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

Date of decision: 25th APRIL, 2023

IN THE MATTER OF:

\+ **W.P.(C) 4008/2022**

RAMAN KAKAR ..... Petitioner

Through: Petitioner in – person.

versus

UNION OF INDIA THROUGH SECRETARY & ORS.

..... Respondents

Through: Mr. Kirtiman Singh, CGSC with Ms. Vidhi Jain, Advocate for R-1 and R-2.

**CORAM:**
**HON'BLE THE CHIEF JUSTICE**
**HON'BLE MR. JUSTICE SUBRAMONIUM PRASAD**

**JUDGMENT(ORAL)**

1. The instant Public Interest Litigation has been filed for issuance of an appropriate writ, order or direction to quash circular bearing D.O.No. 28015/27/2012 –TB (Part II) dated 18.12.2018, issued by Respondent No.2 herein, which, according to the Petitioner herein, discards Streptomycin Injection, which is used in curing category-II Tuberculosis (TB) Patients. It is the submission of the Petitioner that the Government has not given adequate attention towards the cure of TB which is a poor man's disease. It is stated that India accounts for about 27 lakh TB patients out of which 22 lakh patients are fresh/new cases who suffered TB for the first time and they are prescribed a 'milder' therapy (called Category I), consisting of 4 oral

drugs - Ethambutol, Isoniazide, Rifampicin , Pyrazinamide. It is stated that the remaining five Lakh patients are persons who have contracted the disease for the second or the third time and they are called category-II patients. It is stated that category – II patients require a more aggressive treatment which includes Streptomycin Injection in addition to four abovementioned drugs.

2. It is stated that the Petitioner is a qualified Allopathic Doctor and holds a Diploma in TB and Chest Diseases. It is stated that the Petitioner has already filed four PILs which all pertains to treatment of TB patients. It is submitted in the Petition that Ministry of Health and Family Welfare, Government of India, has issued a circular dated 18.12.2018 by which the current regimen for category II patients will no longer be used and all category II patients will be initiated on standard first line anti TB regimen as prescribed for new TB patients. Relevant portion of the said circular reads as under:

> *"**8.** The States may ensure availability of injection Streptomycin for all patients being initiated till date. In case, the stocks of Streptomycin are fully consumed in the entire State, the States may procure only limited stock (5ml along with syringe and needle and water for injection) to complete treatment of patients initiated on previous injectable containing regimen."*

3. The Petitioner places reliance on Order dated 23.01.2017, passed by the Apex Court in Writ Petition (Civil) No.604/2016 titled as Dr. Raman Kakar, Government Medical Officer, Revised National TB Control Program of India v. Union of India and Anr., wherein the Supreme Court had directed that new Fixed-Dose Combination (FDC) drugs for daily regimen for

treating TB patients will be administered to new patients after the expiry of nine months. The Petitioner submits that the present circular is contrary to the judgment passed by the Apex Court wherein the Apex Court had striked down the order passed by the Government of India which stated that "…*the earlier regimen whereby treatment was administered thrice in a week, will not be continued under any circumstances after expiry of a period of nine months from today"*. The Apex Court had granted nine months to the Additional DDG, Directorate General of Health Services, Ministry of Health and Family Welfare, for the nation-wide transition to the new regimen. According to the Petitioner, the Apex Court has put an end to the earlier treatment replacing it by an effective daily dose model, which, according to the Petitioner, would include Streptomycin Injection. The Petitioner has, therefore, filed the instant Petition.

4. Notice in the present petition was issued on 27.04.022 and an affidavit has been filed by the Additional DDG, Central TB Division, Ministry of Health and Family Welfare, Government of India. Relevant portions of the said affidavit reads as under:

> *"**7**. It is respectfully submitted that contrary to the submissions of the Petitioner, [D.O. No. 28015/27/2012-TB (Part II) dated 18.12.2018] by the Respondent No. 2 ("Impugned circular") is not in utter disregard or violation of the Supreme Court order dated 23.01.2017 as well as Article 21 of the Constitution of India., and not issued in a blinded or mechanical manner lacking scientific reasoning or with any ulterior motive.*
>
> *8. The Answering Respondent respectfully submits that prior to the issuance of the Impugned Circular dated 18.12.2018, new Tuberculosis ("TB") patients known*

*as Category-I were treated with four oral drugs. The TB patients who received treatment and were cured and began falling showing ill health again (Relapse Cases), came to fall under Category-II were treated with five drugs [four oral and one injectable drug known as Injection Streptomycin]. This categorization system was replaced with 'Drug susceptibility patternbased' treatment in line with global best practices that excludes "Injection Streptomycin" for the treatment of Drug Susceptible TB.*

*9. It is pertinent to mention herein that Global evidence showed that Category - II treatment was less effective (median success rate of 68%) and it also promoted the emergence of multi-drug resistance TB (MDR-TB).*

*10. The National Technical Expert Group ("NTEG") comprises a group of eminent medical professionals from different fields such as clinicians and public health experts with representation from ICMR, medical colleges, WHO, program partners etc. having decades of experience treating patients with TB and managing the TB program in the country.*

*11. The NTEG under erstwhile RNTCP (now NTEP) studied the global evidence as well as India specific evidence which also showed that Category - II treatment was less effective and led to emergence of multi-drug resistance. Based on the data and information, the NTEG recommended discontinuation of Category - II treatment. Accordingly, Category II line of treatment was replaced by the "Drug Susceptibility pattern-based" treatment. The NTEG comprises a group of eminent medical professionals from different fields such as clinicians and public health experts with representation from ICMR, medical colleges, WHO, program partners etc. having decades of experience treating patients with TB and managing*

*the TB program in the country.*

*12. The transition from "Categorization System" to the 'Drug susceptibility pattern-based' treatment is based on the following reasons:*

*a. Earlier, category - II treatment was associated with very low cure rates (68% globally), high relapse rates and development of drug resistant. Therefore, Category - II was ineffective and dangerous.*

*b. WHO, in the year 2017, had recommended transition from Category II treatment to DST based treatment as the standard of care for all patients of TB relying on global evidence.*

*c. In the year 2018, based on in-country evidence and experience in India, the National Technical Expert Group for TB recommended the same to the Central TB Division.*

*d. Thereafter, the program has shifted to the DST pattern-based regimen. This shift has taken place globally in almost all countries including India.*

*e. It is worth mentioning here that prior to the issuance of the circular dated 18.12.2018, treatment under categorization system was done without testing the patients for drug susceptibility pattern of the disease-causing bacteria. Patients were only tested when they showed signs of treatment failure or suspected drug resistance. Because the laboratory capacity was not equipped at that point of time to test all patients for drug susceptibility pattern. Subsequently the scenario changed. The governments (Centre and State Governments) across the country invested heavily to strengthen and upgrade the laboratory network. Resultantly, the tests to diagnose drug susceptibility*

*patterns in TB patients became accessible for all TB patients.*

*f. As per the diagnostic algorithm under drug susceptibility pattern based treatment regimen, all TB suspects are offered a rapid molecular test for 'diagnosis of TB' and testing 'susceptibility status to Rifampicin' (through Nucleic Acid Amplification Test - NAAT, result within 1 day). If diagnosed with TB on NAAT, all patients are offered Isoniazid susceptibility testing (through First Line - Line Probe Assay - FLLPA, result within 3 days). Rifampicin and Isoniazid are the two most effective drugs for the treatment of Drug Susceptible TB (DSTB). If the patient is susceptible to both the drugs, then the 4 drug DSTB regimen is considered an effective regimen for that patient. In case the patient shows signs of treatment failure due to development of resistance to any drug during treatment course, the guidelines mandate testing the patient for extended panel of drugs to rule out resistance and modify treatment accordingly, if needed.*

*g. When the patient is found resistant to any of the two above mentioned drugs (Rifampicin and Isoniazid), s/he is offered additional tests - i.e., called Second Line LPA (SLLPA) and Liquid Culture DST (LC-DST). This enables the clinician to know the susceptibility status to the entire range of anti-TB drugs at the baseline. Based on drug susceptibility pattern, the patient, thereafter, is initiated on the Drug Resistant TB treatment. The case of the petitioner is confined to the Drug Susceptible TB (DSTB) challenging the elimination of Injection Streptomycin and NOT the Drug Resistant TB (DRTB).*

*h. The petitioner's admiration for the Injection-Streptomycin is not acceded to over and above for the following reasons:*

*i. Toxicity caused by Streptomycin in Category - II treatment.*

*ii. Streptomycin was the reason for irreversible ear and kidney damage in a significant proportion of cases of TB patients who .; were put on Category - II treatment.*

*iii. Repeated painful injections of Streptomycin over long course of treatment.*

*13. The contention of the Petitioner that CBNAAT, which is very expensive, cannot replace "Sputum Smear Microscopy" test but shall complement it in practice and further that the Government of India erred in opting for CBNAAT is negated on the basis of the expert data finding that NAAT detects 130 bacteria per ml of sample while smear microscopy detects bacterial load of> 10,000 per ml. Therefore, large proportion of cases which were missed earlier with "Sputum Smear Microscopy" test are now detected with the use of NAAT. However, for a better result of TB diagnosis, both NAAT and Line Pro Assay (LPA) tests are being conducted to diagnose TB and DR TB in the patients. Hence, it is appalling that the Petitioner on one hand criticizes the CBNAAT machines while on the other hand welcomes the initiative of the Government for the introduction of CBNAAT which is evident from his revelation under para - "M" of the GROUNDS where a prayer for restoration of the use of Injection Streptomycin is made.*

*14. The contention of the Petitioner that the Respondents violated Hon'ble Supreme Court Order dated 23.01.2017 is devoid of merits. It is pertinent to mention herein that Hon'ble Supreme Court vide its order dated 23.01.2017 in the matter of W.P. (C) No.*

> *604 of 2016 directed the Respondents to effect transition from "thrice in a week" regimen to "daily regimen" Anti TB Treatment (ATT). The "daily regimen" treatment is meticulously adhered to by the National TB Elimination Programme (NTEP) and the erstwhile "thrice in a week" treatment regimen is completely stopped in compliance with the afore-said order of Hon'ble Supreme Court. Categorization of TB Patients ( category-I for new and Category-II for old TB Patients) was discontinued on the recommendation of National Technical Expert Group (NTEG) for TB which considered the incountry evidence & experience vis-a-vis the evidence based best practices followed globally with a view to provide more effective and efficient treatment for TB patients leveraging the advent and coverage of improved diagnostic facilities to avoid severe side effects of Injection Streptomycin. Hence, the order of the Apex Court for transition from "thrice in a week" regimen to "daily regimen" ATT is being followed till date.*
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> *15. The contention of the Petitioner that the Central Government has historically displayed antipathy towards optimal purchase of Injection Streptomycin, especially subsequent to the order dated 23.01.2017 passed by the Hon'ble Supreme Court, is denied on· the;grgi;Jnd that the PIL W.P. (C) No. 1034/2017 filed by the petitioner for serious lapses in drug procurement was dismissed by thi$ Hon'ble Court vide its order dated 13.11.2017. Therefore, the Respondent No. 1&2 neither violated Supreme Court order dated 23.01.2017 nor Article 21 of the Constitution as elimination of Category-II treatment brings improvement in patients' health conditions."*

5. A perusal of the affidavit discloses that the new regimen for treatment has been evolved after consultations with experts. It is well settled that

courts, while exercising their jurisdiction under Article 226 of the Constitution of India, do not sit as an Appellate Authority over the decision of experts. It is also well settled that High Courts, while exercising its jurisdiction under Article 226 of the Constitution of India, do not pass writs directing the State to adopt a particular policy. Policy making is purely in the realm of Government and Courts do not pass directions in the matters of framing of policy.

6. The Apex Court in Small Scale Industrial Manufactures Assn. v. Union of India, **(2021) 8 SCC 511,** has observed as under:

> *"**60**. In catena of decisions and time and again this Court has considered the limited scope of judicial review in economic policy matters. From various decisions of this Court, this Court has consistently observed and held as under:*
>
> ***60.1.** The Court will not debate academic matters or concern itself with intricacies of trade and commerce.*
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> ***60.2**. It is neither within the domain of the courts nor the scope of judicial review to embark upon an enquiry as to whether a particular public policy is wise or whether better public policy can be evolved. Nor are the courts inclined to strike down a policy at the behest of a petitioner merely because it has been urged that a different policy would have been fairer or wiser or more scientific or more logical. Wisdom and advisability of economic policy are ordinarily not amenable to judicial review.*
>
> ***60.3.** Economic and fiscal regulatory measures are a field where Judges should encroach upon very warily as Judges are not experts in these matters.*

***61***. *In R.K. Garg [R.K. Garg v. Union of India, (1981) 4 SCC 675 : 1982 SCC (Tax) 30] , it has been observed and held that laws relating to economic activities should be viewed with greater latitude than laws touching civil rights such as freedom of speech, religion, etc. It is further observed that the legislature should be allowed some play in the joints, because it has to deal with complex problems which do not admit of solution through any doctrinaire or straitjacket formula and this is particularly true in case of legislation dealing with economic matters.*

***62.*** *In Arun Kumar Agrawal [Arun Kumar Agrawal v. Union of India, (2013) 7 SCC 1] , this Court (at SCC p. 18, para 43) had an occasion to consider the following observations made by the Supreme Court of the United States in Metropolis Theater Co. v. Chicago [Metropolis Theater Co. v. Chicago, 1913 SCC OnLine US SC 123 : 57 L Ed 730 : 228 US 61 (1913)] :*

> *"43. ... '... The problems of Government are practical ones and may justify, if they do not require, rough accommodation, illogical, if may be, and unscientific. But even such criticism should not be hastily expressed. What is the best is not always discernible; the wisdom of any choice may be disputed or condemned. Mere errors of Government are not subject to our judicial review. It is only its palpably arbitrary exercises which can be declared void.…' (Metropolis Theater Co. case [Metropolis Theater Co. v. Chicago, 1913 SCC OnLine US SC 123 : 57 L Ed 730 : 228 US 61 (1913)] , L Ed p. 734)"*

***63***. *This Court in Nandlal Jaiswal [State of M.P. v. Nandlal Jaiswal, (1986) 4 SCC 566] has observed that the Government, as laid down in Permian Basin Area Rate Cases, In re [Permian Basin Area Rate Cases, In*

*re, 1968 SCC OnLine US SC 87 : 20 L Ed 2d 312 : 390 US 747 (1968)] , is entitled to make pragmatic adjustments which may be called for by particular circumstances. The court cannot strike down a policy decision taken by the State Government merely because it feels that another policy decision would have been fairer or wiser or more scientific or logical. The court can interfere only if the policy decision is patently arbitrary, discriminatory or mala fide.*

***64.*** *In Balco Employees' Union [Balco Employees' Union v. Union of India, (2002) 2 SCC 333] , this Court has observed that wisdom and advisability of economic policies are ordinarily not amenable to judicial review unless it can be demonstrated that the policy is contrary to any statutory provision or the Constitution. In other words, it is not for the courts to consider relative merits of different economic policies and consider whether a wiser or better one can be evolved. It is further observed that in the case of a policy decision on economic matters, the courts should be very circumspect in conducting an enquiry or investigation and must be more reluctant to impugn the judgment of the experts who may have arrived at a conclusion unless the court is satisfied that there is illegality in the decision itself.*

***65****. In Peerless General Finance & Investment Co. Ltd. [Peerless General Finance & Investment Co. Ltd. v. RBI, (1992) 2 SCC 343] , it is observed and held by this Court that the function of the court is to see that lawful authority is not abused but not to appropriate to itself the task entrusted to that authority. It is further observed that a public body invested with statutory powers must take care not to exceed or abuse its power. It must keep within the limits of the authority committed to it. It must act in good faith and it must act reasonably. Courts are not to interfere with economic*

*policy which is the function of experts. It is not the function of the courts to sit in judgment over matters of economic policy and it must necessarily be left to the expert bodies. In such matters even experts can seriously and doubtlessly differ. Courts cannot be expected to decide them without even the aid of experts. It is further observed that it is not the function of the court to amend and lay down some other directions. The function of the court is not to advise in matters relating to financial and economic policies for which bodies like RBI are fully competent. The court can only strike down some or entire directions issued by RBI in case the court is satisfied that the directions were wholly unreasonable or violative of any provisions of the Constitution or any statute. It would be hazardous and risky for the courts to tread an unknown path and should leave such task to the expert bodies. This Court has repeatedly said that matters of economic policy ought to be left to the Government.*

***66.*** *In Narmada Bachao Andolan [Narmada Bachao Andolan v. Union of India, (2000) 10 SCC 664] , in paras 229 and 233, it is observed and held as under : (SCC pp. 762-63)*

> *"229. It is now well settled that the courts, in the exercise of their jurisdiction, will not transgress into the field of policy decision. Whether to have an infrastructural project or not and what is the type of project to be undertaken and how it has to be executed, are part of policy-making process and the courts are ill-equipped to adjudicate on a policy decision so undertaken. The Court, no doubt, has a duty to see that in the undertaking of a decision, no law is violated and people's fundamental rights are not transgressed upon except to the extent permissible under the Constitution.*

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> *233. At the same time, in exercise of its enormous power the Court should not be called upon to or undertake governmental duties or functions. The courts cannot run the Government nor can the administration indulge in abuse or non-use of power and get away with it. The essence of judicial review is a constitutional fundamental. The role of the higher judiciary under the Constitution casts on it a great obligation as the sentinel to defend the values of the Constitution and the rights of Indians. The courts must, therefore, act within their judicial permissible limitations to uphold the rule of law and harness their power in public interest. It is precisely for this reason that it has been consistently held by this Court that in matters of policy the court will not interfere. When there is a valid law requiring the Government to act in a particular manner the court ought not to, without striking down the law, give any direction which is not in accordance with law. In other words, the court itself is not above the law."*

***67**. In Prag Ice & Oil Mills [Prag Ice & Oil Mills v. Union of India, (1978) 3 SCC 459 : AIR 1978 SC 1296] , this Court observed as under : (SCC p. 478, para 24)*

> *"24. ... We do not think that it is the function of this Court or of any court to sit in judgment over such matters of economic policy as must necessarily be left to the Government of the day to decide. Many of them, ... are matters of prediction of ultimate results on which even experts can seriously err and doubtlessly differ. Courts can*

*certainly not be expected to decide them without even the aid of experts."*

***68**. In P.T.R. Exports (Madras) (P) Ltd. [P.T.R. Exports (Madras) (P) Ltd. v. Union of India, (1996) 5 SCC 268] , this Court observed as under : (SCC p. 272, paras 3 & 5)*

*" ... In matters of economic policy, it is settled law that the court gives a large leeway to the executive and the legislature. ... Government would take diverse factors for formulating the policy ... in the overall larger interest of the economy of the country ... The Court therefore would prefer to allow free play to the Government to evolve fiscal policy in the public interest and to act upon the same."*

***69**. What is best in the national economy and in what manner and to what extent the financial reliefs/packages be formulated, offered and implemented is ultimately to be decided by the Government and RBI on the aid and advice of the experts. The same is a matter for decision exclusively within the province of the Central Government. Such matters do not ordinarily attract the power of judicial review. Merely because some class/sector may not be agreeable and/or satisfied with such packages/policy decisions, the courts, in exercise of the power of judicial review, do not ordinarily interfere with the policy decisions, unless such policy could be faulted on the ground of mala fides, arbitrariness, unfairness, etc."*

7. In view of the above, the Writ Petition is dismissed along with the pending application(s), if any.

**SATISH CHANDRA SHARMA, CJ**

**SUBRAMONIUM PRASAD, J**

**APRIL 25, 2023**
*Rahul*