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* **IN THE HIGH COURT OF DELHI AT NEW DELHI**

% *Date of Order* : 28th May, 2019

+ W.P.(C) 6057/2019, CM Appl. 26118/2019 (stay)
SHIKHA THROUGH HER LEGAL GUARDIAN / NEXT FRIEND
MR. RAGHUBIR SINGH Petitioner

versus

UNION OF INDIA AND ANR. Respondents

+ W.P.(C) 6069/2019, CM Appl. 26192/2019 (stay)
MASTER UDAY DAS THORUTH HIS LEGAL GUARDIAN/
NEXT FRIEND MR. UTTAM DAS Petitioner

versus

UNION OF INDIA AND ANR. Respondents

Present : Mr. Ajay Kohli & Ms. Pooja Vohra, Advocates for petitioners
in both items.
Mr. Kirtiman Singh, CGSC for UOI with Mr. Waize Ali Noor,
Advocate in both items.
Mr. Anuj Aggarwal, ASC for R-2 with Mr. Atul Goyal,
Advocate in both items.

CORAM:

HON'BLE MR. JUSTICE G.S.SISTANI

HON'BLE MS. JUSTICE JYOTI SINGH

G.S. SISTANI, J. (ORAL)

CM APPL26119/2019 (Exemption) in W.P.(C) 6057/2019
CM APPL26193/2019 (Exemption) in W.P.(C) 6069/2019

1. Exemptions are allowed subject to all just exceptions.
2. Applications stand disposed of.

W.P.(C) 6057/2019 & W.P.(C) 6069/2019

3. Petitioners claim to be a patient of Cerebral Palsy, which is a movement disorder caused by abnormal development or damage to the parts of the brain that control movement, balance and posture. It is also the case of the petitioners that they visited the clinic 'Nutech Mediworld at Green Park, New Delhi' where stem cell treatments are provided. Since February, 2019 till March, 2019, petitioner in W.P.(C) 6057/2019 and from October, 2018 till March, 2019, petitioner in W.P.(C) 6069/2019 claim that they have shown visible improvement since the transplantation of Embryonic Stem Cells, from October, 2018 onwards as compared to their medical condition prior to the commencement of their treatment.
4. Mr. Kohli, counsel for the petitioners submits that petitioners have been forced to approach this court on account of a notification 'New Drugs and Clinical Rules, 2019 ("New Rules")', which have been notified by respondent no.1, which includes 'stem cell derived products' under the definition of 'new drugs' Clause (v) of sub-clause (w) of Rule 2 of the new Drugs and Clinical Trials Rules, 2019. It is contended that the effect of this notification would be that the medicine prescribed would fall under the definition of 'new drug' and would require approval from the concerned authority in terms of the said rules. Learned counsel submits that in view of the notification, the clinic has stopped providing medical treatment i.e. Embryonic Stem Cell therapy, which is a treatment required by the petitioners for their day to day sustenance of life and basic activities, and in case, this treatment is discontinued further, it would lead to a serious impact on their health. It is further

contended that the clinic in question i.e. Nutech Mediworld, which is administering the medicine at present, cannot function under the New Rules, unless the license is obtained. It is pointed out that till the rules fall in place and the marketing license is provided during the intervening period, serious prejudice would be caused to the health of the petitioners i.e. between the application is made under the authority i.e. Drug Controller, Govt. of India and a decision is taken, which would not take place within a few months, in the interregnum, in the absence of the treatment, life of the petitioners would be in jeopardy and would rapidly lose their muscle strength and is facing growing fatigue on account of their condition.

5. Learned counsel for the petitioners submits that the only relief which he seeks is to seek a direction to the respondents to allow the Nutech Mediworld clinic from where the petitioners are receiving treatment to continue to provide the treatment to the petitioners till such time the formalities are completed and the Nutech Mediworld clinic or at least some other clinic obtains a licence.
6. Notice to show cause as to why these petitions be not admitted. Counsels for the respondents accept notice.
7. In the aforesaid circumstances, this court considers it apposite to direct, as an interim measure, that the treatment being provided to the petitioner will not be impeded. This is subject to the clinic in question submitting all the information as to the treatment being afforded to the petitioners to the Central Drugs Standard Control Organisation (CDSO), within a period of one week from today positively. The concerned authority shall examine whether the said treatment or the

products being administered to the petitioners, prima facie, fall within the scope of the expression 'New Drugs' as defined under Rule 2(1)(w) of New Drugs and Clinical Trials Rules, 2019, and communicate its view to the petitioners and the said clinic.

8. Accordingly, as an interim measure and till such time Nutech Mediworld clinic or at least some other clinic applies for a licence and the licence is processed, the Nutech Mediworld clinic would continue to provide treatment to the petitioners.
9. In view of the agreed directions, the writ petition is disposed of, as prayed by the counsel for the petitioners. This arrangement is without prejudice to the rights and contentions of both the parties.

CM Appl. 26118/2019 (stay) in W.P.(C) 6057/2019

CM Appl. 26192/2019 (stay) in W.P.(C) 6069/2019

10. In view of the order passed in the writ petitions, the applications stand disposed of.

G.S.SISTANI, J

JYOTI SINGH, J

MAY 28, 2019

ck/