

IN THE HIGH COURT OF KERALA AT ERNAKULAM

PRESENT

THE HONOURABLE MR. JUSTICE V.G. ARUN

TUESDAY, THE 20TH DAY OF DECEMBER 2022 / 29TH AGRAHAYANA, 1944

WP (C) NO. 36826 OF 2022

PETITIONER:

DEVANANDA P.P., AGED 17 YEARS
D/O PRATHEESH P.G., PULIKKATHARA HOUSE, KOLAZHY P.O.,
THRISSUR, 680 010 , REPRESENTED THROUGH HER MOTHER
DHANYA M.V., AGED 40 YEARS,
W/O PRATHEESH P.G., PULIKKATHARA HOUSE, KOLAZHY P.O.,
THRISSUR, 680 010.

BY ADV P.R.SHAJI

RESPONDENTS:

1 DEPARTMENT OF HEALTH AND FAMILY WELFARE,
GOVERNMENT OF KERALA, REPRESENTED BY ITS PRINCIPAL
SECRETARY, GOVERNMENT SECRETARIAT, ANNEX 2,
THIRUVANANTHAPURAM KERALA-695 001.

2 THE DIRECTOR, RAJAGIRI HOSPITAL,
CHUNANGAMELVY, ALUVA, KERALA-683 112.
GMAIL@RAJAGIRIHOSPITAL.COM 914842905000

ADDL. R3 IMPEADED

ADDL. R3 THE APPROPRIATE AUTHORITY, DIRECTOR OF MEDICAL
EDUCATION, KERALA, MEDICAL COLLEGE P.O.,
THIRUVANANTHAPURAM, PIN 695 011, KERALA.

ADDL R3 IMPEADED AS PER ORDER DATED 14.12.2022 IN I.A.
3 OF 2022 IN WP(C) 36826/2022.

GP SRI P.S. APPU

THIS WRIT PETITION (CIVIL) HAVING COME UP FOR ADMISSION ON
20.12.2022, THE COURT ON THE SAME DAY DELIVERED THE FOLLOWING:

JUDGMENT

Dated this the 20th day of December, 2022

The petitioner, a hapless minor girl, is pleading for permission to donate her liver to save her ailing father's life through transplantation surgery. The petitioner's father is suffering from Decompensated Chronic Liver Disease with Hepatocellular Carcinoma, non-alcoholic fatty liver disease. The only means to save the life of the petitioner's father is to replace the damaged liver through transplantation surgery. From among the near relatives of the patient, only the petitioner's liver was found to be matching. The petitioner is more than willing to donate her organ to save her father's life. The petitioner's predicament is that, she is only 17 years of age and the provisions of the Transplantation of Human Organs and Tissues Act, 1994 ('Act' for short) and the Rules thereunder, do not permit organ donation by a minor. Hence, this writ petition seeking the following reliefs;

i. Declare that the petitioner is entitled for exemption in her age to be a donor as prescribed under Rule 18 of the Transplantation of Human Organs and Tissues Rules, 2014 to donate a portion of her liver to transplant to her father Mr.Pratheesh P.G. aged 48 years, residing at Pulikkathara House, Kolazhy P.O., Thrissur, 680 010 now undergoing treatment under 2nd respondent hospital with IP No.182759.

ii. Direct the 2nd respondent hospital authority to perform their medical obligations under Rule 18 of the Transplantation of Human Organs and Tissues Rules, 2014 and other provisions of the Transplantation of Human Organs and Tissues Act, 1994, as if petitioner is a major person if she is medically fit otherwise to be a donor.

2. Heard, Adv. P.R. Shaji, learned counsel for the petitioner and Adv. P.S. Appu, learned Government Pleader.

3. For deciding the vexed question whether a statutory prohibition should yield to the entreaties of a doting daughter, it is essential to have an understanding of the Act and the Rules. The objective of the Act, as evident from its preamble, is to provide for the regulation of removal, storage and transplantation of human organs and tissues for therapeutic

purposes and for the prevention of commercial dealings in human organs and tissues and for matters connected therewith or incidental thereto. Section 2 (f) defines "donor" as a person not less than eighteen years of age, who voluntarily authorizes the removal of any of his human organs or tissues or both for therapeutic purposes under sub-section (1) or sub-section (2) of Section 3. Section 2(h) defines "human organ" to mean any part of a human body consisting of a structured arrangement of tissues which, if wholly removed, cannot be replicated by the body. A "minor" is defined under Section 2(hb) as a person who has not completed the age of eighteen years. As per Section 2(i) "near relative" means spouse, son, daughter, father, mother, brother, sister, grandfather, grandmother, grandson or granddaughter. The definition of "recipient" in Section 2(m) means a person into whom any human organ is, or proposed to be, transplanted. The definition of "transplantation" in Section 2(p) means the grafting of any human organ from any living person or deceased person to some other living person

for therapeutic purposes. Section 9 imposes certain restrictions on removal and transplantation of human organs or tissues or both from the body of a donor before his death. Being contextually relevant, Section 9(1) and (1-B) are extracted hereunder;

“9. Restrictions on removal and transplantation of human organs on tissues on both.- (1) Save as otherwise provided in sub-section (3), no human organ or tissue or both removed from the body of a donor before his death shall be transplanted into a recipient unless the donor is a near relative of the recipient.

(1-B) No human organs or tissues or both shall be removed from the body of a minor before his death for the purpose of transplantation except in the manner as may be prescribed.”

4. The prescription envisaged under Section 9(1-B), available at Rule 5(3)(g) of the Transplantation of Human Organs and Tissues Rules, 2014 ('Rules' for short) reads as under;

“5(3)(g).- living organ or tissue donation by minors shall not be permitted except on exceptional medical grounds to be recorded in detail with full justification and with prior

approval of the Appropriate Authority and the State Government concerned.”

5. Initially this Court had passed an interim order on 23.11.2022 directing the Appropriate Authority to hear the petitioner, and arrive at a decision as stipulated in Rule 5(3) (g). In accordance with the direction, the Appropriate Authority appointed an Expert Committee consisting of three specialist doctors to conduct a detailed evaluation of the case after examining the medical reports of the patient and after discussion with the treating doctor. After detailed evaluation the Expert Committee submitted a report, the relevant portion of which reads as under;

“The Committee perused the available medical records of the potential recipient Shri. Pratheesh P.G., His CT Scan Abdomen of 25/10/2022 and lab report including PIVKA of 05/11/2022. The committee noted that the potential recipient is beyond MILAN, UCSF and KYOTO criteria for liver transplant for Hepatocellular cancer in the background of cirrhosis, Liver.

It was also noted that Hepatocellular cancer has not been evaluated by PET scan.

Therefore as per the available reports, the said recipient is

not a candidate for considering liver transplant as a treatment option.”

After examining all aspects and after hearing the petitioner, who repeated her request for permission to donate her organ, the Appropriate Authority came to the conclusion that, as the patient does not qualify for liver transplant as a therapeutic option, the question of donating a portion of petitioner's liver does not arise. Accordingly the following order was passed ;

“Therefore the request of Kumari Devananda, to donate a portion of her liver for the treatment of her father Sri. Pratheesh P G who is under treatment for Parenchymal Liver Disease with Hepato Cellular Carcinoma- Non Alcoholic Fatty Liver, relaxing the age criteria as stipulated in 9(1-B) of the Transplantation of Human Organ and Tissue Act 1994, is declined as the patient does not qualify for preferring liver transplant as a treatment option.”

6. After receipt of report from the Appropriate Authority, the matter was heard in detail. Learned Counsel for the petitioner vociferously contended that the rejection of petitioner's request by the Appropriate Authority is patently illegal, since the decision was arrived at without considering

the petitioner's capacity to donate. On the other hand the focus was entirely on the recipient's health condition. No provision under the Act or the Rules provides for such consideration. As long as the donor is medically fit, is a near relative and is a voluntary donor, the Appropriate Authority is bound to grant permission. The consideration under Rule 5(3)(g) should be whether any exceptional circumstance for declining permission to a minor is made out. Attention is drawn to Ext. P8 certificate to point out that, another set of experts have opined that the only method by which the patient's life can be saved and the Hepatocellular Carcinoma cured is to undergo living donor liver transplantation. It is hence contended that this Court should overrule the decision of the Appropriate Authority and permit transplantation.

7. Learned Government Pleader contended that the Act prohibits organ donation by minors and Rule 5(3)(g) provides exemption only under exceptional circumstances. It is for the Appropriate Authority to decide whether exceptional circumstances exist or not. The authority having taken a

decision, this Court should not sit in judgment over that.

8. As the Appropriate Authority and the Expert Committee had relied on the Milan, USCF protocols to conclude that the patient is not a fit candidate for transplant, Medical Journals were referred to understand as to what the protocols are. It is seen that the Milan criteria was introduced by Mazzaferro in 1996, restricting transplantation in adults with HCC as follows: (1) single tumor diameter less than 5 cm; (2) not more than three foci of tumor, each one not exceeding 3 cm; (3) no angioinvasion; (4) no extrahepatic involvement. Since the introduction of the criteria, long-term recurrence-free survival after liver transplantation in adults with HCC improved from 30% to 75%. Likewise, the USCF protocol was developed by the University of California, San Francisco. As per the above protocols the minimum requirement to qualify for a liver transplant are (i) the patient has clinical signs of liver failure or primary liver cancer, (ii) is well enough to have the surgery and recovery and (iii) is not considered at risk of future alcohol or drug abuse.

9. A contradictory opinion was expressed by the team of experts at the Rajagiri Health Care and Education Trust in Ext. P8, the relevant portion of which reads as under;

"Although his tumour status is outside the usual standard criteria for deceased donor liver transplantation - ((MILAN and UCSF criteria), "Standard Treatment Guidelines Organ Transplant: Liver; Ministry of Health & Family Welfare, Government of India"), we believe at present there is no prohibitive contraindication for a living donor liver transplantation (AFP value < 500, No Macrovascular invasion, No extra hepatic disease and relatively young patient with stable cardiac and pulmonary status). On account of his high MELD score and recurrent encephalopathy due to severe background liver disease, he is not a candidate for any other alternative treatment options like TACE/TARE /SBRT/immunotherapy or Tyrosine Kinase Inhibitors. The only option in front of him to sustain his life and a potential cure from HCC is to undergo a living donor liver transplantation at the earliest. We have also advised him and his family to get a second opinion from a high volume liver transplant centre within or outside the state."

The above opinion was rendered based on the Toronto Criteria. Faced with two different expert opinion and being

conscious of the consequence of rejecting the petitioner's request for permission for organ donation, by interim order dated 16.12.2022, the Appropriate Authority was directed to seek further opinion from the Expert Committee after taking into account the opinion in Ext.P8 certificate also.

10. In terms of the direction, the Expert Committee reconsidered the matter and rendered its opinion pursuant to which the Appropriate Authority recommended to allow the petitioner's plea. Being contextually relevant the conclusion reached by the Appropriate Authority is extracted hereunder.

“A detailed perusal of the statute reveals that the condonation of the age criteria can only be allowed only in exceptional medical grounds. The Act of 1994 clearly shows that the objective of the Act is to provide for the regulation of the human organs or tissues for therapeutic purposes and prevention of commercial dealings. The long object and reasons of the Act show that the underlying legislative intent was to curb commercial dealings in human organs. It is more regulatory than prohibitory.

This authority have examined all aspects of the case in question with the help of the expert committee report and the report of clinical psychologist and the Ext P8 medical report and the submission made by the petitioners.

According to my comprehension of the matter in question, the plea of the petitioner may be allowed subject to the final order of the honorable High Court, relying on the facts that, the petitioner has no other options other than a transplantation and the donor is fully aware of the consequences of her decision to donate a portion of her liver out of compassion to her father and she has taken the decision with her free will and without any coercion or compulsion. Hence ordered accordingly and the order dated 23rd November 2022 in WP (C) No 36826/2022 of Honorable High Court is thus complied with.”

11. It is heartening to note that the unrelenting fight put up by Devananda has finally succeeded. I applaud the petitioner's fight to save her father's life. Blessed are parents who have children like Devananda. I also place on record my appreciation for the prompt manner in which the Appropriate Authority responded to the directions issued by this Court. Appreciation is also due to Advs. P.R. Shaji and P.S. Appu who went beyond the call of their professional duty to help the Court in reaching the right conclusion.

The writ petition is disposed of permitting the petitioner to donate a portion of her liver for conducting her father's transplantation surgery, subject to the other requirements of the Act and the Rules.

Sd/-

V.G. ARUN
JUDGE

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APPENDIX OF WP (C) 36826/2022

PETITIONER EXHIBITS

- Exhibit P1 TRUE COPY OF THE DISCHARGE SUMMARY OF THE PATIENT PRATHEESH P.G. WITH I.P.NO.182759 ISSUED BY THE RAJAGIRI HOSPITAL ON 05-11-2022.
- Exhibit P2 TRUE COPY OF THE CT SCAN REPORT OF THE PATIENT PRATHEESH P.G. WITH I.P.NO.182759 ISSUED BY THE RAJAGIRI HOSPITAL ON 25-10-2022.
- Exhibit P3 TRUE COPY OF THE SECONDARY SCHOOL LEAVING CERTIFICATE OF THE PETITIONER, ISSUED BY THE GOVERNMENT OF KERALA, GENERAL EDUCATION DEPARTMENT WITH REGISTRATION NO.366962.
- Exhibit P4 A TRUE COPY OF THE REPRESENTATION DATED 18.11.2022, SUBMITTED BEFORE THE APPROPRIATE AUTHORITY.
- Exhibit P5 A TRUE COPY OF THE REPRESENTATION 16.11.2022, SUBMITTED BEFORE THE STATE GOVERNMENT.
- Exhibit P6 A TRUE COPY OF THE PROCEEDINGS DATED 26.11.2022, OF THE APPROPRIATE AUTHORITY.
- Exhibit P7 A TRUE COPY OF THE 18-F-FDG PET CT IMAGING REPORT DATED 01.12.2022 ISSUED BY RAJAGIRI HOSPITAL, ALUVA.
- Exhibit P8 A TRUE COPY OF THE LETTER 08.12.2022, ISSUED BY A TEAM OF DOCTORS OF RAJAGIRI HOSPITAL, ALUVA.