/we/am/are of opinion, formed in good faith, that it is necessary to terminate the  
pregnancy of .....  
(Full name of pregnant woman in block letters)

resident of.....  
(Full address of woman in block letters)

for the reasons given below\*\*,

\*I/We hereby give intimation that \*I/we terminated the pregnancy of the woman referred to above who bears the serial No. ....in the Admission Register of the Hospital/approved place.

*Signature of Registered Medical Practitioner*

*Signature of Registered Medical Practitioner*

Place:

Date:

- (i) In order to save the life of the pregnant woman.
- (ii) In order to prevent grave injury to the physical or mental health of pregnant woman.
- (iii) In view of the substantial risk that if the child was born it would suffer from such physical or mental abnormalities as to be seriously handicapped.
- (iv) As the pregnancy is alleged by pregnant woman to have been caused by rape.

(v) As the pregnancy has occurred as a result of failure of any contraceptive device or method used by the married woman or her husband for the purpose of limiting the number of children.

Note- Account may be taken of the pregnant woman's actual or reasonably foreseeable environment in determining whether the continuance of a pregnancy would involve a grave injury to her physical or mental health.

*Signature of Registered Medical Practitioner*

*Signature of Registered Medical Practitioner*

Place:

Date:

\*Strike out whichever is not applicable.

\*\* Of the reasons specified items (i) to (v) write the one which is appropriate.

ANNEXURE-II

**FORM C\***  
(See rule 8)

I,..... daughter/wife  
of..... aged about ..... years of  
..... (here state the permanent  
address) ..... at present residing at ..... do hereby  
give my consent of the termination of my pregnancy at .....  
(state the name of a place where the pregnancy is to be terminated).

*Signature*

Place:

Date:

(To be filled in by guardian where the woman is lunatic or minor)

I,..... son/daughter/wife  
of..... aged about ..... years of .....  
at present residing at ..... (permanent  
address) .....do hereby give my consent to the termination of the  
pregnancy of my ward .....who is a minor/lunatic at  
..... (place of termination of pregnancy).

*Signature*

Place:

Date:

\*Under the MTP Act.

ANNEXURE-III

**FORM II\***  
[See Regulation 4 (5)]

1.Name of the State.

2.Name of Hospital/approved place.

3.Duration of pregnancy (give total number only):

- (a) upto 12 weeks.
- (b) Between 12-20 weeks.

4.Religion of woman:

- (a) Hindu
- (b) Muslim
- (c) Christian
- (d) Others
- (e) Total

5.Termination with acceptance of contraception:

- (a) Sterilization
- (b) I.U.D.

6.Reasons for termination: (give total number under each sub-head):

- (a) Danger to life of the pregnant woman.
- (b) Grave injury to the mental health of the pregnant woman.
- (c) Grave injury to the physical health of the pregnant woman.
- (d) Pregnancy caused by rape.
- (e) Substantial risk that if the child was born it would suffer from such physical or mental abnormalities as to be seriously handicapped.
- (f) Failure of any contraceptive device or method.

*Signature of the  
Officer  
In-charge with date.*

\* Under the MTP Act

ANNEXURE-IV

**FORM III**  
(See Regulation 5)  
**Admission Register**

(To be destroyed on the expiry of five years from the date of the last entry in the Register)

Sl.No.	Date of Admission Religion	Name of Patient	Wife/ Daughter	Age	
1	2	3	4	5	6

Address	Duration of Pregnancy	Reasons on which Pregnancy Is Terminated	Date of termination of pregnancy	Date of discharge of patient	Result and Remarks
7	8	9	10	11	12

Name of Registered Medical Practitioner(s) by whom the Opinion is formed	Name of Registered Medical Practitioner by whom pregnancy is terminated
----- 13	----- 14

## ANNEXURE-V

(Draft of the type of complaint that can be made to the Appropriate Authority)

The Appropriate Authority

Subject: Complaint of breach of provisions of the Pre-Natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994

Dear Sir,

We are a non-governmental organization consisting of lawyers and social workers working in different states of India and working on issues relating to discrimination against women including female foeticide. We were shocked to see the news item dated appearing in the (name of the newspaper/magazine etc.) and we wish to bring the same to your notice.

Your kind attention is invited for immediate investigation and action under Section 17(4) (c) of the Pre-Natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 to the news item that appeared in the (name of the newspaper/magazine etc.) dated . A copy of the news item which is self-explanatory is annexed herewith for your ready reference.

As you are aware, the object of the Act includes regulation of the use of pre-natal diagnostic techniques and the prevention of the misuse of such techniques for the purpose of pre-natal sex determination leading to female foeticide, and for matters connected therewith or incidental thereto.

Despite the existence of the Act on the statute books since 1994, the latest Census Report of 2001 shows that the sex ratio has been declining in an alarming way and it has come down from 882 in 1991 to 874 in 2001 in the State of Punjab. The sex ratio in case of age group of 0-6 is 793 according to 2001 Census whereas it was 875 in the State of Punjab according to 1991 census which accentuates the situation as it shows that the number of females being born is declining.

That you being the Appropriate Authority appointed under the Act are empowered to investigate any violation or possible violation of the PNDT Act and take necessary action.

That a plain reading of the newspaper article demonstrates that there has been a clear cut violation of the provisions of the PNDT Act and that pre-natal diagnostic techniques are misused for the purpose of sex determination and the sex of the child is being conveyed to the family members.

That the said article describes the two diagnostic centres in (areas or the names of the centres) which are being run by (names of the doctors or owners). That one of the said clinics/nursing homes contains (name of the offending equipment such as ultrasound machine) and is fully equipped with ultra sound and x-ray facilities.

That the appropriate authority under Section 30 of the Act has been granted very wide powers and the same is reproduced herein below:

Section 30(1): If the appropriate authority has reason to believe that an offence under this Act has been or is being committed at any Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic or any other place, such authority or any officer authorised thereof in this behalf may subject to such rules as may be prescribed, enter and search at all reasonable times with such assistance, if any, as such authority or officer considers necessary, such Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic or any other place and examine any record, register, document book, pamphlet, advertisement or any other material, object found therein and seize and seal the same if such authority or officer has reason to believe that it may furnish evidence of the commission of an offence punishable under this Act.

That further Section 31 of the Act gives protection to the appropriate authority or any officer authorised thereunder for action taken in good faith.

That in view of the aforementioned facts and circumstances, you are requested to take immediate action and investigate into the matter without any delay.

Kindly treat this letter as a complaint and take appropriate action including filing of a criminal complaint before the Metropolitan Magistrate or a Judicial Magistrate under Section 28 (1) (a) of the Act.

Acknowledgement of this complaint will be appreciated.

Yours sincerely,

The Appropriate Authority  
Under the Pre-Natal Diagnostic Techniques Act  
Government of NCT  
Old Secretariat  
Rajpur Road  
Delhi

Dear Sir,

Subject: Complaint of breach of provisions of the Pre-Natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994

We public spirited lawyers working on issues relating to discrimination against women including female foeticide.

We were shocked to see an advertisement in \_\_\_\_\_ (name of the place) edition of \_\_\_\_\_ (the newspaper/magazine) which is circulated throughout India. The said advertisement openly advertises sex determination tests. We wish to bring the same to your notice. A copy of the said advertisement is annexed hereto. It is pertinent to mention that \_\_\_\_\_ has its registered office at \_\_\_\_\_ (name of the place).

As you are aware, the object of the Act includes regulation of the use of pre-natal diagnostic techniques and the prevention of the misuse of such techniques for the purpose of pre-natal sex determination leading to female foeticide, and for matters connected therewith or incidental thereto. That the said advertisement and what it seeks to provide is clearly violative of the lofty ideals and intention of the Act.

The advertisement in blatant violation of the PNDDT Act reads: (give the wordings of the advertisement)

That the said advertisement is in clear violation of different provisions of the PNDDT Act which have been reproduced herein below:

**22.Prohibition of advertisement relating to pre-natal determination of sex and punishment for contravention-** (1) No person, organization, *Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic*, including clinic, laboratory or center having ultrasound machine or imaging machine or scanner or any other technology capable of undertaking determination of sex of foetus or sex selection shall **issue, publish, distribute, communicate or cause to be issued, published, distributed or communicated any advertisement, in any form, including internet, regarding facilities of pre-natal determination of sex or sex selection before conception** available at such center, laboratory, clinic or at any other place.



(2) **No person or organization including Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic** shall issue, publish, distribute, communicate or cause to be issued, published, distributed or communicated any advertisement in any manner regarding pre-natal determination or pre-conception selection of sex by any means whatsoever, scientific or otherwise.

(3) Any person who contravenes the provisions of sub-section (1) or sub-section (2) shall be punishable with imprisonment for a term which may extend to three years and with fine which may extend to ten thousand rupees.

*Explanation*-For the purposes of this section, "advertisement" includes any notice, circular, label, wrapper or any other document including advertisement through internet or any other media in electronic or print form and also includes any visible representation made by means of any hoarding, wall-painting, signal, light, sound, smoke or gas.

This section prohibits advertisement **by any means, by any person** about conducting sex determination tests **anywhere**. Therefore the aforementioned advertisement clearly falls foul of this provision.

Section 5(2). "No person including the person conducting pre-natal diagnostic procedures shall communicate to the pregnant woman concerned or her relatives or any other person the sex of the foetus by words, signs or in any other manner"

Section 6-Determination of sex prohibited- on and from the commencement of this Act,-

- (a) No Genetic Counselling centre or Genetic Laboratory or Genetic Clinic shall conduct or cause to be conducted in its centre, laboratory or clinic, pre-natal diagnostic techniques including ultrasonography, for the purpose or determining the sex of a foetus;
- (b) No person shall conduct or cause to be conducted any pre-natal diagnostic techniques including ultrasonography for the purpose of determining the sex of the foetus.
- (c) No person shall, by whatever means, cause or allow to be caused selection of sex before or after conception.

That you being the appropriate authority appointed under the Act are empowered to investigate any violation or possible violation of the PNDT Act and take necessary action.

That the appropriate authority under Section 30 of the Act has been granted very wide powers and the same is reproduced herein below:

Section 30(1): If the appropriate authority has reason to believe that an offence under this Act has been or is being committed at any Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic or any other place, such authority or any officer authorised thereof in this behalf may subject to such rules as may be prescribed, enter and search at all reasonable times with such assistance, if any, as such authority or officer considers necessary, such Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic or any other place and examine any record, register, document book, pamphlet, advertisement or any other material, object found therein and seize and seal the same if such authority or officer has reason to believe that it may furnish evidence of the commission of an offence punishable under this Act.

That further Section 31 of the Act gives protection to the appropriate authority or any officer authorized thereunder for action taken in good faith.

That further the Supreme Court in its order dated 4.5.2001 has directed the appropriate authorities to take prompt action against any person or body who issues or causes to be issued any advertisement in violation of section 22 of the Act.

That in view of the aforementioned facts and circumstances, you are requested to take immediate action and investigate into the matter without any delay under Section 17(4) (c) of the Pre-Natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994.

Kindly treat this letter as a complaint and take appropriate action including filing of a criminal complaint before the Metropolitan Magistrate or a Judicial Magistrate under Section 28 (1) (a) of the Act.

Acknowledgement of this complaint will be appreciated.

Yours sincerely,

## ANNEXURE-VI

Though the Appropriate Authority can file a complaint in the Court on the basis of a complaint received by it or suo motu, in some cases, if found necessary, show cause notice may be issued. The format of the same may be as under:

From

District Appropriate Authority

To

Subject: Show Cause Notice under Sections 3 and 18 of the PNDDT Act, 1994 read with the Rules, 1996.

Refer to subject cited above and the inspection dated        by an inspection team of (names of the members comprising the inspection team) and subsequent inspection dated        (if any subsequent inspection has also been undertaken) by an inspection team of (names of the members).

You were found present at the time of inspection along with patient namely w/o        a pregnant woman who had come for ultrasonography by Dr.        at center. You stated before the inspection team that you are a paid employee and assisting Dr.        in ultrasonography including those of pregnant women (or you have stated before the inspection team that you were providing space and other facilities to Dr.        for conducting ultrasonography on pregnant women and other patients. Dr.        visits your laboratory with his portable ultrasound machine on receiving your telephonic message for performing ultrasonography).

You also disclosed that Dr.        used to charge patients for conducting ultrasonography including on pregnant women and records with respect to these diagnostic tests were maintained by him and you also handed over certified copies of your records/documents namely,        (or you did not maintain records of these diagnostic techniques and could not produce the same).

Since you were assisting in the conduct of pre-natal diagnostic techniques for the purpose of determination of the sex of the foetus, you are hereby issued a show cause notice under Section 3 read with Section 18, Section 5 read with Rule 20 and Section 29 read with Rule 9 of the PNDDT Act read with the PNDDT Rules, 1996 why legal action should not be taken against you. Your reply must reach within 7 days of receipt of this notice.

District Appropriate Authority

IN THE COURT OF CHIEF METROPOLITAN MAGISTRATE  
....., DELHI  
CASE No. OF

**BETWEEN:**

Dr. ....  
APPROPRIATE AUTHORITY/ AUTHORISED OFFICER  
..... DISTRICT COMPLAINANT

AND

..... ACCUSED

**COMPLAINT UNDER SECTION 28 OF THE PRE-NATAL  
DIAGNOSTIC TECHNIQUES (REGULATION AND  
PREVENTION OF MISUSE) ACT, 1994 READ WITH THE RULES,  
1996 AND SECTION 200 OF THE CODE OF CRIMINAL  
PROCEDURE**

MOST RESPECTFULLY SHOWETH:

1. That the Complainant Dr. .... s/o ..... aged about ..... years functioning as District Health and Family Welfare officer of the District ..... and being appointed as the Appropriate Authority under the Pre-Natal Diagnostic Techniques (Regulation and Prevention of Misuse), Act, 1994 (hereinafter referred to as the Act) vide Government Notification dated ..... under Section 2(a) of the Act and the Rules framed thereunder.
2. That in discharge of my duties under the Act, I have conducted a survey to ascertain how many *Genetic Counselling Centres/Genetic Laboratories/Genetic Clinics* and Ultrasound scanning centers are existing in the City/District of ..... (name of the place). I came to know that the particular center (can give the name of the center) is in existence since ..... and after verification, I found that such center is not registered with the Appropriate Authority. On personal verification of the relevant register maintained for that purpose in the office of the Appropriate Authority as contemplated under Chapter IV, Section 18, it was found that no registration certificate has been issued to this center. Moreover no application has also been made by the center for registration as contemplated under the Act.
3. That the complainant along with two persons 1 and 2 (two respectable and independent persons of the locality) visited the premises of the center at ..... (time of arrival at the place) bearing ..... (address of the center) to verify and confirm the compliance with the provisions of this Act. On verification, I found the following equipments installed and being used by the center:

4. That the equipments were housed in: (give details of the place of installation)

5. That on enquiry it was learnt that the center is being run by (name of the owner and the details of the staff employed therein). It is pertinent that the owner of the center, namely accused No. failed to produce the certificate of registration on demand. The copy of the certificate of registration was also not displayed as contemplated in the Act. It is submitted that the owner admitted before the inspection team that the premises is not registered under the Act.

6. That in view of the violation of the provisions of the Act, the below mentioned articles and relevant documents in proof of the running of the center were seized:

These were seized under a panchnama (mahzar) prepared in the presence of panchas (details of mahzar). It was found that these equipments are used/capable of being used for the purpose of detection of the sex of the foetus.

7. That the material as seized above proves that an offence has been committed under the PNDT Act, punishable under Section 23 read with Section 25.

8. That this Hon'ble Court has the jurisdiction to try the present matter.

9. That I being a public servant may be exempted from personal appearances on every date of the hearing.

That in the facts and circumstances of the instant case and in the interests of justice, it is respectfully prayed that this Hon'ble Court may be graciously pleased to take cognizance of the offence committed by the accused and punish him/her in accordance with law.

Sd/-  
Appropriate Authority with Seal

Place:

Date:

(if it is a case where the doctors have been caught conducting sex-determination tests or the complaint is being filed for violation of other provisions of the Act, then the relevant facts can be stated and the material documents annexed with the complaint)

**FORMAT OF REPLY TO ANTICIPATORY BAIL APPLICATION**

(In a similar manner, reply to a bail application can be drafted)

**IN THE COURT OF CHIEF JUDICIAL MAGISTRATE**

COMPLAINT NO.-----2001

IN THE MATTER OF:

STATE  
(THROUGH DISTRICT APPROPRIATE  
AUTHORITY CUM CIVIL SURGEON

COMPLAINANT

VERSUS

ACCUSED

**REPLY TO ANTICIPATORY BAIL APPLICATION FILED ON  
BEHALF OF THE ACCUSED**

1. That the aforementioned case is under a special statute specially enacted for the protection and promotion of women and the girl child. The same being the Pre-Natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act 1994 and the Rules of 1996 made thereunder. That the said Act is a social welfare legislation and has been legislated as part of a special provision for women under Article 15 (3) of the Constitution. That a legislation of this nature has been enacted in the specific context of India and its problems relating to female foeticide and deserves the highest respect and protection.
2. That the Statement of Objects and Reasons of this special enactment are:  

“An Act to provide for the prohibition of sex selection, before or after conception, and for regulation of pre-natal diagnostic techniques for the purposes of detecting abnormalities or metabolic disorders or chromosomal abnormalities or certain congenital malformations or sex-linked disorders and for the prevention of their misuse for sex determination leading to female foeticide and for matters connected therewith or incidental thereto.”
3. That this enactment seeks to inter-alia prevent and prohibit pre-natal sex-determination and the salient features of the Act are:

- Registration of genetic counselling centres, genetic clinics and genetic laboratories,
  - Prescribed qualifications for those employed in the aforementioned centres, clinics or laboratories.
  - Prohibition on conducting any test or procedure without the written consent of the woman on whom the test is being performed.
  - Prohibition on conducting any pre-natal diagnostic technique including ultrasonography for the purpose of determining the sex of the foetus.
  - Prohibition on the communication of the sex of the fetus to the pregnant woman or her relatives.
  - Prohibition on any person, organization, genetic counselling centre, genetic laboratory or genetic clinic from issuing or causing to be issued any advertisement in any manner regarding facilities of pre-natal determination of sex available.
  - Appointment of Appropriate Authorities under the Act to investigate and prosecute complaints under the Act
  - Maintenance of all records, charts, forms, reports, consent letters and all documents relating to the pre-natal diagnostic centre and tests.
  -
4. That this Act was enacted specially to check the growing dis-proportionality in the sex ratio among men and women in the last few years. The latest statistics as seen in the census 2001 shows that the sex ratio in Haryana has declined to 820 females for every 1000 males.
  5. That illegal pre-natal diagnostic centres are mushrooming all over the country where sex of the foetus is determined and communicated to the concerned people leading to large scale abortions of female foetus. These figures are shocking and a strict implementation of the Act is the immediate need of the day. The law and law enforcement agencies have to come down heavily on the violators of the Act to bring about any improvement to the present scenario.
  6. That the anticipatory bail application should be rejected on the following among other grounds (the grounds as may be relevant to a particular case may be used):
    - There is a prima facie case of breach of the provisions of the Act by the accused;
    - That the accused have after the registration of the complaint illegally removed the word ultrasonography from the letter pads of their centres and from their name board and thereby tampered with evidence;
    - That the mandatory records as required under the Act have not been maintained by the accused in violation of the Act;
    - That the ultrasound is being conducted by the accused on pregnant women without taking their written consent in violation of the Act;
    - That the centres run by the accused have not been registered as required under the Act;
    - That the employees working in the said centres do not possess the necessary qualifications as required under the Act;

- That the accused are determining the sex of the foetus and communicating the same to the persons concerned in violation of the Act;
- That the accused are publishing or causing to be published advertisements advertising facilities for pre-natal determination of sex;
- That despite repeated show cause notices and applications for production of documents the accused have not done so;
- That the accused have not been present for investigation despite repeated requests and there is a serious threat that they are trying to evade the processes of the law.
- That the accused have already threatened the members of the appropriate authority.
- That there is a grave threat of their intimidating and buying of the witnesses as they are powerful members of the society.
- That the Delhi High Court in the case of **Court of On its own Motion v. Vishnu Pandit and another**, 1993 Cr.L.J. 2025 has held that “crime against women is on the increase and courts have to be circumspect in granting bail to the accused persons accused of committing crimes against women”
- That in such cases of threat to the very life of the girl child, no bail should be granted.

7. That any violation of the provisions of Act is cognizable, non-bailable and non compoundable. The penalty for the violation of any of the provisions of the Act is three years with fine. Therefore bail especially anticipatory bail should not be granted to the accused.

8. That the Hon’ble Supreme Court has in the case of **CEHAT v Union Of India and others** held that:

“1. Appropriate Authorities are directed to take prompt action against any person or body who issues or causes to be issued any advertisement in violation of section 22 of the Act.

2. Appropriate Authorities are directed to take prompt action against all bodies specified in section 3 of the Act as also against persons who are operating without a valid certificate of registration under the Act.”

Thus the Hon’ble Supreme Court has directed that prompt action should be taken against advertisements issued in violation of the Act as well as in cases where registration has not been obtained.

9. That there is a prima facie case of violation of the provisions of the Act. That irreparable loss would be caused to the investigation and all the efforts of the Appropriate Authority if the accused are granted anticipatory bail. That the balance of convenience lies in favour of the State and against the accused.

That in view of the aforementioned facts and circumstances, it is prayed that this Hon’ble Court be pleased to reject the anticipatory bail applications of all the accused.

DATED:  
PLACE:

APPROPRIATE AUTHORITY



ANNEXURE VIII

FORMAT

**QUARTERLY REPORT ON IMPLEMENTATION AND WORKING OF THE  
PRE-NATAL DIAGNOSTIC TECHNIQUES (REGULATION AND  
PREVENTION OF MISUSE) ACT, 1994**

**Report for the quarter ended on .....**

Name of the State/Union Territory : .....

1.	Number of registered facilities <b>existing</b> in the State/UT	<b>During The quarter</b>	<b>Ending Total upto</b>
2.	Of the number shown in item (1) above, number of Government facilities in the State/UT (including Central Government of India/State Govt./UT Admin./Zila Parishad/Municipal): (a) Genetic Counselling Centres (b) Genetic Laboratories (c) Genetic Clinics (d) Jointly as Genetic Counselling Centre/Genetic Laboratory/Genetic Clinic or any combination thereof (e) Any other Body/person using Ultrasound Machine		
3.	Number of fresh applications received for registration as: (From public as well as public sectors) (a) Genetic Counselling Centres (b) Genetic Laboratories (c) Genetic Clinics (d) Jointly as Genetic Counselling Centre/Genetic Laboratory/Genetic Clinic or any combination thereof (e) Any other Body/person using Ultrasound Machine		
4.	Number of fresh registrations granted as: (a) Genetic Counselling Centres (b) Genetic Laboratories (c) Genetic Clinics (d) Jointly as Genetic Counselling Centre/Genetic Laboratory/Genetic Clinic or any combination thereof		

	(e) Any other Body/person using Ultrasound Machine		
5.	<p>Number of applications for registration rejected, in respect of:</p> <p>(a) Genetic Counselling Centres</p> <p>(b) Genetic Laboratories</p> <p>(c) Genetic Clinics</p> <p>(d) Jointly as Genetic Counselling Centre/Genetic Laboratory/Genetic Clinic or any combination thereof</p> <p>(e) Any other Body/person using Ultrasound Machine</p>		
6.	<p>Number of renewals of registration in respect of:</p> <p>(a) Genetic Counselling Centres</p> <p>(b) Genetic Laboratories</p> <p>(c) Genetic Clinics</p> <p>(d) Jointly as Genetic Counselling Centre/Genetic Laboratory/Genetic Clinic or any combination thereof</p> <p>(e) Any other Body/person using Ultrasound Machine</p>		
7.	<p>Number of premises inspected by the Appropriate Authorities or persons authorized by the Appropriate Authorities during the quarter in respect of:</p> <p>(a) Genetic Counselling Centres</p> <p>(b) Genetic Laboratories</p> <p>(c) Genetic Clinics</p> <p>(d) Jointly as Genetic Counselling Centre/Genetic Laboratory/Genetic Clinic or any combination thereof</p> <p>(e) Any other Body/person using Ultrasound Machine</p>		
8.	<p>Number of suspensions or cancellations of registrations under section 20 of the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 in the State/UT in respect of:</p> <p>(a) Genetic Counselling Centres</p> <p>(b) Genetic Laboratories</p> <p>(c) Genetic Clinics</p> <p>(d) Jointly as Genetic Counselling Centre/Genetic Laboratory/Genetic Clinic or any combination thereof</p> <p>(e) Any other Body/person using Ultrasound Machine</p> <p>(Please give details on a separate sheet)</p>		
9.	<p>Action to create public awareness against the practice of pre-natal determination of sex and female foeticide through:</p> <p>(a) Print Media</p> <p>(b) Electronic Media</p> <p>(c) Hoarding</p> <p>(d) Other appropriate means</p> <p>(Please give details on separate sheet)</p>		

10.	<p>(a) Action taken to ensure that the intervening period between meetings of Advisory Committees does not exceed 60 days.</p> <p>(b) Dates of the meetings of the Advisory Committees held after</p> <p>(Please give details on separate sheet)</p>		
11.	<p>Action taken to appoint Appropriate Authorities and Advisory Committees at district and sub-district levels.</p> <p>(Please give details on separate sheet including appointment of such persons on Advisory Committees who can devote some time)</p>		
12.	<p>Action taken to public list of Appropriate Authorities through:</p> <p>(a) Print Media</p> <p>(b) Electronic Media</p> <p>(c) Hoardings</p> <p>(d) Any other appropriate means</p> <p>(Please give details on separate sheet)</p>		
13.	<p>Action taken against any person or body who issued or caused to be issued any advertisement in violation of section 22 of the Act.</p>		
14.	<p>Action taken against all bodies specified in section 3 of the Act i.e. Genetic Counselling Centres, Genetic Laboratories, Genetic Clinics (including bodies using ultrasound machines), as also against the person who are operating without a valid certificate of registration under the Act.</p>		
15.	<p>Information/Report on survey of bodies specified in Section 3 of the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 i.e. Genetic Counselling Centres, Genetic Laboratories, Genetic Clinics (including bodies using ultrasound machines).</p> <p>(Please give details on separate sheet)</p>		
16.	<p>Action taken against non-registered bodies operating in violation of Section 3 of the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 i.e. Genetic Counselling Centres, Genetic Laboratories, Genetic Clinics (including bodies using ultrasound machines) <b>inclusive of search and seizure of records.</b></p> <p>(Please give details on separate sheet)</p>		
17.	<p>Number of complaints received by the Appropriate Authorities</p>		

	under the Act and action taken pursuant thereto. (Please give details on separate sheet)		
18.	Number and nature of the awareness campaigns conducted and results flowing therefrom.  (Please give details including details of advertisements/posters/handbills etc. on separate sheet)		
19.	Number of complaints filed in the court in the State/UT under the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 (by Appropriate Authorities or by others).  (Please give details on separate sheet)		

Certified that all bodies/persons using ultra-sound machines capable of detecting sex of foetus in my area of jurisdiction have been registered under the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 and prosecution has been launched against those who have not got themselves registered.

Date:  
Place

Signature  
Name and Designation  
(On behalf of State Government/U.T.  
Administration)

**N.B.** 1.All bodies/persons using ultra-sound machines capable of detecting sex of foetus are to be registered under the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 in terms of section 3 read with sub-sections (i) and (j) of section 2 thereof irrespective of whether they are actually determining sex of foetus or not. If any such body/person operates without registration, he/she/it is punishable under section 23 of the Act. Case against such body/person should be filed in Court under section 28 of the Act.

2.The Appropriate Authority should certify that all bodies/persons using ultra-sound machines capable of detecting sex of foetus in his area of jurisdiction have been registered under the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 and prosecution has been launched against those who have not got themselves registered.

## APPENDIX-I

### THE PRE-NATAL DIAGNOSTIC TECHNIQUES (REGULATION AND PREVENTION OF MISUSE) ACT, 1994

ACT NO. 57 OF 1994

*[20th September, 1994]*

*An Act to provide for the prohibition of sex selection, before or after conception, and for regulation of pre-natal diagnostic techniques for the purposes of detecting genetic abnormalities or metabolic disorders or chromosomal abnormalities or certain congenital malformations or sex-linked disorders and for the prevention of their misuse for sex determination leading to female foeticide; and, for matters connected therewith or incidental thereto.*

BE it enacted by Parliament in the Forty-fifth Year of the Republic of India as follows:--

#### CHAPTER I PRELIMINARY

**1. Short title, extent and commencement.**- (1) This Act may be called the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994.

(2) It shall extend to the whole of India except the State of Jammu and Kashmir.

(3) It shall come into force on such date as the Central Government may, by notification in the Official Gazette, appoint.

**2. Definitions.**- In this Act, unless the context otherwise requires,--

(a) "Appropriate Authority" means the Appropriate Authority appointed under section 17;

(b) "Board" means the Central Supervisory Board constituted under section 7;

(ba) "conceptus" means any product of conception at any stage of development from fertilization until birth including extra embryonic membranes as well as the embryo or foetus;

(bb) "embryo" means a developing human organism after fertilization till the end of eight weeks (fifty-six days);

(bc) "foetus" means a human organism during the period of its development beginning on the fifty-seventh day following fertilization or creation (excluding any time in which its development has been suspended) and ending at the birth;

(c) "Genetic Counseling Centre" means an institute, hospital, nursing home or any place, by whatever name called, which provides for genetic counselling to patients;

(d) "Genetic Clinic" means a clinic, institute, hospital, nursing home or any place, by whatever name called, which is used for conducting pre-natal diagnostic procedures.

Explanation- For the purposes of this clause, 'Genetic Clinic' includes a vehicle, where ultrasound machine or imaging machine or scanner or other equipment capable of determining sex of the foetus or a portable equipment which has the potential for detection of sex during pregnancy or selection of sex before conception, is used.

- (e) "Genetic Laboratory" means a laboratory and includes a place where facilities are provided for conducting analysis or tests of samples received from Genetic Clinic for pre-natal diagnostic test.

Explanation- For the purposes of this clause, 'Genetic Laboratory' includes a place where ultrasound machine or imaging machine or scanner or other equipment capable of determining sex of the foetus or a portable equipment which has the potential for detection of sex during pregnancy or selection of sex before conception, is used.

- (f) "Gynaecologist" means a person who possesses a post- graduate qualification in gynecology and obstetrics;
- (g) "Medical geneticist" includes a person who possesses a degree or diploma in genetic science in the fields of sex selection and pre-natal diagnostic techniques or has experience of not less than two years in such field after obtaining--
- (i) any one of the medical qualifications recognised under the Indian Medical Council Act, 1956 (102 of 1956); or
- (ii) a post-graduate degree in biological sciences;
- (h) "Pediatrician" means a person who possesses a post- graduate qualification in pediatrics;
- (i) "pre-natal diagnostic procedures" means all gynaecological or obstetrical or medical procedures such as ultrasonography, foetoscopy, taking or removing samples of amniotic fluid, chorionic villi, blood or any other tissue or fluid of a man, or of a woman for being sent to a Genetic Laboratory or Genetic Clinic for conducting any type of analysis or pre-natal diagnostic tests for selection of sex before or after conception;
- (j) "pre-natal diagnostic techniques" includes all pre-natal diagnostic procedures and pre-natal diagnostic tests;
- (k) "pre-natal diagnostic test" means ultrasonography or any test or analysis of amniotic fluid, chorionic villi, blood or any tissue or fluid of a pregnant woman or conceptus conducted to detect genetic or metabolic disorders or chromosomal abnormalities or congenital anomalies or haemoglobinopathies or sex-linked diseases;
- (l) "prescribed" means prescribed by rules made under this Act;
- (m) "registered medical practitioner" means a medical practitioner who possesses any recognised medical qualification as defined in clause (h) of section 2 of the Indian Medical Council Act, 1956, (102 of 1956.) and whose name has been entered in a State Medical Register;
- (n) "regulations" means regulations framed by the Board under this Act;
- (o) "sex selection" includes any procedure, technique, test or administration or prescription or provision of anything for the purpose of ensuring or increasing the probability that an embryo will be of a particular sex;
- (p) "sonologist or imaging specialist" means a person who possesses any one of the medical qualifications recognized under the Indian Medical Council Act, 1956 or who possesses a post-graduate qualification in ultrasonography or imaging techniques or radiology;

- (q) “State Board” means a State Supervisory Board or a Union territory Supervisory Board constituted under Section 16A;
- (r) “State Government” in relation to Union territory with Legislature means the Administrator of that Union territory appointed by the President under article 239 of Constitution.

## CHAPTER II

### REGULATION OF GENETIC COUNSELLING CENTRES, GENETIC LABORATORIES AND GENETIC CLINICS

3. *Regulation of Genetic Counselling Centres, Genetic Laboratories and Genetic Clinics.*- On and from the commencement of this Act,--

(1) no Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic unless registered under this Act, shall conduct or associate with, or help in, conducting activities relating to pre-natal diagnostic techniques;

(2) no Genetic Counselling Centre or Genetic Laboratory or Genetic Clinic shall employ or cause to be employed or take services of any person, whether on honorary basis or on payment who does not possess qualifications as may be prescribed;

(3) no medical geneticist, gynaecologist, paediatrician, registered medical practitioner or any other person shall conduct or cause to be conducted or aid in conducting by himself or through any other person, any pre-natal diagnostic techniques at a place other than a place registered under this Act.

3A. ***Prohibition of sex-selection.***- No person, including a specialist or a team of specialists in the field of infertility, shall conduct or cause to be conducted or aid in conducting by himself or by any other person, sex selection on a woman or a man or on both or on any tissue, embryo, conceptus, fluid or gametes derived from either or both of them.

3B. ***Prohibition on sale of ultrasound machines, etc., to persons, laboratories, clinics, etc. not registered under the Act.***- No person shall sell any ultrasound machine or imaging machine or scanner or any other equipment capable of detecting sex of foetus to any Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic or any other person not registered under the Act.

## CHAPTER III

### REGULATION OF PRE-NATAL DIAGNOSTIC TECHNIQUES

**4. Regulation of pre-natal diagnostic techniques.**- On and from the commencement of this Act,--

(1) no place including a registered Genetic Counselling Centre or Genetic Laboratory or Genetic Clinic shall be used or caused to be used by any person for conducting pre-natal diagnostic techniques except for the purposes specified in clause (2) and after satisfying any of the conditions specified in clause (3);

(2) no pre-natal diagnostic techniques shall be conducted except for the purposes of detection of any of the following abnormalities, namely:--

- (i) chromosomal abnormalities;
- (ii) genetic metabolic diseases;
- (iii) haemoglobinopathies;
- (iv) sex-linked genetic diseases;
- (v) congenital anomalies;
- (vi) any other abnormalities or diseases as may be specified by the Central Supervisory Board;

(3) no pre-natal diagnostic techniques shall be used or conducted unless the person qualified to do so is satisfied for reasons to be recorded in writing that any of the following conditions are fulfilled, namely:--

- (i) age of the pregnant woman is above thirty-five years;
- (ii) the pregnant woman has undergone of two or more spontaneous abortions or foetal loss;
- (iii) the pregnant woman had been exposed to potentially teratogenic agents such as drugs, radiation, infection or chemicals;
- (iv) the pregnant woman or her spouse has a family history of mental retardation or physical deformities such as, spasticity or any other genetic disease;
- (v) any other condition as may be specified by the Central Supervisory Board;

Provided that the person conducting ultrasonography on a pregnant woman shall keep complete record thereof in the clinic in such manner, as may be prescribed, and any deficiency or inaccuracy found therein shall amount to contravention of provisions of section 5 or section 6 unless contrary is proved by the person conducting such ultrasonography;

(4) no person including a relative or husband of the pregnant woman shall seek or encourage the conduct of any pre-natal diagnostic techniques on her except for the purposes specified in clause (2).

(5) no person including a relative or husband of a woman shall seek or encourage the conduct of any sex-selection technique on her or him or both.

**5. Written consent of pregnant woman and prohibition of communicating the sex of foetus.** (1) No person referred to in clause (2) of section 3 shall conduct the pre-natal diagnostic procedures unless—



- (a) he has explained all known side and after effects of such procedures to the pregnant woman concerned;
- (b) he has obtained in the prescribed form her written consent to undergo such procedures in the language which she understands; and
- (c) a copy of her written consent obtained under clause (b) is given to the pregnant woman.

(2) No person including the person conducting pre-natal diagnostic procedures shall communicate to the pregnant woman concerned or her relatives or any other person the sex of the foetus by words, signs or in any other manner.

**6. Determination of sex prohibited.**- On and from the commencement of this Act,--

- (a) no Genetic Counselling Centre or Genetic Laboratory or Genetic Clinic shall conduct or cause to be conducted in its Centre, Laboratory or Clinic, pre-natal diagnostic techniques including ultrasonography, for the purpose of determining the sex of a foetus;
- (b) no person shall conduct or cause to be conducted any pre-natal diagnostic techniques including ultrasonography for the purpose of determining the sex of a foetus;
- (c) no person shall, by whatever means, cause or allow to be caused selection of sex before or after conception.

## CHAPTER IV

### CENTRAL SUPERVISORY BOARD

**7. Constitution of Central Supervisory Board** - (1) The Central Government shall constitute a Board to be known as the Central Supervisory Board to exercise the powers and perform the functions conferred on the Board under this Act.

(2) The Board shall consist of—

- (a) the Minister in charge of the Ministry or Department of Family Welfare, who shall be the Chairman, *ex officio*;
- (b) the Secretary to the Government of India in charge of the Department of Family Welfare, who shall be the Vice-Chairman, *ex-officio*;
- (c) three members to be appointed by the Central Government to represent the Ministries of Central Government in charge of Women and Child Development, Department of Legal Affairs or Legislative Department in the Ministry of Law and Justice, and Indian System of Medicine and Homoeopathy, ex-officio;
- (d) the Director General of Health Services of the Central Government, *ex officio*;

- (e) ten members to be appointed by the Central Government, two each from amongst—
  - (i) eminent medical geneticists;
  - (ii) eminent gynaecologist and obstetrician or expert of *stri-roga or prasuti-tantra*;
  - (iii) eminent paediatricians;
  - (iv) eminent social scientists; and
  - (v) representatives of women welfare organisations;
- (f) three women Members of Parliament, of whom two shall be elected by the House of the People and one by the Council of States;
- (g) four members to be appointed by the Central Government by rotation to represent the States and the Union territories, two in the alphabetical order and two in the reverse alphabetical order:
 

Provided that no appointment under this clause shall be made except on the recommendation of the State Government or, as the case may be, the Union territory;
- (h) an officer, not below the rank of a Joint Secretary or equivalent of the Central Government, in charge of Family Welfare, who shall be the Member-Secretary, ex officio.

**8. Term of office of members.-** (1) The term of office of a member, other than an ex officio member, shall be,--

- (a) in case of appointment under clause (e) or clause (f) of sub-section (2) of section 7, three years; and
- (b) in case of appointment under clause (g) of the said subsection, one year.

(2) If a casual vacancy occurs in the office of any other members, whether by reason of his death, resignation or inability to discharge his functions owing to illness or other incapacity, such vacancy shall be filled by the Central Government by making a fresh appointment and the member so appointed shall hold office for the remainder of the term of office of the person in whose place he is so appointed.

(3) The Vice-Chairman shall perform such functions as may be assigned to him by the Chairman from time to time.

(4) The procedure to be followed by the members in the discharge of their functions shall be such as may be prescribed.

**9. Meetings of the Board.-** (1) The Board shall meet at such time and place, and shall observe such rules of procedure in regard to the transaction of business at its meetings (including the quorum at such meetings) as may be provided by regulations:

Provided that the Board shall meet at least once in six months.

(2) The Chairman and in his absence the Vice-Chairman shall preside at the meetings of the Board.

(3) If for any reason the Chairman or the Vice-Chairman is unable to attend any meeting of the Board, any other member chosen by the members present at the meeting shall preside at the meeting.

(4) All questions which come up before any meeting of the Board shall be decided by a majority of the votes of the members present and voting, and in the event of an equality of votes, the Chairman, or in his absence, the person presiding, shall have and exercise a second or casting vote.

(5) Members other than ex officio members shall receive such allowances, if any, from the Board as may be prescribed.

10. ***Vacancies, etc., not to invalidate proceedings of the Board.***- No act or proceeding of the Board shall be invalid merely by reason of—

- (a) any vacancy in, or any defect in the constitution of, the Board; or
- (b) any defect in the appointment of a person acting as a member of the Board; or
- (c) any irregularity in the procedure of the Board not affecting the merits of the case.

11. ***Temporary association of persons with the Board for particular purposes.*** (1) The Board may associate with itself, in such manner and for such purposes as may be determined by regulations, any person whose assistance or advice it may desire in carrying out any of the provisions of this Act.

(2) A person associated with it by the Board under sub-section (1) for any purpose shall have a right to take part in the discussions relevant to that purpose, but shall not have a right to vote at a meeting of the Board and shall not be a member for any other purpose.

12. ***Appointment or officers and other employees of the Board.***- (1) For the purpose of enabling it efficiently to discharge its functions under this Act, the Board may, subject to such regulations as may be made in this behalf, appoint (whether on deputation or otherwise) such number of officers and other employees as it may consider necessary:

Provided that the appointment of such category of officers, as may be specified in such regulations, shall be subject to the approval of the Central Government.

(2) Every officer or other employee appointed by the Board shall be subject to such conditions of service and shall be entitled to such remuneration as may be specified in the regulations.

13. ***Authentication of orders and other instruments of the Board.***- All orders and decisions of the Board shall be authenticated by the signature of the Chairman or any other member authorised by the Board in this behalf, and all other instruments issued by the Board shall be authenticated by the signature of the Member-Secretary or any other officer of the Board authorised in like manner in this behalf.

14. ***Disqualifications for appointment as member.***- A person shall be disqualified for being appointed as a member if, he—

- (a) has been convicted and sentenced to imprisonment for an offence which, in the opinion of the Central Government, involves moral turpitude; or
- (b) is an undischarged insolvent; or
- (c) is of unsound mind and stands so declared by a competent court; or
- (d) has been removed or dismissed from the service of the Government or a Corporation owned or controlled by the Government; or
- (e) has, in the opinion of the Central Government, such financial or other interest in the Board as is likely to affect prejudicially the discharge by him of his functions as a member; or
- (f) has, in the opinion of the Central Government, been associated with the use or promotion of pre-natal diagnostic technique for determination of sex or with any sex selection technique.

15. **Eligibility of member for reappointment.**- Subject to the other terms and conditions of service as may be prescribed, any person ceasing to be a member shall be eligible for reappointment as such member.

Provided that no member other than an *ex officio* member shall be appointed for more than two consecutive terms.

16. **Functions of the Board.** - The Board shall have the following functions, namely:--

- (i) to advise the Central Government on policy matters relating to use of pre-natal diagnostic techniques, sex selection techniques and against their misuse;
- (ii) to review and monitor implementation of the Act and rules made thereunder and recommend to the Central Government changes in the said Act and rules;
- (iii) to create public awareness against the practice of pre-conception sex selection and pre-natal determination of sex of foetus leading to female foeticide;
- (iv) to lay down code of conduct to be observed by persons working at Genetic Counselling Centres, Genetic Laboratories and Genetic Clinics;
- (v) to oversee the performance of various bodies constituted under the Act and take appropriate steps to ensure its proper and effective implementation;
- (vi) any other functions as may be prescribed under the Act.

16A. **Constitution of State Supervisory Board and Union territory Supervisory Board.**-

(1) Each State and Union territory having Legislature shall constitute a Board to be known as the State Supervisory Board or the Union territory Supervisory Board, as the case may be, which shall have the following functions:-

- i) to create public awareness against the practice of pre-conception sex selection and pre-natal determination of sex of foetus leading to female foeticide in the State;
- ii) to review the activities of the Appropriate Authorities functioning in the State and recommend appropriate action against them;
- iii) to monitor the implementation of provisions of the Act and the rules and make suitable recommendations relating thereto, to the Board;

iv) to send such consolidated reports as may be prescribed in respect of the various activities undertaken in the State under the Act to the Board and the Central Government; and  
v) any other functions as may be prescribed under the Act.

(2) The State Board shall consist of,-

a) the Minister in charge of Health and Family Welfare in the State, who shall be the Chairperson, *ex officio*;

b) the Secretary in charge of the Department of Health and Family Welfare who shall be the Vice-Chairperson, *ex officio*;

c) Secretaries or Commissioners in charge of Departments of Women and Child Development, Social Welfare, Law and Indian System of Medicines and Homoeopathy, *ex officio*, or their representatives;

d) Director of Health and Family Welfare or Indian System of Medicines and Homoeopathy of the State Government, *ex officio*;

e) Three women members of Legislative Assembly or Legislative Council;

f) Ten members to be appointed by the State Government out of which two each shall be from the following categories:

i) eminent social scientists and legal experts;

ii) eminent women activists from non-governmental organizations or otherwise;

iii) eminent gynaecologists and obstetricians or experts of *stri-roga or prasuti tantra*;

iv) eminent paediatricians or medical geneticists;

v) eminent radiologists or sonologists;

g) an officer not below the rank of Joint Director in charge of Family Welfare, who shall be the Member Secretary, *ex officio*.

(3) The State Board shall meet at least once in four months.

(4) The term of office of a member, other than an *ex officio* member, shall be three years.

(5) If a vacancy occurs in the office of any member other than an *ex officio* member, it shall be filled by making fresh appointment.

(6) If a member of the Legislative Assembly or member of the Legislative Council who is a member of the State Board, becomes Minister or Speaker or Deputy Speaker of the Legislative Assembly or Chairperson or Deputy Chairperson of the Legislative Council, she shall cease to be a member of the State Board.

(7) One-third of the total number of members of the State Board shall constitute the quorum.

(8) The State Board may co-opt a member as and when required, provided that the number of co-opted members does not exceed one-third of the total strength of the State Board.

(9) The co-opted members shall have the same powers and functions as other members, except the right to vote and shall abide by the rules and regulations.

(10) In respect of matters not specified in this section, the State Board shall follow procedures and conditions as are applicable to the Board.

## CHAPTER V

### APPROPRIATE AUTHORITY AND ADVISORY COMMITTEE

17. *Appropriate Authority and Advisory Committee.*- (1) The Central Government shall appoint, by notification in the Official Gazette, one or more Appropriate Authorities for each of the Union territories for the purposes of this Act.

(2) The State Government shall appoint, by notification in the Official Gazette, one or more Appropriate Authorities for the whole or part of the State for the purposes of this Act having regard to the intensity of the problem of pre-natal sex determination leading to female foeticide.

(3) The officers appointed as Appropriate Authorities under sub-section (1) or sub-section (2) shall be,--

(a) when appointed for the whole of the State or the Union territory, consisting of the following three members-

- i) an officer of or above the rank of the Joint Director of Health and Family Welfare-Chairperson;
- ii) an eminent woman representing women's organization; and
- iii) an officer of Law Department of the State or the Union territory concerned:

Provided that it shall be the duty of the State or the Union territory concerned to constitute multi-member State or Union territory level Appropriate Authority within three months of the coming into force of the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Amendment Act, 2002:

Provided further that any vacancy occurring therein shall be filled within three months of that occurrence.

(b) when appointed for any part of the State or the Union territory, of such other rank as the State Government or the Central Government, as the case may be, may deem fit.

(4) The Appropriate Authority shall have the following functions, namely:--

- (a) to grant, suspend or cancel registration of a Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic;
- (b) to enforce standards prescribed for the Genetic Counselling Centre, Genetic Laboratory and Genetic Clinic;
- (c) to investigate complaints of breach of the provisions of this Act or the rules made thereunder and take immediate action;
- (d) to seek and consider the advice of the Advisory Committee, constituted under sub-section (5), on application for registration and on complaints for suspension or cancellation of registration;
- (e) to take appropriate legal action against the use of any sex selection technique by any person at any place, suo motu or brought to its notice and also to initiate independent investigations in such matter;
- (f) to create public awareness against the practice of sex selection or pre-natal determination of sex;
- (g) to supervise the implementation of the provisions of the Act and rules;
- (h) to recommend to the CSB and State Boards modifications required in the rules in accordance with changes in technology or social conditions;
- (i) to take action on the recommendations of the Advisory Committee made after investigation of complaint for suspension or cancellation of registration.

(5) The Central Government or the State Government, as the case may be, shall constitute an Advisory Committee for each Appropriate Authority to aid and advise the Appropriate Authority in the discharge of its functions, and shall appoint one of the members of the Advisory Committee to be its Chairman.

(6) The Advisory Committee shall consist of—

- (a) three medical experts from amongst gynaecologists, obstetricians, paediatricians and medical geneticists;
- (b) one legal expert;
- (c) one officer to represent the department dealing with information and publicity of the State Government or the Union territory, as the case may be;
- (d) three eminent social workers of whom not less than one shall be from amongst representatives of women's organisations.

(7) No person who has been associated with the use or promotion of pre-natal diagnostic technique for determination of sex or sex selection shall be appointed as a member of the Advisory Committee.

(8) The Advisory Committee may meet as and when it thinks fit or on the request of the Appropriate Authority for consideration of any application for registration or any complaint for suspension or cancellation of registration and to give advice thereon:

Provided that the period intervening between any two meetings shall not exceed the prescribed period.

(9) The terms and conditions subject to which a person may be appointed to the Advisory Committee and the procedure to be followed by such Committee in the discharge of its functions shall be such as may be prescribed.

17A. ***Powers of Appropriate Authorities.***- The Appropriate Authority shall have the powers in respect of the following matters, namely:-

a) summoning of any person who is in possession of any information relating to violation of the provisions of this Act or the rules made thereunder;

b) production of any document or material object relating to clause (a);

c) issuing search warrant for any place suspected to be indulging in sex selection techniques or pre-natal sex determination; and

d) any other matter which may be prescribed.

## CHAPTER VI

### REGISTRATION OF GENETIC COUNSELLING CENTRES, GENETIC LABORATORIES AND GENETIC CLINICS

18. ***Registration of Genetic Counselling Centres, Genetic Laboratories or Genetic Clinics.*** (1) No person shall open any Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic, including clinic, laboratory or center having ultrasound or imaging machine or scanner or any other technology capable of undertaking determination of sex of foetus and sex selection, or render services to any of them, after the commencement of the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Amendment Act, 2002 unless such centre, laboratory or clinic is duly registered under the Act.

(2) Every application for registration under sub-section (1), shall be made to the Appropriate Authority in such form and in such manner and shall be accompanied by such fees as may be prescribed.

(3) Every Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic engaged, either partly or exclusively, in counselling or conducting pre-natal diagnostic techniques for any of the purposes mentioned in section 4, immediately before the commencement of this Act, shall apply for registration within sixty days from the date of such commencement.

(4) Subject to the provisions of section 6, every Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic engaged in counselling or conducting pre-natal diagnostic techniques shall cease to conduct any such counselling or technique on the expiry of six months from the date of commencement of this Act unless such Centre, Laboratory or Clinic has applied for registration and is so registered separately or jointly or till such application is disposed of, whichever is earlier.

(5) No Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic shall be registered under this Act unless the Appropriate Authority is satisfied that such Centre,



Laboratory or Clinic is in a position to provide such facilities, maintain such equipment and standards as may be prescribed.

19. ***Certificate of registration.***- (1) The Appropriate Authority shall, after holding an inquiry and after satisfying itself that the applicant has complied with all the requirements of this Act and the rules made thereunder and having regard to the advice of the Advisory Committee in this behalf, grant a certificate of registration in the prescribed form jointly or separately to the Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic, as the case may be.

(2) If, after the inquiry and after giving an opportunity of being heard to the applicant and having regard to the advice of the Advisory Committee, the Appropriate Authority is satisfied that the applicant has not complied with the requirements of this Act or the rules, it shall, for reasons to be recorded in writing, reject the application for registration.

(3) Every certificate of registration shall be renewed in such manner and after such period and on payment of such fees as may be prescribed.

(4) The certificate of registration shall be displayed by the registered Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic in a conspicuous place at its place of business.

20. ***Cancellation or suspension of registration.***- (1) The Appropriate Authority may *suo moto*, or on complaint, issue a notice to the Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic to show cause why its registration should not be suspended or cancelled for the reasons mentioned in the notice.

(2) If, after giving a reasonable opportunity of being heard to the Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic and having regard to the advice of the Advisory Committee, the Appropriate Authority is satisfied that there has been a breach of the provisions of this Act or the rules, it may, without prejudice to any criminal action that it may take against such Centre, Laboratory or Clinic, suspend its registration for such period as it may think fit or cancel its registration, as the case may be.

(3) Notwithstanding anything contained in sub-sections (1) and (2), if the Appropriate Authority is, of the opinion that it is necessary or expedient so to do in the public interest, it may, for reasons to be recorded in writing, suspend the registration of any Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic without issuing any such notice referred to in sub-section (1).

21. ***Appeal.*** The Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic may, within thirty days from the date of receipt of the order of suspension or cancellation of registration passed by the Appropriate Authority under section 20, prefer an appeal against such order to—

- (i) the Central Government, where the appeal is against the order of the Central Appropriate Authority; and
- (ii) the State Government, where the appeal is against the order of the State Appropriate Authority, in the prescribed manner.

## CHAPTER VII

### OFFENCES AND PENALTIES

22. ***Prohibition of advertisement relating to pre-natal determination of sex and punishment for contravention.***- (1) No person, organization, Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic, including clinic, laboratory or center having ultrasound machine or imaging machine or scanner or any other technology capable of undertaking determination of sex of foetus or sex selection shall issue, publish, distribute, communicate or cause to be issued, published, distributed or communicated any advertisement, in any form, including internet, regarding facilities of pre-natal determination of sex or sex selection before conception available at such center, laboratory, clinic or at any other place.

(2) No person or organization including Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic shall issue, publish, distribute, communicate or cause to be issued, published, distributed or communicated any advertisement in any manner regarding pre-natal determination or pre-conception selection of sex by any means whatsoever, scientific or otherwise.

(3) Any person who contravenes the provisions of sub-section (1) or sub-section (2) shall be punishable with imprisonment for a term which may extend to three years and with fine which may extend to ten thousand rupees.

*Explanation.*--For the purposes of this section, "advertisement" includes any notice, circular, label, wrapper or any other document including advertisement through internet or any other media in electronic or print form and also includes any visible representation made by means of any hoarding, wall-painting, signal, light, sound, smoke or gas.

23. ***Offences and penalties.***- (1) Any medical geneticist, gynaecologist, registered medical practitioner or any person who owns a Genetic Counselling Centre, a Genetic Laboratory or a Genetic Clinic or is employed in such a Centre, Laboratory or Clinic and renders his professional or technical services to or at such a Centre, Laboratory or Clinic, whether on an honorary basis or otherwise, and who contravenes any of the provisions of this Act or rules made thereunder shall be punishable with imprisonment for a term which may extend to three years and with fine which may extend to ten thousand rupees and on any subsequent conviction, with imprisonment which may extend to five years and with fine which may extend to fifty thousand rupees.

(2) The name of the registered medical practitioner shall be reported by the Appropriate Authority to the State Medical Council concerned for taking necessary action including suspension of the registration if the charges are framed by the court and till the case is disposed of and on conviction for removal of his name from the register of the Council for a period of five years for the first offence and permanently for the subsequent offence.

(3) Any person who seeks the aid of a Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic or ultrasound clinic or imaging clinic or of a medical geneticist, gynaecologist, sonologist or imaging specialist or registered medical practitioner or any other person for sex selection or for conducting pre- natal diagnostic techniques on any pregnant women for the purposes other than those specified in sub-section (2) of section 4, he shall, be punishable with imprisonment for a term which may extend to three years and with fine which may extend to fifty thousand rupees for the first offence and for any subsequent offence with imprisonment which may extend to five years and with fine which may extend to one lakh rupees.

(4) For the removal of doubts, it is hereby provided, that the provisions of sub-section (3) shall not apply to the woman who was compelled to undergo such diagnostic techniques or such selection.

**24. *Presumption in the case of conduct of pre-natal diagnostic techniques.***- Notwithstanding anything contained in the Indian Evidence Act, 1872, the court shall presume unless the contrary is proved that the pregnant woman was compelled by her husband or any other relative, as the case may be, to undergo pre-natal diagnostic technique for the purposes other than those specified in sub-section (2) of section 4 and such person shall be liable for abetment of offence under sub-section (3) of section 23 and shall be punishable for the offence specified under that section.

**25. *Penalty for contravention of the provisions of the Act or rules for which no specific punishment is provided.***- Whoever contravenes any of the provisions of this Act or any rules made thereunder, for which no penalty has been elsewhere provided in this Act, shall be punishable with imprisonment for a term which may extend to three months or with fine, which may extend to one thousand rupees or with both and in the case of continuing contravention with an additional fine which may extend to five hundred rupees for every day during which such contravention continues after conviction for the first such contravention.

**26. *Offences by companies.***- (1) Where any offence, punishable under this Act has been committed by a company, every person who, at the time the offence was committed was in charge of, and was responsible to the company for the conduct of the business of the company, as well as the company, shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly:

Provided that nothing contained in this sub-section shall render any such person liable to any punishment, if he proves that the offence was committed without his knowledge or that he had exercised all due diligence to prevent the commission of such offence.

(2) Notwithstanding anything contained in sub-section (1), where any offence punishable under this Act has been committed by a company and it is proved that the offence has been committed with the consent or connivance of, or is attributable to any neglect on the part of, any director, manager, secretary or other officer of the company, such director,

manager, secretary or other officer shall also be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

*Explanation.*--For the purposes of this section,--

(a) "company" means any body corporate and includes a firm or other association of individuals, and

(b) "director", in relation to a firm, means a partner in the firm.

27. ***Offence to be cognizable, non-bailable and non-compoundable.***--Every offence under this Act shall be cognizable, non-bailable and non-compoundable.

28. ***Cognizance of offences.*** (1) No court shall take cognizance of an offence under this Act except on a complaint made by--

(a) the Appropriate Authority concerned, or any officer authorised in this behalf by the Central Government or State Government, as the case may be, or the Appropriate Authority; or

(b) a person who has given notice of not less than fifteen days in the manner prescribed, to the Appropriate Authority, of the alleged offence and of his intention to make a complaint to the court.

*Explanation.*--For the purpose of this clause, "person" includes a social organisation.

(2) No court other than that of a Metropolitan Magistrate or a Judicial Magistrate of the first class shall try any offence punishable under this Act.

(3) Where a complaint has been made under clause (b) of subsection (1), the court may, on demand by such person, direct the Appropriate Authority to make available copies of the relevant records in its possession to such person.

## CHAPTER VIII

### MISCELLANEOUS

29. ***Maintenance of records.*** (1) All records, charts, forms, reports, consent letters and all other documents required to be maintained under this Act and the rules shall be preserved for a period of two years or for such period as may be prescribed:

Provided that, if any criminal or other proceedings are instituted against any Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic, the records and all other documents of such Centre, Laboratory or Clinic shall be preserved till the final disposal of such proceedings.

(2) All such records shall, at all reasonable times, be made available for inspection to the Appropriate Authority or to any other person authorised by the Appropriate Authority in this behalf.

30. **Power to search and seize records, etc.** - (1) If the Appropriate Authority has reason to believe that an offence under this Act has been or is being committed at any Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic or any other place, such Authority or any officer authorised thereof in this behalf may, subject to such rules as may be prescribed, enter and search at all reasonable times with such assistance, if any, as such authority or officer considers necessary, such Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic or any other place and examine any record, register, document, book, pamphlet, advertisement or any other material object found therein and seize and seal the same if such Authority or officer has reason to believe that it may furnish evidence of the commission of an offence punishable under this Act.

(2) The provisions of the Code of Criminal Procedure, 1973 (2 of 1974) relating to searches and seizures shall, so far as may be, apply to every search or seizure made under this Act.

31. **Protection of action taken in good faith.**- No suit, prosecution or other legal proceeding shall lie against the Central or the State Government or the Appropriate Authority or any officer authorised by the Central or State Government or by the Authority for anything which is in good faith done or intended to be done in pursuance of the provisions of this Act.

31A. **Removal of difficulties.**- (1) If any difficulty arises in giving effect to the provisions of the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Amendment Act, 2002, the Central Government may, by order published in the Official Gazette, make such provisions not inconsistent with the provisions of the said Act as appear to it to be necessary or expedient for removing the difficulty.

Provided that no order shall be made under this section after the expiry of a period of three years from the date of commencement of the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Amendment Act, 2002.

(2) Every order made under this section shall be laid, as soon as may be after it is made, before each House of Parliament.

32. **Power to make rules.**- (1) The Central Government may make rules for carrying out the provisions of this Act.

(2) In particular and without prejudice to the generality of the foregoing power, such rules may provide for--

(i) the minimum qualifications for persons employed at a registered Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic under clause (2) of section 3;

- (ia) the manner in which the person conducting ultrasonography on a pregnant woman shall keep record thereof in the clinic under the proviso to sub-section (3) of section 4;
- (ii) the form in which consent of a pregnant woman has to be obtained under section 5;
- (iii) the procedure to be followed by the members of the Central Supervisory Board in the discharge of their functions under sub-section (4) of section 8;
- (iv) allowances for members other than ex officio members admissible under sub-section (5) of section 9;
- (iva) code of conduct to be observed by persons working at Genetic Counselling Centres, Genetic Laboratories and Genetic Clinics to be laid down by the Central Supervisory Board under clause (iv) of Section 16;
- (ivb) the manner in which reports shall be furnished by the State and Union territory Supervisory Boards to the Board and the Central Government in respect of various activities undertaken in the State under the Act under clause (iv) of sub-section (1) of section 16A;
- (ivc) empowering the Appropriate Authority in any other matter under clause (d) of section 17A;
- (v) the period intervening between any two meetings of the Advisory Committee under the proviso to sub-section (8) of section 17;
- (vi) the terms and conditions subject to which a person may be appointed to the Advisory Committee and the procedure to be followed by such Committee under sub-section (9) of section 17;
- (vii) the form and manner in which an application shall be made for registration and the fee payable thereof under sub-section (2) of section 18;
- (viii) the facilities to be provided, equipment and other standards to be maintained by the Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic under sub-section (5) of section 18;
- (ix) the form in which a certificate of registration shall be issued under sub-section (1) of section 19;
- (x) the manner in which and the period after which a certificate of registration shall be renewed and the fee payable for such renewal under sub-section (3) of section 19;
- (xi) the manner in which an appeal may be preferred under section 21;
- (xii) the period up to which records, charts, etc., shall be preserved under sub-section (1) of section 29;
- (xiii) the manner in which the seizure of documents, records, objects, etc., shall be made and the manner in which seizure list shall be prepared and delivered to the person from whose custody such documents, records or objects were seized under sub-section (1) of section 30;
- (xiv) any other matter that is required to be, or may be, prescribed.

33. ***Power to make regulations.***- The Board may, with the previous sanction of the Central Government, by notification in the Official Gazette, make regulations not inconsistent with the provisions of this Act and the rules made thereunder to provide for--

- (a) the time and place of the meetings of the Board and the procedure to be followed for the transaction of business at such meetings and the number of members which shall form the quorum under sub-section (1) of section 9;
- (b) the manner in which a person may be temporarily associated with the Board under sub-section (1) of section 11;
- (c) the method of appointment, the conditions of service and the scales of pay and allowances of the officer and other employees of the Board appointed under section 12;
- (d) generally for the efficient conduct of the affairs of the Board.

34. ***Rules and regulations to be laid before Parliament.*** – Every rule and every regulation made under this Act shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rule or regulation or both Houses agree that the rule or regulation should not be made, the rule or regulation shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule or regulation.

**THE PRE-NATAL DIAGNOSTIC TECHNIQUES (REGULATION AND PREVENTION OF MISUSE) RULES, 1996**

1. **Short title and commencement.**- (1) These rules may be called the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Rules, 1996.

(2) They shall come into force on the date of their publication in the Official Gazette.

2. **Definitions.**- In these rules, unless the context otherwise requires:-

- (a) "Act" means The Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 (57 of 1994);
  - (b) "employee" means a person working in or employed by a Genetic Counselling Centre, a Genetic Laboratory or a Genetic Clinic, and includes those working on part-time, contractual, consultancy, honorary or on any other basis;
  - (c) "Form" means a Form appended to these rules;
  - (d) xxxx
  - (e) "Section" means a section of the Act;
  - (f) words and expressions used herein and not defined in these rules but defined in the Act, shall have the meanings, respectively, assigned to them in the Act.
3. The qualifications of the employees, the requirement of equipment etc. for a Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centre shall be as under:

(1) Any person being or employing

- (i) a gynaecologist or a paediatrician having six months experience or four weeks training in genetic counseling or
- (ii) a medical geneticist,

having adequate space and educational charts/models/equipments for carrying out genetic counseling may set up a genetic counseling center and get it registered as a genetic counseling center.

(2) (a) Any person having adequate space and being or employing

- (i) a Medical Geneticist and
- (ii) a laboratory technician having a B.Sc. degree in Biological Sciences or a degree or diploma in medical laboratory course with at least one year experience in conducting appropriate pre-natal diagnostic techniques, tests or procedures

may set up a genetic laboratory.



(b)Such laboratory should have or acquire such of the following equipments as may be necessary for carrying out chromosomal studies, bio-chemical studies and molecular studies:-

(i) Chromosomal studies:

- (1) Laminar flow hood with ultraviolet and fluorescent light or other suitable culture hood.
- (2) Photo-microscope with fluorescent source of light.
- (3) Inverted microscope.
- (4) Incubator and oven.
- (5) Carbon-dioxide incubator or closed system with 5% CO<sub>2</sub> atmosphere.
- (6) Autoclave.
- (7) Refrigerator.
- (8) Water bath.
- (9) Centrifuge.
- (10) Vortex mixer.
- (11) Magnetic stirrer.
- (12) pH meter.
- (13) A sensitive balance (preferable electronic) with sensitivity of 0.1 milligram.
- (14) Double distillation apparatus (glass).
- (15) Such other equipments as may be necessary.

(ii) Biochemical studies:  
(requirements according to tests to be carried out)

- (1) Laminar flow hood with ultraviolet and fluorescent light or other suitable culture hood.
- (2) Inverted microscope.
- (3) Incubator and oven.
- (4) Carbon-dioxide incubator or closed system with 5% CO<sub>2</sub> atmosphere.
- (5) Autoclave.
- (6) Refrigerator.
- (7) Water bath.
- (8) Centrifuge.
- (9) Electrophoresis apparatus and power supply.
- (10) Chromatography chamber.
- (11) Spectro-photometer and Elisa reader or Radio-immunoassay system (with gamma betacounter) or fluorometer for various biochemical test.
- (12) Vortex mixer.
- (13) Magnetic stirrer.
- (14) pH meter.
- (15) A sensitive balance (preferable electronic) with sensitivity of 0.1 milligram.
- (16) Double distillation apparatus (glass).

- (17) Liquid nitrogen tank.
- (18) Such other equipments as may be necessary.

(iii) Molecular studies:

- (1) Inverted microscope.
- (2) Incubator.
- (3) Oven.
- (4) Autoclave.
- (5) Refrigerators (4 degree and minus 20 degree Centigrade).
- (6) Water bath.
- (7) Microcentrifuge.
- (8) Electrophoresis apparatus and power supply.
- (9) Vortex mixer.
- (10) Magnetic stirrer.
- (11) pH meter.
- (12) A sensitive balance (preferable electronic) with sensitivity of 0.1 milligram.
- (13) Double distillation apparatus (glass).
- (14) P.C.R. machine.
- (15) Refrigerated centrifuge.
- (16) U.V. Illuminator with photographic attachment or other documentation system.
- (17) Precision micropipettes.
- (18) Such other equipments as may be necessary.

(3) (1) Any person having adequate space and being or employing

(a) Gynaecologist having experience of performing at least 20 procedures in chorionic villi aspirations per vagina or per abdomen, chorionic villi biopsy, amniocentesis, cordocentesis foetoscopy, foetal skin or organ biopsy or foetal blood sampling etc. under supervision of an experienced gynaecologist in these fields, or

(b) a Sonologist, Imaging Specialist, Radiologist or Registered Medical Practitioner having Post Graduate degree or diploma or six months training or one year experience in sonography or image scanning, or

(c) a medical geneticist

may set up a genetic clinic/ultrasound clinic/imaging center.

(2) The Genetic Clinic/ultrasound clinic/imaging center should have or acquire such of the following equipments, as may be necessary for carrying out the tests or procedures-

- (a) Equipment and accessories necessary for carrying out clinical examination by an obstetrician or gynaecologist

- (b) An ultra-sonography machine including mobile ultrasound machine, imaging machine or any other equipment capable of conducting foetal ultrasonography.
- (c) Appropriate catheters and equipment for carrying out chorionic villi aspirations per vagina or per abdomen.
- (d) Appropriate sterile needles for amniocentesis or cordocentesis.
- (e) A suitable foetoscope with appropriate accessories for foetoscopy, foetal skin or organ biopsy or foetal blood sampling shall be optional.
- (f) Equipment for dry and wet sterilization
- (g) Equipment for carrying out emergency procedures such as evacuation of uterus or resuscitation in case of need.
- (h) Genetic Works Station.

### **3A. *Sale of ultrasound machines/imaging machines:***

(1) No organization including a commercial organization or a person, including manufacturer, importer, dealer or supplier of ultrasound machines/imaging machines or any other equipment, capable of detecting sex of foetus, shall sell, distribute, supply, rent, allow or authorize the use of any such machine or equipment in any manner, whether on payment or otherwise, to any Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic, Imaging Centre or any other body or person unless such Centre, Laboratory, Clinic, body or person is registered under the Act.

(2) The provider of such machine/equipment to any person/body registered under the Act shall send to the concerned State/UT Appropriate Authority and to the Central Government, once in three months a list of those to whom the machine/equipment has been provided.

(3) Any organization or person, including manufacturer, importer, dealer or supplier of ultrasound machines/imaging machines or any other equipment capable of detecting sex of foetus selling, distributing, supplying or authorizing in any manner, the use of any such machine or equipment to any Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic, Imaging Centre or any other body or person registered under the Act shall take an affidavit from such body or person purchasing or getting authorization for using such machine/equipment that the machine/equipment shall not be used for detection of sex of foetus or selection of sex before or after conception.

### **4. *Registration of Genetic Counselling Centre, Genetic Laboratory and Genetic Clinic.-***

(1) An application for registration shall be made to the Appropriate Authority, in duplicate, in Form A, duly accompanied by an Affidavit containing-

- (i) an undertaking to the effect that the Genetic Centre/Laboratory/Clinic/ Ultrasound Clinic/Imaging Centre/combination thereof, as the case may be, shall not conduct any test or procedure, by whatever name called, for selection of sex before or after conception or for detection

- of sex of foetus except for diseases specified in Section 4(2) nor shall the sex of foetus be disclosed to any body; and
- (ii) an undertaking to the effect that the Genetic Centre/Laboratory/Clinic/combination thereof, as the case may be, shall display prominently a notice that they do not conduct any technique, test or procedure etc. by whatever name called, for detection of sex of foetus or for selection of sex before or after conception.

(2) The Appropriate Authority, or any person in his office authorized in this behalf, shall acknowledge receipt of the application for registration, in the acknowledgement slip provided at the bottom of Form A, immediately if delivered at the office of the Appropriate Authority, or not later than the next working day if received by post.

**5. Application Fee.-** (1) Every application for registration under rule 4 shall be accompanied by an application fee of:-

- (a) Rs.3000.00 for Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic or Imaging Centre.
- (b) Rs.4000.00 for an institute, hospital, nursing home, or any place providing jointly the service of a Genetic Counselling Centre, Genetic Laboratory and Genetic Clinic, Ultrasound Clinic or Imaging Centre or any combination thereof.

Provided that if an application for registration of any Genetic Clinic/Laboratory/Centre etc. has been rejected by the Appropriate Authority, no fee shall be required to be paid on re-submission of the application by the applicant for the same body within 90 days of rejection. Provided further that any subsequent application shall be accompanied with the prescribed fee. Application fee once paid will not be refunded.

- (2) The application fee shall be paid by a demand draft drawn in favour of the Appropriate Authority, on any scheduled bank payable at the head quarters of the Appropriate Authority concerned. The fees collected by the Appropriate Authority for registration of Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centre or any other body or person under sub-rule (1), shall be deposited by the Appropriate Authority concerned in a bank account opened in the name of the official designation of the Appropriate Authority concerned and shall be utilized by the Appropriate Authority in connection with the activities connected with implementation of the provisions of the Act and these rules.

**6. Certificate of registration.-** (1) The Appropriate Authority shall, after making such enquiry and after satisfying itself that the applicant has complied with all the requirements, place the application before the Advisory Committee for its advice.

(2) Having regard to the advice of the Advisory Committee the Appropriate Authority shall grant a certificate of registration, in duplicate, in Form B to the applicant. One copy of the certificate of registration shall be displayed by the registered Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic or Imaging Centre at a conspicuous place at its place of business:

Provided that the Appropriate Authority may grant a certificate of registration to a Genetic Laboratory or a Genetic Clinic, Ultrasound Clinic or Imaging Centre to conduct one or more specified pre-natal diagnostic tests or procedures, depending on the availability of place, equipment and qualified employees, and standards maintained by such laboratory or clinic.

(3) If, after enquiry and after giving an opportunity of being heard to the applicant and having regard to the advice of the Advisory Committee, the Appropriate Authority is satisfied that the applicant has not complied with the requirements of the Act and these rules, it shall, for the reasons to be recorded in writing, reject the application for registration and communicate such rejection to the applicant as specified in Form C.

(4) An enquiry under sub-rule(1), including inspection at the premises of the Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic or Imaging Centre, shall, be carried out only after due notice is given to the applicant by the Appropriate Authority.

(5) Grant of certificate of registration or rejection of application for registration shall be communicated to the applicant as specified in Form B or Form C, as the case may be, within a period of ninety days from the date of receipt of application for registration.

(6) The certificate of registration shall be non-transferable. In the event of change of ownership or change of management or on ceasing to function as a Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic or Imaging Centre, both copies, of the certificate of registration shall be surrendered to the Appropriate Authority.

(7) In the event of change of ownership or change of management of the Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic or Imaging Centre, the new owner or manager of such Centre, Laboratory or Clinic shall apply afresh for grant of certificate of registration.

**7. Validity of registration.**- Every certificate of registration shall be valid for a period of five years from the date of its issue.

**8. Renewal of registration.**- (1) An application for renewal of certificate of registration shall be made in duplicate in Form A, to the Appropriate Authority thirty days before the date of expiry of the certificate of registration. Acknowledgement of receipt of such application shall be issued by the Appropriate Authority in the manner specified in sub-rule (2) of rule 4.

(2) The Appropriate Authority shall, after holding an enquiry and after satisfying itself that the applicant has complied with all the requirements of the Act and these rules and having regard to the advice of the Advisory Committee in this behalf, renew the certificate of registration, as specified in Form B, for a further period of five years from the date of expiry of the certificate of registration earlier granted.

(3) If, after enquiry and after giving an opportunity of being heard to the applicant and having regard to the advice of the Advisory Committee, the Appropriate Authority is satisfied that the applicant has not complied with the requirements of the Act and these rules, it shall, for reasons to be recorded in writing, reject the application for renewal of certificate of registration and communicate such rejection to the applicant as specified in Form C.

(4) The fees payable for renewal of certificate of registration shall be one half of the fees provided in sub-rule (1) of rule 5.

(5) On receipt of the renewed certificate of registration in duplicate or on receipt of communication of rejection of application for renewal, both copies of the earlier certificate of registration shall be surrendered immediately to the Appropriate Authority by the Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic or Imaging Centre.

(6) In the event of failure of the Appropriate Authority to renew the certificate of registration or to communicate rejection of application for renewal of registration within a period of ninety days from the date of receipt of application for renewal of registration, the certificate of registration shall be deemed to have been renewed.

**9. Maintenance and preservation of records.-** (1) Every Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centre shall maintain a register showing, in serial order, the names and addresses of the men or women given genetic counseling, subjected to pre-natal diagnostic procedures or pre-natal diagnostic tests, the names of their spouses or fathers and the date on which they first reported for such counseling, procedure or test.

(2) The record to be maintained by every Genetic Counselling Centre, in respect of each woman counseled shall be as specified in Form D.

(3) The record to be maintained by every Genetic Laboratory, in respect of each man or woman subjected to any pre-natal diagnostic procedure/technique/test, shall be as specified in Form E.

(4) The record to be maintained by every Genetic Clinic, in respect of each man or woman subjected to any pre-natal diagnostic procedure/technique/test, shall be as specified in Form F.

(5) The Appropriate Authority shall maintain a permanent record of applications for grant or renewal of certificate of registration as specified in Form H. Letters of intimation of every change of employee, place, address and equipment installed shall also be preserved as permanent records.

(6) All case related records, forms of consent, laboratory results, microscopic pictures, sonographic plates or slides, recommendations and letters shall be preserved by the Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic or Imaging Centre for a period of two years from the date of completion of counseling, pre-natal diagnostic procedure or pre-natal diagnostic test, as the case may be. In the event of any legal proceedings, the records shall be preserved till the final disposal of legal proceedings, or till the expiry of the said period of two years, whichever is later.

(7) In case the Genetic Counselling Centre or Genetic Laboratory, Genetic Clinic, Ultrasound Clinic or Imaging Centre maintains records on computer or other electronic equipment, a printed copy of the record shall be taken and preserved after authentication by a person responsible for such record.

(8) Every Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centre shall send a complete report in respect of all pre-conception or pregnancy related procedures/techniques/tests conducted by them in respect of each month by 5<sup>th</sup> day of the following month to the concerned Appropriate Authority.

**10. *Conditions for conducting pre-natal diagnostic procedures.***- (1) Before conducting preimplantation genetic diagnosis, or any pre-natal diagnostic technique/test/procedure such as amniocentesis, chorionic villi biopsy, foetal skin or organ biopsy or cordocentesis, a written consent, as specified in Form G, in a language the person undergoing such procedure understands, shall be obtained from her/him:

Provided that where a Genetic Clinic has taken a sample of any body tissue or body fluid and sent it to a Genetic Laboratory for analysis or test, it shall not be necessary for the Genetic Laboratory to obtain a fresh consent in Form G.

(1A) Any person conducting ultrasonography/image scanning on a pregnant woman shall give a declaration on each report on ultrasonography/image scanning that he/she has neither detected nor disclosed the sex of foetus of the pregnant woman to any body. The pregnant woman shall before undergoing ultrasonography/image scanning declare that she does not want to know the sex of her foetus.

(2) All the State Governments and Union Territories may issue translation of Form G in languages used in the State or Union Territory and where no official translation in a language understood by the pregnant woman is available, the Genetic Clinic may translate Form G into a language she understands.

**11. *Facilities for inspection.***- (1) Every Genetic Counselling Centre, Genetic Laboratory and Genetic Clinic, Ultrasound Clinic, Imaging Centre, nursing home, hospital, institute

or any other place where any of the machines or equipments capable of performing any procedure, technique or pre-natal determination of sex or selection of sex before or after conception is used, shall afford all reasonable facilities for inspection of the place, equipment and records to the Appropriate Authority or to any other person authorized by the Appropriate Authority in this behalf for registration of such institutions, by whatever name called, under the Act, or for detection of misuse of such facilities or advertisement therefore or for selection of sex before or after conception or for detection/disclosure of sex of foetus or for detection of cases of violation of the provisions of the Act in any other manner.

(2) The Appropriate Authority or the officer authorized by it may seal and seize any ultrasound machine, scanner or any other equipment, capable of detecting sex of foetus, used by any organization if the organization has not got itself registered under the Act. These machines of the organizations may be released if such organization pays penalty equal to five times of the registration fee to the Appropriate Authority concerned and gives an undertaking that it shall not undertake detection of sex of foetus or selection of sex before or after conception.

**12. Procedure for search and seizure.-** (1) The Appropriate Authority or any officer authorized in this behalf may enter and search at all reasonable times any Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Imaging Centre or Ultrasound Clinic in the presence of two or more independent witnesses for the purposes of search and examination of any record, register, document, book, pamphlet, advertisement, or any other material object found therein and seal and seize the same if there is reason to believe that it may furnish evidence of commission of an offence punishable under the Act.

Explanation:- In these Rules-

- (1) 'Genetic Laboratory/Genetic Clinic/Genetic Counselling Centre' would include an ultrasound center/imaging center/nursing home/hospital/institute or any other place, by whatever name called, where any of the machines or equipments capable of selection of sex before or after conception or performing any procedure, technique or test for pre-natal detection of sex of foetus is used;
- (2) 'material object' would include records, machines and equipments; and
- (3) 'seize' and 'seizure' would include 'seal' and 'sealing' respectively.

(2) A list of any document, record, register, book, pamphlet, advertisement or any other material object found in the Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic or Imaging Centre and seized shall be prepared in duplicate at the place of effecting the seizure. Both copies of such list shall be signed on every page by the Appropriate Authority or the officer authorized in this behalf and by the witnesses to the seizure:



Provided that the list may be prepared, in the presence of the witnesses, at a place other than the place of seizure if, for reasons to be recorded in writing, it is not practicable to make the list at the place of effecting the seizure.

(3) One copy of the list referred to in sub-rule (2) shall be handed over, under acknowledgement, to the person from whose custody the document, record, register, book, pamphlet, advertisement or any other material object have been seized:

Provided that a copy of the list of such document, record, register, book, pamphlet, advertisement or other material object seized may be delivered under acknowledgement, or sent by registered post to the owner or manager of the Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic or Imaging Centre, if no person acknowledging custody of the document, record, register, book, pamphlet, advertisement or other material object seized is available at the place of effecting the seizure.

(4) If any material object seized is perishable in nature, the Appropriate Authority, or the officer authorized in this behalf shall make arrangements promptly for sealing, identification and preservation of the material object and also convey it to a facility for analysis or test, if analysis or test be required:

Provided that the refrigerator or other equipment used by the Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centre for preserving such perishable material object may be sealed until such time as arrangements can be made for safe removal of such perishable material object and in such eventuality, mention of keeping the material object seized, on the premises of the Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic or Imaging Centre shall be made in the list of seizure.

(5) In the case of non-completion of search and seizure operation, the Appropriate Authority or the officer authorized in this behalf may make arrangement, by way of mounting a guard or sealing of the premises of the Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic Ultrasound Clinic or Imaging Centre, for safe keeping, listing and removal of documents, records, book or any other material object to be seized, and to prevent any tampering with such documents, records, books or any other material object.

**13. *Intimation of changes in employees, place or equipment.*** – Every Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centre shall intimate every change of employee, place, address and equipment installed, to the Appropriate Authority within a period of thirty days of such change.

**14. *Conditions for analysis or test and pre-natal diagnostic procedures.***- (1) No Genetic Laboratory shall accept for analysis or test any sample, unless referred to it by a Genetic Clinic.

(2) Every pre-natal diagnostic procedure shall invariably be immediately preceded by locating the foetus and placenta through ultrasonography, and the pre-natal diagnostic procedure shall be done under direct ultrasonographic monitoring so as to prevent any damage to the foetus and placenta.

**15. Meetings of the Advisory Committees.-** The intervening period between any two meetings of Advisory Committees constituted under sub-section (5) of Section 17 to advise the Appropriate Authority shall not exceed sixty days.

**16. Allowances to members of the Central Supervisory Board.-** (1) The ex-officio members, and other Central and State Government officers appointed to the Board will be entitled to Travelling Allowance and Daily Allowance for attending the meetings of the Board as per the Travelling Allowance rules applicable to them.

(2) The non-official members appointed to, and Members of Parliament elected to the Board will be entitled to Travelling Allowance and Daily Allowance for attending the meetings of the Board as admissible to non-official and Members of Parliament as the case may be, under the Travelling Allowances rules of the Central Government.

**17. Public Information.-** (1) Every Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centre shall prominently display on its premises a notice in English and in the local language or languages for the information of the public, to effect that disclosure of the sex of the foetus is prohibited under law.

(2) At least one copy each of the Act and these rules shall be available on the premises of every Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centre, and shall be made available to the clientele on demand for perusal.

(3) The Appropriate Authority, the Central Government, the State Government, and the Government/Administration of the Union Territory may publish periodically lists of registered Genetic Counselling Centres, Genetic Laboratories, Genetic Clinics, Ultrasound Clinics and Imaging Centres and findings from the reports and other information in their possession, for the information of the public and for use by the experts in the field.

**18. Code of Conduct to be observed by persons working at Genetic Counselling Centres, Genetic Laboratories, Genetic Clinics, Ultrasound Clinics, Imaging Centres etc.-** All persons including the owner, employee or any other person associated with Genetic Counselling Centres, Genetic Laboratories, Genetic Clinics, Ultrasound Clinics, Imaging Centres registered under the Act/these Rules shall-

- i. not conduct or associate with, or help in carrying out detection or disclosure of sex of foetus in any manner;
- ii. not employ or cause to be employed any person not possessing qualifications necessary for carrying out pre-

- natal diagnostic techniques/procedures and tests including ultrasonography;
- iii. not conduct or cause to be conducted or aid in conducting by himself or through any other person any techniques or procedure for selection of sex before or after conception or for detection of sex of foetus except for the purposes specified in sub-section (2) of section 4 of the Act;
  - iv. not conduct or cause to be conducted or aid in conducting by himself or through any other person any techniques or test or procedure under the Act at a place other than a place registered under the Act/the Rules;
  - v. ensure that no provision of the Act and these Rules are violated in any manner;
  - vi. ensure that the person conducting any techniques, test or procedure leading to detection of sex of foetus for purposes not covered under section 4(2) of the Act or selection of sex before or after conception, is informed that such procedures lead to violation of the Act and the Rules which are punishable offences;
  - vii. help the law enforcing agencies in bringing to book the violators of the provisions of the Act and the Rules;
  - viii. display his/her name and designation prominently on the dress worn by him/her;
  - ix. write his/her name and designation in full under his/her signature;
  - x. on no account conduct or allow/cause to be conducted female foeticide;
  - xi. not commit any other act of professional misconduct.

19. **Appeals.**- (1) Anybody aggrieved by the decision of the Appropriate Authority at sub-district level may appeal to the Appropriate Authority at district level within 30 days of the order of the sub-district level Appropriate Authority.

(2) Anybody aggrieved by the decision of the Appropriate Authority at district level may appeal to the Appropriate Authority at State/UT level within 30 days of the order of the District level Appropriate Authority.

(3) Each appeal shall be disposed of by the District Appropriate Authority or by the State/Union Territory Appropriate Authority, as the case may be, within 60 days of its receipt.

**FORM A**

[See rules 4(1) and 8(1)]

(To be submitted in Duplicate with supporting documents as enclosures)

**FORM OF APPLICATION FOR REGISTRATION OR RENEWAL OF  
REGISTRATION OF A GENETIC COUNSELLING CENTRE/GENETIC  
LABORATORY/GENETIC CLINIC/ULTRASOUND CLINIC/IMAGING  
CENTRE**

1.Name of the applicant

(Indicate name of the organization sought to be registered)

2.Address of the applicant

3.Type of facility to be registered

(Please specify whether the application is for registration of a Genetic Counselling Centre/ Genetic Laboratory/Genetic Clinic/Ultrasound Clinic/Imaging Centre or any combination of these)

4.Full name and address/addresses of Genetic Counselling Centre/ Genetic Laboratory/ Genetic Clinic/ Ultrasound Clinic/ Imaging Centre with Telephone/ Fax number(s)/Telegraphic/Telex/ E-mail address(es).

5.Type of ownership of Organisation (individual/ownership/partnership/company/ co-operative/any other to be specified). In case type of organization is other than individual ownership, furnish copy of articles of association and names and addresses of other persons responsible for management, as enclosure.

6.Type of Institution (Govt. Hospital/ Municipal Hospital/ Public Hospital/ Private Hospital/ Private Nursing Home/ Private Clinic/ Private Laboratory/ any other to be stated.)

7.Specific pre-natal diagnostic procedures/tests for which approval is sought

(a) Invasive (i) amniocentesis/ chorionic villi aspiration/ chromosomal/ biochemical / molecular studies

(b) Non-Invasive Ultrasonography  
Leave blank if registration is sought for Genetic Counselling Centre only.

8. Equipment available with the make and model of each equipment. (List to be attached on a separate sheet).

9. (a) Facilities available in the Counselling Centre.

(b) Whether facilities are or would be available in the Laboratory/Clinic for the following tests:

- (i) Ultrasound
- (ii) Amniocentesis
- (iii) Chorionic villi aspiration
- (iv) Foetoscopy
- (v) Foetal biopsy
- (vi) Cordocentesis

(c) Whether facilities are available in the Laboratory, Clinic for the following:

- (i) Chromosomal studies
- (ii) Biochemical studies
- (iii) Molecular studies
- (iv) Preimplantation gender diagnosis

10. Names, qualifications, experience and registration number of employees (may be furnished as an enclosure)

11. State whether the Genetic Counselling Centre/ Genetic Laboratory/ Genetic Clinic/ ultrasound clinic/imaging centre<sup>18</sup> qualifies for registration in terms of requirements laid down in Rule 3.

12. For renewal applications only:

(a) Registration No.

---

<sup>18</sup> Strike out whichever is not applicable or not necessary. All enclosures are to be authenticated by signature of the applicant.

(b) Date of issue and date of expiry  
of existing certificate of registration.

13. List of Enclosures:

(Please attach a list of enclosures/ supporting  
documents attached to this application.

Date:

(.....)

Place

Name, designation and signature of the person authorized  
to sign on behalf of the organization to be registered.

**DECLARATION**

I, Sh./Smt./Kum./Dr..... son/daughter/wife of .....  
aged ..... years resident of  
.....working as (indicate designation)  
..... in (indicate name of the organization to be registered)  
..... hereby declare that I  
have read and understood the Pre-natal Diagnostic Techniques (Regulation and  
Prevention of Misuse) Act, 1994 (57 of 1994) and the Pre-natal Diagnostic Techniques  
(Regulation and Prevention of Misuse) Rules, 1996,

I also undertake to explain the said Act and Rules to all employees of the Genetic  
Counselling Centre/Genetic Laboratory/Genetic Clinic/ultrasound clinic/imaging centre  
in respect of which registration is sought and to ensure that Act and Rules are fully  
complied with.

Date:

Place:

(.....)

Name, designation and signature of the  
person authorized to sign on behalf of the  
organization to be registered

[SEAL OF THE ORGANISATION SOUGHT TO BE REGISTERED]

**ACKNOWLEDGEMENT**

[See Rules 4(2) and 8(1)]

The application in Form A in duplicate for grant\*/renewal\* of registration of Genetic Counselling Centre\*/ Genetic Laboratory\*/ Genetic Clinic\*/ Ultrasound Clinic\*/ Imaging Centre\* by ..... (Name and address of applicant) has been received by the Appropriate Authority ..... On (date).

\*The list of enclosures attached to the application in Form A has been verified with the enclosures submitted and found to be correct.

**OR**

\*On verification it is found that the following documents mentioned in the list of enclosures are not actually enclosed.

This acknowledgement does not confer any rights on the applicant for grant or renewal of registration.

(.....)  
Signature and Designation of  
Appropriate Authority, or authorized  
person in the Office of the  
Appropriate Authority.

Date:  
Place:

**SEAL**

**FORM B**

[See Rules 6(2), 6(5) and 8(2)]

**CERTIFICATE OF REGISTRATION**

**(To be issued in duplicate)**

1. In exercise of the powers conferred under Section 19 (1) of the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 (57 of 1994), the Appropriate Authority ..... hereby grants registration to the Genetic Counselling Centre\*/Genetic Laboratory\*/Genetic Clinic\*/Ultrasound Clinic\*/ Imaging Centre\* named below for purposes of carrying out Genetic Counselling/Pre-natal Diagnostic Procedures\*/Pre-natal Diagnostic Tests/ultrasonography under the aforesaid Act for a period of five years ending on .....

2. This registration is granted subject to the aforesaid Act and Rules thereunder and any contravention thereof shall result in suspension or cancellation of this Certificate of Registration before the expiry of the said period of five years apart from prosecution.

A. Name and address of the Genetic Counselling Centre\*/Genetic Laboratory\*/Genetic Clinic\*/ Ultrasound Clinic\*/Imaging Centre\*.

B. Pre-natal diagnostic procedures\* approved for (Genetic Clinic).

Non-Invasive

(i) Ultrasound

Invasive

(ii) Amniocentesis

(iii) Chorionic villi biopsy

(iv) Foetoscopy

(v) Foetal skin or organ biopsy

(vi) Cordocentesis

(vii) Any other (specify)

C. Pre-natal diagnostic tests\* approved (for Genetic Laboratory)

(i) Chromosomal studies

(ii) Biochemical studies

(iii) Molecular studies

D. Any other purpose (please specify)

3. Model and make of equipments being used (any change is to be intimated to the Appropriate Authority under rule 13).



4.Registration No. allotted

5.Period of validity of earlier Certificate Of Registration.

(For renewed Certificate of Registration only)

From.....To.....

Signature, name and designation of  
The Appropriate Authority

Date:

SEAL

DISPLAY ONE COPY OF THIS CERTIFICATE AT A CONSPICUOUS  
PLACE AT THE PLACE OF BUSINESS

**FORM C**

[See Rules 6(3), 6(5) and 8(3)]

**FORM FOR REJECTION OF APPLICATION FOR GRANT/ RENEWAL  
OF REGISTRATION**

In exercise of the powers conferred under Section 19(2) of the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994, the Appropriate Authority ..... Hereby rejects the application for grant\*/renewal\* of registration of the Genetic Counselling Centre\*/Genetic Laboratory\*/Genetic Clinic\*/ Ultrasound Clinic\*/Imaging Centre\*.

- (1) Name and address of the Genetic Counselling Centre\*/Genetic Laboratory\*/Genetic Clinic\* Ultrasound Clinic\*/Imaging Centre\*
  
- (2) Reasons for rejection of application for grant/renewal of registration:

Signature, name and designation of  
The Appropriate Authority  
with SEAL of office

Date:  
Place:

---

\*Strike out whichever is not applicable or necessary.

**FORM D**  
[See rule 9(2)]

**FORM FOR MAINTENANCE OF RECORDS BY THE GENETIC  
COUNSELLING CENTRE**

1. NAME, ADDRESS OF GENETIC  
COUNSELLING CENTRE

2. REGISTRATION No.

3. Patient's name

4. Age

5. Husband's/Father's name

6. Full address with Tel. No., if any

7. Referred by (Full name and address of  
Doctor(s) with registration No.(s)  
(Referral note to be preserved carefully with case papers)

8. Last menstrual period/weeks of pregnancy

9. History of genetic/medical disease in the family  
(specify)

Basis of diagnosis:

- (a) Clinical
- (b) Bio-chemical
- (c) Cytogenetic
- (d) Other (e.g. radiological, ultrasonography)

10. Indication for pre-natal diagnosis

A. Previous child/children with:

- (i) Chromosomal disorders
- (ii) Metabolic disorders
- (iii) Congenital anomaly
- (iv) Mental retardation
- (v) Haemoglobinopathy
- (vi) Sex linked disorders
- (vii) Single gene disorder
- (viii) Any other (specify)

B. Advanced maternal age (35 years)

C. Mother/father/sibling having genetic disease (specify)

D. Others (specify)

11. Procedure advised<sup>19</sup>

- (i) Ultrasound
- (ii) Amniocentesis
- (iii) Chorionic villi biopsy
- (iv) Foetoscopy
- (v) Foetal skin or organ biopsy
- (vi) Cordocentesis
- (vii) Any other (specify)

12. Laboratory tests to be carried out

- (i) Chromosomal studies
- (ii) Biochemical studies
- (iii) Molecular studies
- (iv) Preimplantation gender diagnosis

13. Result of pre-natal diagnosis

If abnormal give details.

Normal/Abnormal

14. Was MTP advised?

15. Name and address of Genetic Clinic\* to which patient is referred.

16. Dates of commencement and completion of genetic counseling.

Place:

Date:

Name, Signature and Registration No. of the  
Medical Geneticist/ Gynaecologist/  
Paediatrician administering Genetic  
Counselling.

---

<sup>19</sup> Strike out whichever is not applicable or necessary.

**FORM E**  
[See Rule 9(3)]

**FORM FOR MAINTENANCE OF RECORDS BY GENETIC LABORATORY**

1. Name and address of genetic laboratory
2. Registration No.
3. Patient's name
4. Age
5. Husband's/Father's name
6. Full address with Tel. No., if any
7. Referred by/sample sent by (full name and address of Genetic Clinic) (Referral note to be preserved carefully with case papers)
8. Type of sample: Maternal blood/Chorionic villus sample/amniotic fluid/Foetal blood or other foetal tissue (specify)
9. Specify indication for pre-natal diagnosis
  - A. Previous child/children with
    - (i) Chromosomal disorders
    - (ii) Metabolic disorders
    - (iii) Malformation(s)
    - (iv) Mental retardation
    - (v) Hereditary haemolytic anaemia
    - (vi) Sex linked disorder
    - (vii) Single gene disorder
    - (viii) Any other (specify)
  - B. Advanced maternal age (35 years or above)
  - C. Mother/father/sibling has genetic disease (specify)
  - D. Other (specify)
10. Laboratory tests carried out (give details)

- (i) Chromosomal studies
- (ii) Biochemical studies
- (iii) Molecular studies
- (iv) Preimplantation gender diagnosis

11. Result of diagnosis

If abnormal give details.

Normal/Abnormal

12. Date(s) on which tests carried out.

The results of the Pre-natal diagnostic tests were conveyed to .....  
on .....

Name, Signature and Registration No. of the  
Medical Geneticist/Director of the Institute

Place:

Date:

## FORM F

[See Proviso to section 4(3), Rule 9(4) and Rule 10(1A)]

### FORM FOR MAINTENANCE OF RECORDS IN CASE OF A PREGNANT WOMAN BY GENETIC CLINIC/ULTRASOUND CLINIC/IMAGING CENTRE

1. Name and address of Genetic Clinic\*/Ultrasound Clinic\*/Imaging Centre\*

2. Registration No.

3. Patient's name and her age

4. Number of children with sex of each child

5. Husband's/Father's name

6. Full address with Tel. No., if any

7. Referred by (full name and address of Doctor(s)/

Genetic Counselling Centre (Referral note to be preserved carefully with case papers)/ self referral

8. Last menstrual period/weeks of pregnancy

9. History of genetic/medical disease in the family (specify)

Basis of diagnosis:

- (a) Clinical
- (b) Bio-chemical
- (c) Cytogenetic
- (d) Other (e.g. radiological, ultrasonography etc.-specify)

10. Indication for pre-natal diagnosis

A. Previous child/children with:

- (i) Chromosomal disorders
- (ii) Metabolic disorders
- (iii) Congenital anomaly
- (iv) Mental retardation
- (v) Haemoglobinopathy
- (vi) Sex linked disorders
- (vii) Single gene disorder
- (viii) Any other (specify)

B. Advanced maternal age (35 years)

C. Mother/father/sibling has genetic disease (specify)

D. Other (specify)

11. Procedures carried out (with name and registration No. of Gynaecologist/Radiologist/Registered Medical Practitioner) who performed it.

Non-Invasive

- (iv) Ultrasound (specify purpose for which ultrasound is done during pregnancy)

[List of indications for ultrasonography of pregnant women are given in the note below]

Invasive

- (ii) Amniocentesis
- (iii) Chorionic Villi aspiration
- (iv) Foetal biopsy
- (v) Cordocentesis
- (vi) Any other (specify)

12. Any complication of procedure – please specify

13. Laboratory tests recommended<sup>20</sup>

- (i) Chromosomal studies
- (ii) Biochemical studies
- (iii) Molecular studies
- (iv) Preimplantation gender diagnosis

14. Result of

(a) pre-natal diagnostic procedure

(give details)

(b) Ultrasonography

(specify abnormality detected, if any).

Normal/Abnormal

15. Date(s) on which procedures carried out.

16. Date on which consent obtained. (In case of invasive)

17. The result of pre-natal diagnostic procedure were conveyed to .....on....

18. Was MTP advised/conducted?

19. Date on which MTP carried out.

---

<sup>20</sup> Strike out whichever is not applicable or not necessary.



Name, Signature and Registration number of the  
Gynaecologist/Radiologist/Director of the Clinic

Date:  
Place

### **DECLARATION OF PREGNANT WOMAN**

I, Ms. \_\_\_\_\_ (name of the pregnant woman) declare that by undergoing ultrasonography/image scanning etc. I do not want to know the sex of my foetus.

Signature/Thumb impression of pregnant woman

---

3 Strike out whichever is not applicable or not necessary

### **DECLARATION OF DOCTOR/PERSON CONDUCTING ULTRASONOGRAPHY/IMAGE SCANNING**

I, \_\_\_\_\_ (name of the person conducting ultrasonography/image scanning) declare that while conducting ultrasonography/image scanning on Ms. \_\_\_\_\_ (name of the pregnant woman), I have neither detected nor disclosed the sex of her foetus to any body in any manner.

Name and signature of the person conducting ultrasonography/image scanning/Director or owner of genetic clinic/ultrasound clinic/imaging center.

Important Note:

- i. Ultrasound is not indicated/advised/performed to determine the sex of foetus except for diagnosis of sex-linked diseases such as Duchenne Muscular Dystrophy, Haemophilia A & B etc.
- ii. During pregnancy Ultrasonography should only be performed when indicated. The following is the representative list of indications for ultrasound during pregnancy.
  1. To diagnose intra-uterine and/or ectopic pregnancy and confirm viability.

2. Estimation of gestational age (dating).
3. Detection of number of foetuses and their chorionicity.
4. Suspected pregnancy with IUCD in-situ or suspected pregnancy following contraceptive failure/MTP failure.
5. Vaginal bleeding / leaking.
6. Follow-up of cases of abortion.
7. Assessment of cervical canal and diameter of internal os.
8. Discrepancy between uterine size and period of amenorrhoea.
9. Any suspected adnexal or uterine pathology / abnormality.
10. Detection of chromosomal abnormalities, foetal structural defects and other abnormalities and their follow-up.
11. To evaluate foetal presentation and position.
12. Assessment of liquor amnii.
13. Preterm labour / preterm premature rupture of membranes.
14. Evaluation of placental position, thickness, grading and abnormalities (placenta praevia, retroplacental haemorrhage, abnormal adherence etc.).
15. Evaluation of umbilical cord – presentation, insertion, nuchal encirclement, number of vessels and presence of true knot.
16. Evaluation of previous Caesarean Section scars.
17. Evaluation of foetal growth parameters, foetal weight and foetal well being.
18. Colour flow mapping and duplex Doppler studies.
19. Ultrasound guided procedures such as medical termination of pregnancy, external cephalic version etc. and their follow-up.
20. Adjunct to diagnostic and therapeutic invasive interventions such as chorionic villus sampling (CVS), amniocenteses, foetal blood sampling, foetal skin biopsy, amnio-infusion, intrauterine infusion, placement of shunts etc.

21. Observation of intra-partum events.
22. Medical/surgical conditions complicating pregnancy.
23. Research/scientific studies in recognised institutions.

**FORM G**  
[See Rule 10]  
**FORM OF CONSENT**  
(For invasive techniques)

I, ..... wife/daughter of .....  
Age ..... years residing at ..... hereby state that I  
have been explained fully the probable side effects and after effects of the pre-natal  
diagnostic procedures.

I wish to undergo the preimplantation/pre-natal diagnostic  
technique/test/procedures in my own interest to find out the possibility of any  
abnormality (i.e. disease/deformity/disorder) in the child I am carrying.

I undertake not to terminate the pregnancy if the pre-natal procedure/technique/  
test conducted show the absence of disease/deformity/disorder.

I understand that the sex of the foetus will not be disclosed to me.

I understand that breach of this undertaking will make me liable to penalty as  
prescribed in the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse)  
Act, 1994 (57 of 1994) and rules framed thereunder.

Date  
Place

Signature of the pregnant woman.

I have explained the contents of the above to the patient and her companion  
(Name ..... Address .....  
Relationship .....) in a language she/they understand.

Name, Signature and/Registration  
number of Gynaecologist/ Medical  
Geneticist/ Radiologist/  
Paediatrician/ Director of the Clinic/  
Centre/ Laboratory

Date

Name, Address and Registration  
number of Genetic Clinic/ Institute

SEAL

**FORM H**  
[See Rule 9(5)]

**FORM FOR MAINTENANCE OF PERMANENT RECORD OF APPLICATIONS  
FOR GRANT/REJECTION OF REGISTRATION UNDER THE PRE-NATAL  
DIAGNOSTIC TECHNIQUES (REGULATION AND PREVENTION OF  
MISUSE) ACT, 1994**

- 1.Sl. No.
- 2.File number of Appropriate Authority.
- 3.Date of receipt of application for grant of registration.
- 4.Name, Address, Phone/Fax etc. of Applicant:
- 5.Name and address(es) of Genetic Counselling  
Centre\*/Genetic Laboratory\*/Genetic Clinic\*/  
Ultrasound Clinic\*/Imaging Centre\*.
- 6.Date on which case considered by Advisory  
Committee and recommendation of Advisory Committee,  
in summary.
- 7.Outcome of application (state granted/rejected and date of  
issue of orders- record date of issue of order in Form B or Form C).
- 8.Registration number allotted and date of expiry of registration.
- 9.Renewals (date of renewal and renewed upto).
10. File number in which renewals dealt.
11. Additional information, if any.

Name, Designation and Signature of  
Appropriate Authority

**Guidance for Appropriate Authority**

(a)Form H is a permanent record to be maintained as a register, in the custody of the Appropriate Authority.

(b)\* Means strike out whichever is not applicable.

(c) On renewal, the Registration Number of the Genetic Counselling Centre/Genetic Laboratory/Genetic Clinic/Ultrasound Clinic/Imaging Centre will not change. A fresh registration Number will be allotted in the event of change of ownership or management.

(d) Registration number shall not be allotted twice.

(e) Each Genetic Counselling Centre/Genetic Laboratory/Genetic Clinic/Ultrasound Clinic/Imaging Centre may be allotted a folio consisting of two pages of the Register for recording Form H.

(f) The space provided for 'additional information' may be used for recording suspension, cancellations, rejection of application for renewal, change of ownership/management, outcome of any legal proceedings, etc.

(g) Every folio (i.e. 2 pages) of the Register shall be authenticated by signature of the Appropriate Authority with date, and every subsequent entry shall also be similarly authenticated.

## APPENDIX-III

### THE PRE-NATAL DIAGNOSTIC TECHNIQUES (REGULATION AND PREVENTION OF MISUSE) (ADVISORY COMMITTEE) RULES, 1996

**G.S.R. 540 (E), dated 26<sup>th</sup> November, 1996-** In exercise of the powers conferred by Sec.32 of the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 (57 of 1994), the Central Government hereby makes the following rules, namely:-

**1. *Short title and commencement.***- (1) These rules may be called the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) (Advisory Committees) Rules, 1996.  
(2) They shall come into force on the date of their publication in the Official Gazette.

**2. *Definitions.***- In these rules, unless the context otherwise requires:-

- (a) "Act" means the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 (57 of 1994);
- (b) "Advisory Committee" means an Advisory Committee constituted under sub-section (5) of Section 17 of the Act;
- (c) "Chairman" means the Chairman of the Advisory Committee appointed under sub-section (5) of Section 17;
- (d) "Principle rules" means the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Rules, 1996;
- (e) "section" means a section of the Act;
- (f) "words and expressions" used herein and not defined in these rules but defined in the Act or in the principal rules, as the case may be, shall have the meanings, respectively, assigned to them in the Act or in the principle rules.

**3. *Terms and conditions of appointment as a member of an Advisory Committee.***- (1) No person shall be appointed as a member of an Advisory Committee if he –

- (a) has been convicted and sentenced to imprisonment for an offence which, in the opinion of the Central Government or the State Government, as the case may be, involves moral turpitude; or
- (b) is an undischarged insolvent; or
- (c) is of unsound mind and stands so declared by a competent Court; or
- (d) has been removed or dismissed from the service of the Government or a Corporation owned or controlled by the Government; or

(e) has, in the opinion of the Central Government or the State Government, as the case may be, such financial or other interest as is likely to affect prejudicially the discharge by him of his functions as a member of the Advisory Committee; or

(f) has, in the opinion of the Central Government or the State Government, as the case may be, been associated with the sue or promotion of pre-natal diagnostic techniques for determination of sex.

(2) Every member of an Advisory Committee shall be a resident of the State or Union Territory, for which the Advisory Committee to which he is appointed as a member, has been constituted.

(3) A member of an Advisory Committee shall hold office during the pleasure of the Central Government or the State Government, as the case may be.

(4) Subject to the provisions of sub-rule (3), every such member shall hold office for a period not exceeding three years:

Provided that any person holding office as a member of an Advisory Committee immediately before the commencement of these rules shall hold such office only for the term of three years from the date of his appointment.

(5) A retiring member or a member whose term of office has expired by efflux of time shall be eligible for re-appointment.

(6) A casual vacancy in an Advisory Committee caused by the resignation, death, transfer or removal of any member or otherwise shall be filled by fresh appointment and the person so appointed shall hold office for a period not exceeding the term of office of the member in whose place he is appointed.

(7) The Central Government or the State Government, as the case may be, may remove from office any member of an Advisory Committee before the expiration of his term of office.

(8) Every member of an Advisory Committee shall be entitled to draw traveling and daily allowances for journeys performed by him for attending the meetings (including a meeting adjourned for want of quorum), of the Advisory Committee or for the purpose of discharging any other duties prescribed under the Act, or under the Principle rules or under these rules, on the scale admissible to First Grade Officers of the Government of the State or of the Union Territory, as the case may be.

**4. Meetings of the Advisory Committees.-** The intervening period between any two meetings of an Advisory Committee shall not exceed sixty days.

**5. Notice of meetings.-** (1) At least seven clear days' notice of all meetings of the Advisory Committee shall be given to each member, but an urgent meeting may be called by the Chairman at three clear days' notice:

Provided that if the Chairman is not available, and a meeting is required to be held within the time limit prescribed in Rule 4, the Appropriate Authority may call a meeting with seven clear days' notice after consultation with not less than four of the members of the Advisory Committee.

(2) The notice shall state the business to be transacted at the meeting and no business other than that stated shall be transacted at such meeting except with the consent of the Chairman or on his motion.



**6. *Business ordinarily to be transacted at meetings.***- The business of the Advisory Committee shall ordinarily be transacted at a meeting duly called in accordance with the provisions of these rules:

Provided that the Chairman may, if he thinks fit, circulate any urgent matter among the members of the Advisory Committee for their opinion.

**7. *Quorum.***- At every meeting of the Advisory Committee, four members shall form a quorum.

**8. *Chairman of the meeting.***- Meetings of the Advisory Committee shall be presided over by the Chairman or in his absence, or if no Chairman has been appointed, by a member elected by the members present from among themselves.

**9. *Assistance to be rendered by the Appropriate Authority to the Advisory Committee.***-

(1) Every meeting of the Advisory Committee shall be attended by the Appropriate Authority concerned.

(2) All secretarial and other assistance to the Advisory Committee for the discharge of its functions shall be provided by the Appropriate Authority.

(3) The Appropriate Authority shall issue the notice of meeting, agenda, notes on agenda and the minutes of the meeting, in consultation with the Chairman, subject to the provisions of Rules 5, 6, 7 and 12.

**10. *Decisions on questions before the Advisory Committee.***- (1) The advice tendered by the Advisory Committee shall be adopted, and in the event of any difference of opinion amongst the members, the matter shall be put to vote and decided by a simple majority of the members present.

(2) The Appropriate Authority shall not have a right to vote.

(3) In the event of tie in votes, the Chairman or in his absence, the member presiding shall have a second or casting vote.

(4) The fact of any question having been decided by the process of voting instead of by adoption, shall be recorded in the minutes of that meeting of the Advisory Committee.

**11. *Vacancies etc. not to invalidate proceedings of the Advisory Committees.***- No meeting or proceeding of the Advisory Committee shall be invalid merely by reason of-

(a) any vacancy in, or any defect in the constitution of the Advisory Committee; or

(b) any defect in the appointment of a person to be a member of the Advisory Committee; or

(c) any irregularity in the procedure adopted by the Advisory Committee not affecting the merits of the case.

**12. *Record of proceedings of the Advisory Committee.***- One set of the agenda, notes on agenda, supporting documents and minutes of every meeting of the Advisory Committee shall be authenticated by the signature of the Chairman or in his absence by the signature of the member presiding, and preserved by the Appropriate Authority as permanent records.

## APPENDIX-IV

IN THE SUPREME COURT OF INDIA  
CIVIL ORIGINAL JURISDICTION  
WRIT PETITION [CIVIL] NO. 301 OF 2000

Centre for Enquiry into Health  
And Allied themes [CHEHAT] & Ors  
VERSUS  
Union of India & Ors.

Petitioners  
Respondents

### **ORDER**

It is unfortunate that for one reason or the other, the practice of female infanticide still prevails despite the fact that gentle touch of a daughter and her voice has soothing effect on the parents. One of the reasons may be the marriage problems faced by the parents coupled with the dowry demand by the so-called educated and/or rich persons who are well placed in the society. The traditional system of female infanticide whereby female baby was done away with after birth by poisoning or letting her choke on husk continues in a different form by taking advantage of advance medical techniques. Unfortunately, developed medical science is misused to get rid of a girl child before birth. Knowing full well that it is immoral and unethical as well as it may amount to an offence, foetus of a girl child is aborted by qualified and unqualified doctors or compounders. This is prevailing without any hindrance.

For controlling the situation, the Parliament in its wisdom enacted the Pre-Natal Diagnostic Techniques [Regulation and Prevention of Misuse] Act, 1994 [hereinafter referred as “the Act”]. The Preamble inter- alia, provides that the object of the Act is to prevent the misuse of such techniques for the purpose of Pre-natal sex determination leading to female foeticide and for matters connected therewith or incidental thereto. The Act came into force from 1<sup>st</sup> January, 1996.

It is apparent that to a large extent, the PNDT Act is not implemented by the Central Government or by the State Governments. Hence, the petitioners are required to approach this Court under Article 32 of the Constitution of India. One of the petitioners is the Centre for Enquiry Into Health and Allied Themes [CEHAT] which is a research Centre of Anusandhan Trust in Pune and Mumbai. Second petitioner is Mahila Sarvangeen Utkarsh Mandal [MASUM] based in Pune and Maharashtra and the third petitioner is Dr. Sabu M. George who is having experience and technical knowledge in the field. After filling of this petition, this Court issued notices to the concerned parties on 9.5.2000. It took nearly one year for the various States to file their affidavits in reply/written submissions. Prima facie it appears that despite the PNDT Act being enacted by the Parliament five years back, neither the State Governments not the Central Government has taken appropriate actions for its implementation. Hence, after

considering the respective submissions made at the time of hearing of this matter, as suggested by the learned Attorney General for India Mr. Soli J. Sorabjee following directions are issued on the basis of various provisions for the proper implementation of the PNDT Act.-

**I Directions to the Central Government**

1. The Central Government is directed to create Public awareness against the practice of Pre-natal determination of sex and female foeticide through appropriate releases/programmes in the electronic media. This shall also be done by Central Supervisory Board. ["CSB" for short] as provided under Section 16[iii] of the PNDT Act.
2. The Central Government is directed to implement with all vigor and zeal the PNDT Act and the Rules framed in 1996. Rule 15 provides that the intervening period between two meetings of the Advisory Committees constituted under sub-section [5] of Section 17 of the PNDT Act to advice the appropriate authority shall not exceed 60 days. It would be seen that this Rule is strictly adhered to.

**II Directions to the Central Supervisory Board [CSB]**

1. Meetings of the CSB will be held at least once in six months [Re Proviso to Section 9(1)]. The constitution of the CSB is provided under Section 7. It empowers the Central Government to appoint ten members under section 7(2)(e), which includes eminent medical practitioners including eminent social scientist and representatives of women welfare organizations. We hope that this power will be exercised so as to include those persons who can genuinely spare some time for implementation of the Act.
2. The CSB shall review and monitor the implementation of the Act. [Re. Section 16(ii)].
3. The CSB shall issue directions to all State/UT Appropriate Authorities to furnish quarterly returns to the CSB giving a report on the implementation and working of the Act. These returns should inter-alia contain specific information about:-
  - [I] Survey of bodies specified in section 3 of the Act.
  - [ii] Registration of bodies specified in section 3 of the Act.
  - [iii] Action taken against non-registered bodies operating in violation of section 3 of the act, inclusive of search and seizure of records.
  - [iv] Complaints received by the Appropriate Authorities under Act and action taken pursuant thereto.
  - [V] Number and nature of awareness campaigns conducted and results flowing therefrom.
4. The CSB shall examine the necessity to amend the Act keeping in mind emerging technologies and difficulties encountered in implementation of the Act and to make recommendations to the Central Government. [Re. Section 16]

5. The CSB shall lay down a code of conduct under section 16[iv] of the Act to be observed by persons working in bodies specified therein and to ensure its publication so that public at large can know about it.
6. The CSB will require medical professional bodies/associations to create awareness against the practice of pre-natal determination of sex and female foeticide and to ensure implementation of the Act.

### **III Directions to State Governments/UT Administrations.**

1. All State Governments/UT Administrations are directed to appoint by notification, fully empowered Appropriate Authorities at district and sub-district levels and also Advisory Committees to aid and advise the appropriate Authority in discharge of its functions [Re. Section 17(5)]. For the Advisory Committee also, it is hoped that members of the said Committee as provided under section 17(6) (d) should be such persons who can devote some time for the work assigned to them.
2. All State Governments/UT Administrations are directed to publish a list of the Appropriate Authorities in the print and electronic media in its respective State/UT.
3. All State Governments/UT Administrations are directed to create public awareness against the practice of pre-natal determination of sex and female foeticide through advertisement in the print and electronic media by hoardings and other appropriate means.
4. All State Governments/UT Administrations are directed to ensure that State/UT Appropriate Authorities furnish quarterly returns to the CSB giving a report on the implementation and working of the Act. These returns should inter-alia contain specific information about:-

[I] Survey of bodies specified in section 3 of the Act.

[ii] Registration of bodies specified in section 3 of the Act.

[iii] Action taken against non-registered bodies operating in violation of section 3 of the act, inclusive of search and seizure of records.

[iv] Complaints received by the Appropriate Authorities under Act and action taken pursuant thereto.

[v] Number and nature of awareness campaigns conducted and results flowing therefrom.

### **IV. Directions to Appropriate Authorities**

1. Appropriate Authorities are directed to take prompt action against any person or body who issues or causes to be issued any advertisement in violation of Section 22 of the Act.
2. Appropriate Authorities are directed to take prompt action against all bodies specified in Section 3 of the Act as also against persons who are operating without a valid certificate of registration under the Act.

3. All State/UT Appropriate Authorities are directed to furnish quarterly returns to the CSB giving a report on the implementation and working of the Act. These returns should inter-alia contain specific information about:-

- [I] Survey of bodies specified in section 3 of the Act.
- [ii] Registration of bodies specified in section 3 of the Act.
- [iii] Action taken against non-registered bodies operating in violation of section 3 of the act, inclusive of search and seizure of records.
- [iv] Complaints received by the Appropriate Authorities under Act and action taken pursuant thereto.
- [v] Number and nature of awareness campaigns conducted and results flowing therefrom.

The CSB and the State Governments/Union Territories are directed to report to this Court on or before 30<sup>th</sup> July 2001. List the matter on 6.8.2001 for further directions at the bottom of the list.

New Delhi May 4, 2001

SUPREME COURT OF INDIA  
RECORD OF PROCEEDINGS

Writ Petition [Civil] No. 301/2000

Cehat & Ors.

Petitioner [s]

Versus

Union of India and ors.

Respondent [s]

Date: 19.9.2001 This petition was called on for hearing today.

CORAM :

HON'BLE MR. JUSTICE M.B. SHAH  
HON'BLE MR. JUSTICE R.P. SETHI.

Upon hearing counsel the Court made the following

O R D E R

Heard the learned counsel for the parties and considered the affidavits filed on behalf of various States. From the said affidavits, it appears that the directions issued by this Court are not complied with.

1. At the outset, we may state that there is total Slackness by the Administration in implementing the Act. Some learned counsel pointed out that even though the Genetic Counselling Centre, Genetic Laboratories or Genetic Clinics are not registered, no action is taken as provided under Section 23 of the Act, but only a warning is issued. In our view, those Centres which are not registered are required to be prosecuted by the Authorities under provisions of the Act and there is no question of issue of warning and to permit them to continue their illegal activities.

It is to be stated that the Appropriate Authorities or any officer of the Central or the State Government authorised in this behalf is required to file complaint under Section 28 of the Act for prosecuting the offenders.

Further wherever at District Level, appropriate authorities are appointed, they must carry out the necessary survey of Clinics and take appropriate action in case of non-registration or no-compliance of the statutory provisions including the Rules. Appropriate authorities are not only empowered to take Criminal action, but to search and seize documents, records, objects etc. of unregistered bodies under Section 30 of the Act.

2. It has been pointed out that the States/Union Territories have not submitted quarterly returns to the Central Supervisory Board on implementation of the pre-Natal Diagnostic Techniques [Regulation and Prevention of Misuse] Act, 1994 [hereinafter referred to as “the Act”]. Hence it is directed that the quarterly returns to Central Supervisory Board should be submitted giving the following information:-

- [a] Survey of Centres, Laboratories/Clinics,
- [b] Registration of these bodies,
- [c] Action taken against unregistered bodies.
- [d] Search and Seizure,
- [e] Number of awareness campaigns, and
- [f] Results of Campaigns.

3. From the record, it is apparent that the State of Chhatisgarh and on behalf of Union Territory of Chandigarh, affidavits are not filed.
4. For the State of Jammu and Kashmir, learned counsel appearing on behalf of the State submits that at present, the Act is not applicable to the State of Jammu and Kashmir. However, till there is similar enactment, the State authorities would take appropriate action on the basis of the directions which may be issued by the Court.
5. As per various affidavits, learned counsel for the petitioners and respondent no. 1 pointed out that some States have complied with the directions issued by this Court on 4<sup>th</sup> May, 2001, but following directions are not complied with by the States mentioned herein below:

[a] For the direction of issuing Notification of Appropriate Authorities at District Levels, following States/UTs have not complied with:

-States-

Goa, Jammu & Kashmir, Nagaland, Tripura.

UTs.

Andaman and Nicobar Islands, Chandigarh, D & N Haveli, Daman & Diu, Lakshadweep, Pondicherry and NCT of Delhi.

[b] For the direction regarding issue of Notification for appointing Appropriate Authorities at Sub-District Level, following States/UTs have not complied with:-

States:

Arunachal Pradesh, Goa, Gujarat, Haryana, Himachal Pradesh, Jammu and Kashmir, Jharkhand, Karnataka, Kerala, Maharashtra, Mizoram, Nagaland, Orissa, Sikkim, Tamil Nadu, Tripura, Uttar Pradesh and West Bengal.

UTs:

Andman and Nicobar Islands, Chandigarh, D & N Haveli, Daman and Diu , Lakshadweep, Pondicherry and N C T of Delhi.

[c] With regard to the direction issued for the Advisory Committees to aid and advise the Appropriate Authorities, the following States/UTs have not complied with:-

States:

Arunachal Pradesh, Goa, Himachal Pradesh, Jammu & Kashmir, Jharkhand, Maharashtra, Meghalaya, Mizoram, Nagaland, Rajasthan, Sikkim, Tripura and West Bengal.

UTs :

Andaman and Nicobar islands, Chandigarh, D&N Haveli, Daman & Diu, Lakshadweep, Pondicherry and NCT of Delhi.

[d] For constitution of the sub-District Level Advisory Committees, the following States/UTs have not done the needful:

States:

Andhra Pradesh, Arunachal Pradesh, Goa, Gujarat, Haryana, Himachal Pradesh, Jharkhand, Karnataka, Kerala, Maharashtra, Meghalaya, Mizoram, Nagaland, Orissa, Rajasthan, Sikkim, Tamil Nadu, Tripura, Uttar Pradesh and West Bengal.

UTs :

Andaman and Nicobar islands, Chandigarh, D & N Haveli, Daman & Diu, Lakshadweep, Pondicherry and NCT of Delhi.

For the direction to publish a list of Appropriate Authorities in Print Media, Electronic Media, Hoarding and other means, the following States/UTs have not done the needful:

[I] Re: Print Media: no action is taken by the following.

States:

Assam, Goa, Himachal Pradesh, Jammu and Kashmir, Kerala, Maharashtra, Meghalaya, Manipur, Nagaland, Orissa, Sikkim, Uttaranchal, and Uttar Pradesh.

UTs:

D&N Haveli, Lakshadweep, and NCT of Delhi.

[II] Re: Electronic Media:; no action is taken by following States:

Andhra Pradesh, Arunachal Pradesh, Assam, Bihar, Goa, Gujarat, Haryana, Himachal Pradesh, Jammu & Kashmir, Jharkhand, Kerala, Maharashtra, Meghalaya, Manipur, Nagaland, Orissa, Punjab, Sikkim, Tamil Nadu, Tripura, Uttaranchal, Uttar Pradesh and West Bengal.

UTs:

D&N Haveli, Daman and Diu, Lakshadweep, and NCT of Delhi.



(III) Re: Hoardings- no action is taken by following

States:

Andhra Pradesh, Arunachal Pradesh, Assam, Bihar, Goa, Gujarat, Haryana, Himachal Pradesh, Jammu & Kashmir, Jharkhand, Kerala, Madhya Pradesh, Maharashtra, Meghalaya, Mizoram, Manipur, Nagaland, Orissa, Punjab, Sikkim, Tamil Nadu, Tripura, Uttaranchal, Uttar Pradesh and West Bengal.

UTs:

Andaman and Nicobar Islands, D & N Haveli, Lakshadweep and NCT of Delhi.

In this view of the matter, we direct all the State Governments/Union Territories to implement the Act and submit the compliance report as directed by our order dated 4<sup>th</sup> May, 2001 as well as this order within six weeks from today.

List this matter after six weeks.

Sd/-  
(D.L. Chugh)  
Court Master

Sd/-  
(K.K. Chadha)  
Court Master

ITEM No.8

Court No.8

SECTION PIL A/N MATTER

SUPREME COURT OF INDIA  
RECORD OF PROCEEDINGS

Writ Petition (Civil) No.301/2000

CEHAT & ORS.

Petitioner (s)

VERSUS

UNION OF INDIA AND ORS.

Respondent (s)

With Appln(s). for permission to submit additional document(s)  
and exemption from filing OT  
(for further directions)

Date : 07/11/2001 This Petition was called on for hearing today.

CORAM :

HON'BLE MR. JUSTICE M.B. SHAH  
HON'BLE MR. JUSTICE B.N. AGRAWAL

UPON hearing counsel the Court made the following

ORDER

Heard the learned counsel for the parties.

Learned counsel appearing for some of the States submit that necessary affidavit  
alongwith compliance report would be filed within a period of three weeks from today.

Mr. Mahajan, the learned counsel appearing for the Union of India states that  
Central Government has also decided to take concrete steps for the implementation of the  
Act and suggested to set National Inspection and Monitoring Committee for the  
implementation of the Act.

Stand over to 11.12.2001.

(Vijay Kumar Sharma)  
Court Master

(K.K. Chadha)  
Court Master

Item No. 2

Court No. 8 Section PIL, A/N Matter

IN THE SUPREME COURT OF INDIA  
RECORD OF PROCEEDINGS

Writ Petition [Civil] No. 301/2000

In the Matter of:

Cehat & Ors.

Petitioner[s]

Versus

Union of India & Ors

Respondent[s]

Date: 11.12.2001

This Petition was called on for hearing today.

CORAM:

Hon'ble Mr. Justice M.B. Shah  
Hon'ble Mr. Justice B.N. Agarwal  
Hon'ble Mr. Justice Arijit Pasayat

Upon hearing counsel the Court made the following

O R D E R

Learned counsel for the petitioners has pointed out that in the affidavits tendered on behalf of the State Governments names of the members of the advisory committee are not disclosed and in any case are not published at the relevant places. In this view of the matter the concerned state Governments are directed to publish the names of advisory committee in various districts so that if there is any complaint any citizen can approach them. Further the statistics and information which is to be given in affidavit should be given district-wise.

Mr. Krishan Mahajan, the learned counsel appearing on behalf of the Union of India states that despite the necessary warning by the Secretary, Health Department.[Family Welfare] Health Secretaries of various States are not responding and are not interested in implementing the Act as well as the various directions issued by this Court. Today, the learned counsel appearing on behalf of the petitioners has produced the chart based on the affidavits filled by the various states which indicates that there is no desire on the part of the concerned administrators to implement seriously the law and orders passed by this court, Secretary [Health Department] of the following States are directed so remain present before this Court on 29.1.2002.

“[1] Punjab, [2] Delhi, [3] Bihar, [4] Rajasthan, [5] Gujrat, [6] Haryana [7] Utter Pradesh, [8] Maharashtra, and [9] West Bengal.”

The learned counsel for the petitioners states that Dr. Dahia is transferred from Faridabad to Chandigarh only because he was taking appropriate action against defaulting clinics. For this purpose, learned counsel has placed reliance on the newspaper reports. In our view if efficient officer is transferred only because he was taking action against the defaulting clinics then certainly the action of the State Government is an unjustified one. In addition, the State of Haryana through its Health Secretary is directed to file necessary affidavit stating reasons for transfer of Dr. Dahia. The learned counsel for the petitioners further submitted that the officers of various State Governments are wasting lot of time in verifying where ultrasound machines are kept. She pointed out that data of ultrasound machines supplied to the clinics is available from the manufacturing companies as well as from the service contracts entered by these clinics with those companies. It is also pointed out that in some cases these machines are also imported. For that also, name of the importers are easily available from the customs Department. We, therefore, direct the following companies to supply the information as to how many machines they have sold to various clinics within last five years including their names and addresses and also service contract to those clinics or individual as the case may be.

1. Uma Paremashwaran, CEO, Wipro GE Medical System Ltd.  
A-1, Corporate Towers, Golden Enclave, Airport Road. Bangalore-660017
2. Toshbro Bhimandzu Ltd. khetan Bhawan, 2<sup>nd</sup> floor, Mumbai-400020.
3. Erbis Engineering Co. Ltd. 2E/12, 4<sup>th</sup> Jhandewalan Extn., New Delhi-110005.
4. V. Prabhakar, CEO, ATL India Ltd. 79 & 94 Developed, Plot, Perunagadi, Chennai – 600096.
5. Larsen & Toubro Ltd. [Medical Equipment Divn.] L & T. House 10, Club House Road, Anna Salai, Post Bag no. 55247, Chennai 600002.
6. International Medical Service Pvt. Ltd., 17 Industrial Estate, Maruti Complex, Gurgoan-122012.
7. A.K. Kosla, Chairman, General Electric Co. of India Ltd., E-16, Greater Kailash, Part-I, New Delhi-110048.
8. Rajeev Dayal, President & CEO, HCL Picker Ltd., D-3, Community Centre, Purvi Marg, Vasant Vihar, New Delhi-110057
9. Siemens Ltd., Mahape Workshop Shilphata Road, Behind MTDC Area of Thane Belapur Road, Vill. Mahape, Thane-400601.

For implementation of the Act and the rules it appears that it would be desirable if the Central Government frames appropriate rules with regard to sale of ultrasound machines to various clinics and issue directions not to sell machines to unregistered clinics. Learned counsel Mr. Mahajan appearing for Union of India submitted that appropriate action would be taken in this direction as early as possible.

Adjourned to 29.1.2002.

[Vijay Kumar Sharma]  
Court Master

[K.K. Chadha]  
Court Master.

Item No. 2

Court No. 6 Section PIL, A/N Matter  
IN THE SUPREME COURT OF INDIA  
RECORD OF PROCEEDINGS

Writ Petition [Civil] No. 301/2000

In the Matter of:

Cehat & Ors.

Petitioner [s]

Versus

Union of India & Ors

Respondent[s]

Date: 29.1.2002

This Petition was called on for hearing today.

CORAM:

Hon'ble Mr. Justice M.B. Shah  
Hon'ble Mr. Justice B.N. Agarwal  
Hon'ble Mr. Justice Arijit Pasayat

Upon hearing counsel the Court made the following

O R D E R

In the affidavit filed on behalf of the Central Government by the Director, Department of Family Welfare, it has been stated that the lists received from the companies and Non-governmental Organisations have been forwarded to the relevant States/UTs for pursuing appropriate actions in the event that the organisations using ultrasound machines/scanners are not registered under the Act. From this averment it is clear that the concerned States/UTs have received the information with regard to the purchase of the machines and, therefore, the concerned State Government/UTs are directed to take immediate action on the basis of the said information and if such organisations are using the ultrasound machines/scanners without getting themselves registered under the Act, the said machines should be sealed and seized for the time being.

It has been further pointed out in the affidavit that the National Inspection and Monitoring Committee reported. "Under Section 19 of the Pre-Natal Diagnostic Techniques [Regulation and Prevention of Misuse] Act, 1994 there has to be an enquiry by the appropriate authority followed by the expression of satisfaction of compliance with the Act and the Rules after receiving the advice of the Advisory Committee. It is only by following this mandatory procedure that the Appropriate Authority can grant a Certificate of registration to a person applying for starting a genetic clinic/lab/counseling centre. The committee found in Chandigarh that there was a complete violation of these mandatory provisions of the Act."

In our view, the concerned authorities are required to follow the mandatory procedure provided under the Act and should not grant any certificate or registration to any person if the form is in any way incomplete. Hence, the concerned authorities are directed to follow the mandatory procedure prescribed under the Act before granting certificate or registration to any person or organization using the said machines/scanners.

It has also been pointed out by the learned counsel for the petitioner that the Union of India/concerned authorities may also take the help of the following Associations or Members for the purpose of obtaining information about the user of the ultrasound machines/scanners:

1. INDIAN MEDICAL ASSOCIATION [IMA]
2. INDIAN RADIOLOGISTS ASSOCIATION
3. FEDERATION OF OBSTETRICS AND GYNAECOLOGISTS SOCIETY OF INDIA[FOGSI]

For the time being personal presence of the officers of the States is dispensed with.

List this matter after four weeks.

[D.L. Chugh]  
Court Master

[K.K. Chada]  
Court Master

W.P(C)No. 301 OF 2000

ITEM No.7

Court No.7

SECTION PIL

A/N MATTER

S U P R E M E C O U R T O F I N D I A  
R E C O R D O F P R O C E E D I N G S

Writ Petition(Civil) No.301/2000

CEHAT & ORS.

Petitioner (s)

VERSUS

UNION OF INDIA AND ORS.

Respondent (s)

(Appln . for permission to submit addl. documents and exemption from filing OT and impleading party and intervention & modification and intervention)

WITH IA 13 & 14 : Appln. for intervention and clarification

IA 15 : Appln. for impleadment and

IA 16 : Appln. for permission to take on record the supplementary affidavit) filed by GS Chatterjee, Adv.

Date : 05-3-2002 This Petition was called on for hearing today.

CORAM :

HON'BLE MR. JUSTICE M.B. SHAH

HON'BLE MR. JUSTICE DORAISWAMY RAJU

UPON hearing counsel the Court made the following

O R D E R

Heard the learned counsel for the parties.

Learned counsel for the petitioner has drawn out attention to the affidavits of the States/ Union Territories and pointed out that number of States have not complied with the directions issued by this Court on 29th January, 2002. Comparative chart for the aforesaid purpose is produced for our perusal. That chart reveals that necessary action is not taken against the persons who are having ultrasound machines despite the fact that they are not registered/ licenced one. Relevant chart is as under:

S. No.	Name of the State/ UT	Survey conducted by the authorities	Information supplied by the manufacturing Companies for the sale of ultra sound machines	Registered Clinics
1.	Bihar	297	345	226
2.	Delhi	777	420	525
3.	Gujarat	750	813	484
4.	Kerala	562	756	496
5.	Jharkhand	No figure	123	81
6.	Orissa	No figure	210	--
7.	Uttar Pradesh	1096	945	625
8.	Pondicherry	37	3	27
9.	West Bengal	No figure	462	257

Still however, time to comply with the order is granted upto 9th April, 2002 on which date the concerned Health Secretary/Family Welfare-Health Secretary of the aforesaid States/UT shall remain personally present.

(D.L. Chugh)  
Court Master

(K.K. Chadha)  
Court Master



W.P(C)No. 301 OF 2000

ITEM No.6                      Court No. 6                      SECTION PIL  
A/N MATTER

SUPREME COURT OF INDIA  
RECORD OF PROCEEDINGS

Writ Petition(Civil) No.301/2000

CEHAT & ORS.    Petitioner (s)

VERSUS

UNION OF INDIA AND ORS.    Respondent (s)

( With Appln(s). for permission to submit additional document(s)& exemption from filing O.T.& impleading party & intervention & modification& interventionand intervention& clarification& impleading party& Appln. for taking affidavit on record

Date : 30/04/2002 This Petition was called on for hearing today.

CORAM :

HON'BLE MR. JUSTICE M.B. SHAH  
HON'BLE MR. JUSTICE BISHESHWAR PRASAD SINGH  
HON'BLE MR. JUSTICE H.K. SEMA

UPON hearing counsel the Court made the following

O R D E R

On 9th April, 2002, when the matter was called out Mr.Verma appearing for the State of U.P. submitted that appropriate action would be taken within 15 days from that day against the unregistered clinics in compliance with the directions issued by this Court. On the said undertaking the presence of the concerned Health Secretary was dispensed with.

Today, when the matter is called out, Mr. Jhinjiani, learned counsel appearing on behalf of Mr. Verma for the State of U.P. is not in a position to point out as to what action has been taken after 1998 by the State so far. He further states that he does not know the reason as to why the ultra sound machines in the unregistered clinics have not been seized. He seeks some time for filing necessary affidavit of the action taken by the State. Four weeks time is granted for filing affidavit and for taking necessary further

action. Considering the fact that this matter is prolonged by the inaction of some officers of the State, time is granted as prayed for, on the condition that the State of U.P. shall pay Rs.5,000/- as costs. It would be to the State of U.P. to recover the said amount from defaulting officers. The said amount shall be deposited with the Supreme Court Legal Aid Committee.

Learned counsel appearing on behalf of the State of West Bengal states that further necessary action for seizing and sealing the Ultra Sound Machines owned by the clinics, which are not registered, will be taken within 15 days from today, and further survey would be carried out and necessary affidavit would be filed within 8 weeks from today.

Learned counsel for the State of Assam seeks four weeks time for filing necessary affidavit stating inter alia how many unregistered clinics having Ultra Sound Machines, are operating in State of Assam. She further states unregistered clinics would not be permitted to operate and their Ultra Sound Machines would be seized within four weeks from today and necessary affidavit would be filed before this Court within six weeks.

With regard to the remaining States, it is directed that concerned Officers shall take further steps for finding out unregistered clinics. If such unregistered clinics are found to be operating in any part of the State, the concerned Officers are directed to seize and seal the said machines, and they are also directed not to permit them to operate. All the States are directed to file necessary affidavit on or before 5th August, 2002.

By order dated 29.01.2002, we, inter alia, directed that the Union of India/concerned authorities may also take the help of the following Associations for the purpose of obtaining information about the user of the ultra sound machines/ scanners:

1. INDIAN MEDICAL ASSOCIATION (IMA)
2. INDIAN RADIOLOGISTS ASSOCIATION
3. FEDERATION OF OBSTETRICS AND GYNAECOLOGISTS SOCIETY OF INDIA (FOGSI)

In view of this order, Secretary to Family Welfare Department is directed to file necessary affidavit indicating status of further action taken and the information gathered so far.

Stand over to 13th August, 2002.

(Y.P.Dhamija)  
Court Master

(K.K. Chadha)  
Court Master

## **GLOSSARY**

**COGNISABLE OFFENCE:** An offence for which the police may arrest without a warrant, the offender, or a person who is suspected of committing the offence on account of reasonable belief.

**COMPLAINT:** Any allegation made orally or in writing to a Magistrate with the intention of requiring him to take action under the Criminal Procedure Code against a person who has allegedly committed an offence.

**NON-BAILABLE OFFENCE:** Offences for which getting bail is not the right of the accused. Bail may be granted or refused based on the discretionary power of the Court.

**NON-COMPOUNDABLE OFFENCE:** Those offences on the commission of which no prosecution can be withdrawn or in simple terms where no settlement between the parties is possible to drop the criminal proceedings.

