

CONFIDENTIAL

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LOK SABHA

THE PRE-NATAL DIAGNOSTIC TECHNIQUES
(REGULATION AND PREVENTION OF MISUSE)
BILL, 1991

~~SECRET~~ REPORT

OF THE JOINT COMMITTEE

[Presented on December, 1992]

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LOK SABHA SECRETARIAT
NEW DELHI

December, 1992/ Agastya, 1914 (Saka)

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JOINT COMMITTEE ON THE PRE-NATAL DIAGNOSTIC
TECHNIQUES (REGULATION AND PREVENTION OF
MISUSE) BILL, 1991

COMPOSITION OF THE COMMITTEE

Smt. L.K. Tharadevi Siddhartha - Chairperson

MEMBERS
LOK SABHA

2. Smt. Dil Kumari Bhandari
3. Smt. Malini Bhattacharya
4. Smt. Saroj Dubey
5. Smt. Girija Devi
6. Dr. Mahavirsinh Harisinhji Gohil
7. Dr. Viswanathan Kanithi
8. Smt. Sumitra Mahajan
9. Smt. Geeta Mukherjee
- *10. Dr. (Smt.) Padma
11. Dr. Kartikeswar Patra
12. Dr. Vasant Niwruddhi Pawar
13. Dr. (Smt.) K.S. Soundaram
14. Km. Uma Bharati
15. Km. Vimla Verma

RAJYA SABHA

16. Smt. Chandrika Jhinganandan Jain
17. Smt. Sarla Maheshwari
18. Shri Sarda Mohanty
19. Shri V. Narayanasamy
20. Smt. Satya Bahin
21. Smt. Sushma Swaraj
- **22.

*Appointed w.e.f. 20.12.1991 vice Shri K.R. Narayanan resigned.

**Shri Bhaskar Annaji Masodkar ceased to be a member of the Committee w.e.f. 4.7.1992 on the expiry of his term in Rajya Sabha and the vacancy was not filled up.

SECRETARIAT

1. Shri G.L. Batra - Additional Secretary
2. Shri S.C. Gupta - Joint Secretary
3. Shri R.K. Chatterjee - Deputy Secretary
4. Shri T.D. Dhingra - Under Secretary

REPRESENTATIVES OF THE MINISTRY OF LAW,
JUSTICE AND COMPANY AFFAIRS (LEGISLATIVE
DEPARTMENT)

1. Shri B.P. Jayakar - Joint Secretary and
Legislative Counsel.
2. Shri N.K. Agrawal - Joint Secretary and
Legislative Counsel
3. Shri M.S. Shama - Additional Legislative
Counsel.
4. Shri T.K. Vishwanathan - Additional Legislative
Counsel.

REPRESENTATIVES OF THE MINISTRY OF HEALTH
AND FAMILY WELFARE (DEPARTMENT OF FAMILY
WELFARE)

1. Shrimati Usha Vohra - Secretary
2. Shri A.K. Mukherjee - Acting D.G.H.S.
3. Shri S.B. Mishra - Joint Secretary
4. Shri S.S. Kapur - Director

REPORT OF THE JOINT COMMITTEE ON PRE-NATAL
DIAGNOSTIC TECHNIQUES (REGULATION AND
PREVENTION OF MISUSE) BILL, 1991

I, the Chairperson of the Joint Committee to which the Bill * viz. the Pre-Natal Diagnostic Techniques (Regulation and Prevention of Misuse) Bill, 1991 was referred, having been authorised to submit the Report on their behalf, present this Report.

2. The Bill was introduced in the Lok Sabha on 12 September, 1991. The motion for reference of the Bill to a Joint Committee of both Houses of Parliament was moved in Lok Sabha by Shri M.L. Fotedar, Minister of Health and Family Welfare on 16 September, 1991 and was adopted (Appendix I).

3. The Rajya Sabha concurred in the said motion on 17 September, 1991 (Appendix II).

4. The message from Rajya Sabha was published in Lok Sabha Bulletin Part II on 19 September, 1991.

5. The Committee held 18 sittings in all.

6. The first sitting was held on 22 October, 1991. At this sitting, the Committee considered their future programme of work and decided to issue a press communique inviting memoranda containing suggestions/comments on the Bill by 22 November, 1991 from the State Governments, Union Territory

*Published in the Gazette of India Extra-ordinary Part II Section II, dated 12 September, 1991.

Administrations, Bar Councils, medical Associations and other individuals interested in the subject matter of the Bill for their consideration. They also desired that the contents of the press communique be given wide publicity through the Press/ Television/A.I.R.. etc. The Ministry should also consider the measures to give wide publicity to the contents of the Bill to create public awareness.

The Committee also decided that a letter might be addressed to all the State Governments, Union Territory Administrations, Women Organisations, other social organisations, educational institutes, persons in medical and legal profession and other individual experts who have worked in this field, inviting their comments/ suggestions on the Bill.

The Committee also suggested that a specific questionnaire might be framed by the Ministry of Health and Family Welfare, which could be sent to those organisations/experts for eliciting their views. The Committee agreed to give a period of four weeks to the organisations/bodies/individuals to submit their memoranda to the Committee.

7. Accordingly, a press communique inviting Memoranda and requests for oral evidence was issued on 23 October, 1991.

As per decision taken by the Committee a letter inviting Memoranda containing comments/suggestions on the provisions of the Bill was also issued to all the State Governments/Union Territory Administrations and individuals whose names were

furnished by the Ministry of Health and Family Welfare. The Ministry of Health and Family Welfare also gave publicity through leading newspapers inviting memoranda from the general public by 25 December, 1991.

8. 304 Memoranda containing comments/suggestions on the provisions of the Bill were received by the Committee from various organisations/individuals etc. (Appendix III)

9. The Committee visited Bombay and Jaipur from 18 to 20 May, 1992. At Bombay, the Committee took oral evidence of three non-official organisations and also held discussion with 19 other persons representing different organisations/hospitals/individuals/experts, etc. on 18 May, 1992. On 19 May, 1992 the Committee visited two hospitals in Bombay viz. J.J. Hospital and Bombay Hospital and held informal discussion with the Senior Doctors. The Committee also held discussion with the representatives of the State Government of Maharashtra on 19 May, 1992.

At Jaipur, the Committee took oral evidence of some non-official organisations and some other individuals representing different hospitals/organisations, etc. The Committee also held discussion with the officials of the State Government of Rajasthan on 20 May, 1992.

10. The Committee took oral evidence of 23 non-official organisations, five experts in the field and a number of other individuals also at their sittings held on 20 and 21 January, 20 February, 18 to 20 May and 7 July, 1992. A list of persons who gave evidence before the Committee is at (Appendix IV.)

facilities should be permitted only in the Government Hospitals. Some other Members, however, opined that there is already pressure on Government institutions for the facilities available for pre-natal diagnosis and they may not be able to cater to the needs of the people all over the country. Therefore, it would not be desirable to prohibit such facilities in the private institutions. The Committee are of the view that the facilities for the pre-natal diagnosis should be permitted both in the Government as well as the private sector, provided the latter conform to the requirements of the Act.

17. Sub clause (c)

While considering the existing definition of "Genetic Counselling Centre", the Committee were of the opinion that "Counselling" the patient can be done even at any place other than that where obstetrical or gynaecological procedures are being conducted. The Committee have therefore decided to modify the definition of Genetic Counselling Centre to read as "an Institute, Hospital, Nursing Home or any place by whatever name called, which provides for genetic counselling to patients".

18. Sub clause (d)

The Committee feel that as distinct from the "Counselling Centre" a "genetic clinic" is a place, by whatever name called, where pre-natal diagnostic procedures are conducted. Therefore, the Committee have modified the existing definition accordingly.

19. Sub-clause (e)

The Committee feel that the "Genetic Laboratory" conducts analysis or tests of samples received from the "Genetic Clinic" which undertakes the gynaecological procedures and not from the "Counselling" Centre which may be only by word of mouth and, therefore, the sub-clause has been modified accordingly to substitute the words "Counselling Centre" by the word "Clinic".

20. The Committee are of the opinion that although it is desirable to have the (i) Genetic Counselling Centre; (ii) Genetic Clinic; and (iii) Genetic Laboratory, under one composite umbrella, it may not *always* be feasible to have them at one place, ~~altogether~~ at places especially in smaller towns.

21. Sub clause(f)

The Committee feel that there is no difference between a "gynaecologist" and "Obstetrician" who possess the same basic qualifications. Therefore, the Committee have amended this sub clause to incorporate in the definition of a "gynaecologist", an "Obstetrician" also.

22. The Committee are also of the opinion that since a gynaecologist, an obstetrician and a paediatrician are the group which is involved in the ^{field of medical genetics} ~~generic programme~~, and at places only a paediatrician may be rendering the counselling, it is necessary to provide a separate definition of a "paediatrician" also. The Committee have, therefore, decided to add a new sub-clause to define the "paediatrician".

23. Sub clause (h) & (i)

While considering the definition of "pre-natal diagnostic procedures" and "pre-natal diagnostic tests" in clause 2(h) and 2(i), the Committee felt that "ultrasonography" is one of the techniques which is being used extensively not only to detect certain abnormalities or diseases but also for determination of sex. In order to check misuse of this technique by unscrupulous institutions, the Committee have decided to include "ultrasonography" in the ambit of these procedures and tests and amended the definitions of "pre-natal diagnostic procedures" and

"pre-natal diagnostic tests" accordingly.

Clause 3

24. While considering the various amendments to this clause which provides for regulation of Genetic Counselling Centres, Laboratories, and Clinics, the Committee discussed at length the question whether suitable provision should be made in the Bill for registration of the ultrasound machine to check its misuse by some unscrupulous persons for sex determination. While some Members were in favour of such registration, the Committee decided that there are already adequate regulatory provisions in the Bill regarding misuse of the ultrasound machines for pre-natal sex determination and hence it was not necessary to register them as these machines are also used for various other purposes. Further, there are a large number of other sophisticated machines and equipment which are being used for genetic and other investigations for which no such registration is prescribed. It was, therefore, not necessary to make any provision in the Bill for registration of ultrasound machines.

Sub-clause (3)

25. The Committee have decided to add the word "paediatrician" after the word "gynaecologist" for the reasons explained in para 22 above.

Clause 4

Sub clause 3(iii)

26. This sub clause inter alia provides that no person shall seek or encourage the performance of any pre-natal diagnostic technique on any pregnant woman except for the purposes mentioned therein. According to this sub-clause a pre-natal diagnostic technique can be performed on a pregnant woman if she had been exposed to potentially teratogenic drugs, radiation, infection or hazardous chemicals. However, the Committee feel that even non-hazardous chemicals can be teratogenic. The key word in the provision is "teratogenic". Therefore, the Committee have decided to delete the word "hazardous" before the word "chemicals". Besides, the Committee have added the words "agents such as" before the word "drugs" to make the provision more comprehensive.

Clause 5

27. This clause provides that before the pregnant woman is subjected to pre-natal diagnostic technique the person conducting such test shall explain all the side and after effects of undertaking such tests and has obtained her consent in writing to undergo such procedures. The Committee observe that sometime a pregnant woman is made to undergo these tests without understanding fully their implications. Therefore, in order to inform the woman about the tests being done on her, it is necessary that

all known side and after effects of the pre-natal diagnostic procedures are explained to the pregnant woman in the regional language in which she can understand. Besides, it is also necessary that, except in cases, where the test is specifically meant for the detection of sex linked disorder, sex of the foetus is not conveyed to the woman or her relatives in any manner. The clause has been amended accordingly to incorporate that the written consent of the pregnant woman should be obtained in the concerned regional language as may be prescribed by the rules and regulations of this Act, and after giving a copy of the same to the woman; and unless a test is specifically meant for the detection of sex-linked disorders, the sex of the foetus shall not be communicated verbally or symbolically or in writing or in any other form to the woman on whom it is conducted, or her relatives.

28. Besides, for the existing phrase "all possible effects" the Committee have decided to change it to the words "all known effects", because with the rapid advances being made in the medical field at any given point of time the doctor performing the diagnostic procedures may not be aware of the developments; therefore, it is necessary to protect the doctor acting in good faith. Therefore, the doctor is bound to inform the woman only all the "known" effects and not necessarily all the "possible" effects.

Clause 7

29. This clause provides for the constitution of Central Supervisory Board to exercise the powers and perform the functions conferred on the Board, under Clause 16. The Minister incharge of Family Welfare is the Chairman, ex-officio. The Committee feel that the Board should be strengthened to include the Director-General of Health Services of the Central Government, ex-officio: 2 paediatricians and three women members of Parliament, 2 from Lok Sabha and 1 from Rajya Sabha. The Committee are of the opinion that since the Bill concerns a large section of our female population and the Members of Parliament represent them, the women Members of Parliament should find a representation on the Board even though they have multifarious responsibilities. The Committee also feel that as against 2 members to be appointed by the Central Government to represent the States and Union Territories, there should be 4 members from the States. Further, the Bill provides for appointment of Members of States in alphabetical order. The Committee, however, feel that if the alphabetical order is followed strictly the States which may be in the lower alphabetical order may find representation on the Board only after a number of years and their view point may not find adequate representation even though the intensity of their problem may be very acute. The Committee have, therefore, decided that instead of following the alphabetical order for all the 4 members representing the States, 2 members may be in the alphabetical order and

2 in the reversed alphabetical order to represent the States and Union Territories. The Committee have made the amendments accordingly.

Clause 8

30. This clause provides for the term of office of the members appointed to the Central Advisory Board. The Committee feel that in order that the Board gets the view of the various States, in a short span of time, the term of the office of the representatives of the States may be fixed at one year as against 3 years for other categories of representatives contemplated in the Bill.

Clause 14

31. This clause provides for disqualification for appointment as members of the Central Supervisory Board. The Committee feel that those persons who have been associated with the use or promotion of pre-natal diagnostic techniques for determination of sex should be disqualified from being members of the Supervisory Board. Accordingly, the Committee have decided to provide a new sub-clause (f) which provides that a person should be disqualified from being appointed as a member if he has, in the opinion of the Central Government, been associated with the use or promotion of pre-natal diagnostic techniques for the determination of sex.

Clause 16

32. One of the functions of the Central Supervisory Board is stated to be to create public awareness against the practice of female foeticide. The purpose of the Bill is to discourage the practice of pre-natal sex-determination itself to prevent its misuse. Therefore, the Committee have modified the relevant provision to provide for creating public awareness not just against the practice of female foeticide but basically against the pre-natal sex-determination, whether or not it leads to female foeticide. Therefore, the words "pre-natal sex determination and" have been added at the appropriate place.

Clause 17

33. This clause provides for the appointment of Appropriate Authorities for discharging the functions of granting registration enforcing standards prescribed for such Centres, Laboratories and Clinics, suspension or cancellation of a Genetic Counselling Centre, Genetic laboratory or Genetic Clinic and to enforce standards prescribed for such Centres, Laboratories and Clinics. It also provides for the appointment of Advisory Committee to advise the Appropriate Authorities in the discharge of their functions.

Sub-clauses(1) and (2)

34. In sub-clause (1) and sub-clause (2), the existing Bill provides that the Central Government or the State Government shall appoint one or more "officers" as Appropriate Authorities for each of the Union territories/ States etc. The Committee feel that the existing provision needs to be amplified inasmuch as there could be one or more appropriate Authorities for the whole or part of the State or Union Territory for the purposes of this Act keeping in view the intensity of the problem of pre-natal sex determination leading to female foeticide. Therefore, the Committee have amended these sub-clauses accordingly.

Sub-clause (3)

35. In this sub-clause the present provision states that the Appropriate Authorities contemplated in sub-clauses(1) and (2) shall be of or above the rank of Joint Director of Health and Family Welfare of the State Government or a Union Territory, as the case may be. In this connection, the Committee appreciate that at the district level officers of the rank of Joint Director or above may not be available. Therefore, the Committee have amended the clause to provide inter-alia for officers "of or above the rank of Joint Director of Health and Family Welfare or such other rank of the State Government or of the Union Territory, as the Central Government or the State Government, as the case may be, may deem fit to appoint."

Sub-clause (4)

36. While discussing this sub-clause, the Committee have felt that while discharging the functions of appropriate Authority, it should be obligatory for the Authority to seek and consider the advice of the Advisory Committee, constituted under sub-clause (5) of clause 17 on matters relating to grant of registration, complaints or suspension or cancellation of the registration etc. Accordingly, the Committee have added a new sub-clause to this sub-clause to provide for it.

Sub-clause 5

37. The existing provisions in the Bill do not give adequate representation to certain interests to make the Advisory Committee effective. The Committee are of the opinion that the Advisory Committee should include a paediatrician, a legal expert as also an officer concerned with the information and publicity of the concerned Department. The Committee feel that since the appropriate Authority is to be guided by this Advisory Committee, the opinions emerging from the Advisory Committee should be well considered from all angles, for which these interests should be properly represented. The Committee have also decided to include a provision that one of the Members of the Advisory Committee should be appointed as the Chairman of the Committee by Central Government or the State Government

as the case may be, to guide the deliberations and to discharge the various functions of the Committee. The Committee also feel that only those persons should be represented on this Committee who are in no way associated with the use or promotion of the pre-natal diagnostic techniques for determination of sex. This sub-clause has been amended accordingly. The Committee have also come to the conclusion that the Advisory Committee should meet at reasonably fixed intervals which could be provided in the rules so that the Advisory Committee can render useful advise to the appropriate authority at the appropriate times. The sub-clause has been amended accordingly.

Clause 18

38. This clause provides for registration of all Genetic Counselling Centres, Genetic Laboratories and Genetic Clinics engaged in conducting pre-natal diagnostic techniques. The Committee feel that in order to cover any loophole, it is necessary to provide for registration of the Genetic Centre, Laboratory or clinic functioning "either separately or jointly". The Committee have amended sub-clauses(1), (3) and (4) of this clause accordingly.

Clause 19.

39. Sub-clause (1) has been amended to include the words "Either separately or jointly" as explained in regard to clause 18 above.

11. The Report of the Committee was to be presented to the House by the end of the Budget Session, 1992. However, the Committee were granted two extensions of time for presentation of their Report - first on 27 February, 1992 upto the end of the Monsoon Session, 1992; and the second on 19 August, 1992 upto the end of the Winter Session, 1992.

12. The Committee held Clause-by-Clause discussion on the provisions of the Bill on the basis of amendments proposed by the Members at their sittings held on 2, 3, 19 and 20 November, 1992.

13. At their sitting held on 16 December, 1992, the Committee decided that (i) the evidence tendered before the Committee might be laid on the Table of both the Houses of Parliament; and (ii) two copies each of Memoranda received by the Committee might be placed in the Parliament Library, after the report has been presented, for reference by the Members of Parliament.

14. The Committee considered and adopted the Report at their sitting held on 16 December, 1992.

15. The observations of the Committee with regard to the principal changes proposed in the Bill are detailed in the succeeding paragraphs.

Clause 2 - Definitions

16. While considering this clause in the light of the amendments proposed to clause 2(c) (d) (e), some Members expressed the view that, in order to prevent misuse of pre-natal diagnostic techniques for the purpose of determining the sex of foetus, these

44. The Committee deliberated on the question at length whether the pregnant woman who undergoes such pre-natal diagnostic techniques should be exempted from such punishment, considering the social status and compulsions in which the Indian woman is placed today. However, the Committee felt that providing for punishment for the pregnant woman herself will go a long way in achieving cherished objectives of the Bill. Therefore, The Committee decided not to make any change in the present clause and to retain it as it is.

Clause 28

45. This clause provides that the court shall take cognizance of an offence under the Act only on a complaint made by the appropriate authority or any officer authorised by the Central Government or State Government or the appropriate authority or by a person who has given notice of not less than sixty days to the appropriate authority of the alleged offence and his intention to make a complaint to the court.

46. In clause (b) of sub-clause (1), the Committee have decided to amplify the existing provision to provide that any person "including a person representing any social organisation" could give a notice of his intention to make a complaint to the court.

47. The Committee have also felt that the existing provision of sixty days' notice is too long for approaching

Note.

MINUTES OF DISSENT

Having gone through the evidence from various groups, organisations and individuals, the undersigned discovered that in a large majority of cases, recommendations have been for keeping pre-natal diagnostic techniques confined to the Government sector. The available data leads us to agree with this point of view. It was suggested by some of us that at most, some specified apex institutions outside the Govt. sector may be allowed to conduct these tests.

We also found that some of the procedures and techniques are not exclusively for the detection of genetic defects or anomalies, but are used for more general purposes. Yet these too are being often utilised for pre-natal sex-determination. Ultra-sonography is so far the commonest technique to be misused in this way. Since such techniques serve many diverse medical purposes, it is not possible to keep them confined to the public sector like the tests for the detection of genetic defects and anomalies. However, it may be possible to check their misuse by a stringent system of registration.

In the Bill as reported by the Joint Committee, there is no provision for registration of ultrasonography equipments etc. unless they are included among the equipments of a Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic. We are apprehensive, that this is likely to leave a loophole in the way allowing misuse of ultrasonography technique and equipments. At the same time, in view of the fact that the recent proliferation of genetic clinics,

the court. The Committee, have, therefore, decided to reduce it to thirty days. The Committee have amended the clause accordingly.

48. The Joint Committee recommend that the Bill, as amended, be passed.

NEW DELHI;

16 December, 1992.

SMT. D.K. THARADEVI SIDDHARTHA
CHAIRPERSON
Joint Committee on Pre-Natal
Diagnostic Techniques (Regulation
and Prevention of Misuse) Bill, 1991.

laboratories etc. in the private sector is largely due to the rampant increase in the practice of pre-natal sex-determination with the use of genetic tests which may be misused for the purpose and which have a limited application anyway, should have been confined, as a precautionary measure, to the Government sector.

We would like to record our dissent on these two points and would request that it be incorporated into the report.

GEETA MUKHERJEE
MALINI BHATTACHARYA
SARLA MANESHWARI

BILL No. 155 of 1991

THE PRE-NATAL DIAGNOSTIC TECHNIQUES
(REGULATION AND PREVENTION OF
MISUSE) BILL, 1991

(AS REPORTED BY THE JOINT COMMITTEE)

Defini-
tions.

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

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

(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;

(7) 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
prohibition
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 pro-
hibited.

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
supervi-
sory
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, *ex officio*;

(b) the Secretary to the Government of India in charge of the department of Family Welfare, who shall be the Vice-Chairman, *ex officio*;

(c) 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 (c) or clause (f) of sub-section (2) of section 7, three years; and

(b) in case of appointment under clause (g) 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.

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