

**IN COLLABORATION WITH GOVERNMENT OF INDIA
GOVERNMENT OF KARNATAKA & UNITED NATIONS
POPULATION FUND (UNFPA)**



**SOUTHERN STATES' WORKSHOP
WITH APPROPRIATE AUTHORITIES**

ON

PNDT ACT 1994

ON 20-04-2002

AT

HOTEL CAPITOL, BANGALORE

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31/5/02

Regional Workshop of Appropriate Authorities appointed at Karnataka, Kerala, Tamil Nadu and Pondicherry under the PNDT Act

**at Bangalore - in collaboration with UNFPA
(20th April, 2002)**

Background Note

In order to check female foeticide, the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994, was enacted and brought into operation from 1st January, 1996. Rules have also been framed under the Act. The Act prohibits determination and disclosure of the sex of the foetus. It also prohibits any advertisements relating to pre-natal determination of sex and prescribes punishments for its contravention. A person who contravenes the provisions of this act is punishable with imprisonment upto five years and fine upto Rs. 50,000.

Under the Act, pre-natal diagnostic techniques and genetic counseling may be provided only by facilities/clinic registered under the Act. Use of these techniques is permissible solely for the detection of specified abnormalities subject to specified conditions.

Under the Act, the Central Government shall appoint one or more Appropriate Authorities for each of the UTs and State Government shall appoint one or more Appropriate Authorities for whole or part of State. The Appropriate Authorities are the instruments for the implementation of the Act. As the implementation of the Act was not satisfactory in various States/UTs, a PIL was filed by CEHAT and Ors. and the Hon'ble Supreme Court gave directions in its order dated 4-5-2001 to Central and State Governments for effective implementation of the Act by appointing Appropriate Authorities at district and sub-district levels also in all the States and UTs. **Some of the directions of the Supreme Court to the Appropriate Authorities are as under:-**

- 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.
- To take prompt action against all Genetic Counseling Centres, Genetic Laboratories and Genetic Clinics as also against persons who are operating without a valid certificate of registration under the Act.
- To furnish quarterly returns to the CSB giving a report on the implementation and working of the Act. These returns should inter-alia contain specified information about:
 1. Survey of Genetic Counseling Centres, Genetic Laboratories and Genetic Clinics
 2. Registration of Genetic Counseling Centers, Genetic Laboratories and Genetic clinics including bodies using ultra-sound machines.

3. Action taken against non-registered bodies operating in violation of section 3 of the Act, inclusive of search and seizure of records.
4. Complaint received by the Appropriate Authorities under the Act and action taken pursuant thereto.
5. Number and nature of awareness campaigns conducted and results flowing there from.

Immediately after the Court's directions, a meeting of the Appropriate Authorities appointed in States/UTs including the Appropriate Authorities appointed at district and sub-district level was held on 30-6-2001 to review and monitor the implementation of the Act at grassroots level. The meeting was well represented from all States/UTs except from South States. Since the Appropriate Authorities who are generally the District Health Officers have been made responsible to implement the Act in the districts and sub-district level it has become essential to sensitize them about the seriousness of the actions to be taken as per the provisions of the PNDDT Act and Rules made there under. The Government of India in collaboration with the UNFPA decided to hold regional workshops. The workshop, which is scheduled to be held in Bangalore on 20-4-2002, will be the first regional workshop, wherein Appropriate Authorities at State and district levels from the States/UTs of Karnataka, Kerala, Tamil Nadu, and Pondicherry will be participating.

Though the sex ratio among the child population in the age group 0-6 years in these States/UT is more than All India level, both in 1991 and 2001 Census but there is decline in child sex ratio in 2001 Census as compared to 1991 Census except Kerala. Unless the corrective measures are taken by the State Governments child sex ratio may decline further. Therefore, there is need to strengthen the Act by holding regular workshops, meetings, seminars to mount effective awareness campaign about the Act.

Latest position on the implementation of the Act, according to the quarterly progress reports received and affidavits filed in the Court is as under:-

Karnataka

- Appropriate Authorities and Advisory Committees have been set up only at district level.
- 1090 Centres have been given registration.
- Appropriate Authorities have sealed and seized five equipments.
- Five cases have been filed in the Court under the violation of the PNDT Act.

Kerala

- Quarterly Reports received from Government of Kerala are never received in time.
- Appropriate Authorities and Advisory Committees have been set up both at district and sub- district levels.
- Out of 562 centers surveyed, 496 Centres have been given registration.
- No violation of the provisions of the PNDT Act has been reported from Kerala.

Tamil Nadu

- Appropriate Authorities and Advisory Committees have been set up both at district and sub-district levels.
- Survey of 1631 Genetic Counseling Centres, Genetic Laboratories and Genetic Clinics has been conducted.
- Out of 1631 Centres 1625 have been given registration.
- Appropriate Authorities have sealed and seized 51 scan equipments.
- There were 5 cases of suspension/cancellation of registration after conducting raids. These five cases are filed in the Judicial Magistrate Court, Chennai.

Pondicherry

- Appropriate Authorities and Advisory Committees have been set up both at district and sub- district levels.
- There are 29 registered Clinics using ultrasound machines in the UT of Pondicherry.
- No violation of the provisions of the PNDT Act has been reported from the UT of Pondicherry.

Actions need urgent attention of the Appropriate Authorities:

- Survey of all bodies using ultrasound machines has to be completed, immediately.
- Ultrasound machines/imaging machines using by **unregistered centers** are to be sealed and seized.

- Intervening period between meetings of Advisory Committee should not exceed 60 days.
- Quarterly Reports regarding the implementation of the Act to be submitted to the Department of Family Welfare, regularly, by 15th of the preceding month.
- Details given in the reports submitted by the States/UTs do not indicate whether the figures are up to the quarter or for the particular quarter only. To avoid confusion the report must indicate both the figures i.e. up to the quarter and during the quarter. Revised format has already been sent to the States/UTs.
- The consolidated report of the State/UT should indicate whether the details given in the report include details from all districts.
- Details of the Court cases, if any, should be attached to the Quarterly Reports.
- The report received from the States/UTs normally give total figures of registered facilities, fresh application received and fresh registration granted, but does not give break up of Genetic Council³/Centres, Genetic Clinics, Genetic Laboratories, combination thereof, and bodies using ultrasound machines. They should give category wise break-up.
- The Appropriate Authorities may comply with all directions of the Supreme Court.

REVISED 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 31.12.2001

Name of the State/Union Territory : _____

1.	Number of registered facilities existing in the State/UT (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	During the quarter ending 31.12.01	Total up to 31.12.01
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 application 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>Any other Body/person using Ultrasound Machine</p>		
7.	<p>Number of premises inspected by the Appropriate Authorities or person 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>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 4.5.2001.</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 publish 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 Counseling 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 Counseling 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 Counseling Centres, Genetic Laboratories, Genetic Clinics (including bodies using ultrasound machines) inclusive of search and seizure of records.</p> <p>(Please give details on separate sheet)</p>		

17	Number of complaints received by the Appropriate Authorities 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.

Regional Workshop of Appropriate Authorities appointed at Karnataka,
Kerala, Tamil Nadu and Pondicherry under the PNDT Act

at Bangalore - in collaboration with UNFPA
(20th April, 2002)

Brief background on sex ratio:

The provisional figures of Census 2001 have revealed that sex ratio in the country has improved in the last decade. The national figures of 927 females per 1000 males in the Census 1991 has moved to 933 in 2001. In contrast the child sex ratio for the age group of 0-6 years in 2001 is 927 girls per thousand boys against 945 recorded in 1991 Census. The encouraging trend in the sex ratio during 1991-2001 was marred by the decline of 18 points in the sex ratio of children below the age of 6 years.

The Census 2001, further reveals that the situation is worse in respect of child population in the age group 0-6, particularly in the affluent regions of Punjab (793), Haryana (820), Chandigarh (845), Delhi (865), Gujarat (878) and Himachal Pradesh (897). State/UT wise position of sex-ratio is shown in **Annexure**.

Sex Ratio of Child Population by Districts:

The distribution of all the 591 districts in India on the basis of sex ratio of the child population according to 2001 Census is given below:

Range	Number of Districts	Percentage
Less than 800	16	3
800-849	33	6
850-899	72	12
900-949	213	36
950-999	245	41
1000-1049	12	2

In 16 out of 591 districts, 10 from Punjab, 5 from Haryana and 1 from Gujarat, less than 800 girls below age six were reported for every 1000 boys of that age. **The lowest girls-boys ratio of 754 was recorded in Fatehgarh Sahib district of Punjab followed by 770 in Patiala district of Punjab and Kurukshetra district of Haryana.**

In 33 districts, the sex ratio of child population are between 800 to 849. Of these, 12 districts are from Haryana and seven districts are from Punjab, three districts each from Gujarat and M.P., two each from HP and UP and one each from Chandigarh, Delhi and

Tamil Nadu and J&K. The Salem district from Tamil Nadu known for the practice of female infanticide is a member of this group.

The largest group comprising **43%** of the total districts in **India i.e. 257 districts** with **ratio of 950 or more girls to 1000 boys** is represented largely by districts from Southern, Eastern and North-Eastern States. Out of the 76 districts of 8 North Eastern States including Assam, 62 districts have sex ratio of child population above 950. Also in 17 out of 18 districts of West Bengal the sex ratio of child population is above 950. In States from east and south India, the sex ratios of child population age 0-6 years are not very much different from those observed all over the world. **In the States from north and west parts of India the sex ratios are much lower than the normal levels of sex ratio.**

The table given below gives a comparison between child sex ratio (0-6 years) during 1991 and 2001. It shows that there is a sharp increase in the number of districts having child sex ratio below 800. There was not a single district in this range in 1991 while as per 2001 Census, 16 districts are now having less than 800 girls/1000 boys. As per 2001 Census there are as many as 48 districts where the child sex ratio is under 850, while there was only one such district in 1991. Sharp decline in the sex ratio is also noticed in 950-999 and above 1000 categories.

Ranges of child Sex ratio(0-6)	1991		2001	
	No. of districts*	Share of Population(%)	Number of districts*	Share of Population(%)
Total	577	100.00	577	100.00
Less than 800	-	-	16	2.18
800-849	1	0.31	32	4.72
850-899	68	9.98	71	15.34
900-949	181	34.41	208	37.59
950-999	306	54.27	242	39.80
1000-1049	21	1.04	8	0.38

* Note: Total number of districts exclude J&K State

The sharp decline in sex ratio is a matter of serious concern as it is expected to lead to serious demographic imbalances and social consequences. Several reasons are adduced to explain the consistently low levels of sex ratio. Some of the reasons commonly put forward are:

- Son preference
- Neglect of the girl child resulting in their higher mortality at younger age
- Higher maternal mortality
- Female infanticide
- Female Foeticide
- Male bias in enumeration of population.

The Pre-Natal Diagnostic Techniques (Regulation Prevention and Misuse) Act, 1994:

In order to check female foeticide, the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994, was enacted and brought into operation from 1st January, 1996. Rules have also been framed under the Act. The Act prohibits determination and disclosure of the sex of foetus. It also prohibits any **advertisements** relating to pre-natal determination of sex and prescribes punishment for its contravention. The person who contravenes the provisions of this Act is punishable with **imprisonment upto 5 years and fine upto Rs.50,000.**

Under the Act, pre-natal diagnostic techniques and genetic counseling may be provided only by facilities/clinic registered under the Act. Use of these techniques is permissible solely for the detection of specified abnormalities (like Chromosomal abnormalities, genetic metabolic diseases, sex linked genetic diseases, etc.) subject to specified conditions.

The pre-natal diagnostic techniques like amniocentesis and sonography are useful for the detection of genetic or chromosomal disorders or congenital malformations or sex linked disorders, etc. However, this technology is misused on a large scale for sex determination of the foetus and mostly if the foetus is pronounced as female, this prompts termination of the pregnancy and brings to an end the unborn child.

Simultaneously, techniques are also being developed and refined to select the sex of the child prior to conception. Large-scale dissemination of these technologies may, in future precipitate a severe imbalance in the male-female ratio. It has, therefore, become necessary to enact and implement a legislation that will ban the use of both sex selection techniques before conception as well as the misuse of pre-natal diagnostic techniques for sex selective abortions.

Keeping in view the directions of the Hon'ble Supreme Court's Order dated 4th May, 2001, the present Act needs to be amended to incorporate therein certain emerging technologies like selection of sex prior to conception as well as those in current use which are being misused for pre-natal determination of sex of the foetus.

It is also proposed to make punishments prescribed under the Act more stringent, so that they serve as a deterrent, which will minimize violations.

Implementation Instruments:

The PNDT Act provides for two main instruments for implementation of its provisions viz.,

- a) The Central Supervisory Board at the Central Govt. level and
- b) The Appropriate Authorities **assisted by Advisory Committees** in States and UTs for whole or parts thereof.

Central Supervisory Board (CSB):

The CSB consists of 23 members including representatives of States/UTs, non-official members from amongst medical geneticist, gynaecologist and obstetricians, pediatricians, social scientists, women activists and women Members of Parliament.

The main functions of the CSB are to advise the Govt. on policy matters relating to use of pre-natal diagnostic techniques, to review implementation of the Act and Rules and recommend changes therein to create public awareness against the practice of pre-natal determination of sex.

The **Seventh meeting** of the Central Supervisory Board presided over by the Cabinet Minister for Health and Family Welfare was held on April 2, 2002. Amendments to the Pre-Natal Diagnostic Techniques (Regulation and Prevention of Misuse) Rules, 1996 were deliberated in this meeting, and a decision taken that the amendments to the Rules may be examined in detail by the Technical Sub-Committee of the Central Supervisory Board.

Appropriate Authorities and Advisory Committees:

Appropriate Authorities and Advisory Committees are appointed at State/UT, district and sub-district in most of the States and UTs.

The main functions of Appropriate Authorities are to grant, suspend or cancel registration of the Genetic counseling Centres, Genetic laboratory or Genetic Clinic, to enforce standards to investigate complaints of breach of provisions of the Act/Rules to seek and consider the advice of the Advisory Committee for consideration of applications for registration or complaints for suspension or cancellation of registration.

Sub-Committees of CSB:- The CSB has constituted the following **two** sub-committees :-

1. Technical Sub-Committee

The Technical Sub-Committee has been constituted to examine and suggest amendments to the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994/Rules to cover (i) changing technologies such as pre-conception sex selection, (ii) matters connected with the registration of ultra-sound clinics, radiological laboratories, etc. who conduct tests for detection and disclosure of sex of foetus and (iii) provisions in other related Acts. **The Committee met on 26.5.2001, 9.6.2001, 14.8.2001 and 2.4.2002.**

The Technical Sub-Committee deliberated in detail the amendments to the PNDT Rules in its last meeting held on 2.4.2002 and suggested some changes, modifications and additions. It was decided in the meeting that the Department of Family Welfare may modify the draft amendments in the Pre-natal Diagnostic Techniques (Regulation and

Prevention of Misuse) Rules incorporating the suggestions of the Members. The modified draft has been sent to the Members of the Technical Sub-Committee again for final suggestions, before the same is forwarded to Ministry of Law for final vetting. The comments are being received.

2. Sub-Committee on Implementation Strategy

The sub-Committee on Implementation Strategy has been constituted to (i) evaluate the implementation of the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 (ii) evolve a suitable mechanism to identify agencies doing good work for effective implementation of the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994, (iii) collection of data related to implementation/violation of the Act, (iv) to conduct independent study through qualified people, medical research centers/institutions for collection of authentic information, (v) sensitizing the people about the provisions of the Act, (vi) strengthening the Information, Education and Communication activities, (vii) to implement the direction of the Supreme Court for implementation of the Act and (viii) any other activity found necessary by the Central Supervisory Board for the effective implementation of the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994. **The Committee met on 26.5.2001, 9.6.2001 and 10.9.2001.**

Groups:

The CSB has also constituted **two groups** viz. (i) Group for considering proposals for research studies on sex ratio and female foeticide and (ii) Group for considering the proposals for creating video films, TV spots etc.

The Group constituted for considering the proposals for research studies on sex ratio and female foeticide met on 16th November, 2001. It has recommended the following three research study proposals for consideration.

1. "Missing Girls: A Case Study of Delhi" submitted by Prof. (Mrs.) Usha Nayar, Chairperson, *Tinnari*, The Third World Centre for Comparative Studies, New Delhi.
2. "A Preliminary Investigation into the sharp decline in the female-male ratio in the age group of 0-6 years: Policy implications for restoring gender balance" submitted by Shri Alok Mukhopadhyay, Chief Executive, Voluntary Health Association of India, New Delhi.
3. "Impact of Gender-Bias on Population Aged 0-6 Years" submitted by Shri Alakh N. Sharma, Director, Institute for Human Development, New Delhi.

The Department of Family Welfare has sanctioned financial assistance for carrying out all these research studies. **Grant-in-aid has also been released.**

The Group constituted to examine and consider proposals on audio-video programs for generating awareness about the importance of girl child and provisions of the PNDT

Act has met four times. In its meeting held on 14.1.2002, the Group has constituted a sub-Group consisting of Dr. Mira Siva, Dr. Nalini Abraham and Mrs. Bhamati.

In the last meeting held on 19.3.2002, 11 films were short listed. Thereafter, the Sub-Group members once again examined these 11 scripts keeping in view the messages in the scripts, duration, rural/urban background and specific treatment of subject matter. Finally 4 scripts were short-listed. They are being processed for funding.

ACTIONS TAKEN TO IMPLEMENT THE ACT

The States/UTs have been advised by the Central Government to mount effective awareness campaign to make the public and service providers aware of the provisions of the Act. The States/UTs have also been advised to provide protection to social activists and Non-Governmental Organizations giving information or filing complaints of violation of provisions of the Act.

After the Census 2001 figures became available, letters have been addressed to the Chief Ministers of all States/UTs for giving focussed attention to the issue of female foeticide leading to adverse sex ratio. Chief Secretaries of all the States/UTs have also been addressed for implementation of the provisions of the PNDT Act. The Minister for Health and Family Welfare has also addressed a D.O. letter to more than two lakhs doctors all over the country requesting them to extend their help and co-operation for eradication of the evil of female foeticide.

Shri A.R. Nanda, Secretary, Department of Family Welfare, Ministry of Health and Family Welfare addressed letters on March 13, 2002 to the Principal Secretaries and/or Secretaries in charge of the Department of Health and Family Welfare of all States/UTs directing that immediate action be taken to implement the provisions of the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 in compliance with the directions of the Hon'ble Supreme Court.

Attention was drawn in the said letter of March 13, 2002, to the gaps in the number of bodies surveyed by the Appropriate Authorities, the number of bodies registered under the Act and the number of ultrasound machines/scanners seized and sealed by different States and UTs in compliance with the Hon'ble Supreme Court's Order dated 29th January, 2002.

The State/UT level Appropriate Authorities have been asked to organize the conduct of raids in the ultrasound clinics operating in all the districts and sub-districts of the State/UT by deploying decoy customers. For this purpose they may use the services of the staff available in the offices of the district and sub-district level Appropriate Authorities. They have also been advised to complete the registration inter-alia, of all those clinics and centres using ultrasound machines whose lists have been supplied to them by the Department of Family Welfare, Government of India.

Involvement of NGOs:

Workshops/seminars are being organized at State/regional/district/block levels to create awareness about the provisions of the Act. Voluntary Organizations are also being involved to carry out projects for creating awareness about the provisions of the Act. Grant-in-aid has been released to the following NGOs for creating awareness about the provisions of the PNDD Act:-

1. Orissa Voluntary Health Association (Area: Orissa).
2. Voluntary Health Association of India, New Delhi (Area: of Punjab, Madhya Pradesh, Uttar Pradesh, Himachal Pradesh, Rajasthan and Tamil Nadu).
3. Maharashtra Voluntary Health Association, Maharashtra (Area: Wardha).
4. Uttar Pradesh Voluntary Health Association, Lucknow (Area: U.P.).
5. SAMNAVAY, C-234, Sector A, Mahanagar, Lucknow (Area: Uttaranchal).
6. Family Planning Association of India, Mumbai [Area: Madhya Pradesh (Bhopal, Gwalior, Indore and Jabalpur), Bihar (Patna), Jharkhand (Gomia), Rajasthan (Jaipur), Haryana (Panchkula and Yamunanagar) and Punjab (Mohali)].
7. Kerala Voluntary Health Services, Kottayam (Area: Kerala).
8. Family Planning Association of India, Madurai (Area: Madurai).
9. Rural Education and Development Society (REDS), Sivagangai District, Tamil Nadu (Area: South Tamil Nadu).

Other Activities:

Religious leaders' meets were organised at New Delhi (organised by National Commission for Women, IMA and UNICEF) and at Fatehgarh Sahib(Punjab) against the practice of female foeticide where this practice was widely condemned and pledge was taken stop it. Akal Takhat in Punjab has issued a Hukumnama to Sikh community to stop the practice of female foeticide.

Various activities are being undertaken regularly for creating public awareness through Government media viz. Radio, TV and other media units. Various stations of AIR are broadcasting spots, group discussions, talks and panel discussions on PNDD Act in various languages.

Two spots are being telecast once a week on National Network and a film 'NIRANKUSH' is being telecast on Punjabi Channel. NFDC has been asked to produce a small film on female foeticide. A film 'ATMAJA' produced by Plan International India on female foeticide is being telecast on National Channel of Doordarshan.

Reports from the States:

All States/UTs have been advised to register all organizations using Ultrasound machines, failing which their machines may be sealed and seized in terms of the Supreme Court's Order dated 29.1.2002. Quarterly returns are being received from the States/UT, in terms of Supreme Court's Order dated 4.5.2001.

According to the reports received from the States/UT Govts. about 14,000 bodies are registered. As part of the compliance of the orders of the Hon'ble Supreme Court, more than 80 machines have been sealed and seized in States like Haryana, Karnataka, Maharashtra, Orissa, Punjab, Rajasthan, Tamil Nadu, Uttar Pradesh and Delhi. 191 complaints have been filed against the violators of law by various States/UTs. State/UT wise details are given below:-

Sl. No.	State/UT	Number of Complaints filed in the Court/Police	Number of Ultrasound machines seized and sealed
1	Andhra Pradesh	7	-
2	Bihar	7	-
3	Gujarat	7	
4	Haryana	8	8
5	Karnataka	5	5
6	Madhya Pradesh	6	-
7	Maharashtra	41	7
8	Orissa	1	1
9	Punjab	3	3
10	Rajasthan	2	2
11	Tamil Nadu	5	51
12	Uttaranchal	1	-
13	Uttar Pradesh	10	3
14	West Bengal	46	-
15	Chandigarh	2	
16	Delhi	40	1
	Total	191	81

National Monitoring and Implementation Committee:

A National Monitoring and Implementation Committee has also been constituted at the Centre to take stock of the ground realities by field visits. The Committee will visit the problem States and will submit their report along with suggestions for effective action to implement the Act, eradication of female foeticide and improvement of sex ratio. The

Committee has already visited Chandigarh on 4.1.2002, Faridabad (Haryana) on 2.2.2002 and Muzaffarnagr (U.P.) on 26.3.2002.

SUPREME COURT'S DIRECTIONS

The Supreme Court has issued certain directions to both Central and State Governments in a Public Interest Litigation filed by the Centre for Enquiry into Health & Allied Themes (CEHAT) & Others vs. Union of India and others. The directions include among other things wide publicity both at national and state levels for generating awareness about the Act.

I. Directions dated 4.5.2001:

Directions to the Central Government

- To create public awareness against the practice of pre-natal determination of sex of foetus and female foeticide through appropriate releases/programs in the print and electronic media.
- To implement with all vigor and zeal the PNDT Act and the Rules framed in 1996.
- The intervening period between the two meetings of the Advisory Committees constituted to advise the Appropriate Authority should not exceed 60 days. It would be seen that this Rule is strictly adhered to.

Directions to Central Supervisory Board (CSB)

- To ensure holding of meetings of the CSB at least once in six months.
- To appoint those eminent medical practitioners including eminent social scientists and representatives of women welfare organizations in the CSB, who can genuinely spare time for implementation of the Act.
- To review and monitor the implementation of the Act.
- To 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:
 1. Survey of bodies specified in section 3 of the Act.
 2. Registration of bodies specified in section 3 of the Act.
 3. Action taken against non-registered bodies operating in violation of section 3 of the Act, inclusive of search and seizure of records.
 4. Complaints received by the Appropriate Authorities under the Act and action taken pursuant thereto.
 5. Number and nature of awareness campaigns conducted and results flowing therefrom.
- To 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.

- 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 public at large can know about it.
- To 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.

Directions to State Governments/UT Administrations

- To appoint fully empowered Appropriate Authorities and Advisory Committees at State/UT, district and sub-district levels with such members of Advisory Committees who can devote sometime for the work assigned to them.
- To publish a list of appropriate authorities in the print and electronic media.
- 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 hoarding and other appropriate means.
- 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 –
 1. Survey of Genetic Counselling Centres, Genetic Laboratories and Genetic Clinics
 2. Registration of Genetic Counselling Centres, Genetic Laboratories and Genetic Clinics
 3. Action taken against non-registered bodies operating in violation of Section 3 of the Act, inclusive of search and seizure of records.
 4. Complaint received by the Appropriate Authorities under the Act and action taken pursuant thereto.
 5. Number and nature of awareness campaigns conducted and results flowing therefrom.

Directions to 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.
- To take prompt action against all Genetic Counseling Centres, Genetic Laboratories and Genetic Clinics as also against persons who are operating without a valid certificate of registration under the Act.
- To furnish quarterly returns to the CSB giving a report on the implementation and working of the Act. These returns should inter-alia contain specified information about:-
 1. Survey of Genetic Counseling Centres, Genetic Laboratories and Genetic Clinics
 2. Registration of Genetic Counseling Centres, Genetic Laboratories and Genetic Clinics including bodies using ultra-sound machines

3. Action taken against non-registered bodies operating in violation of Section 3 of the Act, **inclusive of search and seizure of records.**
4. Complaint received by the Appropriate Authorities under the Act and action taken pursuant thereto.
5. Number and nature of awareness campaigns conducted and results flowing therefrom.

II. Directions dated 11.12.2001:

The Supreme Court of India in its Order dated 11th December, 2001 had directed that:-

- (i) States/UTs should furnish district wise information about the implementation of the Act.
- (ii) Information about buyers of ultrasound machines may be obtained from the manufacturers, importers, suppliers etc. of such machines.
- (iii) Rules should be framed restricting sale of ultrasound machines to clinics registered under the PNDT Act.

III. Directions dated 29.1.2001:

The Supreme Court of India in its Order dated 29th January, 2002 has directed that:

- (i) State Governments/UTs should seal and seize the ultrasound machines/ scanners used by such organizations as have not got themselves registered under the Pre-Natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994.
- (ii) The mandatory procedure prescribed for registration of any person or organization using the ultrasound machines/scanners should be followed.
- (iii) Help of Indian Medical Association (IMA), Indian Radiologists Association and The Federation of Obstetrics and Gynaecologists Societies of India (FOGSI) may be taken to identify the users of ultrasound machines/scanners.

Action taken on the directions of the SC:

The Central Government have requested all the State/UTs for ensuring strict compliance of the directions of the Hon'ble Supreme Court of India. Quarterly returns as directed by the Supreme Court are being obtained from States/UTs about the implementation of the Act.

A list of over 11,000 buyers of ultrasound machines received from the manufacturers, importers, suppliers, dealers, service providers etc. of such machines has already been forwarded to the States/UTs for ensuring registration of the clinics using the same and for prosecution of those found misusing these machines for detection of sex of foetus.

Further, list of Members of Indian Radiological & Imaging Association and list of State level Presidents/Secretaries of Indian Medical Association (IMA) have also been forwarded to the States/UTs with the request to obtain from them the list of their members using ultrasound machines/imaging machines/scanners.

They have also been requested to launch prosecution against those persons who are using ultrasound machine/scanner/imaging machine without getting themselves registered under the Act and also against those who are found violating the provisions of the Pre-Natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994.

Amendments:

Action is being taken to amend **the Pre-Natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994** in the light of the directions of the Supreme Court. The proposed amendments inter-alia include –

1. bringing of the technique of pre-conception sex selection within the ambit of this Act so as to pre-empt the use of such technologies which significantly contribute to the declining sex ratio;
2. to bring the use of ultrasound machines within the purview of this Act **more explicitly** so as to curb their misuse for detection and disclosure of sex of the foetus lest it should lead to female foeticide;
3. to further empower the Central Supervisory Board for monitoring the implementation of the Act;
4. to introduce State level Supervisory Board for monitoring and reviewing the implementation of the Act in States/UTs;
5. to constitute a multi member State Appropriate Authority for better implementation and monitoring of the Act in the States;
6. to make punishments prescribed under the Act more stringent so as to serve as a deterrent for minimizing violations of the Act;
7. to empower the Appropriate Authorities with the powers of Civil Court for search, seizure and sealing the machines, equipments and records of the violators of law including sealing of premises and commissioning of witnesses;
8. making mandatory the maintenance of proper records in respect of the use of ultrasound machines and other equipments capable of detection of sex of foetus and also in respect of tests and procedures leading to pre-conception selection of sex.

Keeping in view the proposed amendments to the PNDT Act and directions of the Supreme Court, **the PNDT Rules, 1996 are also being amended** to inter-alia provide for restricting sale of ultrasound machines/scanners capable of detection of sex of foetus, prescribe code of conduct for persons working in such clinics, etc. in accordance with directions of the Supreme Court.

The amendment to the PNDT Act, which was sent to the Ministry of Law for vetting, has been sent by them to Legislative Department for preparing the draft Bill. On receipt of the same, the proposed amendments to the PNDT Act will be placed before the Cabinet for approval.

Sex Ratio among the Child Population in the age group 0-6

Sl.No.	States	1991	2001
1.	Punjab	875	793
2.	Haryana	879	820
3.	Chandigarh	899	845
4.	Himachal Pradesh	951	897
5.	Jammu & Kashmir	N.A.	937
6.	Delhi	915	865
7.	Rajasthan	916	909
8.	U.P.	927	916
9.	Bihar	953	938
10.	Orissa	967	950
11.	Madhya Pradesh	941	929
12.	Uttranchal	948	906
13.	Jharkhand	979	966
14.	Chhatisgarh	984	975
15.	Sikkim	965	986
16.	Arunachal Pradesh	982	961
17.	Nagaland	993	975
18.	Manipur	974	961
19.	Mizoram	969	971
20.	Tripura	967	975
21.	Meghalaya	986	975
22.	Assam	975	964
23.	West Bengal	967	963
24.	Gujarat	928	878
25.	Daman & Diu	958	925
26.	Dadra & Nagar Haveli	1013	973
27.	Maharashtra	946	917
28.	Andhra Pradesh	975	964
29.	Karnataka	960	949
30.	Goa	964	933
31.	Lakshadweep	941	974
32.	Kerala	958	963
33.	Tamil Nadu	948	939
34.	Pondicherry	963	958
35.	A & N Islands	973	965
	All India	945	927



भारत का राजपत्र The Gazette of India

असाधारण
EXTRAORDINARY

भाग II—खण्ड 3—उप-खण्ड (i)
PART II—Section 3—Sub-section (i)

प्रतिष्ठापन से प्रकाशित
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स्वास्थ्य और परिवार कल्याण मंत्रालय

(परिवार कल्याण विभाग)

अधिसूचना

नई दिल्ली, 1 जनवरी, 1996

सा.का.नि. 1(अ).—केन्द्रीय सरकार, प्रसवपूर्व निदान तकनीक (विनियमन और दुरुपयोग निवारण) अधिनियम, 1994 (1994 का 57) की धारा 32 द्वारा प्रदत्त शक्तियों का प्रयोग करते हुए, निम्नलिखित नियम बनाती है, अर्थात्—

1. संक्षिप्त नाम और प्रारम्भ :—(1) इन नियमों का संक्षिप्त नाम प्रसवपूर्व निदान तकनीक (विनियमन और दुरुपयोग निवारण) नियम, 1996 है।

(2) ये राजपत्र में प्रकाशन की तारीख को प्रवृत्त होंगे।

2. परिभाषाएँ :—इन नियमों में, जब तक कि संदर्भ से अन्यथा अपेक्षित न हो,

(क) “अधिनियम” से प्रसवपूर्व निदान तकनीक (विनियमन और दुरुपयोग निवारण अधिनियम, 1994 (1994 का 57) अभिप्रेत है :

(ख) “कर्मचारी” से किसी आनुवंशिक परामर्श केन्द्र, आनुवंशिक प्रयोगशाला या आनुवंशिक क्लिनिक में कार्यरत व्यक्ति नियोजित व्यक्ति अभिप्रेत है और इसके अन्तर्गत वे भी हैं जो अंशकालिक, संविदात्मक, परामर्शी, अवैतनिक आधार पर या किसी अन्य आधार पर कार्य कर रहे हैं;

(ग) “प्ररूप” से इन नियमों से संलग्न प्ररूप अभिप्रेत है;

(घ) “अनुसूची” से इन नियमों से संलग्न अनुसूची अभिप्रेत है;

(ङ) “धारा” से अधिनियम की धारा अभिप्रेत है।

(च) उन शब्दों और पदों के जो इन नियमों में प्रयुक्त हैं और परिभाषित नहीं हैं किन्तु अधिनियम में परिभाषित हैं, वही अर्थ होंगे जो उस अधिनियम में हैं।

3. न्यूनतम अपेक्षाएँ :—(1) किसी आनुवंशिक परामर्श केन्द्र, आनुवंशिक प्रयोगशाला और आनुवंशिक क्लिनिक के लिए कर्मचारियों की न्यूनतम आख्याएँ, न्यूनतम उपस्कर और न्यूनतम स्थान वह होगा जो अनुसूची 1, 2 और 3 में विनिर्दिष्ट है।

(2) जहाँ कोई संस्थान, अस्पताल, परिवर्धन गृह या कोई स्थान, चाहे वह किसी भी नाम से ज्ञात हो, आनुवंशिक

परामर्श केन्द्र, आनुवंशिक प्रयोगशाला और आनुवंशिक क्लिनिक की संयुक्त रूप से या इनके किसी सन्मुख की सेवाएं उपलब्ध कराता है वहां वह अनुसूची 1, 2, 3 में यथाविनिर्दिष्ट अपेक्षाओं के अनुरूप होगा।

4. आनुवंशिक परामर्श केन्द्र, आनुवंशिक प्रयोगशाला और आनुवंशिक क्लिनिक का रजिस्ट्रीकरण :—(1) रजिस्ट्रीकरण के लिए आवेदन दो प्रतियों प्ररूप "क" में समुचित प्राधिकारी को किया जाएगा।

(2) समुचित प्राधिकारी या उसके कार्यालय में इस निमित्त प्राधिकृत कोई व्यक्ति रजिस्ट्रीकरण के आवेदन की अभिलेखीकृत रसीद प्ररूप "क" के अंत में दी गई अभिलेखीकृत पर्वों में तुरन्त दी जाएगी यदि उसे समुचित प्राधिकारी के कार्यालय में परिदत्त किया जाता है या अगले कार्य दिवस के अग्रवात् दी जाएगी यदि वह डाक द्वारा प्राप्त किया जाता है।

5. आवेदन फीस :—(1) नियम (4) के अधीन रजिस्ट्रीकरण के लिए प्रत्येक आवेदन के साथ निम्नलिखित के लिए आवेदन फीस होगी :—

(क) आनुवंशिक परामर्श केन्द्र के लिए	2000.00 रुपए
(ख) आनुवंशिक प्रयोगशाला के लिए	3000.00 रुपए
(ग) आनुवंशिक क्लिनिक के लिए	3000.00 रुपए
	और

(घ) किसी संस्थान, अस्पताल, परिचर्या गृह या किसी अन्य स्थान, जो आनुवंशिक परामर्श केन्द्र, आनुवंशिक प्रयोगशाला और आनुवंशिक क्लिनिक की संयुक्त रूप से या ऐसे केन्द्र प्रयोगशाला या क्लिनिक के किसी समुच्चय की सेवाएं उपलब्ध करा रहा है, के लिए 4000.00 रुपए।

(2) आवेदन फीस समुचित प्राधिकारी के मुख्यालय में स्थित किसी अनुसूचित बैंक में समुचित प्राधिकारी के पक्ष में लिए गए मांगदेय ड्राफ्ट द्वारा संदत्त किया जाएगा।

6. रजिस्ट्रीकरण प्रमाणपत्र :—(1) समुचित प्राधिकारी, ऐसी जांच करने के पश्चात् और स्वयं का यह समाधान करने के पश्चात् कि आवेदक ने सभी अपेक्षाओं का पालन किया है, आवेदन को सलाहकार समिति के समक्ष उसकी सलाह के लिए प्रस्तुत करेगा।

(2) समुचित प्राधिकारी, सलाहकार समिति की सलाह को ध्यान में रखते हुए आवेदक को प्ररूप "ख" में, दो प्रतियों में, रजिस्ट्रीकरण प्रमाणपत्र प्रदान करेगा। रजिस्ट्रीकरण प्रमाणपत्र की एक प्रति रजिस्ट्रीकृत आनुवंशिक परामर्श केन्द्र, आनुवंशिक प्रयोगशाला या आनुवंशिक क्लिनिक द्वारा अपने कार्य के स्थान में किसी सहज दृश्य स्थान पर प्रदर्शित की जाएगी :

परन्तु समुचित प्राधिकारी किसी आनुवंशिक प्रयोगशाला या आनुवंशिक क्लिनिक को एक या अधिक विनिर्दिष्ट प्रसव-

पूर्व निदान परीक्षण या प्रक्रियाएं करने के लिए रजिस्ट्रीकरण प्रमाणपत्र प्रदान कर सकेगा जो स्थान, उपस्कर और अहित वर्धचारियों की उपलब्धता तथा ऐसे प्रयोगशाला या क्लिनिक द्वारा बनाए रखे गए स्तरमानों पर निर्भर करेगा।

(3) यदि समुचित प्राधिकारी की जांच के पश्चात् और आवेदक को सुनवाई का अवसर देने के पश्चात् तथा सलाहकार समिति की सलाह को ध्यान में रखते हुए, यह समाधान हो जाता है कि आवेदक ने अधिनियम और इन नियमों की अपेक्षाओं का पालन नहीं किया है तो वह ऐसे कारणों से जो लेखबद्ध किए जाएंगे, रजिस्ट्रीकरण के आवेदन को नामंजूर कर देगा और ऐसी नामंजूरी की संसूचना प्ररूप "ग" में विनिर्दिष्ट रूप में आवेदक को देगा।

(4) उपनियम (1) के अधीन कोई जांच जिसके अंतर्गत आनुवंशिक परामर्श केन्द्र, आनुवंशिक प्रयोगशाला या आनुवंशिक क्लिनिक के परिसर में निरीक्षण करना भी है, समुचित प्राधिकारी द्वारा आवेदक को सम्यक् सूचना देने के पश्चात् ही की जाएगी।

(5) रजिस्ट्रीकरण प्रमाणपत्र की मंजूरी या रजिस्ट्रीकरण के आवेदन की नामंजूरी, रजिस्ट्रीकरण के आवेदन की प्राप्ति की तारीख से नब्बे दिन की अवधि के भीतर यथास्थिति प्ररूप "ख" या प्ररूप "ग" में यथाविनिर्दिष्ट आवेदक को संसूचित की जाएगी।

(6) रजिस्ट्रीकरण प्रमाणपत्र अनंतरणीय होगा। आनुवंशिक परामर्श केन्द्र, आनुवंशिक प्रयोगशाला या आनुवंशिक क्लिनिक के स्वामित्व में परिवर्तन या प्रबन्ध में परिवर्तन की श्रववा उस रूप में कार्य करना समाप्त होने की दशा में, रजिस्ट्रीकरण प्रमाणपत्र की दोनों प्रतियां समुचित प्राधिकारी को अभ्यर्पित की जाएगी।

(7) आनुवंशिक परामर्श केन्द्र, आनुवंशिक प्रयोगशाला या आनुवंशिक क्लिनिक के स्वामित्व में परिवर्तन या प्रबन्ध में परिवर्तन की दशा में ऐसे केन्द्र, प्रयोगशाला या क्लिनिक का नया स्वामी या प्रबन्ध रजिस्ट्रीकरण प्रमाणपत्र प्रदान किए जाने के लिए पुनः आवेदन करेगा।

7. रजिस्ट्रीकरण की विधिमान्यता :—प्रत्येक रजिस्ट्रीकरण प्रमाणपत्र जारी होने की तारीख से पांच वर्ष की अवधि के लिए विधिमान्य होगा।

8. रजिस्ट्रीकरण का नवीकरण :—(1) रजिस्ट्रीकरण प्रमाणपत्र के नवीकरण के लिए आवेदन रजिस्ट्रीकरण प्रमाणपत्र के समाप्त होने की तारीख से तीस दिन पहले प्ररूप "क" में दो प्रतियों में समुचित प्राधिकारी को दिया जाएगा। ऐसे आवेदन की अभिलेखीकृत रसीद नियम 4 के उपनियम (2) में विनिर्दिष्ट रीति से समुचित प्राधिकारी द्वारा जारी की जाएगी।

(2) समुचित प्राधिकारी, जांच करने के पश्चात् और स्वयं का यह समाधान हो जाने के पश्चात् कि आवेदक ने

[भाग II-खण्ड 3(i)]

इस अधिनियम और इन नियमों की सभी अपेक्षाओं का पालन किया है और इस निमित्त सलाहकार समिति की सलाह को ध्यान में रखते हुए, पहले दिए गए रजिस्ट्रीकरण प्रमाणपत्र के समाप्त होने की तारीख से पांच वर्ष की और अवधि के लिए प्रारूप "ख" में विनिर्दिष्ट रूप से रजिस्ट्रीकरण प्रमाणपत्र का नवीकरण करेगा।

(3) यदि समुचित प्राधिकारियों की जांच के पश्चात् और आवेदक को उसकी सुनवाई का अवसर देने के पश्चात् तथा सलाहकार समिति की सलाह को ध्यान में रखते हुए, यह समाधान हो जाता है कि आवेदक ने अधिनियम और इन नियमों की अपेक्षाओं का पालन नहीं किया है तो वह ऐसे कारणों से, जो लेखबद्ध किए जाएंगे, रजिस्ट्रीकरण प्रमाणपत्र के नवीकरण के आवेदन को नामंजूर कर देगा और ऐसी नामंजूरी की संसूचना प्रारूप "ग" में विनिर्दिष्ट रूप में आवेदक को देगा।

(4) रजिस्ट्रीकरण प्रमाणपत्र के नवीकरण के लिए संदेय फीस नियम 5 के उपनियम (1) में उपबंधित फीस की आधी होगी।

(5) दो प्रतियों में नवीकृत रजिस्ट्रीकरण प्रमाणपत्र या नवीकरण के लिए आवेदन की नामंजूरी की संसूचना के प्राप्त होने पर, पहले के रजिस्ट्रीकरण प्रमाणपत्र की दोनों प्रतियां आनुवंशिक/परामर्श केन्द्र, आनुवंशिक प्रयोगशाला या आनुवंशिक क्लिनिक द्वारा समुचित प्राधिकारी को तुरन्त अभ्यापित की जाएंगी।

(6) समुचित प्राधिकारी के रजिस्ट्रीकरण प्रमाणपत्र को नवीकरण करने में असफल होने या रजिस्ट्रीकरण के नवीकरण के लिए आवेदन की प्राप्ति की तारीख से नब्बे दिन की अवधि के भीतर रजिस्ट्रीकरण के नवीकरण के आवेदन की नामंजूरी की संसूचना न दिए जाने की दशा में, रजिस्ट्रीकरण प्रमाणपत्र नवीकरण हुआ समझा जाएगा।

9. अभिलेखों का रखा जाना और उनका परिरक्षण—

(1) प्रत्येक आनुवंशिक परामर्श केन्द्र, आनुवंशिक प्रयोगशाला और आनुवंशिक क्लिनिक एक रजिस्टर रखेगा जिसमें क्रमवार उन महिलाओं के जिन्हें आनुवंशिक परामर्श दिया गया प्रसवपूर्व निदान प्रक्रियाओं या प्रसवपूर्व निदान परीक्षणों के अधीन रखा गया नाम और पते, उनके पतियों या पिताओं के नाम और वह तारीख, जिसको वे प्रथमतः ऐसे परामर्श, प्रक्रिया या परीक्षण के लिए उपस्थित हुईं, दर्शित होंगे।

(2) प्रत्येक आनुवंशिक परामर्श केन्द्र द्वारा ऐसी प्रत्येक महिला, जिसे परामर्श दिया गया है, की बाबत रखा जाने वाला अभिलेख प्रारूप "घ" में विनिर्दिष्ट रूप में होगा।

(3) प्रत्येक आनुवंशिक प्रयोगशाला द्वारा ऐसी प्रत्येक महिला, जिसे किसी प्रसवपूर्व निदान परीक्षण के अधीन रखा गया, की बाबत रखा जाने वाला अभिलेख प्रारूप "ङ" में विनिर्दिष्ट रूप में होगा।

(4) प्रत्येक आनुवंशिक क्लिनिक द्वारा ऐसी प्रत्येक महिला, जिसे किसी प्रसवपूर्व निदान प्रक्रिया के अधीन रखा गया, की बाबत रखा जाने वाला अभिलेख प्रारूप "च" में विनिर्दिष्ट रूप में होगा।

(5) समुचित प्राधिकारी रजिस्ट्रीकरण प्रमाणपत्र की भंजूरी या उसके नवीकरण के आवेदनों का स्थाई अभिलेख प्रारूप "ज" में विनिर्दिष्ट रूप में रखेगा। कर्मचारी, स्थान, पते और संस्थापित उपस्कर के प्रत्येक तबदीली के सूचनापत्रों को भी स्थाई अभिलेखों के रूप में परिरक्षित रखेगा।

(6) आनुवंशिक परामर्श केन्द्र, आनुवंशिक प्रयोगशाला या आनुवंशिक क्लिनिक द्वारा केस से संबंधित सभी अभिलेख, सहमति-प्रारूपों, प्रयोगशाला परिणाम, सूक्ष्मदर्शी चित्र, सोनोग्राफिक प्लेट या स्लाइड, सिफारिशों और पत्र, यथास्थिति, परामर्श, प्रसवपूर्व प्रक्रिया या प्रसवपूर्व निदान परीक्षण के पूरा होने की तारीख से दो वर्ष की अवधि के लिए परिरक्षित रखे जाएंगे। किन्हीं विधि कार्यवाहियों की दशा में, अभिलेखों को विधिक कार्यवाहियों के अंतिम निपटारे तक या दो वर्ष की उक्त अवधि के समाप्त होने तक, इनमें से जो भी पश्चात्तुर्वर्ती हो, परिरक्षित रखा जाएगा।

(7) यदि आनुवंशिक परामर्श केन्द्र या आनुवंशिक प्रयोगशाला या आनुवंशिक क्लिनिक कम्प्यूटर या अन्य इलेक्ट्रॉनिक उपस्कर के संबंध में अभिलेख रखा है तो उस अभिलेख की एक नुद्धित प्रति ली जाएगी और ऐसे अभिलेख के लिए उत्तरदायी व्यक्ति द्वारा अधिप्रमाणित करने के पश्चात् परिरक्षित रखी जाएगी।

10. प्रसवपूर्व निदान प्रक्रियाएं करने की शर्तें—(1) किसी प्रसवपूर्व निदान प्रक्रिया करने से पहले, गर्भवती महिला से, उस भाषा में, जो वह समझती हो, प्रारूप "छ" में विनिर्दिष्ट रूप में ही उससे लिखित सहमति ली जाएगी।

परन्तु जहां आनुवंशिक क्लिनिक ने शरीर के किसी उत्तक या शरीर के द्रव्य का नमूना लिया हो और उसे विश्लेषण या परीक्षण के लिए किसी आनुवंशिक प्रयोगशाला को भेजा हो वहां आनुवंशिक प्रयोगशाला के लिए यह आवश्यक नहीं होगा कि वह प्रारूप "छ" में पुनः सहमति प्राप्त करे।

(2) सभी राज्य सरकारें और संघ राज्यक्षेत्र राज्य या संघ राज्यक्षेत्रों में प्रयोग की जाने वाली भाषाओं में प्रारूप "छ" का अनुवाद जारी कर सकती हैं और जहां गर्भवती महिला द्वारा समझी गई भाषा में प्राधिकृत अनुवाद उपलब्ध नहीं है वहां आनुवंशिक क्लिनिक प्रारूप "छ" का उस भाषा में, जो वह समझती है, अनुवाद कर सकता है।

11. निरीक्षण के लिए सुविधाएं—प्रत्येक आनुवंशिक परामर्श केन्द्र, आनुवंशिक प्रयोगशाला और आनुवंशिक क्लिनिक स्थान, उपस्कर तथा अभिलेखों के निरीक्षण के लिए उपयुक्त सुविधाएं समुचित प्राधिकारी को या समुचित प्राधिकारी द्वारा इस निमित्त प्राधिकृत अन्य किसी व्यक्ति को प्रदान करेगा।

12. तलाशी और अभिग्रहण के लिए प्रक्रिया—(1) समुचित प्राधिकारी या इस निमित्त प्राधिकृत कोई अधिकारी

धारा 30 के प्रयोजनों के लिए हो या अधिक स्वतंत्र और प्रतिष्ठित व्यक्तियों की उपस्थिति में किसी आनुवंशिक परामर्श केन्द्र, आनुवंशिक प्रयोगशाला या आनुवंशिक क्लिनिक में एक उचित समय पर प्रवेश कर सकेगा और उसकी तलाशी ले सकेगा।

(2) आनुवंशिक परामर्श केन्द्र, आनुवंशिक प्रयोगशाला और आनुवंशिक क्लिनिक में पाए गए और अभिगृहीत किसी दस्तावेज, अभिलेख, रजिस्टर, पुस्तक, पैम्फलेट, विज्ञापन या किसी अन्य तात्विक वस्तु की सूची अभिग्रहण करने वाले स्थान पर दो प्रतियों में तैयार की जाएगी। ऐसी सूची की दोनों प्रतियों के प्रत्येक पृष्ठ पर समुचित प्राधिकारी या इस निमित्त प्राधिकृत अधिकारी द्वारा और अभिग्रहण साधियों द्वारा हस्ताक्षर किए जाएंगे।

परन्तु यह सूची साधियों की उपस्थिति में अभिग्रहण के स्थान से भिन्न किसी स्थान पर हो सकेगा, यदि ऐसे कारणों से जो लेखबद्ध किए जाएंगे, अभिग्रहण करने के स्थान पर सूची तैयार करना साध्य नहीं है।

(3) उपनियम (2) में निर्दिष्ट सूची की एक प्रति अभिस्वीकृति के अधीन उस व्यक्ति को दी जाएगी जिसकी अभिरक्षा से दस्तावेज, अभिलेख, रजिस्टर, पुस्तक, पैम्फलेट, विज्ञापन या कोई अन्य तात्विक वस्तु अभिग्रहण की गई है :

परन्तु अभिगृहीत ऐसे दस्तावेज, अभिलेख, रजिस्टर, पुस्तक, पैम्फलेट, विज्ञापन या अन्य तात्विक वस्तु की सूची की एक प्रति अभिस्वीकृति के अधीन आनुवंशिक परामर्श केन्द्र, आनुवंशिक प्रयोगशाला या आनुवंशिक क्लिनिक के स्वामी या प्रबंधक को परिदत्त की जा सकेगी या रजिस्ट्रीकृत डाक द्वारा भेजी जा सकेगी, यदि अभिगृहीत दस्तावेज, अभिलेख, रजिस्टर, पुस्तक, पैम्फलेट, विज्ञापन या अन्य तात्विक वस्तु की अभिरक्षा को अभिस्वीकार करने वाला कोई व्यक्ति अभिग्रहण करने के स्थान पर उपलब्ध नहीं है।

(4) यदि अभिगृहीत कोई तात्विक वस्तु विनमयर प्रकृति की है तो समुचित प्राधिकारी या इस निमित्त प्राधिकृत अधिकारी तात्विक वस्तु को मुद्रांकित करने, उसकी पहचान तथा उसके परिरक्षण के लिए तत्परतापूर्वक प्रबंध करेगा और यदि उसका विश्लेषण या परीक्षण अपेक्षित है तो उसे विश्लेषण या परीक्षण के लिए वहाँ भी भेजेगा जहाँ ऐसी सुविधा है।

परन्तु ऐसी विनमयर तात्विक वस्तु परिरक्षण करने के लिए आनुवंशिक परामर्श केन्द्र, आनुवंशिक प्रयोगशाला या आनुवंशिक क्लिनिक द्वारा प्रयुक्त प्रतीतक या अन्य उपस्कर को ऐसे समय तक मुद्रांकित किया जा सकेगा जब तक ऐसी विनमयर तात्विक वस्तु को सुरक्षित रखा जाने के लिए प्रबंध नहीं किया जा सकता हो और ऐसी सम्भाव्यता में आनुवंशिक परामर्श केन्द्र या आनुवंशिक प्रयोगशाला या आनुवंशिक क्लिनिक के परिसरों में अभिगृहीत तात्विक वस्तु को रखने का उल्लेख अभिग्रहण की सूची में किया जाएगा।

(5) तलाशी और अभिग्रहण संक्रिया के पूरा न करने की दशा में, समुचित प्राधिकारी या इस निमित्त प्राधिकृत अधिकारी अभिगृहीत कि जाने वाले दस्तावेजों, अभिलेखों, पुस्तक या किसी अन्य तात्विक वस्तु को सुरक्षित रखने, सूचीबद्ध करने और हटाने के लिए ऐसे दस्तावेजों, अभिलेखों, पुस्तकों या किसी तात्विक वस्तु में किसी गड़बड़ी को रोकने के लिए आनुवंशिक परामर्श केन्द्र, आनुवंशिक प्रयोगशाला या आनुवंशिक क्लिनिक के परिसरों में गार्ड रखकर या मुद्रांकित करके प्रबंध कर सकेगा।

13. कर्मचारियों, स्थान या उपस्कर में तद्वत्तरी की सूचना—

प्रत्येक आनुवंशिक परामर्श केन्द्र, आनुवंशिक प्रयोगशाला या आनुवंशिक क्लिनिक कर्मचारी, स्थान, पता और संस्थापित उपस्कर में की गई प्रत्येक तद्वत्तरी की सूचना ऐसी तद्वत्तरी के तीस दिन की अवधि के भीतर समुचित प्राधिकारी को देगा।

14. विश्लेषण या परीक्षण की शर्तें और प्रसवपूर्ण निदान प्रक्रियाएँ—

(1) कोई आनुवंशिक प्रयोगशाला किसी नमूने को विश्लेषण या परीक्षण के लिए तब तक स्वीकार नहीं करेगा जब तक कि उसे किसी आनुवंशिक क्लिनिक द्वारा उसको निर्दिष्ट न किया गया हो।

(2) प्रत्येक प्रसवपूर्व निदान प्रक्रिया सदैव अल्ट्रा सोनोग्राफी से भ्रूण और अपरा का पता लगाकर तुरंत आरंभ की जाएगी और प्रसवपूर्व निदान प्रक्रिया सीधे अल्ट्रासोनोग्राफीय अनुश्रवण के अधीन की जाएगी ताकि भ्रूण और अपरा को कोई नुकसान होने से रोका जा सके।

15. सलाहकार समितियों की बैठकें: समुचित प्राधिकारी को सलाह देने के लिए धारा 17 की उपधारा (5) के अधीन गठित सलाहकार समितियों की केंद्रीय दो बैठकों के बीच अन्तर्वर्ती अवधि साठ दिन से अधिक नहीं होगी।

16. केन्द्रीय पर्यवेक्षण बोर्ड के सदस्यों के भत्ते :

(1) बोर्ड में नियुक्त पदेन सदस्य और केन्द्रीय सरकार तथा राज्य सरकार के अन्य अधिकारी बोर्ड की बैठकों में उपस्थित होने के लिए उनकी यात्रा यात्रा भत्ता नियमों के अनुसार यात्रा भत्ता और दैनिक भत्ता के हकदार होंगे।

(2) बोर्ड में नियुक्त किए गए गैर-सरकारी सदस्य और चरान्त किए गए संसद सदस्य बोर्ड की बैठकों में उपस्थित होने के लिए यात्रा भत्ता और दैनिक भत्ता के हकदार होंगे जैसाकि केन्द्रीय सरकार के यात्रा भत्ता नियमों के अधीन, यथास्थिति, गैरसरकारी सदस्यों और संसद सदस्यों को अनुमति है।

17. सार्वजनिक सूचना : (1) प्रत्येक आनुवंशिक परामर्श केन्द्र, आनुवंशिक प्रयोगशाला और आनुवंशिक क्लिनिक जनता की सूचना के लिए इस आशय की एक सूचना कि

[भाग II-खण्ड 3(i)]

भ्रूण का लिंग प्रकट करना विधि के अधीन प्रतिबंधित है, अंग्रेजी में और स्थानीय भाषा या भाषाओं में अपने परिसरों में प्रमुख रूप से प्रदर्शित करेंगे।

(2) अधिनियम और इन नियमों की कम से कम एक-एक प्रति प्रत्येक आनुवंशिक परामर्श केंद्र, आनुवंशिक प्रयोगशाला और आनुवंशिक क्लिनिक के परिसरों में उपलब्ध होगी तथा ग्राहकों के लिए मांग पर परीक्षण के लिए उपलब्ध होगी।

(3) समुचित प्राधिकारी, केन्द्रीय सरकार, राज्य सरकार, संघ राज्य क्षेत्र की सरकार/प्रशासन रजिस्ट्रीकृत

आनुवंशिक परामर्श केंद्रों, आनुवंशिक प्रयोगशालाओं और आनुवंशिक क्लिनिकों की सूचियों और रिपोर्टों के निष्कर्षों तथा अपने पास उपलब्ध अन्य सूचना को, जनता की जानकारी के लिए और इस क्षेत्र में विशेषज्ञों द्वारा उपयोग के लिए आधिकारिक रूप से प्रकाशित कर सकेगी/सकेगा।

[सं. 23011/59/94-पी.एल. आई.]

के. एस. मुगधन, संयुक्त सचिव

अनुसूची 1

[नियम 3 (1) देखिए]

आनुवंशिक परामर्श केंद्र के रजिस्ट्रीकरण के लिए अपेक्षाएं

- क. स्थान
सात (7) वर्ग मीटर के क्षेत्रफल वाला एक कमरा
- ख. उपस्कर
शैक्षिक चार्ट/माडल
- ग. कर्मचारी
निम्नलिखित में से कोई एक :-

- (1) चिकित्सा आनुवंशिकीविज्ञ।
- (2) स्त्री रोग विशेषज्ञ, जिसे आनुवंशिक परामर्श में 6 मास का अनुभव हो, या जिसने आनुवंशिक परामर्श में 4 सप्ताह का प्रशिक्षण पूरा किया हो।
- (3) बाल चिकित्सक, जिसे आनुवंशिक परामर्श में 6 मास का अनुभव हो, या जिसने आनुवंशिक परामर्श में 4 सप्ताह का प्रशिक्षण पूरा किया हो।

अनुसूची - 2

[नियम 3 (1) देखिए]

आनुवंशिक प्रयोगशाला के रजिस्ट्रीकरण के लिए अपेक्षाएं

- क. स्थान
परीक्षण करने के लिए पर्याप्त स्थान सहित एक कमरा।
- ख. उपस्कर
इन्हें निम्नलिखित प्रत्येक अध्ययन के लिए पृथक रूप से वर्गीकृत किया जाता है।
गुणसूत्री अध्ययन
- (1) पराबैंगनी और प्रतिदीप्ति प्रकाश सहित पटलीय प्रवाहदृष्ट या अन्य उपयुक्त संवर्धनदृष्ट।
 - (2) प्रकाश के प्रतिदीप्ति स्रोत सहित फोटो सूक्ष्मदर्शी
 - (3) प्रतिलोमित सूक्ष्मदर्शी
 - (4) ऊष्मायित और भट्टी
 - (5) कार्बन डाइऑक्साइड उष्माचित्र या 5 प्रतिशत सी. ओ. 2 वातावरण सहित बंद तंत्र।
 - (6) ऑटोफ्लोरो
 - (7) प्रणीतक
 - (8) जल स्थान

- (9) अपकेन्द्रित
- (10) वोटैक्स मिश्रक
- (11) चुम्बकीय विलोडक
- (12) पी. एच. मीटर
- (13) 0.1 मिलीग्राम की सूक्ष्मग्रहिता सहित सूक्ष्मग्राही तुला (अधिमनतः इलेक्ट्रानिक)
- (14) द्वि आसवन साधन (शीशा)

जैव-रासायनिक अध्ययन

(किए जाने वाले परीक्षणों के अनुसार अपेक्षाएं)

- (1) पराबैंगनी और प्रतिदीप्ति सहित पटलीय प्रवाहहुड या अन्य उपयुक्त संवर्धन हुड।
- (2) प्रतिलोमित सूक्ष्मदर्शी
- (3) उष्मायित और भट्टी
- (4) कार्बन डाईआक्साइड उष्मायित या 5 प्रतिशत सी. ओ. वातावरण सहित बंद तंत्र।
- (5) आटोक्लेव
- (6) प्रशीतक
- (7) जल स्नान
- (8) अपकेन्द्रित
- (9) इलेक्ट्रोफोरेसिस साधन और शक्ति आपूर्ति
- (10) क्रोमेटोग्राफी चैम्बर
- (11) विभिन्न जैव रासायनिक परीक्षणों के लिए स्पेक्ट्रो-फोटोमीटर और इलिसा रीडर या रेडियो-इम्यूनोएसे प्रणाली (गामा बेटा काउन्टर सहित) या फ्लुओरोमीटर।
- (12) वोटैक्स मिश्रक
- (13) चुम्बकीय विलोडक
- (14) पी. एच. मीटर
- (15) 0.1 मिलीग्राम की सूक्ष्मग्रहिता सहित सूक्ष्मग्राही तुला (अधिमनतः इलेक्ट्रानिक)
- (16) द्वि आसवन साधन (शीशा)
- (17) द्रव नाइट्रोजन टैंक

आण्विक अध्ययन

- (1) प्रतिलोमित सूक्ष्मदर्शी
- (2) उष्मायित
- (3) भट्टी
- (4) आटोक्लेव
- (5) प्रशीतक (4 डिग्री और माइनस 20 डिग्री सेंटीग्रेड)
- (6) जल स्नान
- (7) सूक्ष्म अपकेन्द्रित
- (8) इलेक्ट्रोफोरेसिस साधन और शक्ति आपूर्ति
- (9) वोटैक्स मिश्रक
- (10) चुम्बकीय विलोडक

[भाग II-खण्ड 3(i)]

- (11) पी. एच. मीटर
- (12) 0.1 मिलीग्राम की सूक्ष्मग्रहिता सहित सूक्ष्मग्राही तुला (अधिमानतः इलेक्ट्रॉनिक)
- (13) दि आसवन साधित (शीशा)
- (14) पी. सी. आर. मशीन
- (15) प्रशीतक अपकेन्द्रित
- (16) फोटोग्राफिक अटैचमेंट सहित यू. वी. इल्यूमीनेटर या अन्य प्रलेखन प्रणाली
- (17) प्रीसीजन माइक्रोपिपेट्स

ग. कर्मचारी

- (1) एक चिकित्सा आनुवंशिकीविज्ञ
- (2) एक प्रयोगशाला तकनीशियन, जिसके पास जीवविज्ञान में बी. एस. सी. डिग्री हो या चिकित्सीय प्रयोगशाला पाठ्यक्रम में डिग्री या डिप्लोमा हो और उपयुक्त प्रसवपूर्व निदान परीक्षण करने में काम से कम एक वर्ष का अनुभव हो।

अनुसूची 3

[नियम 3 (1) देखिए]

आनुवंशिक विधनिक के रजिस्ट्रीकरण के लिए अपेक्षाएं

क. स्थान

उपयुक्त अपेक्षित व्यवस्थाओं सहित बीस (20) वर्ग मीटर का शीत फल वाला एक कमरा।

ख. उपस्कर

- (1) किसी प्रसूति विशेषज्ञ/स्त्री रोग विशेषज्ञ द्वारा निदान परीक्षा करने के लिए आवश्यक उपकरण और उपसाधन।
- (2) इस अधिनियम में परिक्लिप्त संक्रियाओं के लिए अपेक्षित उपस्कर, उपसाधन, सामग्री और अन्य सुविधाएं।

* (क) एक अल्ट्रासोनोग्राफी मशीन

* (ख) प्रति योनि या प्रति उदर कोरियोनिक विल्ली एसपिरेशन करने के लिए उपयुक्त नाल-शलाका और उपस्कर

* (ग) एम्नियोसेटेसिस या कोर्डोसेटेसिस के लिए उपयुक्त विसंक्रमित सुइयां।

(घ) फोइटोस्कोप, फोइटल त्वचा या अंग जीवोतिपरीक्षा या भ्रूण रक्त नमूना के लिए उपयुक्त उपसाधनों सहित एक उपयुक्त फोइटोस्कोप वैकल्पिक होगा।

(3) शुष्क और आर्द्र विसंक्रमण के लिए उपस्कर।

(4) आवश्यकता की दशा में गर्भाशय निकालने या पुनरुज्जीवित करने जैसी आयात प्रक्रिया करने के लिए उपस्कर।

ग. कर्मचारी

- (1) एक स्त्री रोग विशेषज्ञ, जिसे प्रसवपूर्व निदान प्रक्रिया में पर्याप्त अनुभव हो उसे किसी ऐसे स्त्रीरोग विशेषज्ञ के, जो उस प्रक्रिया में, जो किया जाने वाला है, उदाहरणार्थ, कोरियोनिक विल्ली, जीवोतिपरीक्षा, एम्नियोसेटेसिस, कोर्डोसेटेसिस और जैसा ऊपर "ख" में उपरक्षित है में अनुभव हो, पर्यवेक्षण के अधीन कम से कम 20 प्रतिक्रियाएं निष्पादित किया होना चाहिए।

- (2) अल्ट्रासोनोग्राफी करने के लिए एक विकिरण चिकित्सा या रजिस्ट्रीकृत चिकित्सा व्यवसायी अपेक्षित अनुभव इन तकनीकों में अनुभवों उसी प्रकार के किसी अहित व्यक्ति के पर्यवेक्षण के अधीन 100 केस होगा।

* इनसे सुसंगत प्रक्रिया करने के लिए उपस्कर की न्यूनतम अपेक्षा गठित होती है।

प्रमाण "क"

[नियम 4 (1) और नियम 8(1) देखिए]

(दो प्रतियों में प्रस्तुत किया जाना है)

संलग्नक के रूप में समर्थक दस्तावेज भी दो प्रतियों में

आनुवंशिक परामर्श केन्द्र/आनुवंशिक प्रयोगशाला/आनुवंशिक क्लिनिक के रजिस्ट्री या रजिस्ट्रीकरण के नवीकरण के लिए आवेदन ।

1. आवेदक का नाम
(श्री/श्रीमति/कुमारी/डा.,
विनिर्दिष्ट करें)
2. आवेदक का पता
3. किस हैसियत में आवेदन कर रहे हैं ।
(स्वामी/भागीदार/प्रबंध निदेशक/अन्य उल्लेख करें)
4. रजिस्ट्रीकृत की जाने वाली सुविधा का प्रकार
(आनुवंशिक परामर्श केन्द्र/आनुवंशिक
प्रयोगशाला/आनुवंशिक क्लिनिक/
इनका कोई समुच्चय विनिर्दिष्ट करें)
5. दूरभाष/तार/टैलेक्स/फैक्स/सुरत संख्या सहित
आनुवंशिक परामर्श केन्द्र/आनुवंशिक
प्रयोगशाला/आनुवंशिक क्लिनिक का पूरा नाम और पता/पते
6. स्वामित्व और संगठन का प्रकार
(व्यक्तिगत स्वामित्व/भागीदारी/
कम्पनी/सहकारी/कोई अन्य विनिर्दिष्ट करें)

व्यक्तिगत
स्वामित्व से भिन्न संगठन के प्रकार की दशा में संलग्नक के
रूप में संगम अनुच्छेद और प्रबंध
के लिए उत्तरदायी अन्य व्यक्तियों के
नामों और पतों की प्रति दें ।
7. संस्थान का प्रकार
(सरकारी अस्पताल/नगर पालिका अस्पताल/
सार्वजनिक अस्पताल/प्राइवेट अस्पताल/
प्राइवेट परिचर्या गृह/प्राइवेट क्लीनिक/
प्राइवेट प्रयोगशाला/कोई अन्य, उल्लेख करें ।
8. विनिर्दिष्ट प्रसवपूर्व निदान प्रक्रियाएं/
परीक्षण, जिनके लिए अनुमोदन चाहा गया
है (उदाहरणार्थ एमनियोसेंटेसिस, कोरियोनिक
विल्ली एसपिरेशन/गुणसूची
जैव रसायनिक/आणविक अध्ययन आदि)
यदि रजिस्ट्रीकरण केवल आनुवंशिक परामर्श
केन्द्र के लिए चाहा गया है
तो खाली छोड़ दें ।

9. (क) आनुवंशिक परामर्श केन्द्र/क्लिनिक/
प्रयोगशाला के लिए उपलब्ध स्थान
(सॉबी प्रतीकांकनों, सीढ़ियों,
आदि को छोड़कर कुछ कार्य क्षेत्र दें
और रेखांक संलग्न करें)

[भाग II-खण्ड 3(i)]

10. प्रत्येक उपस्कर का मेक और
मॉडल सहित उपलब्ध उपस्कर
(एक अलग पक्ष पर सूची संलग्न करें)
11. (क) परामर्श केन्द्र में उपलब्ध
सुविधाएं
- (ख) क्या निम्नलिखित परीक्षणों के लिए
प्रयोगशाला/क्लिनिक में सुविधाएं उपलब्ध हैं
1. अल्ट्रासाउंड
 2. एम्नियोसेंटेसिस
 3. कोरियोनिक दिल्ली, एसपीरेशन
 4. फोइटोस्कोपी
 5. भ्रूण बायोप्सी
 6. कोडोसेंटेसिस
- (ग) क्या निम्नलिखित के लिए प्रयोगशाला/क्लिनिक में
सुविधाएं उपलब्ध हैं :—
1. गुणसूत्री अध्ययन
 2. जैव रासायनिक अध्ययन
 3. आण्विक अध्ययन
12. कर्मचारियों का नाम, अर्हताएं, अनुभव
और रजिस्ट्रीकरण संख्याएं इन्हें
असंलग्नक के रूप में दिया जाए
(संदर्भ अनुसूची 1, 2 और 3)
13. यह बताएं कि क्या आनुवंशिक
परामर्श केन्द्र/आनुवंशिक
प्रयोगशाला/आनुवंशिक
क्लिनिक
अनुसूची 1, 2 और
3 में अधिकतम न्यूनतम अपेक्षाओं के अनुसार
रजिस्ट्रीकरण के लिए अर्हता करता है और यदि नहीं
तो उसके कारण
14. केवल नवीकरण आवेदनों के लिए
- (क) रजिस्ट्रीकरण संख्या
- (ख) विद्यमान रजिस्ट्री प्रमाणपत्र
के जारी होने की तारीख
और उसके समाप्त होने की तारीख
15. संलग्नकों की सूची
कृपया इस आवेदन के साथ संलग्न
किए गए समर्थक दस्तावेज देते हुए संलग्नकों की सूची
संलग्न करें।

आवेदक का नाम और हस्ताक्षर

तारीख :

स्थान :

1 GI/96—2

घोषणा

मैं, श्री/श्रीमती/कुमारी/डा.

का/की पुत्र/पुत्री/पत्नी

आयु

वर्ष

की/का निवासी

यह घोषणा करता/करती हूँ कि मैंने प्रसवपूर्व निदान तकनीक (विनियमन और दुरुपयोग निवारण), अधिनियम 1994 (1994 का 57) और प्रसवपूर्व निदान तकनीक (विनियमन और दुरुपयोग निवारण) नियम, 1995 को पढ़ लिया है और समझ लिया है।

(ii) मैं उक्त अधिनियम और नियमों को उस आनुवंशिक परामर्श केन्द्र/आनुवंशिक प्रयोगशाला/आनुवंशिक क्लिनिक के सभी कर्मचारियों को समझाने का वचन भी देता/देती हूँ जिसकी वास्तव रजिस्ट्रीकरण अपेक्षित है और यह सुनिश्चित करने का वचन देता/देती हूँ कि अधिनियम तथा नियमों का पूर्णतः पालन किया जाएगा।

आवेदक का नाम और हस्ताक्षर

तारीख :

स्थान :

*जो लागू न हो या आवश्यक न हो उसे काट दें।

सभी संलग्नकों को आवेदक के हस्ताक्षर द्वारा अधिप्रमाणित किया जाना है।

अभिस्वीकृति

[नियम 4(2) और 8(1) देखिए]

..... (आवेदक का नाम और पता) द्वारा आनुवंशिक परामर्श केन्द्र/आनुवंशिक प्रयोगशाला/आनुवंशिक क्लिनिक के रजिस्ट्रीकरण की मंजूरी/नवीकरण* के लिए आवेदन प्रारूप "क" में, दो प्रतियों में समुचित प्राधिकारी द्वारा (तारीख) को प्राप्त हुआ है।

*प्रारूप "क" में आवेदन के साथ लगे संलग्नकों की सूची का प्रस्तुत किए गए संलग्नकों से सत्यापन कर लिया गया है और सही पाया गया है।

अथवा

*सत्यापन करने पर यह पाया गया है कि संलग्नकों की सूची में उल्लिखित निम्नलिखित दस्तावेज वस्तुतः संलग्न नहीं किए गए हैं।

यह अभिस्वीकृति रजिस्ट्रीकरण की मंजूरी या आवेदन के लिए आवेदक को कोई अधिकार प्रदान नहीं करती है।

समुचित प्राधिकारी या
समुचित प्राधिकारी के कार्यालय
में प्राधिकृत व्यक्ति के हस्ताक्षर
और पदनाम

तारीख

मुहर

*जो लागू न हो या आवश्यक न हो उसे काट दें।

प्रारूप 'ख'

मूल प्रति*
प्रदर्शित करने के लिए दूसरी प्रति

[नियम 6(2), नियम 6(5) और नियम 8(2) देखिए]

रजिस्ट्रीकरण प्रमाण पत्र

(दो प्रतियाँ में जारी किया जाना है)

1. समुचित प्राधिकारी प्रसवपूर्व निदान तकनीक (विनियमित और दुरुपयोग निवारण) अधिनियम, 1994 (1992 का 57) की धारा 19(1) के अधीन प्रदत्त शक्तियों का प्रयोग करते हुए, नीचे नाभित आनुवंशिक परामर्श केन्द्र*/आनुवंशिक प्रयोगशाला* आनुवंशिक क्लिनिक* को आनुवंशिक परामर्श/प्रसवपूर्व निदान प्रक्रियाएं/प्रसवपूर्व निदान परीक्षण करने के प्रयोजनों के लिए, जैसा कि उक्त अधिनियम में परिभाषित है, को समाप्त होने वाली 5 वर्ष की अवधि के लिए रजिस्ट्रीकरण मंजूर करता है।

2. यह रजिस्ट्रीकरण पूर्वोक्त अधिनियम और उसके अधीन बनाए गए नियमों के अधीन रहते हुए मंजूर किया गया है और उनका कोई उल्लंघन करने पर यह रजिस्ट्रीकरण प्रमाणपत्र उक्त पांच वर्ष की अवधि की समाप्ति से पूर्व निलम्बित या रद्द कर दिया जाएगा।

क. आनुवंशिक परामर्श केन्द्र*/आनुवंशिक प्रयोगशाला*।

आनुवंशिक क्लिनिक का नाम और पता

ख. रजिस्ट्रीकरण के लिए आवेदक का नाम

ग. आनुवंशिक क्लिनिक के लिए अनुमोदित प्रसवपूर्व निदान प्रक्रियाएं

1. अल्ट्रासाउंड

2. एम्नियोसेंटेसिस

3. कोरिओनिक विल्ली बायोप्सी

4. फोइटोस्कोपी

5. फोइटल स्किनकुया आर्गन बायोप्सी

6. क्रोडोसेंटेसिस

7. कोई अन्य (विनिर्दिष्ट करें)

घ. (आनुवंशिक प्रयोगशाला के लिए) अनुमोदित प्रसवपूर्व निदान परीक्षण

1. गुणसूत्री अध्ययन

2. जैव रासायनिक अध्ययन

3. आणविक अध्ययन

3. आवंटित रजिस्ट्रीकरण सं.

4. केवल नवीकृत रजिस्ट्रीकरण प्रमाणपत्र के लिए

पहले रजिस्ट्रीकरण प्रमाणपत्र की विधि मान्यता अवधि से

..... तक

समुचित प्राधिकारी के हस्ताक्षर,
नाम और पदनाम

मुहर

तारीख

(*) जो लागू न हो या आवश्यक न हो उसे काट दें।

इस प्रमाणपत्र की एक प्रति कारोबार के स्थान में सहज दृश्य स्थान पर प्रदर्शित करें।

प्ररूप "ग"

[नियम 6(3), नियम 6(5) और नियम 8(3) देखिए]

रजिस्ट्रीकरण के लिए या रजिस्ट्रीकरण के निरीकरण के लिए आवेदन का नामंजूर किया जाना

समुचित प्राधिकारी प्रसवपूर्व निदान तकनीक (विनियमन और दुरुपयोग निवारण) अधिनियम, 1994 की धारा 19(2) के अधीन प्रदत्त शक्तियों का प्रयोग करते हुए नीचे नामित आनुवंशिक परामर्श केन्द्र*/आनुवंशिक प्रयोगशाला*/आनुवंशिक क्लिनिक के रजिस्ट्रीकरण की/के मंजूरी*/नवीकरण के आवेदन को कथित कारणों से नामंजूर करता है।

आनुवंशिक परामर्श केन्द्र*/
आनुवंशिक प्रयोगशाला*/
आनुवंशिक क्लिनिक *का नाम और पता

रजिस्ट्रीकरण के लिए आवेदन करने वाले

आवेदक का नाम

रजिस्ट्रीकरण के लिए आवेदन को
नामंजूर करने के कारण

समुचित प्राधिकारी के हस्ताक्षर,
नाम और पदनाम

मुहर

तारीख

(*) जो लागू न हो या आवश्यक न हो उसे काट दें।

प्ररूप "घ"

[नियम 9(2) देखिए]

आनुवंशिक परामर्श केन्द्र का नाम, पता और रजिस्ट्रीकरण संख्यांक
आनुवंशिक परामर्श केन्द्र द्वारा रखा जाने वाला अभिलेख

1. रोगी का नाम
2. आयु
3. पति/पिता का नाम
4. पूरा पता, दूरभाष सं. सहित, यदि कोई हो
5. (डाक्टर/डाक्टरों का पूरा नाम और पता तथा रजिस्ट्रीकरण संख्यांक द्वारा निर्दिष्ट टिप्पण को वेस के कागजपत्रों के साथ सावधानीपूर्वक परिरक्षित किया जाना है)
6. अंतिम रजोधर्म गर्भावस्था के सप्ताह
7. कुटुम्ब में आनुवंशिक/आयुर्विज्ञान रोग का वृत्तांत (विनिर्दिष्ट करें)

निदान का आधार

- (क) क्लिनिकल
- (ख) जैव-रासायनिक
- (ग) कोशिका आनुवंशिक
- (घ) अन्य (उदाहरणार्थ, विकिरण चिकित्सा विज्ञान)

8. प्रसवपूर्व निदान के लिए उपदर्शन

- (क) निम्नलिखित सहित पूर्ववर्ती संतान
 - (1) गुणसूत्री विकार
 - (2) उपापचयी विकार
 - (3) जन्मजात विषमता
 - (4) मानसिक मन्दन
 - (5) हीमोग्लोबिनोपैथी
 - (6) यौन संबंधी विकार
 - (7) कोई अन्य (विनिर्दिष्ट करें)
- (ख) अधिक मातृ आयु (> 35 वर्ष)
- (ग) माता/पिता/सहोदर भाई या बहन को आनुवंशिक रोग है (विनिर्दिष्ट करें)
- (घ) अन्य (विनिर्दिष्ट करें)

9. प्रस्तापित प्रक्रियाएँ

- (1) अल्ट्रासाउंड
- (2) एम्नियो सेंटेसिस
- (3) कॉरियोकि दिल्ली बायोप्सी
- (4) फोइटोस्कोपी
- (5) फोइटल स्किन या आर्गन बायोप्सी
- (6) कॉर्डोसेंटेसिस
- (7) कोई अन्य (विनिर्दिष्ट करें)

10. किए जाने वाले प्रयोगशाला परीक्षण

- (1) गुणसूत्री अध्ययन
- (2) जैव रासायनिक अध्ययन
- (3) आण्विक अध्ययन

11. प्रसवपूर्व निदान परिणाम

यदि असामान्य हो
तो ब्यौरे दें।

12. क्या गर्भ के चिकित्सीय समापन की सलाह दी गई थी

13. उस आनुवंशिकी क्लिनिक* का नाम और पता जहाँ रोगी का निदिष्ट किया गया

14. आनुवंशिक परामर्श के आरंभ और पूरा होने की तारीख

तारीख

चिकित्सा आनुवंशिकी विज्ञ/रोग विशेषज्ञ/
बालचिकित्सक का नाम हस्ताक्षर और रजिस्ट्रीकरण संख्या

सामान्य/असामान्य

प्ररूप—ड

[नियम 9(3) देखिए]

आनुवंशिक प्रयोगशाला का नाम, पता और रजिस्ट्रिकरण संख्यांक आनुवंशिक प्रयोगशाला द्वारा रखा जाने वाला अभिलेख

1. रोगी का नाम

2. आयु

3. पति/पिता का नाम

4. पूरा पता, दूरभाष सं. सहित, यदि कोई हो

5. (आनुवंशिक क्लिनिक का पूरा नाम और पता निर्देश टिप्पण को निर्दिष्ट द्वारा भेजा गया नमूना

(केस के कागज-पत्रों के साथ सावधानी पूर्वक परिरक्षित किया जाना है।

6. नमूने का प्रकार: मातृ रक्त/कोरियोनिक विलस नमूना/एम्नियोटिक फ्लूइड/भ्रूण रक्त या अन्य भ्रूण ऊतक (विनिर्दिष्ट करें)

7. प्रसवपूर्व निदान के लिए उपदर्शन विनिर्दिष्ट करें।

(क) निम्नलिखित सहित पूर्ववर्ती संतान

(1) गुणसूत्री विकार

(2) उपापचयी विकार

(3) कुरचना

(4) मानसिक मंदन

(5) वंशानुगत रक्तसंलायी रक्ताल्पता

(6) यौन संबंधी विकार

(7) कोई अन्य (विनिर्दिष्ट करें)

(ख) अधिक मातृ आयु (35 वर्ष)

(ग) माता/पिता/सहोदर भाई या बहन को आनुवंशिक रोग है (विनिर्दिष्ट करें)

(घ) अन्य (विनिर्दिष्ट करें)

8. किए गए प्रयोगशाला परीक्षण (ब्यौरे दें)

(1) गुणसूत्री अध्ययन

(2) जैव रासायनिक अध्ययन

(3) आणविक अध्ययन

9. प्रसवपूर्ण निदान का परिणाम

यदि असामान्य हो तो ब्यौरे दें।

सामान्य/असामान्य

10. तारीख/तारीखें जिसको/जिनको परीक्षण किया गया/किए गए

प्रसवपूर्ण निदान परीक्षणों के परिणाम—

को तारीख—

को सूचित किए गए।

तारीख :

चिकित्सा आनुवंशिक विज्ञान का नाम,
हस्ताक्षर और रजिस्ट्रिकरण संख्यांक

प्रारूप--व

[नियम 9(4) देखिए]

आनुवंशिक क्लिनिक का नाम, पता और रजिस्ट्रीकरण संख्याएं

आनुवंशिक क्लिनिक द्वारा रखा जाने वाला अभिलेख

1. रोगी का नाम
2. आयु
3. पति/पिता का नाम
4. पूरा पता, दूरभाष (सं. सहित) यदि कोई हो
5. डाक्टर/डाक्टरों/आनुवंशिक परामर्श केन्द्र का पूरा नाम और पता द्वारा निर्दिष्ट रोगी
(निर्देश टिप्पणी को केन्द्र के कागजपत्रों के साथ सावधानी पूर्वक परिरक्षण किया जाना है)
6. अंतिम रजिस्ट्रेशन गणनास्थान के सप्ताह
7. कुटुम्ब में आनुवंशिक आनुवंशिक रोग का वृत्तांत (विनिर्दिष्ट करें)
निदान का आधार :
 - (क) क्लिनिक
 - (ख) जैव-रासायनिक
 - (ग) कोशिका आनुवंशिक
 - (घ) अन्य (उदाहरणार्थ विकिरण चिकित्सा विज्ञान) (विनिर्दिष्ट करें)
8. प्रसवपूर्व निदान के लिए उपदर्शन
 - (क) निम्नलिखित सहित पूर्ववर्ती संतान
 - (1) गुणसूत्री विकार
 - (2) उपापचयी विकार
 - (3) जन्मजात विषमता
 - (4) मानसिक मन्दता
 - (5) हीमोग्लोबिनोपैथी
 - (6) यौन संबंधी विकार
 - (7) कोई अन्य (निर्दिष्ट करें)
 - (ख) अधिक मातृ आयु (35 वर्ष)
 - (ग) माता/पिता/सहोदर भाई बहन को आनुवंशिक रोग है
(विनिर्दिष्ट करें)
 - (घ) कोई अन्य (विनिर्दिष्ट करें)
9. की गई प्रक्रिया (स्त्री रोग विशेषज्ञ विकिरण चिकित्सा विज्ञानी रजिस्ट्रीकृत चिकित्सा व्यवसायी जिसने इसे निष्पादित किया,
का नाम रजिस्ट्रीकरण संख्याएं सहित
 - (1) अल्ट्रासाउण्ड
 - (2) एम्नियोसेंटेसिस
 - (3) कोरियोनिक दिल्ही एसपिरेशन
 - (4) भ्रूण बायोप्सी
 - (5) कॉर्डोसेंटेसिस
 - (6) कोई अन्य (विनिर्दिष्ट करें)

10. प्रक्रिया की कोई जटिलता, कृपया विनिर्दिष्ट करें
11. सिफारिश किए गए प्रयोगशाला परीक्षण
 - (i) गणसूत्री अध्ययन
 - (ii) जैव-रासायनिक अध्ययन
 - (iii) आण्विक अध्ययन
12. प्रसवपूर्व निदान प्रक्रिया

परिणाम और पता लगाई गई असामान्यता यदि कोई हो, विनिर्दिष्ट करें
13. क्या गर्भ की चिकित्सीय समापन की सलाह दी गई थी/किया गया था
14. वह तारीख/वे तारीख जिसको/जिनके प्रक्रियाएं की गई
15. वह तारीख जिसको गर्भ का चिकित्सीय समापन किया गया
16. वह तारीख जिसको सहमति प्राप्त की गई
17. प्रसवपूर्व निदान प्रक्रिया का परिणाम-----को सूचित किया गया ।

तारीख
स्थान

स्त्री रोग विशेषज्ञ चिकित्सा विज्ञानी
रजिस्ट्रीकृत चिकित्सा व्यवसाय का नाम, हस्ताक्षर और
रजिस्ट्रीकरण संख्यांक

*जो लागू नहीं या आवश्यक न हो उसे काट दें ।

प्रकाश - छ

(नियम 10 देखिए)

सहमति का प्राप्ति

मैं -----की पत्नी/पुत्री -----आयु -----वर्ष-----
की निवासी यह कथन करती हूं कि मुझे प्रसवपूर्व निदान प्रक्रियाओं के सम्भावित प्रासंगिक प्रभावों तथा उसके पश्चात् होने वाले प्रभावों के बारे में पूर्ण रूप से बताया गया है । मैं अपने हित में प्रसवपूर्व निदान प्रक्रिया कराना चाहती हूं ताकि मेरे गर्भ में पलने वाले जिण्ड में किसी असामान्यता (अर्थात् विरूपता या विकार) की संभावना का पता लगाया जा सके ।

मैं गर्भ का समापन न करने का वचन देती हूं कि यदि की गई प्रसवपूर्व प्रक्रिया और बिना प्रसवपूर्व परीक्षणों में विरूपता या विकार नहीं दिखाई देते हैं । मुझे पता है कि गर्भ भ्रूण के लिए वे बारे में मुझे नहीं बताया जाएगा ।

मुझे पता है कि इस वचन का भंग करने पर मैं शास्त्र के दायित्ववादी होऊंगी जैसा कि प्रसवपूर्व निदान तकनीक (विनियमन और दुरुपयोग निवारण) अधिनियम, 1994 (1994 का 57) में विहित है ।

तारीख

हस्ताक्षर

स्थान

मैंने उपरोक्त सहमति की विषय-वस्तु के बारे में रोगी और उसके माथी (नाम-----पता-----
-----नातेदारी-----) को उस भाषा में जिसे वह/वे समझती हैं/समझते हैं बताया दिया है ।

तारीख

स्त्री रोग विशेषज्ञ का नाम, हस्ताक्षर
और रजिस्ट्रीकरण संख्यांक का नाम

आनुवंशिक क्लिनिक का नाम, पता और
रजिस्ट्रीकरण संख्यांक

[नियम 9 (51) देखिए]

रजिस्ट्रीकरण के लिए आवेदन रजिस्ट्रीकरण की मंजूरी, रजिस्ट्रीकरण के लिए आवेदन नामंजूरी और रजिस्ट्रीकरण के नवीकरण का स्थाई अभिलेख

1. क्रम संख्यांक
2. समुचित प्राधिकारी की फाइल संख्यांक
3. रजिस्ट्रीकरण की मंजूरी के लिए आवेदन प्राप्त होने की तारीख
4. आवेदक का नाम, पता, फोन/फैक्स आदि
5. आनुवंशिक परामर्श केन्द्र/आनुवंशिक प्रयोगशाला/आनुवंशिक क्लिनिक का/के नाम और पता/पते
6. वह तारीख जिसको केस पर सलाहकार समिति द्वारा विचार किया और सलाहकार समिति की संक्षेप में सिफारिश
7. आवेदन का परिणाम (मंजूर किया गया/नामंजूर किया गया—बतार्) और आदेशों के जारी होने की तारीख
8. आबंटित रजिस्ट्रीकरण संख्यांक और रजिस्ट्रीकरण समाप्त होने की तारीख
9. नवीकरण (नवीकरण की तारीख और कब तक नवीकरण किया गया)
10. नवीकरण संबंधी फाइल संख्यांक
11. अतिरिक्त सूचना, यदि कोई हो।

समुचित प्राधिकारी का नाम,
पदनाम और हस्ताक्षर

समुचित प्राधिकारी के लिए मार्गदर्शन

- (क) प्रारूप ज समुचित प्राधिकारी को अभिरक्षा में रजिस्टर के रूप में रखा जाने वाला अस्थायी अभिलेख है
- (ख) *से अभिप्रेत है जो लागू न हो उसे काट दें।
- (ग) मद 7 के सामने, प्रारूप "ख" या प्रारूप "ग" में आदेश के जारी होने की तारीख अभिलिखित करें।
- (घ) नवीकरण होने पर आनुवंशिक परामर्श केन्द्र/आनुवंशिक प्रयोगशाला/आनुवंशिक क्लिनिक के रजिस्ट्रीकरण संख्यांक में परिवर्तन नहीं होगा। स्वामित्व या प्रबंध में परिवर्तन होने की दशा में एक नया रजिस्ट्रीकरण संख्यांक आबंटित किया जाएगा।
- (ङ) रजिस्ट्रीकरण संख्यांक दो बार नहीं दिया जाएगा।
- (च) प्रत्येक आनुवंशिक परामर्श केन्द्र/आनुवंशिक प्रयोगशाला/आनुवंशिक क्लिनिक को एक फोलियो आबंटित किया जा सकता है जिसमें प्रारूप ज अभिलिखित करने के लिए रजिस्टर के आधारे-आधारे के पृष्ठ होंगे।
- (छ) "अतिरिक्त सूचना" के लिए दिया गया स्थान नवीकरण के आवेदन के निलम्बन/रद्दकरण और नामंजूरी, स्वामित्व प्रबंध में परिवर्तन, किन्हीं विधि कार्यवाहियों, आदि का परिणाम अभिलिखित करने के लिए उपयोग किया जा सकेगा।
- (ज) रजिस्टर का प्रत्येक फोलियो (अर्थात् दो पृष्ठ) समुचित प्राधिकारी के तारीख सहित हस्ताक्षर द्वारा अधिप्रमाणित किया जाएगा और प्रत्येक पञ्चात्वर्ती प्रविष्टि को भी उसी प्रकार से अधिप्रमाणित किया जाएगा।

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Family Welfare)

NOTIFICATION

New Delhi, the 1st January, 1996

G.S.R. 1(E).—In exercise of the powers conferred by section 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) 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) "Schedule" means a Schedule appended to these rules;
- (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. Minimum requirements.—(1) The minimum qualifications of the employees, the minimum equipment and minimum place for a Genetic Counselling Centre, Genetic Laboratory and Genetic Clinic shall be as specified in Schedules I, II and III.

(2) Where an institute, hospital, nursing home, or any place, by whatever name called, provides services jointly of Genetic Counselling Centre, Genetic Laboratory and Genetic Clinic, or any combination of these, it shall conform to the requirements as specified in Schedules I, II and III.

4. Registration of Genetic Counselling Centre, Genetic Laboratory and Genetic Clinic.—(1) An application or registration shall be made to the Appropriate Authority, in duplicate, in Form A.

(2) The Appropriate Authority, or any person in his office authorised 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. 2000.00 for Genetic Counselling Centre;
- (b) Rs. 3000.00 for Genetic Laboratory;
- (c) Rs. 3000.00 for Genetic Clinic; and

(d) Rs. 4000.00 for an institute, hospital, nursing home, or any place providing jointly the services of a Genetic Counselling Centre, Genetic Laboratory and Genetic Clinic or any combination of such Centre, Laboratory or Clinic.

(2) The application fee shall be paid by a demand draft drawn in favour of the Appropriate Authority, on any scheduled bank located at the headquarters of the Appropriate Authority.

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 or Genetic Clinic 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 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 or Genetic Clinic, 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 or Genetic Clinic, 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 or Genetic Clinic, 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 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 or Genetic Clinic.

(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 and Genetic Clinic shall maintain a register showing, in serial order, the names and addresses of the women given genetic counselling, subjected to pre-natal diagnostic procedures or pre-natal diagnostic tests, the names of their husbands or fathers and the date on which they first reported for such counselling, procedure or test.

(2) The record to be maintained by every Genetic Counselling Centre, in respect of each woman counselled, shall be as specified in Form D.

(3) The record to be maintained by every Genetic Laboratory, in respect of each woman subjected to any pre-natal diagnostic test, shall be as specified in Form E.

(4) The record to be maintained by every Genetic Clinic, in respect of each woman subjected to any pre-natal diagnostic procedure, 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 a 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 or Genetic Clinic for a period of two years from the date of completion of counselling, 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 or Genetic Clinic 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.

10. Conditions for conducting pre-natal diagnostic procedures. (1) Before conducting any pre-natal diagnostic procedure, a written consent, as specified in Form G, in a language the pregnant woman understands, shall be obtained from her:

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.

(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.—Every Genetic Counselling Centre, Genetic Laboratory and Genetic Clinic shall afford reasonable facilities for inspection of the place, equipment and records to the Appropriate Authority or to any other person authorised by the Appropriate Authority in this behalf.

12. Procedure for search and seizure.—(1) The Appropriate Authority or any officer authorised in this behalf may enter and search at all reasonable times any Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic, in the presence of two or more independent and respectable persons, for the purposes of section 30.

(2) A list of any document, record, register, book, pamphlet, advertisement or any other material object found in the Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic 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 authorised 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 or Genetic Clinic, 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 authorised 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 or Genetic Clinic 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 or Genetic Laboratory or Genetic Clinic 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 authorised in this behalf may make arrangements, by way of mounting a guard or sealing of the premises of the Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic, 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 or Genetic Clinic 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 Allowances 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-officials 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 and Genetic Clinic shall prominently display on its premises a

notice in English and in the local language or languages for the information of the public, to the 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 and Genetic Clinic, 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 and Genetic Clinics 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.

[No. 2301/59/94-PLY]
K. S. SUGATHAN, Jt. Secy.

SCHEDULE I

[See rule 3 (1)]

REQUIREMENTS FOR REGISTRATION OF A GENETIC COUNSELLING CENTRE

A. PLACE

A room with an area of seven (7) square metres.

B. EQUIPMENT

Educational charts/models.

C. EMPLOYEES :

Any one of the following :—

(1) Medical Geneticist.

(2) Gynaecologist with 6 months experience, in genetic counselling, or having completed 4 weeks' training in genetic counselling.

(3) Paediatrician with 6 months experience in genetic counselling, or having completed 4 weeks' training in genetic counselling.

SCHEDULE II

[See rule 3(1)]

REQUIREMENTS FOR REGISTRATION OF A GENETIC LABORATORY

A. PLACE

A room with adequate space for carrying out tests.

B. EQUIPMENT

These are categorised separately for each of the undermentioned studies.

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% CO₂ atmosphere.
- (6) Autoclave.
- (7) Refrigerator.
- (8) Water bath.
- (9) Centrifuge.
- (10) Vortex mixer.
- (11) Magnetic stirrer.
- (12) pH meter.
- (13) A sensitive balance (preferably electronic) with sensitivity of 0.1 milligram.
- (14) Double distillation apparatus (glass).

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% CO₂ 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 beta-counter) or fluorometer for various biochemical tests.
- (12) Vortex mixer.
- (13) Magnetic stirrer.
- (14) pH meter.
- (15) A sensitive balance (preferably electronic) with sensitivity of 0.1 milligram.
- (16) Double distillation apparatus (glass).
- (17) Liquid nitrogen tank.

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 (preferably 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.

C. EMPLOYEES :

- (1) A Medical Geneticist
- (2) A laboratory technician having a B.Sc. degree in Biological Sciences or a degree or a diploma in medical laboratory course with at least one year's experience in conducting appropriate pre-natal diagnostic tests.

SCHEDULE III

[See rule 3(1)]

REQUIREMENTS FOR REGISTRATION OF A
GENETIC CLINIC

A. PLACE

A room with an area of twenty (20) square metres with appropriate aseptic arrangements.

B. EQUIPMENT

- (1) Equipment and accessories necessary for carrying out clinical examination by an obstetrician/gynaecologist.
- (2) Equipment, accessories, materials and other facilities required for operations envisaged in the Act.
 - *(a) An ultra-sonography machine.
 - *(b) Appropriate catheters and equipment for carrying out chorionic villi aspirations per vagina or per abdomen.
 - *(c) Appropriate sterile needles for amniocentesis or cordocentesis.
 - (d) A suitable foetoscope with appropriate accessories for foetoscopy, foetal skin or organ biopsy or foetal blood sampling shall be optional.
- (3) Equipment for dry and wet sterilization.
- (4) Equipment for carrying out emergency procedures such as evacuation of uterus or resuscitation in case of need.

C. EMPLOYEES

- (1) A gynaecologist with adequate experience in pre-natal diagnostic procedures (should have performed at least 20 procedures under supervision of a gynaecologist experienced in the procedure which is going to be carried out, for example chorionic villi biopsy, amniocentesis, cordocentesis and others as indicated at B above).
- (2) A Radiologist or Registered Medical Practitioner for carrying out ultrasonography. The required experience shall be 100 cases under supervision of a similarly qualified person experienced in these techniques.

*These constitute the minimum requirement of equipment for conducting the relevant procedure.

FORM A

[See rules 4(1) and 8(1)]

(TO BE SUBMITTED IN DUPLICATE)

WITH SUPPORTING DOCUMENTS AS ENCLOSURES, ALSO IN DUPLICATE

FORM OF APPLICATION FOR REGISTRATION OR RENEWAL OF REGISTRATION OF A GENETIC
COUNSELLING CENTRE/GENETIC LABORATORY/GENETIC CLINIC*

1. Name of the applicant
(specify Sh./Smt./Kum./Dr.)
2. Address of the applicant
3. Capacity in which applying
(specify owner/partner/managing director/other-to be stated)
4. Type of facility to be registered
(specify Genetic Counselling Centre/Genetic Laboratory/Genetic Clinic/any combination of these)
5. Full name and address/addresses of Genetic Counselling Centre/Genetic Laboratory/Genetic Clinic with Telephone/Telegraphic Telx/Fax E-mail numbers.

6. Type of ownership and organisation (specify individual ownership/partnership/company/co-operative/any other). In case of type of organisation other than individual ownership, furnish copy of articles of association and names and addresses of other persons responsible for management, as enclosure.
7. Type of Institution (Govt. Hospital/Municipal Hospital/Public Hospital/Private Hospital/Private Nursing Home/Private Clinic/Private Laboratory/any other to be stated).
8. Specific prenatal diagnostic procedures/tests for which approval is sought (for example amniocentesis, chorionic villi aspiration/chromosomal/biochemical/molecular studies etc).

Leave blank if registration sought for Genetic Counselling Centre only

9. (a) Space available for the Counselling Centre/Clinic/Laboratory give total work area excluding lobbies, waiting rooms, stairs etc. and enclose plan)
10. Equipment available with the make and model of each equipment. List to be attached on a separate sheet).
11. (a) Facilities available in the Counselling Centre.
(b) Whether facilities are 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
12. Names, qualifications, experience and registration number of employees. May be furnished as an enclosure (Refer Schedules I, II or III)
13. State whether the Genetic Counselling Centre, Genetic Laboratory/Genetic Clinic* qualifies for registration in terms of minimum requirements laid down in Schedule I, II and III and if not, reasons therefor.
14. For renewal applications only :
 - (a) Registration No.
 - (b) Date of issue and date of expiry of existing certificate of registration.
15. List of Enclosures :
Please attach a list of enclosures giving the supporting documents enclosed to this application.

(_____)
Name and signature of applicant

Date :
Place :

DECLARATION

I, Sh./Smt./Kumr./Dr. son/
daughter/wife of
..... aged years resident of

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, 1995.

(ii) I also undertake to explain the said Act and Rules to all employees of the Genetic Counselling Centre/Genetic Laboratory/Genetic Clinic in respect of which registration is sought and to ensure that Act and rules are fully complied with

(.....)
Name and signature of applicant

Date :

Place :

*Strike out whichever is not applicable or not necessary. All enclosures are to be authenticated by signature of the applicant.

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* 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 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 :

SEAL

*Strike out whichever is not applicable or not necessary.

ORIGINAL*
DUPLICATE FOR DISPLAY

FORM B
[Sec 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 Prenatal 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* named below for purposes of carrying out Genetic Counselling*/Prenatal Diagnostic Procedures*/Prenatal Diagnostic Tests* as defined in 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.

A. Name and address of the Genetic Counselling Centre*/Genetic Laboratory*/Genetic Clinic*

B. Name of Applicant for registration

C. Prenatal diagnostic procedures approved for (genetic clinic)

- (i) Ultrasound
- (ii) Amniocentesis
- (iii) Chorionic Villi biopsy
- (iv) Foetoscopy
- (v) Foetal skin or organ biopsy
- (vi) Cordocentesis.
- (vii) Any other (specify)

D. Prenatal diagnostic tests* approved (for Genetic Laboratory)

- (i) Chromosomal studies
- (ii) Biochemical studies
- (iii) Molecular studies

3. Registration No. allotted

4. For renewed Certificate of Registration only

Period of validity of earlier Certificate From..... To..... of Registration.

Signature, name and designation of the
Appropriate Authority.....

Date :

SEAL

*Strike out whichever is not applicable or necessary.

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)]

REJECTION OF APPLICATION FOR REGISTRATION OR
RENEWAL OF REGISTRATION

In exercise of the powers conferred under section 19(2) of the Prenatal 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* named below for the reasons stated.

Name and address of the Genetic Counselling Centre*/Genetic Laboratory*/Genetic Clinic*

Name of Applicant who has applied for registration

Reasons for rejection of application for registration

Signature, name and designation of
Appropriate Authority.....

Date :

SEAL

*Strike out whichever is not applicable or necessary.

FORM D

[See rule 9(2)]

NAME ADDRESS AND REGISTRATION. NO OF GENETIC COUNSELLING CENTRE
RECORD TO BE MAINTAINED BY THE GENETIC COUNSELLING CENTRE

1. Patient's name
2. Age
3. Husband's/Father's name
4. Full address with Tel. No. if any
5. Referred by (Full name and address of Doctor(s) with registration No.(s) (Referral note to be preserved carefully with case papers)
6. Last menstrual period/.....weeks of pregnancy
7. History of genetic/medical disease in the family (specify)
Basis of diagnosis:
 - (a) Clinical
 - (b) Bio-Chemical
 - (c) Cyto-genetic
 - (d) Other (e.g. radiological)
8. Indication for prenatal diagnosis*
 - A. Previous child/children with:
 - (i) Chromosomal disorders
 - (ii) Metabolic disorders
 - (iii) Congenital anomaly

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- (iv) Mental retardation
- (v) Haemoglobinopathy
- (vi) Sex linked disorders
- (vii) Any other (specify)
- B. Advanced maternal age (—35 years)
- C. Mother/father/sibling has genetic disease (specify)
- D. Others (specify)
- 9. Procedure advised*
 - (i) Ultrasound
 - (ii) Amniocentesis
 - (iii) Chorionic Villi biopsy
 - (iv) Foetoscopy
 - (v) Foetal skin or organ biopsy
 - (vi) Cordocentesis
 - (vii) Any other (specify)
- 10. Laboratory tests to be carried out
 - (i) Chromosomal studies
 - (ii) Biochemical studies
 - (iii) Molecular studies
- 11. Result of prenatal diagnosis:

Normal/Abnormal

 If abnormal give details.
- 12. Was MTP advised?
- 13. Name and address of Genetic Clinic*
to which patient referred.
- 14. Dates of commencement and completion of genetic counselling.

Name, Signature and Registration No.
of the Medical Geneticist/Gynaecologist/
Paediatrician.

Date

*Strike out whichever is not applicable or not necessary.

Form E
[See rule 9 (3)]

**NAME, ADDRESS AND REGISTRATION NO. OF GENETIC LABORATORY
RECORD TO BE MAINTAINED BY THE GENETIC LABORATORY**

1. Patient's name
2. Age
3. Husband's/Father's name
4. Full address with Tel. No., if any
5. Referred by/sample sent by (full name and address
of Genetic Clinic (Referral note to be preserved care-
fully with case paper).
6. Type of sample : Maternal blood/Chorionic villus
sample/amniotic fluid/Foetal blood or other foetal tissue
(Specify)

7. Specify indication for prenatal 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) Any other/(specify)
- (B) Advanced maternal age (—35 years)
- (C) Mother/father/sibling has genetic disease (specify)
- (D) Other /specify)

8. Laboratory tests carried out (give details)

- (i) Chromosomal studies
- (ii) Biochemical studies
- (iii) Molecular studies

9. Result of pre-natal diagnosis:
if abnormal, give details

Normal/Abnormal

10. Date(s) on which tests carried out

The results of the pre-natal diagnostic tests were conveyed to.....
on.....

Date

Name, signature and Registration number of the
Medical Geneticist

Form F
[See rule 9 (4)]

NAME, ADDRESS AND REGISTRATION NO. OF GENETIC CLINIC
RECORD TO BE MAINTAINED BY THE GENETIC CLINIC

1. Patient's name
2. Age
3. Husband's/Father's name
4. Full Address with Tel. No., if any
5. Referred by (full name and address of doctor(s)/Genetic Counselling Centre (Referral note to be preserved carefully with case papers).
6. Last menstrual period/.....weeks of pregnancy.
7. History of genetic/medical disease in the family (specify).

Basis of diagnosis:

- (a) Clinical
- (b) Bio-Chemical
- (c) Cyto-genetic
- (d) Other (e.g. radiological-specify)

8. Indication for prenatal diagnosis

(A) Previous child/children with:

- (i) Chromosomal disorders
- (ii) Metabolic disorders
- (iii) Congenital anomaly
- (iv) Mental retardation
- (v) Haemoglobinopathy
- (vi) Sex linked disorder
- (vii) Any other (specify)

(B) Advanced maternal age (—35 years)

(C) Mother/father/sibling has genetic disease (specify)

(D) Other (specify)

9. Procedures carried out (with name and registration No. of Gynaecologist/Radiologist/Registered Medical Practitioner) who performed it.

- (i) Ultrasound
- (ii) Amniocentesis
- (iii) Chorionic Villi aspiration
- (iv) Foetal biopsy
- (v) Cordocentesis
- (vi) Any other (specify)

10. Any complication of procedure—please specify

11. Laboratory tests recommended*

- (i) Chromosomal studies
- (ii) Biochemical studies
- (iii) Molecular studies

12. Result of pre-natal diagnostic procedure and specify abnormality detected, if any.

Normal/Abnormal

13. Was MTP advised/conducted

14. Date(s) on which procedures carried out.

15. Date on which MTP carried out.

16. Date on which consent obtained.

17. The result of pre-natal diagnostic procedure were conveyed to

.....On.....

Date
Place

Name, signature and Registration number of the
Gynaecologist/Radiologist/Registered Medical Prac-
titioner

* Strike out whichever is not applicable or not necessary.

FORM G

[See rule 10]

FORM OF CONSENT

I, wife/daughter of

ago years residing at

hereby state that I have been explained fully the probable side effects and after effects of the pre-natal diagnostic

[भाग-II कृषि 2(i)]

नमस्ते का प्रयोग, प्रयोगारम्भ

procedures. I wish to undergo the pre-natal diagnostic procedures in my interest to find out the possibility of any abnormality (i.e. deformity or disorder) in the child I am carrying.

I undertake not to terminate the pregnancy if the pre-natal procedure and any pre-natal tests conducted show the absence of deformity or disorders. 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).

Signature

Date

Place

I have explained the contents of the above consent to the patient and her companion (Name.....Address.....
.....) in a language she/they understand.
relationship.....

Date

Name, signature and Registration number of Gynaecologist

Name, address and Registration number of Genetic Clinic

FORM H

(See rule 9(5))

PERMANENT RECORD OF APPLICATION FOR REGISTRATION, GRANT OF REGISTRATION,
REJECTION OF APPLICATION FOR REGISTRATION AND RENEWALS OF REGISTRATION

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.*
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).
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 whether is not applicable.
- (c) Against item 7, record date of issue of order in Form B or Form C.
- (d) On renewal, the Registration Number of the Genetic Counselling Centre/Genetic Laboratory/Genetic Clinic will not change. A fresh registration Number will be allotted in the event of change of ownership or management.
- (e) No registration number shall be allotted twice.
- (f) Each Genetic Counselling Centre/Genetic Laboratory/Genetic Clinic may be allotted a folio consisting of two facing pages of the Register for recording Form H.
- (g) 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.
- (h) 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.



भारत का राजपत्र The Gazette of India

प्रसाधारण
EXTRAORDINARY

भाग II—खण्ड 1
PART II—Section 1

प्राधिकार से प्रकाशित
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इस भाग में मिश्र पृष्ठ संख्या दी जाती है जिससे कि यह अलग संकलन के रूप में रखा जा सके।
Separate paging is given to this Part in order that it may be filed as a separate compilation.

MINISTRY OF LAW, JUSTICE AND COMPANY AFFAIRS
(Legislative Department)

New Delhi, the 20th September, 1994/Bhadra 29, 1916 (Saka)

The following Act of Parliament received the assent of the President on the 20th September, 1994, and is hereby published for general information:—

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

No. 57 OF 1994

[20th September, 1994.]

An 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 malformations or sex linked disorders and 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.

Enacted by Parliament in the Forty-fifth Year of the Republic of India as follows:—

CHAPTER I

PRELIMINARY

1. (1) This Act may be called the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994.

Short title,
extent and
commence-
ment.

(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.

Definitions.

2. 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;

(c) "Genetic Counselling 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;

(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;

(f) "gynaecologist" means a person who possesses a post-graduate qualification in gynaecology and obstetrics;

(g) "medical geneticist" means a person who possesses a degree or diploma or certificate in medical genetics in the field of 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; or

102 of 1956.

(ii) a post-graduate degree in biological sciences;

(h) "paediatrician" means a person who possesses a post-graduate qualification in paediatrics;

(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 tissue of a pregnant woman for being sent to a Genetic Laboratory or Genetic Clinic for conducting pre-natal diagnostic test;

(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 of a pregnant woman 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

(ii) of section 2 of the Indian Medical Council Act, 1956, and whose name has been entered in a State Medical Register;

102 of 1956

(n) "regulations" means regulations framed by the Board under this Act.

CHAPTER II

REGULATION OF GENETIC COUNSELLING CENTRES GENETIC LABORATORIES AND GENETIC CLINICS

3. 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, Genetic Laboratory or Genetic Clinic shall employ or cause to be employed any person who does not possess the prescribed qualifications;

(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.

Regulation of Genetic Counselling Centres, Genetic Laboratories and Genetic Clinics.

CHAPTER III

REGULATION OF PRE-NATAL DIAGNOSTIC TECHNIQUES

4. 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 that any of the following conditions are fulfilled, namely:—

(i) age of the pregnant woman is above thirty-five years;

Regulation of pre-natal diagnostic techniques.

(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 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;

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

Written
consent of
pregnant
woman and
permission
of commu-
nicating the
sex of
foetus

5. (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 conducting pre-natal diagnostic procedures shall communicate to the pregnant woman concerned or her relatives the sex of the foetus by words signs or in any other manner.

Determi-
nation of
sex of
foetus

6. 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.

CHAPTER IV

CENTRAL SUPERVISORY BOARD

Constitu-
tion of
Central
Supervisory
Board.

7. (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, or 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) two members to be appointed by the Central Government to represent the Ministries of Central Government in charge of Woman and Child Development and of Law and Justice, *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 gynaecologists and obstetricians;

(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. (1) The term of office of a member, other than an *ex officio* member, shall be,—

Term of
office of
members.

(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 (a) of the said sub-section, 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.

Meeting
of the
Board.

9. (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.

Vacancy
in the
Board
invalidates
proceed-
ings
of the
Board

10 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.

Person
associated
with the
Board for
particular
purpose

11. (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.

Appoint-
ment of
officers
and
other em-
ployees of
the Board

12. (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. 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.

Authentica-
tion of
orders and
other in-
struments
of the
Board.

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

Disqualifi-
cations
for
appoint-
ment as
member.

(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.

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

Eligibility
of member
for re-
appoint-
ment.

16. The Board shall have the following functions, namely:—

Func-
tions
of the
Board.

(i) to advise the Government on policy matters relating to use of pre-natal diagnostic techniques;

(ii) to review implementation of the Act and the rules made thereunder and recommend changes in the said Act and rules to the Central Government;

(iii) to create public awareness against the practice of pre-natal determination of sex and 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) any other functions as may be specified under the Act.

CHAPTER V

APPROPRIATE AUTHORITY AND ADVISORY COMMITTEE

17. (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.

Appro-
priate
Autho-
rity and
Advisory
Committee.

(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, of or above the rank of the Joint Director of Health and Family Welfare; and

(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; and

(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.

(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, in the opinion of the Central Government or the State Government as the case may be, has been associated with the use or promotion of pre-natal diagnostic technique for determination of sex 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.

CHAPTER VI

REGISTRATION OF GENETIC COUNSELLING CENTRES, GENETIC LABORATORIES AND GENETIC CLINICS

18. (1) No person shall open any Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic after the commencement of this Act unless such Centre, Laboratory or Clinic is duly registered separately or jointly under this Act.

Registration
of Genetic
Counselling
Centres,
Genetic
Laboratories
or
Genetic
Clinics.

(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. (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.

Certificate
of regis-
tration.

(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.

Cancellation or suspension of registration.

20. (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).

Appeal.

21. 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—

(a) the Central Government, where the appeal is against the order of the Central Appropriate Authority; and

(b) the State Government where the appeal is against the order of the State Appropriate Authority,

in the prescribed manner

CHAPTER VII

OFFENCES AND PENALTIES

Prohibition of advertisement relating to pre-natal determination of sex and punishment for contravention.

22. (1) No person or organisation, Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic shall issue or cause to be issued any advertisement in any manner regarding facilities of pre-natal determination of sex available at such Centre, Laboratory, Clinic or any other place.

(2) No person or organisation shall publish or distribute or cause to be published or distributed any advertisement in any manner regarding facilities of pre-natal determination of sex available at any Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic or any other place.

(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 other document and also includes any visible representation made by means of any light, sound, smoke or gas.

23. (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.

Offences and penalties.

(2) The name of the registered medical practitioner who has been convicted by the court under sub-section (1), shall be reported by the Appropriate Authority to the respective State Medical Council for taking necessary action including the removal of his name from the register of the Council for a period of two 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 or Genetic Clinic or of a medical geneticist, gynaecologist or registered medical practitioner for conducting pre-natal diagnostic techniques on any pregnant woman (including such woman unless she was compelled to undergo such diagnostic techniques) for purposes other than those specified in clause (2) of section 4, 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.

1 of 1872.

24. Notwithstanding anything in the Indian Evidence Act, 1872, the court shall presume unless the contrary is proved that the pregnant woman has been compelled by her husband or the relative to undergo pre-natal diagnostic technique 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.

Presumption in the case of conduct of pre-natal diagnostic techniques.

25. 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.

Penalty for contravention of the provisions of the Act or rules for which no specific punishment is provided.

Offences
by com-
panies.

26. (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.

Offence to
be cogni-
zable, non-
bailable
and non-
compound-
able.

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

Cognizance
of offences.

28. (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 thirty 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 sub-section (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. (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;

Maintenance of records.

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. (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, 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 and examine any record, register, document, book, pamphlet, advertisement or any other material object found therein and seize 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.

Power to search and seize records, etc.

2 of 1974.

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

31. 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.

Protection of action taken in good faith.

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

Power to make rules.

(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 (1) of section 3;

(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 subsection (4) of section 8;

(iv) allowances for members other than *ex officio* members admissible under sub-section (5) of section 9;

(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.

Power
to make
regula-
tions.

33 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. 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.

Rules and regulations to be laid before Parliament.

K. L. MOHANPURIA,
Secy. to the Govt. of India.

DRAFT

GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF FAMILY WELFARE

Proposed Amendments in PNDT Act 1994

1. TITLE

Existing Title:

The Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994.

Suggested Title:

"The Sex Selection and Pre-Natal Diagnostic Techniques (Prohibition and Regulation) Act, 2002"

2. LONG TITLE (PREAMBLE)

Existing Long Title :

An Act to provide for regulation of the use of pre-natal diagnostic techniques for the purpose of detecting genetic or metabolic disorders, chromosomal abnormalities or certain congenital malformations or sex-linked disorders and for the prevention of misuse of such techniques for the purpose of prenatal sex determination leading female foeticide and for matters connected therewith or incidental thereto.

Suggested Long Title:

An Act to provide for prohibition of sex selection, before or after conception, and for regulation of and 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.

CHAPTER 1
PRELIMINARY

3. Add the following to sub-section (b) of section 2:-

“or State/UT Supervisory Board constituted under Section 16 A”

4. Add the following explanation below sub-section (d) of Section 2:-

“Explanation – Any place, including a vehicle, where ultrasound machine/imaging machine (capable of determining sex of foetus) or any other equipment including portable equipment which has the potential for detection of sex during pregnancy or selection of sex before conception, is used shall fall within the above definition of Genetic Clinic.”

5. Add the following explanation below sub-section (e) of Section 2:-

“Explanation – Any place, where ultrasound machine/imaging machine (capable of determining sex of foetus) or any other equipment including a portable equipment which has the potential for detection of sex during pregnancy or selection of sex before conception, is used shall fall within the above definition of Genetic Laboratory.”

6. Substitute Sub Section (g) of Section 2 with the following: -

“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 *any of these fields* after obtaining –

(i) any one of the medical qualifications recognized under the Indian Medical Council Act, 1956; or

(ii) a post graduate degree in biological sciences”;

7. Substitute sub-section (i) of sub-section (2) with the following:-

“(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 willi, **embryo**, blood or any **other tissue or fluid of a men, or of 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;**”

Add to the definitions, the following

In sub-section (k) of section 2 add "*or fluid*" after the word "any tissue" and "*or conceptus*" after the words "pregnant woman".

8. Add the following definition

(o) "*Sonologist/Imaging Specialist*" means a person who possesses any one of the medical qualifications recognised under the Indian Medical Council Act 1956 or who possesses a post graduate qualification in ultrasonography/imaging techniques/radiology.

9. Add the following definitions

(p) "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.

(q) "Embryo"

means a developing human organism after fertilization till the end of eight weeks (56 days).

(r) "Foetus"

means a human organism during the period of its development beginning on the 57th day following fertilization or creation (excluding any time in which its development has been suspended) and ending at birth.

(s) "Conceptus"

The product of conception at any stage of development from fertilization until birth including extra embryonic membranes as well as the embryo or foetus.

CHAPTER II

REGULATION OF GENETIC COUNSELING CENTRES, GENETIC LABORATORIES AND GENETIC CLINICS.

10. Amendment of section 3:

Existing sub-section (2)

- (2). no genetic counseling center, genetic laboratory or genetic clinic shall employ or cause to be employed any person who does not possess the prescribed qualifications

Suggested sub-section (2)

- (2) no genetic counseling center, 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 the prescribed qualifications:

Justification: Unqualified person should not be employed by the centre/ clinic/ laboratory.

Add: Following explanation may be added after sub-section (3) of Section 3 of the Act:-

“Explanation - Any person/body/institution, by whatever name called, using ultrasound machines/imaging machine/scanner or other equipment capable of detecting sex of foetus of a pregnant woman or capable of selection of sex before or after conception shall be treated as a genetic clinic and shall be registered as such clinic under this Section”

11. Add the following chapter: -

CHAPTER II A PROHIBITION OF SEX SELECTION

“3 A. 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/themselves or by any other person, a sex selection technique 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.”

Justification: Include prohibition of pre-conception sex selection
Ref: SC order, ref to emerging technologies.

CHAPTER III

REGULATION OF PRENATAL DIAGNOSTIC TECHNIQUES

12. **Amendment of Section 4:**

Existing Sub-Section (3)

- (3) no prenatal diagnostic techniques shall be used or conducted unless the person qualified to do so is satisfied that any of the following conditions are fulfilled namely:
- (i) age of the pregnant woman is above 35 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 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.

Suggested Sub-Section (3)

(3) no prenatal 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 35 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.

Add: The following proviso may be added below Section 4(3):-

“Provided that the person conducting ultrasonography on a pregnant woman shall keep complete record thereof in the clinic in prescribed manner and any deficiency or inaccuracy found therein shall amount to deliberate contravention of the provisions of Sections 5 and 6 punishable under Section 23 unless contrary thereto is proved by the person conducting ultrasonography.”

13. Existing Sub Section (4)

(4) no person being 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 purpose specified in the clause (2).

Suggested Sub Section (4)

(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 purpose specified in the clause (2).

Justification: to include people other than husband or relative

14. **Add:** 4(5) *no person, including a relative or the husband of a woman shall seek or encourage the conduct of any sex selection technique on her, of him or both.*

Justification: Including pre-conception sex selection

15. **Amendment of Section 5**

Prohibition on communicating the sex of foetus:

Existing Sub Section (2)

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

Suggested Sub Section (2)

(2) No person *including* the person conducting prenatal 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.

Justification: Violation of law often takes place through the agent of gynecologist/sonologist, rather than the specialist himself / herself.

16. **Add** sub-section (3) to section 5:

[the proposed addition of sub-section (3) to Section 5 has been dropped in view of Ministry of Law's suggestion – para No. 2(v)]

17. **Amendment of Section 6**

Add clause (c)

“(c) No person shall, by whatever means, cause or allow to be caused selection of sex before or after conception.”

Justification: To include pre-conception sex selection.

17A. **Amendment of Section 7**

The existing Section 7(2)(c) may be substituted as under:

“(c) three members to be appointed by the Central Government to represent the Ministries of Central Government in charge of Women and Child

Development, Law and Justice and Indian System of Medicine and Homeopathy, ex-officio;"

The existing section 7(2)(e)(ii) may be substituted as under:

"(ii) eminent gynaecologist and obstetricians/experts of Stri Roga/Prasuti Tantra;"

CHAPTER IV

CENTRAL SUPERVISORY BOARD

DISQUALIFICATION FOR APPOINTMENT AS MEMBERS:

18. **Amendment of Section 14 (f)**

Existing clause (f)

(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.

Suggested Clause (f)

(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 of any sex selection technique.*

Justification: Inclusion of sex selection technique.

19. **Add the following proviso below section 15:-**

"Provided that no member other than ex-officio members shall serve the board for more than two full terms"

20. **Amendment of Section 16**

Existing Clause

16(i) To advise the government on policy matters relating to use of prenatal diagnostic techniques,

Suggested Clause

16(i) To advise the government on policy matters relating to use of prenatal diagnostic techniques, *sex selection techniques and their misuse.*

21. **Existing clause**

16(ii) to review implementation of the Act and rules made thereunder and recommend changes in the said Act and rules to the Central Government.

Suggested Clause

16(ii) to review *and monitor* implementation of the Act and rules made thereunder and recommend changes in the said Act and rules to the Central Government.

Justification: To implement the direction of the Supreme Court

22. **Existing clause**

16(iii) To create public awareness against the practice of prenatal determination of sex and female foeticide.

Suggested Clause

16(iii) To create public awareness against the practice of *sex selection* and prenatal determination of sex *leading to* female foeticide.

Justification: Avoid antiabortion terminology
Add pre-conception sex selection

23. Add the following sub-section (v) to section 16:-

“(v) To oversee the performance of various bodies constituted under this Act and take appropriate steps to ensure its proper and effective implementation”

Re-number the existing sub-section (v) as sub-section (vi) in section 16.

24. Add : **CHAPTER IV-A**

“CHAPTER IV-A”

Add Section 16A:

“16-A.

(1) *Government of each State/UT with legislature shall constitute a Board known as the State/UT Supervisory Board which shall have the following functions in respect of the areas falling under the State/UT :*

(i) *to create public awareness against the practice of pre-conception sex selection and prenatal determination of sex of foetus leading to female foeticide in the concerned State/UT;*

- (ii) *to review the activities of the Appropriate Authorities functioning in the State and take appropriate action against the Appropriate Authorities, as provided in their conduct rules, in case of dereliction of duty;*
 - (iii) *to monitor and review implementation of the provision of the Act and Rules in the State/UT; and*
 - (iv) *to send consolidated reports as may be required under the rules, in respect of the various activities under this Act to the Central Supervisory Board and the Central Government.*
 - (v) *Any other functions as may be specified in the Act.*
- (2) *The State/UT Supervisory Board shall consist of :-*
- (a) *The Minister incharge of Health/Family Welfare in the State who shall be the Chairman, ex-officio*
 - (b) *Secretary incharge of Department of Health/Family Welfare who shall be the Vice-Chairman, ex-officio*
 - (c) *Secretaries/Commissioners in-charge of Departments of Women and Child Development, Social Welfare, Law and Indian System of Medicines and Homeopathy (ISM&H), ex-officio or their representatives*
 - (d) *Director of Health and Family Welfare/ISM&H of the State Government, ex-officio*
 - (e) *Three women members of Legislative Assembly*
 - (f) *Ten members to be appointed by the State/UT Government two each from amongst:-*
 - (i) *eminent social scientists including legal expert*
 - (ii) *eminent women activists/NGOs*
 - (iii) *eminent gynaecologist & Obstetricians/ Stri Roga/Prasuti Tantra*
 - (iv) *eminent pediatrician*
 - (v) *eminent radiologists/sonologist*
 - (h) *An officer not below the rank of Joint Director incharge of Family Welfare will be Member Secretary, ex-officio*
- (3) *The Board shall meet at least once in four months.*
- (4) *The terms 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 non-ex-officio member, it shall be filled by making fresh appointment.*
- (6) *If an MLA/MLC who is a member of the State/UT Supervisory Board becomes Minister or Speaker/Deputy Speaker of the Legislative*

Assembly or Chairperson/Deputy Chairperson of the Legislative Council, she shall ceased to be a member of the Board.

- (7) *One-third of the total number of members of the Board shall constitute the quorum.*
- (8) *The Board may co-opt member as and when required, provided that the number of co-opted members does not exceed one third of the total strength of the 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 same rules and regulations as others.*
- (9) *In matters not specified in section 16 A, the board shall follow procedures and conditions as applicable to the Central Supervisory Board.*

Justification: A Supervisory Board is considered necessary at the State/UT level to review and monitor the activities of the Appropriate Authorities and to ensure that quarterly reports/returns are filed to the Central Supervisory Board correctly and timely.

CHAPTER V

APPROPRIATE AUTHORITY AND ADVISORY COMMITTEE

25. Amendment of Section 17

Existing Section 17(3)

17(3): The officers appointed as appropriate authorities under sub-section (1) or sub section (2) shall:

- (a) when appointed for the whole of the State or the Union Territory of or above the rank of Joint Director of Health and Family Welfare, and

Suggested Section 17(3)

17(3): The officers appointed as appropriate authorities under sub-section (1) or sub section (2) shall:

- (a) when appointed for the whole of the State or the Union Territory *consist of the following three members -*
 - (i) *an officer of or above the rank of the Joint Director of Health and Family Welfare when appointed for the whole of the State or Union Territory or an officer not below the rank of Civil Surgeon/District Health Officer (when appointed for a part of State or UT - Chairperson;*

- (ii) *an eminent woman representing women's organization; and*
- (iii) *an officer of Law Department of State/UT concerned.*

Provided that it shall be the duty of the Government of the State/UT concerned to constitute the multi-member State/UT level Appropriate Authority within three months of coming into force of the amended provisions of this Act and that vacancies occurring therein shall be filled within three months of occurrence thereof."

Justification: to make it more efficient with the support of women member and a legal expert

26. Add the following clauses to sub-section (4) of section 17:

- (e) *to take appropriate legal action against the use of sex selection techniques by any person at any place, brought to its attention or suo moto and also to initiate independent investigations in such matters.*
- (f) *to create public awareness against the practice of sex selection or pre-natal determination of sex*
- (g) *to supervise the implementation of the provision of the Act and Rules,*
- (h) *to recommend to the Central Supervisory Board and State Supervisory Board modifications required in the Act or Rules in accordance with changes in technology or social conditions.*
- (i) *to take action on the recommendations of the Advisory Committee on the complaint received and investigated by the Advisory Committee."*

Justification: I) Define functions clearly.
II) Include pre-conception sex selection.

27. Add: Section 17A - Powers of Appropriate Authorities:

17-A. The Appropriate Authority shall have the same powers as are vested in a civil court under the Code of Civil Procedure, 1908 (5 of 1908), while trying a suit in respect of the following matters, namely:

- (a) *The summoning and enforcing attendance of any person and examining him on oath or on solemn affirmation;*
- (b) *The discovery and production of any document or material object producable as evidence;*
- (c) *The reception of evidence on affidavits;*
- (d) *Issuing of any commission for the examination of any witness;*
- (e) *Issuing search warrant for any place suspected to be indulging in sex selection techniques or pre-natal sex determination; and*
- (f) *Any other matter which may be prescribed.*

Justification: without these powers, appropriate authority will not be able to discharge its functions.

28. **Add:** Sub-Section 17(6B) -

[the proposed addition of Section 17(6B) has been dropped in view of Ministry of Law's suggestion – para No. 2(viii)]

29. **Existing Section 17(7)**

17(7) No person, who in the opinion of the Central Government or the state government, as the case may be, has been associated with the use or promotion of prenatal diagnostic techniques for determination of sex shall be appointed as a member of the Advisory Committee.

Suggested Section 17(7)

17(7) No person, who in the opinion of the Central Government or the state government, as the case may be, has been associated with the use or promotion of prenatal diagnostic techniques for determination of sex *or sex selection* shall be appointed as a member of the Advisory Committee.

Justification – include pre-conception sex selection.

CHAPTER VI

REGISTRATION OF GENETIC COUNSELING CENTRES, GENETIC LABORATORIES AND GENETIC CLINICS

30. **Amendment of Section 18(1)**

Existing Section 18(1)

18(1) No person shall open any Genetic Counselling Centre, Genetic Laboratory or genetic clinics after the commencement of this Act unless such, Centre, Laboratory or Clinic is duly registered separately or jointly under this Act.

Suggested Section 18(1)

18(1) No person shall open **or render services** to any Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic, *including clinic, laboratory or centre having ultrasound /imaging machine/ any other technology capable of undertaking determination of sex of foetus and sex selection*, after the

commencement of this Act unless such Centre, Laboratory or Clinic is duly registered separately or jointly under this Act.

Justification: Registration of ultrasound machines which have the potential of determining sex of the foetus.

CHAPTER VII

OFFENCES AND PENALTIES

31. Amendment of Section 22

Existing Section 22(1)

22.(1): No person, organization, genetic counseling centre, genetic laboratory or genetic clinic shall issue or cause to be issued any advertisement in any manner regarding facilities of pre-natal determination of sex, available at such centre, laboratory, clinic or any other place.

Suggested Section 22(1)

22.(1): No person, organization, genetic counseling centre, genetic laboratory or genetic clinic, *including clinic, laboratory or centre having ultrasound machine or any other technologies capable of undertaking determination of sex of foetus* or sex selection shall issue or cause to be issued, publish or cause to be published any advertisement in any *form including Internet* regarding facilities of pre-natal determination of sex or *sex selection before conception* available at such centre, laboratory, clinic or at any other place.

Justification: To include ultrasound machines and pre-conception sex selection and advertisement thereof on Internet.

32. Add Section 22(1A):

[the proposed addition of Sections 22(1A) and 22(2A) have been dropped and sub-sections (1) and (2) of Section 22 modified in view of Ministry of Law's suggestion – para No.2(ix)]

33. Existing Section 22(2)

22(2): No person or organization shall publish or distribute or cause to be published or distribute any advertisement in any manner regarding facilities of pre-natal determination of sex available at any genetic counseling centre, genetic laboratory, genetic clinic or any other place.

Suggested Section 22(2)

22(2): No person or organization including genetic counseling centre, genetic laboratory or genetic clinic shall issue, publish, distribute or communicate or cause to be issued, published, distributed or communicated any advertisement in any manner regarding pre-natal determination/pre-conception selection of sex by any means scientific or otherwise.

34. Explanation below Section 22(3) may be modified as under:

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

35. **Add** Section 22(4):

[the proposed addition of Section 22(4) has been dropped in view of Ministry of Law's suggestion – para No. 2(x)]

36. **Amendment of Sub Section 23(2)**

Existing Sub Section 23(2)

The name of the registered Medical Practitioner **who has been convicted by the Court under Sub-Section (1)**, shall be reported by the Appropriate Authority to the respective State Medical Council for taking necessary action including the removal of his name from the register of the Council for a period of two years for the first offence and permanently for the subsequent offence.

Suggested Sub Section 23(2)

The name of the registered Medical Practitioner, shall be reported by the Appropriate Authority to the respective State Medical Council for taking necessary action including *suspension of registration till the disposal of the complaint, if the charges are framed, and 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 *if convicted*.

37. **Amendment of Section 23(3)**

Existing Section 23(3)

23(3): Any person who seeks the aid of a genetic counseling centre, genetic laboratory or genetic clinic or of a medical geneticist, gynecologist or registered

medical practitioner for conducting prenatal 'diagnostics techniques on any pregnant women (including such woman unless she was compelled to undergo such diagnostic techniques) for purposes other than those specified in clause (2) of section 4 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.

Suggested Section 23(3)

23(3) Any person who seeks the aid of *any* genetic counseling centre, genetic laboratory, genetic clinic *or ultrasound clinic /imaging clinic* or of a medical geneticist, gynecologist, *sonologist/ imaging specialist* or registered medical practitioner or *any other person* for *sex selection or for* conducting prenatal diagnostics techniques on any pregnant women (*excluding such woman*) for purposes other than those specified in clause (2) of section 4 shall be punishable with imprisonment for a term which may extend to three years and with fine which may extend to *fifty* thousand rupees and on any subsequent conviction with imprisonment which may extend to five years and with fine which may extend to *one lakh* rupees.

38 Amendment of section 24

Notwithstanding anything in the Indian Evidence Act, 1872, the court shall presume unless the contrary is proved that the pregnant women has been compelled by her husband or the relative to undergo pre-natal diagnostic technique 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.

Suggested Amendment of section 24

Notwithstanding anything in the Indian Evidence Act, 1872, the court shall presume unless the contrary is proved that the pregnant women has been compelled by her husband or the relative to undergo pre-natal diagnostic technique *for the purpose 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.

39. **Amendment of Section 28(1)**

Existing Section 28(1)

Cognizance of offence: Sec 28 (1)

No court shall take cognizance of an offence under this, except on a complaint made by-

- (a) the appropriate authority concerned, or any office authorized 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 thirty 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 organization.

Suggested Section 28(1)

Cognizance of offence: Section 28 (1)

No court shall take cognizance of an offence under this, except on a complaint made by-

- a. the appropriate authority concerned, or any officer authorized 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 organization.

Justification: To curtail delay on the part of Appropriate Authority to file a complaint in the court.

CHAPTER VIII
MISCELLANEOUS

40. **Existing Section 30(1)**

Power to search, seize records etc.

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 counseling centre, genetic

laboratory or genetic clinic, such authority or any officer authorized 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 counseling centre, genetic laboratory or genetic clinic and examine any record, register, document, book, pamphlet, advertisement or any other material object found therein and seize 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.

Suggested Section 30(1)

Power to search, seize records etc.

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 counseling centre, genetic laboratory, genetic clinic *or any other place* such authority or any officer authorized 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 counseling centre, genetic laboratory, genetic clinic *or any other place* and examine any record, register, document, book, pamphlet, advertisement or any other material object found therein and seize or *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.

Justification: offence may be committed at places other than registered clinic / lab/ centre.

41 **Add:** Following Section may be added after Section 34 of the Act:-

“35. For the purpose of avoiding any conflicting interpretations and to make this Act harmonious, all consequential changes, which have not been explicitly incorporated, shall be deemed to have been made.”

Statement of Objects and Reasons:

The prenatal diagnostic techniques like amniocentesis and sonography are useful for the detection of genetic or chromosomal disorders or congenital malformations or sex linked disorders etc. However, they are being used on a large scale to detect the sex of the foetus and to terminate the pregnancy of the unborn child if found to be female. Techniques are also being developed to pre-select the sex of child before conception. These practices are wholly discriminatory to the female sex and affect the dignity and status of women. They also contravene the principles of medical ethics. They are violative of Article 14 of the Constitution of India, that guarantees equality before law and equal protection of law to woman and also of Article 51A that lays down the duties of every citizen to renounce practices derogatory to the dignity of women. The proliferation of these technologies may, in future, precipitate a catastrophe, in the form of severe imbalance in male-female ratio. The State is also duty bound to intervene in such matters to uphold the welfare of society, specially of the women and children. It is therefore necessary to enact and implement in letter and spirit a legislation to ban the pre-conception sex selection techniques and the misuse of pre-natal diagnostic techniques for sex-selective abortions and to provide for the regulation of the later for the appropriate scientific use for which they are intended. Such a law is also needed to uphold medical ethics and initiate the process of regulation of medical technology in the larger interests of society.

Accordingly, it is proposed to amend the Act with a view to include emerging technologies such as pre-conception sex selection and ensuring effective implementation of the Act at all levels.

IN THE SUPREME COURT OF INDIA
CIVIL ORIGINAL JURISDICTION
WRIT PETITION (CIVIL) No. 301 of 2000

Centre for Enquiry Into Health
And Allied Themes (CEHAT) & Ors.

... Petitioners

Versus

Union of India & Others

... 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 has affected overall sex ratio in various States where female infanticide 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 to as "the PNDT 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 infanticide and for matters connected therewith or incidental thereto. The Act came into force from 1st 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 center of

Anusandhan Trust based 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. Georges who is having experience and technical knowledge in the field. After filing 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 nor 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 Supervisor/

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 advise 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 scientists 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 the 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 all 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 the 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 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.
- (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 30th July 2001. List the matter on 6.8.2001 for further directions at the bottom of the list.

New Delhi;
May 4, 2001.

REC'D (M.B. Shah)
S.N. Variava

OUT TODAY

17.8.2001
D.NO. 1476/2000/SC/PILC

MATTER FOR
10.8.2001

256
DATED: 8th August, 2001

FROM : Inder Pal
Assistant Registrar(PIL.CELL)

TO : Mr. D.S. Mahra, Advocate

IN THE MATTER OF:

WRIT PETITION (CIVIL) NO. 301 OF 2000
(Under Article 32 of the Constitution of India)

Centre for Enquiry into Health and Allied Themes (CEHAT) & Ors. ... Petitioners

Versus

Union of India & Ors. ... Respondents

Sir,

I am to inform you that the Writ Petition above-mentioned came up for hearing before the Court on 6th August, 2001 when the Court was pleased to pass the following Order:-

"As per the office Report dated 2nd August, 2001 the following States/Union Territories have not filed their affidavits despite specific directions..

State of Arunachal Pradesh, Assam, Bihar, Chhattishgarh, Gujarat, Himachal Pradesh, Jammu & Kashmir, Jharkhand, Kerala, Maharashtra, Manipur, Meghalaya, Mizoram, Nagaland, Sikkim, Tamil Nadu, Tripura, Uttar Pradesh, Uttaranchal, Union Territory of Andaman & Nicobar Islands, Chandigarh, Dadar & Nagar Haveli and Lakshadweep.

However, learned counsel for some of the States submit that on or after 2nd August, 2001 some States have tendered

...2/-

255

- 2 -

their affidavit. Hence office to prepare a fresh Report and submit to this Court on 10th August, 2001.

In the meanwhile, learned counsel appearing for the Union of India to prepare a chart stating how many States/Union Territories have complied with the directions issued by this Court and also to state specifically which directions are not complied with. For the time being Registry to supply copies of the affidavits to the counsel for Union of India as well as to the counsel for the petitioner.

Adjourned to 10.8.2001."

As per directions of the Court, you are requested to file forthwith, a chart stating how many States/Union Territories have complied with the directions issued by this Court and also to state specifically which directions are not complied with.

Yours faithfully,

[Signature]
ASSISTANT REGISTRAR

[Signature]

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)

With Appln(s). for permission to submit additional document(s)
and exemption from filing O.T. ~~exemption~~
(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

For Petitioner (s)

Ms. Indira Jaising, Sr. Adv.,
Mr. Sanjay Parikh, Adv.,
Mr. R.R. Chandrachud, Adv.,
Ms. Jayna Kothari, Adv.

For Respondent (s)

Attorney General for India (N/P)

For UOI:

Krishan Mahajan, Adv.,
Ms. Sunita Sharma, Adv.,
Mr. D.S. Mahra, Adv.

for Gujarat State:

Ms. Hemantika Wahi, Adv.

for Orissa State:

Mr. Radha Shyam Jena, Adv.

for Jharkhand State:

Mr. Ashok Mathur, Adv.,

Mr. Rakesh Pathak, Adv.

for Rajasthan State:

Mr. Javed Mahmud Rao, Adv.,

Mr. Ranji Thomas, Adv.

for Kerala State:

Mr. K.R. Sasiprabhu, Adv.,

Mr. John Mathew, Adv.

for Haryana State:

Mr. J.P. Phanda, Adv.,

Mr. K.P. Singh, Adv.

for Goa State:

Mr. Bhawani Shankar Gadnis, Adv.,

Mr. Shiv Sagar Tiwari, Adv.,

Ms. Divya Suri, Adv.

for Karnataka State:

Mr. Sanjay R. Hegde, Adv.,

Mr. Satya Mitra, Adv.

for Punjab State:

Ms. Jayshree Anand, AAG Punjab

Mr. Kaleev Sharma, Adv.

for Nagaland State:

Mrs. V.D. Khanna, Adv.,

Mr. Sanjay K. Shandilva, Adv.

for Maharashtra State:

Mr. V. Deshpande, Adv.

for Manipur State:

Mr. Phwalrakpam Nobin Singh, Adv.

for Andhra Pradesh State: Ms. T. Anamika. Adv.,
 Mr. Guntur Prabhakar. Adv.
 for Arunachal Pradesh: Mr. Anil Shrivastav, Adv.
 for Meghalaya State: Mr. Ranjan Mukherjee, Adv.
 for Tamil Nadu State: Mr. T. L. Viswanatha Iyer, Sr. Adv.,
 Mr. V. Balaji. Adv.,
 for West Bengal State: Mr. P. N. Ramalingam, Adv.,
 Mr. Tara Chandra Sharma, Adv.,
 Mr. Ajay Sharma, Adv.,
 Ms. Neelam Sherma, Adv.
 for Madhya Pradesh: Mr. S. K. Agnihotri, Adv.,
 Mr. Sakesh Kumar, Adv.,
 Mr. B. B. Singh, Adv.,
 Mr. R. C. Verma, Adv.,
 for Bihar State: Mr. V. G. Pragasaam, Adv.,
 for U.P. State: Ms. Rachana Srivastava, Adv.,
 for Pondicherry: Mr. Mahesh Chandra, Adv.,
 for Uttranchal: Mr. Prakash Shrivastava, Adv.,
 Ms. Asha G. Nair, Adv.,
 for Chhattisgarh: Ms. Krishna Sharma, Adv.,
 for Assam State: Mr. V. K. Sidharthan, Adv. for
 M/s. Corporate Law Group
 Ms. Kamini Jaiswal, Adv.,
 for UT Chandigarh: Ms. Shomila Bakshi, Adv.,
 Ms. Aiswarya Rao, Adv.,
 for Tripura State: Mrs. Vimla Sinha, Adv.,
 Mr. Gopal Singh, Adv.,
 for Himachal Pradesh: Mr. Naresh K. Sharma, Adv.,
 for Sikkim State: Ms. Aruna Mathur, Adv.,
 Mr. A. Mariarputham, Adv.,
 for J & K State: Mr. Anis Suhrawardy, Adv. (N/P)
 for Intervenor: Mr. Jay Savla, Adv.,
 Ms. Reema Bhatnagar, Adv.

UPON hearing counsel the Court made the following
 O R D E R

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

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)

(With Appln(s) for permission to submit additional document(s)
and exemption from filing O.T. and impleading party)

Date : 11/12/2001 This Petition was called on for hearing today.

CORAM :

HON'BLE MR. JUSTICE H.B. SHAH
HON'BLE MR. JUSTICE B.N. AGRAWAL
HON'BLE MR. JUSTICE ARIJIT PASAYAT

For Petitioner (s)

Ms. Indira Jaising, Sr. Adv.,
Mr. Sanjay Parikh, Adv.,
Mr. Avinash K. Misra, Adv.,
Mr. R.R. Chandrachud, Adv.,
Ms. Jayna Kothari, Adv.,
Mr. A.N. Singh, Adv.

For Respondent (s)

Attorney General for India (N/P)

for UOI:

Krishan Mahajan, Adv.,

for Delhi State:

Ms. Sunita Sharma, Adv.,
Mr. D.S. Mahra, Adv.

for Gujarat State:

Ms. Hemantika Wahi, Adv.,
Mr. Radha Shyam Jena, Adv.,

for Orissa State:

Mr. Ashok Mathur, Adv.,

for Jharkhand State:

Mr. Rajesh Pathak, Adv.,

for Rajasthan State:

Mr. Ranjit Thomas, Adv. for
Mr. Javed Mahmood Rao, Adv.,

for Kerala State:

Mr. K.R. Sasiprabhu, Adv.,

for Haryana State:

Mr. J.P. Dhanda, Adv.,
Mr. K.P. Singh, Adv.

for Goa State:

Mr. Bhawani Shankar Gadnis, Adv.,
Mr. Shiv Sagar Tiwari, Adv.,

for Karnataka State:

Mr. Sanjay R. Hegde, Adv.,

for Punjab State:

Mr. Satya Mitra, Adv.,
Ms. Jayshree Anand, AAG Punjab

Andhra Pradesh State: Mr. Guntur Prabhakar, Adv.
 Arunachal Pradesh : Mr. Anil Shrivastav, Adv.
 Meghalaya State: Mr. Ranjan Mukherjee, Adv.
 or Tamil Nadu State: Mr. T. L. Viswanatha Iyer, Sr. Adv.,
 Ms. Shweta Garg, Adv.,
 Ms. Revathy Raghavan, Adv.
 Mr. P. N. Ramalingam, Adv.
 for West Bengal State: Mr. Tara Chandra Sharma, Adv.,
 Mr. Ajay Sharma, Adv.,
 for Madhya Pradesh: Mr. S. K. Agnihotri, Adv.,
 Mr. Sakesh Kumar, Adv.
 for Bihar State: Mr. B. B. Singh, Adv.
 for U.P. State: Mr. R. C. Verma, Adv.
 for Pondicherry: Mr. V. G. Pragasam, Adv.
 for Uttranchal : Ms. Rachana Srivastava, Adv.
 for Chhatisgarh: Mr. Prakash Shrivastava, Adv.
 for Assam State: Ms. Asha G. Nair, Adv.,
 Mr. V. K. Sidharthan, Adv. for
 M/s. Corporate Law Group
 for UT Chandigarh: Ms. Kamini Jaiswal, Adv.,
 Ms. Shomila Bakshi, Adv.,
 Ms. Aiswarya Rao, Adv.
 for Tripura State: Mrs. Vimla Binha, Adv.,
 Mr. Gopal Singh, Adv.,
 Mr. Rahul Singh, Adv.
 for Himachal Pradesh: Mr. Naresh K. Sharma, Adv.
 for Sikkim State: Ms. Aruna Mathur, Adv.,
 Mr. A. Mariarputham, Adv.
 for J & K State: Mr. Anis Suhrawardy, Adv.
 for intervenor: Mr. Jay Savla, Adv.,
 Ms. Reema Bagga, Adv.,
 Ms. M. Ogra, Adv.

UPON hearing counsel the Court made the following

ORDER

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 statistice 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 filed 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. For non-compliance of the orders passed by this Court, Secretary (Health Department) of the following States are directed to remain present before this Court on 29.1.2002.

"(1) Punjab, (2) Delhi, (3) Bihar, (4) Rajasthan, (5) Gujarat, (6) Haryana, (7) Uttar Pradesh, (8) Maharashtra, and (9) West-Bengal."

It is alleged by the learned counsel for the petitioners that Dr. Dahiya 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 newspapers' 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 unjustified one. In addition, the State of Haryana through its Health Secretary is directed to file necessary affidavit stating reasons for transfer of Dr. Dahiya.

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, names 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 addressees and also service contract to those clinics or individual as the case may be.

1. Uma Parameshwaran, CEO, Wipro Ge Medical Systems Ltd., A-1, Corporate Towers, Golden Enclave, Airport Road, Bangalore - 560017. ✓
2. Toehbro Shimandzu Ltd., Khatan Bhawan, 2nd floor, Mumbai - 400020. ✓
3. Erbis Engineering Co.Ltd., 2E/12, 4th Jhandewalan Extn., New Delhi - 110005. ✓
4. V. Prabhakar, CEO, ATL India Ltd., 79 & 94, Developed Plots, Perungudi, Chennai - 600096. =
5. Larsen & Toubro Ltd. (Medical Equipment Divn.), LAT House, 10, Club House Road, Anna Salai, Post Bag NO. 55247, Chennai - 600002. X
6. International Medical Services Pvt.Ltd., 17 Industrial Estate, Maruti Complex, Gurgaon - 122015. ✓
7. A.K. Khosla, 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, Poorvi Marg, Vasant Vihar, New Delhi - 110057. }
9. Siemens Ltd., Mahape Workshop Shilphata Road, Behind MIDC Area Off Thane Belapur Road, Vill.Mahape, Thane - 400601. X }

: -5:-

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
(Vijay Kumar Sharma)
Court Master

K.K. Chadha
(K.K. Chadha)
Court Master

12/12/2001

530061

ITEM No.02

Court No.08

S U P R E M E C O U R T O F I N D I A
RECORD OF PROCEEDINGS

Writ Petition(Civil) No.301/2000

CEHAT & ORS.

Petitioner (s)

VERSUS

UNION OF INDIA AND ORS.

Respondent (s)

(with appin. for permission to submit addl. documents
and exemption from filing OT and exemption from filing OT
and permission to submit addl. documents and exemption
from filing OT)

(for further directions)

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

For Petitioner (s) Ms. Indira Jai Singh, Sr. Adv.
Mr. Sanjay Parikh, Adv.
Mr. RR Chandrachud, Adv.
Ms. Jayna Kothari, Adv.

For Respondent (s)

for States of Gujarat Ms. Hemantika Wahi, Adv.
and Mizoram Ms. Sumita Hazarika, Adv.

for UOI

Mr. Krishan Mahajan, Adv.
Ms. Sunita Sharma, Adv.
Mr. Ajay Sharma, Adv.
Mr. C Radhakrishnan, Adv.
Mr. D.S. Mahra, Adv. (NP)
Mr. BV Balram Das, Adv. (NP)

for State of Punjab

Mrs. Jayshree Anand, Addl. Adv. Genl. Pb,
Mr. G. Sivabalamurugan, Adv., for
Mr. R.S. Suri, Adv.

For State of Assam

Ms. Asha G Nair, Adv. for
Ms. Krishna Sharma, Adv.
Mr. VK Sidharthan, Adv.
M/s Corporate Law Group, Adv.

for State of Orissa

Mr. Radha Shyam Jena, Adv.

Certified to be a true copy

Indira Jai Singh

Advocate General (Judl.)

25.9.2001

Supreme Court of India

39

for State of Sikkim	Mr. A Mariarputham, Adv. Ms. Aruna Mathur, Adv. Mr. Anurag D Mathur, Adv.
for State of Rajasthan	Mr. Ranji Thomas, Adv. for Mr. Javed M Rao, Adv.
for State of Kerala	Mr. KR Sasiprabhu, Adv. Mr. John Mathew, Adv.
for State of Haryana	Mr. Mahabir Singh, Adv.
for Res.State of Goa	Mr. Bhavanishanker V Gadnis, Adv. for Mr. Shiv Sagar Tiwari, Adv.
for State of Arunachal Pradesh	Mr. Anil Shrivastav, Adv.
for State of Karnatska	Mr. Sanjay R. Hegde, Adv. Mr. Sanjay Mitra, Adv.
for State of Nagaland	Mr. Sanjay K Shandilya, Adv. Mrs. VD Khanna, Adv.
for State of MP	Mr. Satish K Agnihotri, Adv. Mr. Sakesh Kumar, Adv.
State of Tripura	Mr. Gopal Singh, Adv.
State of UP	Mr. R.C. Verma, Adv., Mr. KL Janjani, Adv. Mr. Pramod Swarup, Adv. Mr. Praveen Swarup, Adv.
State of Uttranchal	Mr. Ajay K Agrawal, Adv.
State of West Bengal	Ms. Rachana Srivastava, Adv. Mr. Tara Chandra Sharma, Adv.
State of Bihar	Mr. B.B. Singh, Adv. (NP)
State of Manipur	Mr. KH Nobin Singh, Adv.
State of Meghalaya	Mr. Ranjan Mukherjee, Adv.
State of HP	Mr. Naresh K Sharma, Adv.
State of Pondicherry	Mr. VG Pragasam, Adv.
State of Maharashtra	Mr. SV Deshpande, Adv.

State of Tamil Nadu: Mr. TLV Iyer, Sr. Adv.
Mr. V Balaji, Adv. for
Mr. PN Ramalingam, Adv.

State of J & K Mr. Anis Suhrawardy, Adv.

Dadar Nagar Haveli: Ms. Sunita Sharma, Adv.

State of Jharkhand: Mr. Ashok Mathur, Adv.

State of Chhattisgarh Mrs. Madhur Dadlani, Adv.
Mr. Prakash Shrivastava, Adv.

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 the 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 non-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

4. From the record, it is apparent that the State of Chhattisgarh and on behalf of Union Territory of Chandigarh, affidavits are not filed.

5. 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.

6. 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 4th 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

Andaman and Nicobar Islands, Chandigarh, D & N Haveli, Daman and Diu, Lakshadweep, Pondicherry and NCT 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 & 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 4th 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.2

Court No. 8

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

GEHAT & 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 O.F. and impleading party)

Date : 11/12/2001 This Petition was called on for hearing today.

BY : HON'BLE MR.

JUSTICE H.B. SHAH
HON'BLE MR. JUSTICE B.N. AGRAWAL
HON'BLE MR. JUSTICE ARIJIT PASAYAT

For Petitioner (s)

Ms. Indira Jaising, Sr. Adv.,
Mr. Sanjay Parikh, Adv.,
Mr. Avinash K. Misra, Adv.,
Mr. R.R. Chandrachud, Adv.,
Ms. Jayna Kothari, Adv.,
Mr. A.N. Singh, Adv.

For Respondent (s)

Attorney General for India (N/P)

For UOI:

Krishan Mahajan, Adv.,

For Delhi State:

Ms. Sunita Sharma, Adv.,
Mr. D.S. Mahra, Adv.

For Gujarat State:

Ms. Hemantika Wahi, Adv.

For Orissa State:

Mr. Radha Shyam Jena, Adv.

For Jharkhand State:

Mr. Aehok Mathur, Adv.,

For Rajasthan State:

Mr. Rajesh Pathak, Adv.,
Mr. Ranjit Thomas, Adv. for
Mr. Javed Mahmood Rao, Adv.

For Kerala State:

Mr. K.R. Sasiprabhu, Adv.,

For Haryana State:

Mr. J.P. Dhanda, Adv.,

For Goa State:

Mr. K.P. Singh, Adv.

For Karnataka State:

Mr. Bhawani Shankar Gadnis, Adv.,

For Punjab State:

Mr. Shiv Sagar Tiwari, Adv.,

Mr. Sanjay R. Hegde, Adv.,

Mr. Satya Mitra, Adv.

Ms. Jayshree Anand, AAG Punjab

Andhra Pradesh State: Mr. Guntur Prabhakar, Adv.
Jharkhand Pradesh : Mr. Anil Shrivastava, Adv.
Jharkhand State: Mr. Ranjan Mukherjee, Adv.

Tamil Nadu State: Mr. T. L. Viswanatha Iyer, Sr. Adv.,
Ms. Shweta Garg, Adv.,
Ms. Revathy Raghavan, Adv.
Mr. P. N. Ramalingam, Adv.

For West Bengal State: Mr. Tara Chandra Sharma, Adv.,
Mr. Ajay Sharma, Adv.,

for Madhya Pradesh: Mr. S. K. Agnihotri, Adv.,
Mr. Sakesh Kumar, Adv.

for Bihar State: Mr. B. B. Singh, Adv.

for U.P. State: Mr. R. C. Verma, Adv.

for Pondicherry: Mr. V. G. Pragasam, Adv.

for Uttaranchal : Ms. Rachana Srivastava, Adv.

for Chhattisgarh: Mr. Prakash Shrivastava, Adv.

for Assam State: Ms. Asha G. Nair, Adv.,

Mr. V. K. Bidharthan, Adv. for
M/s. Corporate Law Group

for UT Chandigarh: Ms. Kamini Jaiswal, Adv.,

Ms. Shomila Bakshi, Adv.,

Ms. Aiswarya Rao, Adv.

for Tripura State: Mrs. Vimla Binha, Adv.,

Mr. Gopal Singh, Adv.,

Mr. Rahul Singh, Adv.

for Himachal Pradesh: Mr. Naresh K. Sharma, Adv.

for Sikkim State: Ms. Aruna Mathur, Adv.,

Mr. A. Mariarputham, Adv.

for J & K State: Mr. Anis Suhrawardy, Adv.

Intervenor: Mr. Jay Savla, Adv.,

Ms. Reema Bagga, Adv.,

Ms. M. Ogra, Adv.

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 filed by the various states which indicates that there is no compliance on the part of the concerned administrators to implement seriously the law and orders passed by this Court.

Non-compliance of the orders passed by this Court, (Family Welfare Health Department) of the following States are directed to remain present before this Court on 29.1.2002.

(1) Punjab. (2) Delhi, (3) Bihar, (4) Rajasthan, (5) Madhya Pradesh, (6) Haryana. (7) Uttar Pradesh, (8) Jharkhand, and (9) West-Bengal."

It is alleged by the learned counsel for the petitioners that Dr. Daniya is transferred from Faridabad to another place only because he was taking appropriate action against defaulting clinics. For this purpose, learned counsel has placed reliance on the newspapers' reports. In our view, if efficient officer is transferred only because he is taking action against the defaulting clinics then certainly the action of the State Government is unjustified. In addition, the State of Haryana through its Health Department is directed to file necessary affidavit stating reasons for transfer of Dr. Daniya.

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, names 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 addressees and also service contract to those clinics or individual as the case may be.

1. Uma Parameshwaran, CEO, Wipro Ge Medical Systems Ltd.,
A-1, Corporate Towers, Golden Enclave, Airport Road,
Bangalore -560017.
2. Toshbro Shimadzu Ltd., Khetan Bhawan. 2nd floor,
Mumbai - 400020.
3. Erbie Engineering Co.Ltd., 2E/12, 4th Jhandewalan Extn.,
New Delhi - 110005.
4. V. Prabhakar, CEO, ATL India Ltd., 79 & 94, Developed
Plots, Perungudi, Chennai -600096.
5. Larsen & Toubro Ltd. (Medical Equipment Divn.), LAT House,
10, Club House Road, Anna Salai, Post Bag NO. 55247,
Chennai -600002.
6. International Medical Services Pvt.Ltd., 17 Industrial
Estate, Maruti Complex, Gurgaon - 122015.
7. A.K. Khosla, 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, Poorvi Marg, Vasant Vihar,
New Delhi- 110057.
9. Siemens Ltd., Mahape Workshop Shilphata Road, Behind
MIDC Area Off Thane Belapur Road. Vill.Mahape.
Thane - 400801.

: -5: -

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.

[Signature] 12/2/01
Jai Kumar Sharma
Court Master

[Signature]
(K.K. Chaudha)
Court Master

[Signature] 12/12/2001

SUPREME COURT OF INDIA
RECORD OF PROCEEDINGS

- 573133

Writ Petition(Civil) No.301/2000

JEHAT & 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

For Petitioner (s)

Ms. Indira Jai Singh, Sr. Adv.

Mr. Sanjay Parikh, Adv.

Mr. RR Chandrachud, Adv.

Mr. AK Misra, Adv.

For Respondent (s)

JOI

Mr. Harish N Salve, SG

Mr. DS Mehra, Adv.

for States of Gujarat
and Mizoram

Ms. Anu Sawhney, Adv.

Ms. Sumita Hazarika, Adv. for

Ms. H Wahi, Adv.

for State of Punjab

Mrs. Jayshree Anand, Addl. Adv. Genl. Pb,

Mr. Rajeev Sharma, Adv.

For State of Assam

Ms. Krishna Sarma, Adv.

Mr. VK Sidarthan, Adv. for

M/s Corporate Law Group, Adv.

for State of Orissa

Mr. Radha Shyam Jena, Adv.

for State of Sikkim

Mr. A Mariarputham, Adv.

Arputham Aruna & Co., Adv.

for State of Rajasthan

Mr. Ranji Thomas, Adv. for

Mrs. KV Bharati Upadhyay, Adv. for

Mr. Javed M Rao, Adv.

for State of Kerala

Mr. John Mathew, Adv. for

Mr. KR Sasisrabhu, Adv.

Certified to be a true copy

Assistant Registrar

8.3.2002
Supreme Court of India

for Res.State of Goa	Mr. Bhavanishankar V Gadnis, Adv. Mr. Shiv Sagar Tiwari, Adv. Ms. Sumita Inna, Adv. Ms. Divya Singh, Adv.
for State of Arunachal Pradesh	Mr. Anil Shrivastav, Adv.
for State of Tamil Nadu	Mr. S Balakrishnan, Sr. Adv. Mrs. S Revathy Raghavan, Adv.
for State of Karnataka	Mr. Sanjay R. Hegde, Adv. Mr. Sanjay Mitra, Adv.
for State of Nagaland	Mr. Sanjay K Shandilya, Adv. for Mr. VD Khanna, Adv.
for State of MP	Mr. Satish K Agnihotri, Adv.
State of Tripura	Mr. Rahul Singh, Adv. Mr. Gopal Singh, Adv.
State of UP	Mr. RC Verma, Adv. Mr. Mukesh Verma, Adv. Ms. Neeta Sinha, Adv.
State of Uttranchal	Ms. Rachna Srivastava, Adv. Mr. Mahesh C Kaushik, Adv.
State of West Bengal	Mr. Tara Chandra Sharma, Adv. Mr. Ajay Ssharma, Adv. Ms. Neelam Sharma, Adv.
State of Bihar	Mr. BB Singh, Adv. Mr. Kumar Rajesh Singh, Adv.
State of Manipur	Mr. KH Nobin Singh, Adv.
State of Meghalaya	Mr. Ranjan Mukherjee, Adv.
State of HP	Mr. Naresh K Sharma, Adv.
State of Pondicherry	Mr. VG Pragasam, Adv. (NP)
State of Maharashtra	Mr. SV Deshpande, Adv.
UT Chandigarh	Ms. Kamini Jaiswal, Adv. Ms. Aishwarya Rao, Adv.
Andaman, Lakshadweep Dadar Nagar Haveli Daman and Diu, & Delhi	Mr. Ashok Bhan, Adv. Ms. Sunita Sharma, Adv. for Mr. DS Mehra, Adv.
State of Chhattisgarh	Mr. Prakash Shrivastava, Adv.. Ms. Madhur Dadlani, Adv.
State of Jharkhand	Mr. Ashok Mathur, Adv. Mr. Rajesh Pathak, Adv.
For M/s WIPRO	Mr. Bhargava V Desai, Adv. Mr. Sanjeev Kr. Singh, Adv.

For Intervenor

Mr. PK Roy, Sr. Adv.
Mr. GS Chatterjee, Adv.
Mr. Pramit K Roy, Adv.
Mr. Feroze Ahmed, Adv.

Mr. Jay Savla, Adv.
Ms. Reena Bagga, Adv.

IA No.15

Mr. BB Sawhney, Adv.
Mrs. Indra Sawhney, Adv.

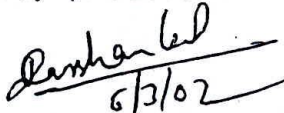
UPON hearing counsel the Court made the following
O R D E R

Heard the learned counsel for the parties.

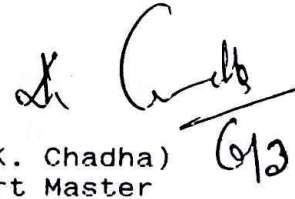
Learned counsel for the petitioner has drawn out attention to the affidavits of the States/ Union Territories and pointed out that number of States have not complied with the directions issued by this Court on 29th January, 2002. Comparative chart for the aforesaid purpose is produced for our perusal. That chart reveals that necessary action is not taken against the persons who are having ultra sound 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.


6/3/02

(D.L. Chugh)
Court Master


6/3

(K.K. Chadha)
Court Master

6/3

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)

(Appln. for permission to submit addl. documents and exemption from filing OT and impleading party and intervention))

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. AGRAWAL
HON'BLE MR. JUSTICE ARIJIT PASAYAT

For Petitioner (s)

Ms. Indira Jai Singh, Sr. Adv.
Mr. Sanjay Parikh, Adv.
Mr. RR Chandrachud, Adv.
Mr. AK Misra, Adv.For Respondent (s)
UOIMr. Soli J Sorabjee, Attorney General
Mr. Manish Singhvi, Adv.
Mr. Krishan Mahajan, Adv.
Ms. Sushma Suri, Adv.
Ms. Sunita Sharma, Adv.
Mr. DS Mehra, Adv.for States of Gujarat
and MizoramMs. Hemantika Wahi, Adv.
Ms. Anu Sawhney, Adv.

for State of Punjab

Mrs. Jayshree Anand, Addl. Adv. Genl. Pb.
Mr. Rajeev Sharma, Adv.

For State of Assam

Ms. Asha G Nair, Adv.
Ms. Krishna Sarma, Adv.
Mr. VK Sidarthan, Adv. for
M/s Corporate Law Group, Adv.

for State of Orissa

Mr. Radha Shyam Jena, Adv.

for State of Sikkim

Mr. A Mariarputham, Adv.
Ms. Aruna Mathur, Adv.
Mr. Anurag Mathur, Adv. for
Arputham Aruna & Co., Adv.

for State of Rajasthan

Mr. Ranji Thomas, Adv.
Mr. Javed M Rao, Adv.

for State of Kerala

Mr. John Mathew, Adv.
Mr. Manish Garg, Adv.
Mr. KR Sasisprabhu, Adv.

for State of Haryana

Mr. Jai Prakash Dhanda, Adv.
Mr. KP Singh, Adv.*Qan*

for Res.State of Goa	Mr. Bhavanishankar V Gadnis, Adv. Mr. HA Raichura, Adv. Ms. Divya Singh, Adv.
for State of Arunachal Pradesh	Mr. Anil Shrivastav, Adv.
for State of Karnataka	Mr. Sanjay R. Hegde, Adv. Mr. Sanjay Mitra, Adv.
for State of Nagaland	Mr. Kailash Vasdev, Sr. Adv. Mr. VD Khanna, Adv. Mr. Sanjay K Shandilya, Adv.
for State of MP	Mr. Satish K Agnihotri, Adv. Mr. Sakesh Kumar, Adv.
State of Tripura	Ms. Vimla Sinha, Adv. Mr. Rahul Singh, Adv. Mr. Gopal Singh, Adv.
State of UP	Mr. RC Vermla, Adv. Mr. Mukesh Verma, Adv. Mr. Abhishek Chaudhary, Adv.
State of Uttranchal	Mr. L.P. Naithani, Adv. Genl. Ms. Rachna Srivastava, Adv. Mr. Mahesh C Kaushik, Adv.
State of West Bengal	Mr. Tara Chandra Sharma, Adv. Mr. Ajay Ssharma, Adv.
State of Bihar	Mr. BB Singh, Adv.
State of Manipur	Mr. KH Nobin Singh, Adv.
State of Meghalaya	Mr. Ranjan Mukherjee, Adv.
State of HP	Mr. Naresh K Sharma, Adv.
State of Pondicherry	Mr. VG Pragasam, Adv.
State of Maharashtra	Mr. SV Deshpande, Adv.
UT Chandigarh	Ms. Kamini Jaiswal, Adv.
Andaman, Lakshadweep Dadar Nagar Haveli Daman and Diu, & Delhi	Mr. Ashok Bhan, Adv. Ms. Sunita Sharma, Adv. Mr. DS Mehra, Adv.
State of Chhattisgarh	Mr. Prakash Shrivastava, Adv..
State of Jharkhand	Mr. Ashok Mathur, Adv. Mr. Rajesh Pathak, Adv. Mr. Harvardhan Jha, Adv.
For M/s WIPRO	Mr. Bhargava V Desai, Adv. Mr. Anand Kumar, Adv. Ms. Sweta Kakkad, Adv.
For Intervenor	Mr. GS Chatterjee, Adv. Mr. Pramit K Roy, Adv. Mr. Feroze Ahmed, Adv.

Don

UPON hearing counsel the Court made the following
O R D E R

Heard the learned counsel for the parties.

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 the 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 Governments/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."

Jan


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.


31/1/02
(D.L. Chugh)
Court Master


(K.K. Chadha) 31/1
Court Master


31/1/02