
(2006) 08 KL CK 0016

In the High Court Of Kerala

Case No : O.P. No. 39084 of 2001 and connected cases

Qualified Private Medical Practitioners and Hospitals
Association

APPELLANT

Vs

State of Kerala

RESPONDENT

Date of Decision : 01-08-2006

Acts Referred:

Citation : (2006) 4 KarLJ 81

Hon'ble Judges : V.K.Bali, C.J;P.R. Raman, J

Bench : Division Bench

Advocate : P.B. Sahasranaman, K. Jagadeesh and T.S. Harikumar, for the Appellant; Noorji Noushad, Government Pleader, for the Respondent

Judgement

P.R. Raman, J.—In all the above Original Petitions there is a common prayer for a declaration that laboratories and clinics which do not conduct pre-natal diagnostic, test using ultrasonography will not come within the purview of the Pre-Natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 (hereinafter referred to as "the Act") and for a direction to the respondents not to insist for registration of all ultrasound scanning centres irrespective of the fact as to whether they are conducting ultrasonography, under the Act, 1994.

2. First petitioner in O.P. 10193/2002 is the Lourdes Matha Hospital and the second petitioner is the P.V.S. Memorial Hospital, Kaloor. O.P. 39084/2001 is filed by the Qualified Private Medical Practitioners and Hospitals Association, represented by its President. O.P. 3446/2002 is also filed by hospitals. In O.P. 2704/2002, there are seven petitioners who are also hospitals situated in different places of State of Kerala. O.P. 2194/2002 is filed by persons representing various hospitals. O.P. 563/2002 is also filed by a Hospital situated in Ernakulam.

3. It is averred in the Original Petitions that the petitioners hospitals are engaged in treatment of all ailments except genetic counselling and are not conducting any prenatal diagnosis using ultrasonography. They also undertake that they will

not undertake any pre-natal diagnostic procedures as contemplated under the Act. This Court, while admitting the Original Petitions, after taking notice of the specific averments made by the petitioners that they are not conducting any pre-natal diagnosis using ultrasonography in their hospitals, passed an interim direction that Registration u/s 18 of the Prenatal Diagnosis (Regulation and Prevention of Misuse) Act, 1994 shall not be insisted in their case. However, it was made clear that the said order shall not prevent the authorities concerned to inspect the hospitals as to whether the petitioners are conducting any such pre-natal test.

4. It is the case of the petitioners that only institutions which are using ultrasonography for the purpose of pre-natal Diagnosis will come within the purview of the Act and only such institutions are required to register with the authority. In other words, institutions having ultrasonography used for the purposes other than for conducting prenatal diagnostic test cannot be said to be a genetic laboratory or clinic for the purpose of the Act.

5. Ext.P3 in O.P. 39084/2001 is a press release dated 20.8.2001 issued by the District Medical Officer, Ernakulam, who is the second respondent therein, directing all ultrasound clinics and genetic counselling centres in the city to register before the date specified therein. There is a further direction that scanning clinics associated with private hospitals also should register. Though, in reply thereto, petitioner had sent a letter to the second respondent that it is not at all necessary to obtain registration for all the institutions by Ext. P5 dated 28.11.2001, the second respondent issued another press release reiterating that ultrasound scanning centres will have to obtain licence.

6. The short question that arises for consideration is as to whether hospitals which are equipped with ultra sound scanning equipment for purpose other than conducting any Pre-natal Diagnostic test requires registration and whether such hospitals will come within the purview of the said Act.

7. The respondent would contend that based on the order of the Supreme Court reported in *Cehat v. Union of India* AIR 2002 SC 3689, all clinics with ultrasound machines require registration. It is also their case that irrespective of the fact as to whether the said ultrasound scanning machines are used for any pre-natal detection or not such institution must be registered.

8. At the outset, we may say that the order of the apex court as referred to supra is only an interim order and the respondents have no case that any final judgment is rendered by the apex court and as a matter of fact, no such final judgment is placed on record. We have gone through the order of the apex court and we find that there was no occasion for the apex court to consider the applicability of the Act to institutions which are using ultrasound scanning for any purposes other than pre-natal detection. In the circumstances, we shall proceed to dispose of these Original Petitions with reference to the provisions contained in the Act.

9. The Pre-Natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 is an Act provided for regulation of the use of pre-natal diagnostic techniques for the purpose of detecting genetic or metabolic disorders or chromosomal abnormalities or certain congenital mal-formations or sex linked disorders 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. Section 2(c) of the said act defines "Genetic Counselling Centre" as an institute, hospital, nursing home or any place, by whatever name called, which provides for genetic counselling to patients. As per Section 2(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. Section 2(e) defines "Genetic Laboratory" as 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. Section 2(i) defines "pre-natal diagnostic procedures" as gynecological 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. As per Section 2(j) "pre-natal diagnostic techniques" includes all pre-natal diagnostic procedures and pre-natal diagnostic tests. As per Section 2(k) "prenatal 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.

10. Chapter II of the said Act deals with Regulation of Genetic Counselling Centres, Genetic Laboratories and Genetic Clinics, As per Section 3(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. As per Sub-section (2) of Section 3, 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. Likewise, Sub-section (3) of Section 3 bars medical geneticist, gynecologist paediatrician, registered medical practitioner or any other person from conducting or causing 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.

11. Section 4(1) under Chapter III provides that on and from the commencement of the said Act, 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). As per Section 4(2) no pre-natal diagnostic techniques shall be conducted except for the purposes of detection of (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. As per Sub-section (3) of Section 4 no pre-natal diagnostic techniques shall be used or conducted unless the person qualified to do so is satisfied that any of the conditions prescribed thereunder are fulfilled. The conditions prescribed are (i) the age of the pregnant woman is above thirty-five years, (ii) the pregnant woman has undergone of two or more spontaneous abortions or foetal loss; (iii) the pregnant woman had been exposed to potentially teratogenic agents such as drugs, radiation, infection or chemicals, (iv) the pregnant woman has a family history of mental retardation or physical deformities such as spasticity or any other genetic disease and (v) any other condition as may be specified by the Central Supervisory Board. Section 6 prohibits determination of sex. As per this Section on and from the commencement of the Act, 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 and no person shall conduct or cause to be conducted any prenatal diagnostic techniques including ultrasonography for the purpose of determining the sex of a foetus.

12. Next chapter, which is relevant is Chapter VI which deals with registration of Genetic Counselling Centres, Genetic Laboratories or Genetic Clinics. As per Section 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 the Act. Section 19 deals with grant of certificate of registration. Section 20 deals with cancellation or suspension of registration. Chapter VII deals with offence and penalties. Section 22 thereunder deals with prohibition of advertisement relating to pre-natal determination of sex and punishment for contravention. As per Sub-section (1) of Section 22 no person, organisation, Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic shall issue or cause to be issued any advertisement in any manner regarding facilities or pre-natal determination of sex available at such Centre, Laboratory, Clinic or any other place. As per Sub-section (2) of Section 22 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 or Genetic Clinic or any other place. In case any person contravenes any provision as aforesaid, he shall be punished with imprisonment as provided under Sub-section (3) of Section 22.

13. As per Sub-section (1) of Section 30 if the appropriate authority has reason to believe that an offence under this Act has been or is, being committed by any Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic, such authority or any officer authorised thereof in this behalf may, subject to such rule 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.

14. On a reading of the above provisions, it can thus be seen that Section 18 of the Act compels registration of Genetic Counselling Centres, Genetic Laboratory or Genetic Clinics without which no person shall open any such centres, laboratory or clinic, after the commencement of the Act. But the expression "Genetic Counselling Centre" as defined u/s 2(c) makes it clear that any institute, hospital, nursing home or any place by whatever name called, which provides for genetic counselling to patients come within the ambit of the expression "Genetic Counselling Centre". In other words, such of those institutions must provide for Genetic Counselling to patients. Likewise; a Genetic clinic as defined u/s 2(d) will take in only clinic/institute/hospital or nursing home which is used for conducting Pre-natal diagnosis. The specific contention of the petitioners is that they are not conducting any Pre-natal diagnostic procedures. If so, going by the definition, it cannot be treated as a diagnostic clinic or diagnostic counselling centre as defined under the Act. But, at the same time, even the registered genetic counselling centre, genetic laboratory or genetic clinic as the case may be, can Use of cause to use for conducting any pre-natal diagnostic techniques except for the purpose specified in Clause 2 of Section 4, if they are satisfied that the conditions specified in Clause (3) thereunder are fulfilled. Further, as per Section 4(1) of the Act, it prohibits use of conducting any Pre-natal diagnostic technics in any place including a registered counselling centre or genetic centre or clinic as the case may be. By use of the expression "including a registered Genetic Counselling Centre..." the legislature has intended to extend the prohibition contained in Section 4 even to unregistered counselling centre or diagnostic centre or Genetic clinic, as the case may be. In other words, even institutions which may not require registration will still be governed by the restrictive provision and cannot indulge in any activities contrary to the legislative mandate imposed u/s 4 and the prohibitions contained therein equally apply to all such institutions Further, as per Section 22 there is a ban for issuance of any advertisement in any manner . regarding the facilities of pre-natal determination of sex, available at such centre, laboratory, clinic, including any person or organisation, genetic counselling centre etc. Further, powers have been vested in the authorities to conduct inspection or to hold such enquiries for the purpose of satisfying themselves that the institutions to whom certificate of registration is granted is strictly complied with the requirements of the Act and rules thereunder. Therefore, with a view to prevent misuse of any pre-natal diagnostic techniques except for the purpose of genetic or metabolic diseases etc. as the case may be, the authorities will be free to conduct inquiries or to hold inspections at places where such device is available and to take action in case

any person or institution is indulged in activities contrary to the provisions of the Act. This will equally apply to non-registered institutions as well. While the registration only permits prenatal diagnostic techniques being used for restricted purposes mentioned in Clause (2) of Section 4, it cannot be said that merely because the institutions are not registered they can indulge in the use of such techniques even for the purposes clearly prohibited under the Act. Therefore, the authorities will be fully competent to ensure due compliance of the provisions of the Act whether it be registered or unregistered institution. However, petitioners, so long as they don't act in violation of the undertaking given and so long as they are not conducting any such pre-natal diagnostic tests using any techniques including ultrasonography, cannot be insisted to be registered u/s 18 of the Act. So however, it will be open to the authorities concerned to inspect the hospitals and to ensure that petitioners are not conducting any such pre-natal test as undertaken by them. As a matter of fact, even the letter of the Director of Health Services, addressed to all District Medical Officers of health, only directs the District Medical Officers of Health to identify the units which are yet to be registered under the Act which direction as such does not affect any of the petitioners so long as they are not conducting any pre-natal diagnostic test and there is no room for any apprehension that such institutions will be compelled to be registered u/s 18 of the Act.

15. As we have already indicated, registration will be compulsory only in case of Genetic Counselling Centres, Genetic Clinic, Genetic Laboratory, etc. which are used for conducting any pre-natal diagnostic procedures or pre-diagnostic test. However, if any of the hospitals are found using such pre-diagnostic techniques and/or does any act in violation of the provisions contained in the Act, necessarily the authorities will have the power to proceed in accordance with law.

The Original Petitions are accordingly disposed of with the above observations.