IN THE SUPREME COURT OF INDIA

CIVIL ORIGINAL JURISDICTION

WRIT PETITION (C) NO. OF 2015

PUBLIC INTEREST LITIGATION

A PIL FILED UNDER ARTICLE 32 SEEKING ISSUANCE OF WRIT IN THE NATURE OF MANDAMUS AND APPROPRIATE DIRECTIONS TO THE RESPONDENTS TO:

ABOLISH ITS CURRENT PRACTICE OF ADMINISTERING 'THREE DOSES OF MEDICINES PER WEEK' TO ALL PATIENTS, SUFFERING FROM TUBERCULOSIS (TB). AND TO REPLACE IT WITH TIME-TESTED 'DAILY-DOSE' REGIMEN.

IN THE MATTER OF:

Dr. Raman kakar, Governement Medical Officer,

Revised National TB Control Program of India .....Petitioner

VERSUS

Union of India and ANR ……Respondents

WITH

I.A. NO. OF 2015

APPLICATION FOR APPEARING, ARGUING BY PETITIONER-IN-PERSON

WITH

I.A No. OF 2015

APPLICATION FOR DIRECTIONS / INTERIM RELIEF

WITH

I.A No. OF 2015

APPLICATION FOR FILING ADDITIONAL / UPDATED DOCUMENTS

PAPER BOOK

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PETITIONER-IN-PERSON – DR. RAMAN KAKAR

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IN THE SUPREME COURT OF INDIA

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PETITIIONER

New Delhi Date: July 3, 2015

PROFORMA FOR FIRST LISTING

SECTION-X

The case pertains to (Please tick/check the correct box):

□Central Act: **N.A.**

□Section: **N.A.**

□ Central Rule: (Title) **N.A.**

□ Rule No(s): **N.A.**

□ State Act: (Title)- **N.A.**

□ Section: **N.A.**

□ State Rule: (Title) **N.A.**

□ Impugned Interim Order: (Date) **N.A.**

□ Impugned Final Order: Dated **N.A.**

□ High Court: (Name) **N.A.**

□ Names of Judges: **N.A.**

□ Tribunal/Authority: (Name) **N.A.**

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1. Nature of matter: **Civil**

2.(a) Petitioner: **Dr. Raman kakar, Governement Medical Officer, Revised National TB Control Program of India**

(b) e-mail ID: raman24march@yahoo.com

(c) Mobile phone number: **9891397528**

3. (a) Respondent No.1: **Union of India and Anr**.

(b) e-mail ID: **N.A.**

(c) Mobile phone number: **N.A.**

4. (a) Main category classification: **PIL UNDER ARTICLE 32 OF THE CONSTITUTION OF INDIA**

(b) Sub classification: **CIVIL WRIT PETITION**

5. Not to be listed before: **N.A.**

6. Similar/Pending matter: **N.A.**

7. **Criminal Matters:** **N.A.**

(a) Whether accused/convict has surrendered: □Yes□No

(b) FIR No. Date: **N.A.**

(c) Police Station: **N.A.**

(d)Sentence Awarded: **N.A.**

(e)Sentence Undergone: **N.A.**

8. **Land Acquisition Matters:**

(a) Date of Section 4 notification: **N.A.**

(b) Date of Section 6 notification: **N.A.**

(c) Date of Section 17 notification: **N.A.**

9. **Tax Matters**: State the tax effect: **N.A.**

10. **Special Category** (first petitioner/appellant only): **N.A.**

□Senior citizen **N.A**.

11. Vehicle Number (in case of motor Accident Claim matters): **N.A.**

12. Decided cases with citation: **N.A.**

(DR. RAMAN KAKAR)

Date:03.08.2015 PETITIONER-IN-PERSON

raman24march@yahoo.com

SYNOPSIS AND LIST OF DATES

A. 60 years ago, man found cure for Tuberculosis (TB) in the form of 5 drugs – a miracle for mankind.

B. West was able to control TB – a historic proof that these 5 drugs when given in Daily dose (in vogue then) work perfect.

C. Later, some researchers claimed that these 5 drugs were equally effective even when given as 'three doses per week' (3/7). That reduces drug-cost to 43% and facilitates supervision. But, most nations were not convinced; they continue daily dose, till date.

D. However, India hastily adopted that low-cost, thrice-weekly therapy in to her Revised Program called DOTS (Directly Observed Treatment Short Course) in 1997, and has since placed about 15 million patients on it, self-claiming 85% success. On paper!

E. Situation on the ground, however, seems no better; India continues to harbor maximum patients world-wide, 2 Indians continue to die every 3 minutes, incurable (drug-resistant) TB is on steep rise.

F. India's DOTS model is defective. Thrice-weekly dosing truncates the therapy; weakens it; wrenches out the very soul of treatment. Cure is elusive. Even when achieved, cure doesn't last long. Symptoms initially abate, patients feel better for some time but then, many return sick, for yet another course (called Relapse). Relapse is known to be the best indicator of efficacy of therapy. It is about 12% in India (compared to below 5% internationally).

G. Petitioner's team scrutinized long term fate of 36785 patients registered under DOTS in Faridabad. Of them, 4675 (12.7%) returned sick and were found re-registered. That is risky because curing them a second time is that much harder – recurrence is a bad omen; it is like stepping in to a quagmire of incurability. Relapsed patients when re-treated, cure rates are low - 65% (as against 84% in new, first-time TB cases). Indian DOTS has been operating like an obscure slow poison; rather than eradicating TB, it has been doing the very opposite –

generating lethal, drug-resistant strains (through recurrence) and that too on an industrial scale, ominous for human kind.

H. Indian DOTS program never conducted any systematic follow up of treated patients to formally compute Relapse!

I. Is thrice weekly really as effective as Daily? Researchers found insufficient evidence. Several justify Daily. But few favor thrice-weekly concept. On what scientific basis did India change her regimen in 1997? And why? - remain mystery. Especially, when there was no pressing need, because Daily dose works perfect. 20 (out of 22) high TB burden countries use daily dose. Even extremely poor nations e.g. Nepal etc. rejected that cheaper option of thrice-weekly therapy! Did India act penny-wise pound-foolish?

J. A re-treatment patient in India gets only 24 (Streptomycin) injections; everywhere else in the world, such a patient would get 60 injections!

K. Thus, an unscientific model that flouts the basic tenets of medicine was silently designed by Central government. That it thrives on unchallenged for 18 years, ignoring ominous indicators epitomizes total govt. apathy, neglect and dishonesty. Govt. (and her technical adviser, WHO) have converted India into a massive laboratory and sick citizens in to guinea pigs for the largest and longest human experiment ever. Despite overwhelming evidence against it pouring in.

L. Predictably, the evil experiment has backfired. Now, it is pay-back time; drug resistant strains are rising; present and future generations will pay the price. Honorable court is the last hope for damage control.

M. By way of this petition, the petitioner prays that current practice of giving three doses per week to TB patients may kindly be abolished at once. And the time-tested, traditional and original Daily dosing therapy may be re-installed. Urgently.

LIST OF DATES

Date		Annexure
For Ages	Consumption (TB) was feared as a family killer.	
1882	Sputum test discovered; diagnosis yes, but cure no…..only wait…… for death.	
1895	X-ray invented; one could witness the shadows ……..of certain death.	
1944-66	Cure found! 5 drugs (SEHRZ)! A miracle for humankind!	
1970's	These 5 drugs in Daily doses worked wonders for mankind; TB began to decline in West - a historic proof that original 'Daily dose' method works perfect.	
1962	India launched 1st National TB Program, with STH drug-regime, which took 12-18 months to heal. Soon, in 1966, wonder drug (Rifamycin) was discovered. But, govt. of India slept. It didn't include newer, potent drugs (like Rifamycin, Ethambutol and Pyrazinamide), which heal faster - in 6 months. Govt. continued to feed ancient, outdated, weak drugs (like Thiacetazone) to innocent patients ….till 1997 (when DOTS arrived). India remained backward for 30 years.	
1970-2000	TB declines in the West; global R&D switched off; zero research. Even though poor world kept visibly burning.	
1992	After 30 yrs, 1st program reviewed. Only 30% patients documented to have completed 12-18 month long treatment, others defaulted. Program a tacit Failure.	
1993-96	3 year pilot testing of the new package	

	namely thrice-weekly DOTS. Follow up of treated patients was impossible within brief 3 years; so, only operational (and not technical) testing was conducted.	
1997	India implements Thrice-weekly DOTS in phased manner; drugs cost 43% of Daily regimen. Quota of Injections reduced from 60 to 24 vials! But, at last, newer drugs included – 30 years late.	
1997-2015	Little global R&D. No new drugs since. Even today, Indian DOTS uses ancient tools; sputum test is 133, five drugs are 50 and BCG vaccine is 95 years old.	
2004	Government inducts Petitioner into advisory committee on TB program	
2005	Research in South India DOTS: Relapse = 12%.	P-18
2006	Chang et al: (i) Relapse is best indicator of efficacy of therapy. (ii) the more the doses, lesser the relapses; Daily has maximum doses, so may have less Relapse (iii) In cavity: Daily dose better, at least initially.	P-25
2007	Maharashtra DOTS: New, 1st time TB cases get best cure - 84%. Next time (Re-treatment) - 68%. (Hence, Recurrence is ominous; a risky shift … to incurability).	P-26
2007	Munsiff et al: TB patients with advanced HIV should get daily dose initially.	P-23
2007	Petitioner filed a PIL (CWP No. 185 of 2007) in Delhi High Court, praying several reforms (inter alia suggesting that number of doses may be increased from 3 to 5 but without proffering any evidence).	P-29, P-30

28.2.2008	BMJ Review: Paucity of research on DOTS; little evidence that patients get long-lasting cure.	P-16
March 2008	Honorable High Court disposed of Petitioner's PIL.	P-30
26.6.2008	Delhi DOTS: A vast, 11 year follow-up of 5576 NSP patients. Of them 3.4% failed treatment. Of the 4905 cured, 9% relapsed.	P-19
2009	Cochrane Review: Insufficient evidence to equate thrice weekly with Daily.	P-14
2010	Thorax Review: Justifies Daily dose; finds high levels of evidence for it, at least initially in some situations.	P-15
2010	Wells et al: Out of 22 high TB burden countries, 20 use Daily dose (So, India is an exception that uses 'thrice-weekly').	P-7
2010	Meta-analysis: In children, twice-weekly is less effective than daily.	P-21
2012	Desai et al: In TB Meningitis, outcome is better with Daily than thrice-weekly.	P-22
2012	Kumar et al: India uses thrice-weekly for HIV+ TB, while WHO recommends daily, at least initially.	P-24
2012	Azhar's India-specific Review: Cured patients are not followed up; Relapse in India is almost 10%, higher than internationally.	P-17
2013	Paresh et al: At 2 years after being cured by Indian DOTS, 10.85% had Relapsed. Another 5.9% patients died due to TB.	P-20
2013	Sikkim study: cure rates in Retreatment (relapse etc.) = 62.4%. (So, high Relapse is ominous; risky shift to incurability).	P-27
2014	BMJ publishes (as a response letter) Petitioner's serious concerns over India's	P-13

	thrice-weekly model.	
2010-16	Petitioner scrutinized long term fate of 36785 patients of DOTS era in Faridabad. Of them, 4675 returned sick, were found re-registered (12.7%). Research continues.	P-8
24th March 2015	Legal Notice and then reminder to govt. to re-adopt Daily dose system but in vain.	P-28
July 2015	Petitioner's Research (Annx. P-1) accepted for oral presentation (of abstract) at 46th Union World Conference on Lung Health.	P-12
3.8.2015	Present PIL filed in Honorable Supreme Court.	
Dec 2015	Petitioner visits South Africa, presents paper in world conference; audio is online.	
24.3.2016	Petitioner's Research (Annexure P-1) gets published and placed online.	

IN THE SUPREME COURT OF INDIA

CIVIL ORIGINAL JURISDICTION

WRIT PETITION (C) NO. OF 2015

PUBLIC INTEREST LITIGATION

IN THE MATTER OF :

Dr. Raman Kakar (Medical Officer,
Revised National TB Control Program of India,
Govt. District Civil Hospital)
s/o Late Sh. V.N. Kakar
R/o House No. 593, Sector 16,
Faridabad 121002, Haryana. ……..PETITIONER

VERSUS

1. The Union of India
   Through Secretary
   Ministry of Health & Family Welfare
   Nirman Bhavan, New Delhi.

2. The Director
   Revised National TB Control Program of India
   Ministry of Health & Family Welfare
   Govt. of India, Nirman Bhavan
   New Delhi …….. RESPONDENTS

CIVIL WRIT PETITION IN PUBLIC INTEREST FILED UNDER ARTICLE 32 SEEKING ISSUANCE OF WRIT IN THE NATURE OF MANDAMUS AND APPROPRIATE DIRECTIONS TO THE GOVERNMENT TO ABOLISH ITS CURRENT PRACTICE OF ADMINISTERING 'THREE DOSES OF MEDICINES PER WEEK' TO ALL PATIENTS SUFFERING FROM TUBERCULOSIS (TB), AND TO REPLACE THAT WITH TIME-TESTED 'DAILY-DOSE' REGIMEN.

TO

THE HON'BLE CHIEF JUSTICE AND

HIS COMPANION JUDGES OF THE

HON'BLE SUPREME COURT OF INDIA

THE HUMBLE PETITION OF THE
PETITIONER ABOVE NAMED

MOST RESPECTFULLY SHEWETH:

1. That the Petitioner is a patriotic citizen of India, a qualified MBBS doctor with a PG diploma in Tuberculosis (TB) having 3 decades of clinical experience. He has closely seen and felt the misery of the persons suffering from the dreaded disease of Tuberculosis. A life time of cumulative pain and shame have forced him into a whistle-blower.

1 (A). Eradication of TB is Petitioner's singular life-time goal. To that end, he has several books, documentaries, research papers, radio / television programs, awards & citations to his credit, some of these posted on his website - **www.tbfreeworld.org**. Earlier, Govt. of India had inducted him into advisory committee on national TB program, which is at the heart of this PIL.

1 (B). That the Petitioner's name is Raman Kakar, Address: House No. 593, sector 16, Faridabad, Haryana (Pin 121002). Mob. No. 9891397528; Adhar

card No. 407814341502; Email ID raman24march@yahoo.com,

Driving licence No. HR-5119970023971; Election card No. R/06/52/558316; Pan No. ADTPK7461P; annual Income: about Rs. 3.75 lacs (but uncertain future). Occupation: Doctor, serving (on a yearly contract) under Government's TB Control program for the past 6 years at a district TB hub, Faridabad (services terminated in Oct. 2015, soon after filing this PIL).

1 (C). That the Petitioner has no personal interest, whatsoever, in the present matter. The petitioner is not involved in any civil, criminal and/or revenue litigation which has or could have a legal nexus with the issues involved in this PIL. That the petitioner has no personal gain, private motive or any other oblique reason in filing the present PIL, which is purely in public interest.

1 (D). That the Petitioner has not filed any other petition invoking the above issue nor is any such petition pending in any High Court or Hon'able Supreme Court. In 2007, Petitioner had filed a PIL in Delhi high Court regarding broad based reforms in TB-care and public health-care as detailed in Para 42 (Page 34).

1 (E). That the petitioner has no pending representation before any government authority on the present matter or the relief sought herein. In 2015, a legal notice (as detailed in Para 40, Page 26) was indeed served to the respondents but in vain.

2. That this PIL documents “Iatrogenic (induced by therapy) injury” being inflicted on innocent citizens by their own government. The fence is eating the crop. The Petitioner has witnessed first-hand the infinite injustice being done to TB patients in India as illustrated in case-study of six TB patients (Annexure P-1 to P-6, Page 42-48). All these 6 patients took treatment from government’s Revised National TB Control Program (popularly called DOTS) but did not get proper (long-lasting) recovery. Despite several long courses, they kept falling sick over and over again.

   i. Nihal took 6 cycles of government therapy (DOTS) in 7 years (Annexure P-1, page 42-43).

   ii. Vijay underwent 7 innings of govt. medication in 9 years, turned drug-resistant (incurable) and eventually died (Annexure P-2, page 44).

iii. Rambir suffered and finally died despite 5 courses in 8 years (Annexure P-3, page 45).

iv. Om Parkash is currently taking 4th course from government (Annexure P-4, page 46).

v. Priyanka took 4, her father 3 cycles of govt.'s free TB therapy. Result: transmission to other family members, who too contracted TB, a merry-go-round (Annexure P-5, page 47).

vi. Subhash died despite undergoing 5 protracted courses under national program (Annexure P-6, page 48).

Each of these six TB patients above underwent several cycles (4 to 7) of therapy! Something is gravely wrong with this therapy. Does it cure or is it a deception? These 6 tragic life-scripts were carefully selected (for their demonstrative value) out of about 5000 similar condemned cases, found re-registered twice (or thrice or four times) by Petitioner during his day to day routine OPD duties at a district TB hub. Of the 5000 twin-registrations (Repeaters), many are destined to emulate similar tragic fate in years to come. Which ones? Only time will tell. Kindly see related details under 'Grounds' (Page 27 to 33).

3. That about 60 years ago, man found cure for (then incurable) disease, tuberculosis, in the form of 5 drugs. As a result, several nations managed to reign in TB since.

   But India failed to control it. India continues to be home to maximum TB patients for a single country world-wide. TB continues to kill 2 Indians every 3 minutes. Drug-resistance (the most dangerous dimension) is on steep rise.

   India has failed while others have succeeded. Why? There are several reasons; only one fundamental reason has been taken up in this petition.

4. That there are 5 primary anti-tuberculosis (TB) drugs known to man. When discovered, they were originally administered in Daily-doses. Always! By default. And Daily dose worked wonders for humanity!

5. That Daily dose regimen for anti-TB drugs is perfect. It remains gold standard. Its proof lies embedded in history. Discovery of drugs [then, given in daily dose (by default)] ushered in a miraculous decline in the West leaving no doubts about its efficacy; no need to look for any more evidence; why to re-invent the wheel?

6. That later, some scientific studies claimed that TB-drugs were equally effective even if patient swallowed them intermittently, say as three doses per week (say on Monday, Wednesday and Friday). This novel concept was quite tempting for poor nations; it reduces drug costs to less than half, offers convenience to patients and health workers. It also makes supervision of doses (a tool to ensure compliance and check default) more feasible.

7. That India hastily adopted that low-cost, thrice-weekly regimen into her Revised National TB Control Program (RNTCP) in 1997.

8. No doubt, (during 1993 to 1996) a 3-year pilot project was put in place, which preceded its large scale implementation. But 3 years is too brief a period for any meaningful follow-up of treated patients – imperative for 'technical' testing of any anti-TB therapy, which itself is a long affair – 6 to 8 months (or even longer). In mere 3 years, follow-up of treated cases (so crucial to know the truth) was not feasible. Obviously, there was no follow up at all of patients who were treated in the 3rd year of pilot period. Therefore, it is fair to infer that before adoption on a massive scale in

India, the new concept of thrice-weekly dose was never put to the ultimate test – the test of time. The said pilot project assessed only 'operational feasibility'. 'Technical' evaluation was simply dispensed with; never done since - a historic blunder that is at the root-cause of this petition.

9. That cost of drugs in India's thrice-weekly program is very low - about 43% of its Daily-dose counterpart; because quantities of most drugs ingested by a patient are very low (almost 3/7).

Number of Injections too was drastically reduced in Indian model – from 60 to 24 vials per patient. Retreatment patients around the world get 60 injections (please see details in Para 23, Page 20).

Placing orders in bulk further reduces costs. A box containing complete 6-month course of medicines for a Category 1 patient costs to India's exchequer about Rupees 280 (when checked last, several years ago)!

10. That 20 (out of 22) High TB Burden Countries (globe's real TB battleground) remain unconvinced with thrice-weekly concept; they still continue to practice traditional, time-tested Daily dosing (Annexure P-7,

Page 49). Presumably, respecting the dictum ‘old is gold’, they chose to act cautiously and rejected what India hastily accepted!

[Annexure P-7 is a True/re-typed copy of a Chart published in an international journal that shows that 20 out of 22 High TB burden countries use Daily dose regimen].

11. That India is one of the rare exceptions to have implemented such a unique thrice-weekly dosing regime in 1997. Since 18 years, India’s huge national program has been administering Thrice-weekly doses to about 15 million TB patients, self-claiming 85% success. On paper!

12. That the situation on the ground however, appears no better; it is rather worsening. There seems no respite for the suffering millions (as stated in Para 3, page 6).

13. That there is widespread skepticism (even amongst Program-insiders) about India’s reported glorious 85% success rates though without any hard evidence whatsoever - till now.

    Only one-sided picture, self-generated by government is available in public domain and which remains unchallenged. This self-declaration has forever been

serving as sole basis of validity of India's DOTS program.

14. That no independent, third party clinical audit of the National TB program has ever been conceived or conducted. No outside agency has ever systematically verified official claims of 85% cure nor its other parameters. Independent evaluation of actual long term outcome (fate) of registered patients has never been undertaken!

    Never, except now - by the Petitioner (Para 17 & Para 18, page 11 to 18). Petitioner's 6-year research is therefore unprecedented and deserves due consideration.

15. That it is a paradox that fate of 15 million registered Indian TB patients stands recorded in black and white within hand written DOTS registers – a gold-mine for retrospective research. Answers to each and every question on intermittent regimen that puzzles human beings lies hidden in its womb. Alas, this mammoth data languishes idle under strict govt. custody, stays out of reach of potential researchers, untapped by scientists. Year after year, it simply keeps piling up - to rot in government's dusty, dingy, moth-ridden and locked

record rooms in rusted almirahs. Govt. and her technical adviser (WHO) did not begin to digitize (till recently, by web-based Nikshay software) or share or publish it.

16. That in the current Indian set-up, independent audit by an outsider of real patients registered & treated under govt.'s program is almost impossible. Because patient's name, address, Tel No. etc. remain in absolute, exclusive & protective custody of govt. officials/workers, and hence, out of reach of potential free-lance researchers.

Only insiders have the privilege of remaining in constant touch with registered patients. Registered patients themselves visit them for investigations, drugs, follow up and advice etc. So only insiders have the opportunity to interview them and audit their original data. But an insider will conduct any research only if he is so inclined and so wishes, and that too after obtaining prior (and elusive) permission from govt., and at his own peril, risking retribution (if the results he publishes inconvenience the policy makers and which is highly likely).

17. That that is exactly what the Petitioner has accomplished. He and his dedicated team (all insiders) collectively and silently set out in 2010 to systematically find the truth of DOTS in district Faridabad. Operating from deep within the belly of DOTS, meticulous research (largest and longest over the subject) has silently gone on for 6 years since; still continues (Annexure P-8, Page 50-80). Petitioner believes that this is the single most important controversy for India to resolve urgently.

18. That the Petitioner set out to revisit the long-term fate of all registered patients and/or their records in the district since inception of thrice-weekly DOTS. The sole objective was to find a patient who didn't get long-lasting relief with a single course and was later found re-registered for a second innings (nicknamed as Repeater). Thus, his name figures twice in National Registry. Govt. allocated (not one but) two unique IDs. Both UID's were tracked as far as possible.

    For the past 6 years, Petitioner heads one of the 2698 sub-district TB Units of the government at District Tuberculosis Center, Faridabad. His job has been to monitor thousands of current / ex-patients on Thrice-

weekly regimen in TB OPD. This, by providence, offers him unique and unlimited access to meet and interview registered patients, examine their original reports, first hand data, ample opportunity to interview families, and TB workers of entire district. Petitioner motivated district work-force; jointly they set out to conduct Retrospective Record Review of hand-written registers of past 15 years, one at a time – thus identified 1575 Repeaters. Simultaneously, author conducted exhaustive clinical audit in his busy TB OPD (a natural hub for such work), cherry-picked (on an average) one repeater per day; thus tracked 3100 Repeaters in 6 years [Of these, about half had already been diagnosed and referred in for Re-treatment from (neighboring) Delhi's premier TB institutes. They would arrive at district center seeking formalities of local registration].

A copy of the entire research dated Nil is being filed herewith vide Annexure P-8 (Page No. 50-80).

In all, long-term fate of 36785 registered TB patients could be analyzed. Of them, 4675 patients found to have returned / Re-registered for Re-treatment (Annexure P-9, page 81-272); thus over 12.7 % identified as Repeaters.

Extrapolating over 15 million total registrations in DOTS-era in India, about 2 million patients had to possibly get Re-registered! Mind boggling!

Besides, study found about 5% Deaths (Annexure P-10, Page 273-342) and 8% Default (Annexure P-11, Page 343-451).

It is concluded that under India's routine program conditions, Thrice-weekly regimen is ineffective. Recurrence (re-registration) is high which may be promoting drug-resistance on an industrial scale, a global threat!

18 (A). This Research Annexure P-8 (page 50-80) was very recently published.

Supporting excel dynamic data - Names of 4475 Repeaters (Annexure P-9, Page 81-272), 1618 Deaths (Annexure P-10, Page 273-342), 2553 defaulters (Annexure P-11, Page 343-451) have been transparently and verifiably enclosed.

It may kindly be noted that after initial filing of this PIL and while curing 32 defects, and at the time of re-filing, 10 months elapsed. Therefore, updated versions of Annexures P-8, P-9, P-10 & P-11 have been submitted, replacing their previous versions, filed originally on

03.08.2015. Besides, to make ‘Grounds’ more clear (as instructed in a very thorough scrutiny by Mr. Rajinder Ahuja), additional documents P-1, P-2, P-3, P-4, P-5, P-6 were searched out from Petitioner’s vast data bank and are being additionally submitted, which may kindly be permitted.

18 (B). This voluminous data has been carefully collected bit by bit from various human, written and other sources over a period of 6 years. Imperfections like un-erased, duplicate, inaccurate or wrong entries about some patients may have been recorded inadvertently. However, study is so vast that such occasional human errors, if any, would have negligible impact over final percentages. On the other hand, several frustrated relapse patients may have gone elsewhere - to private doctors or other govt. centers. Whether cured or died, either way, their fate never got recorded here in our govt. data. So, actual percentages are likely to be even higher than 12.7%.

18 (C). This Research (Annexure P-8) stands endorsed by international scientific community:

(i) Most recently, on 24th March, 2016, the research has been published in Journal of Health Science and can

be accessed on the internet at: http://www.davidpublisher.org/index.php/Home/Article/index?id=25164.html.

(ii) Earlier, abstract of the same research was one of the 259 accepted (out of about 2200 submissions) for oral presentation at 46th Union World Conference on Lung Health held in South Africa in Dec.2015 (Annexure P-12, pg 452-454).

(iii) Petitioner's 8-minute World Conference Lecture (oral presentation of abstract), which can help comprehend the gist of this petition with economy of time and effort, can be heard - at one of the 2 following sites on the internet:

(a) (Re-recorded version is on Petitioner's website: http://tbfreeworld.org/world-conference-dr-raman-kakars-lecture-oral-presentation-of-abstract-re-recorded-unofficially/.

(b) Original recording posted by organizers of the world conference (curiously, shows error) at: http://html5.slideonline.eu/event/15UNION/presentation/56af80efdf14e7dc1220463d///thrice-weekly-dose-of-anti-tb-drugs-efficay-under-indias-program-conditions.

(iv) Earlier, Petitioner's serious concerns over Thrice-weekly dose model of India were also published in British Medical Journal as a response letter in 2014 (Annexure P-13, Page 455-456).

18 (D). Even though this research stands validated by international scientific community, still, if Hon'able Court so wishes:

(i) Verification of supporting data may kindly be got done, if felt necessary.

(ii) Petitioner offers to provide his OPD diaries, original paperwork, his laptop, which contains much more detailed and up to date information than enclosed in this PIL - all Excel lists, software tailor-made for his research with entries, and heavy photo-albums of patients etc. 6 case studies (Annexure P-1 to P-6) are sample of the kind of details that may be available in there.

(iii) All recent entries made during the past 2 years can be easily verified through govt.'s own web based Nikshay software.

(iv) However, it is humbly prayed that verification process may kindly not be entrusted to

Ministry of Health, an interested party; that might go against the spirit of natural justice.

(v) The verification task may kindly be entrusted to a third neutral party e.g. Central Bureau of Investigation by way of constituting an SIT under supervision of Honorable Court. Even otherwise, it is a simple though laborious job; one doesn't have to be a health-care professional to verify whether a listed person is dead or alive, or how often he undertook govt.'s therapy.

18 (E). Indian studies are scarce but have often warned that India's Relapse is about 10%, while it is about 3% in other countries. Petitioner's findings depict an even worse scenario: overall 12.7% ex-patients come back sick. But, it must be noted that this study includes all types of cases – Pulmonary, Extra-Pulmonary, Sputum positive and negative cases. In other words, of total registered cases, 12.7% return sick (irrespective of whether last time around they had been cured, completed treatment, defaulted midway or failed treatment). Besides, it must be confessed that an unknown but very small number of patients are of

Extra-pulmonary variety (say Bone TB) which were re-registered for a second course (of category I) simply because Orthopedic surgeons popularly insisted in treating such cases for 12 months or more (whereas government program believes in treating them all for 6 months only – another unresolved, sore controversy). Please also see other limitations under the heading 'constraints' within the study (Annexure P-8).

12.7% Re-registration obviously is an 'unfavorable outcome', which ought to be deducted from reported success 85%. Calculated thus, success rate of Indian program would come down to 72.4%; though it would be oversimplification of a complex matter.

19. That what use are glorious 85% cure rates (even if true) if so many ex-patients are likely to come back sick - over & over again; is it a therapy or a deception? (Please also see 6 case studies Annexure P-1 to P-6, Page 42-48) Top TB managers slumber in ivory towers, cut off from reality, insulated from the heat of ongoing misery of patients. Some of them may have never seen a single patient suffering from TB and remain unaware of what it involves. They bask in euphoria over 'self-generated' rosy printed papers & research based

entirely on ‘Self-Reported’ data (and not based on baseline ground data) and that too by hand-picked, pliable, biased cronies often on govt. or WHO payrolls, either directly or indirectly. So, by design, world has been kept blinded from reality. World has been consistently mislead with one-sided picture since 18 years as already detailed in Para 13-16 above (page 9 to 11).

20. That interestingly, as per Indian design, a single person - an STS (senior treatment supervisor) alone monopolizes over entire gamut of reporting from a basic TB Unit. Being on contract, he is kept on a tight leash. He has no option but to report India’s pre-set targets (85%); or else lose his job! Hence, fudging is an essential survival skill across India.

21. That one must ponder as to who is in the wrong – India or the rest of the world? Is the approach of doctors of 20 high TB-burden countries incorrect that they continue to practice Daily dose schedule? After all, why everyone else has been rejecting a far cheaper option that India hails (Annexure P-7, Page 49)?

22. That sensitive or resistant, the germ remains the same, namely mycobacterium tuberculosis, isn’t it? For

treating drug-resistant variety of TB, India has recently launched in 2009 a new program (called DOTS Plus), in a phased manner across some districts of India.

In that, India has silently adopted Daily Regime! And NOT Thrice weekly regime! Why this U turn?

After 18 years of Thrice-weekly era, is it not a tacit admission that thrice-weekly has failed? And that it was a mistake! Because, sensitive or resistant, the germ is the same; as are all pharmaco-dynamics. Celebrated theories - of lag period & feasibility of direct observation etc. vociferously and relentlessly cited in favor of Thrice weekly regimen – have they all suddenly become invalid?

23. That one more glaring anomaly of 'thrice-weekly system' manifests as a drastic cut (from 60 to 24) in quota of injections:

There are five primary anti-TB drugs known - four oral & one injection (Streptomycin). Since their discovery (1944 - 66), these drugs are administered in daily doses, world over. A fresh, new patient is generally treated with 4 oral drugs. A Retreatment patient (who has taken anti-TB drugs in the past, & is now sick again) is given all 5 drugs; that include 60 injections (one daily for

initial 2 months) of 8 month therapy – a standard practice almost world over. Hence, a patient would get 60 injections if he happens to live in any of the 20 high TB burden countries, which practice daily-dosing.

An unfortunate sick Indian, on the other hand, gets only 24 injections (three per week for 8 weeks) under India's thrice-weekly design. This drastic (but obscure) cut (from 60 to 24 injections) is highly controversial; it truncates, enfeebles therapy, rendering it ineffective; an inhuman secret move.

Ominously, Govt. of India is failing to provide with certainty even 24 doses of injections – a shocking conclusion in another research done by Petitioner. However, that doesn't concern the present matter and deserves a separate PIL, which may be in the pipeline.

24. That the key question (as it is shrewdly framed by wizards) is not as to "Which schedule is better - Daily or intermittent?" No, your lordship. Framed thus, it is misleading.

Because, daily dose is perfect and is gold standard, as stated earlier in Para 4 & Para 5, Page 6.

The question actually is this - “Is thrice-weekly as good as daily?’’

And which has been researched (directly or indirectly) in literature by 4 (four) thorough Reviews & at least 10 (ten) research papers & which represents the crux of contemporary knowledge; all are given hereunder in the following 14 paragraphs (Para 25 to 38), one by one:

25. That Cochrane Review (Annexure P-14, Page 457-458) concluded that there is insufficient evidence to compare equivalence of effect between fully intermittent and daily treatment. [Petitioner further submits: India claimed way back in 1997 that its thrice-weekly concept was evidence-based. And yet, 12 years later (in 2009) sufficient evidence is found non-existent!]

26. That Thorax Review (Annexure P-15, Page 459-460) justifies the use of daily schedules, despite the lack of head-to-head comparison between daily and intermittent regimens. Findings suggest high levels of evidence FOR using daily dosing, especially during the initial phase in presence of cavity etc.

27. That BMJ systematic review (Annexure P-16, Page 461-462) laments paucity of overall research on DOTS (chiefly run as national programs in high-burden, third-

world countries); not possible to assess recurrence or whether patients indeed got long lasting cure or not. Reviewers failed to assess the strength or sufficiency of evidence to support DOTS.

28. That solitary Review of all India-specific studies on thrice-weekly DOTS by Azhar (Annexure P-17, Page 463-464) concludes that after successful treatment, patients are not followed up in India; Relapse rate is high (almost 10%) in India, higher than international studies.

29. That in 2005, a South India study (Annexure P-18, Page 465) had warned of 12% relapse within 18-months follow up in Indian DOTS.

30. That a large, 11 year follow up of DOTS patients in Delhi (Annexure P-19, Page 466) scrutinized the long-term fate of 5576 new sputum positive cat I patients registered. Of them 3.4% failed treatment. Further, out of 4905 successfully treated patients, 9% presented as relapse.

31. That Paresh et al (Annexure P-20, Page 467-468) found that at 2 years after successful treatment under Indian DOTS, 10.85% had relapsed and another 5.9% patients died due to TB [Petitioner's submits that that is the

worst indictment of Indian model yet. Because ‘after cure, deaths due to TB’ also means only one thing: that Relapse killed them too. So, Relapse is 10.85+5.9 = 16.75%)!]

32. That a meta-analysis concludes that ‘Twice weekly intermittent short course therapy is less likely to cure tuberculosis in children as compared to daily therapy’ (Annexure P-21, Page 469-470).

33. That patients with Tubercular Meningitis if treated with daily ATT have better outcomes as compared to thrice weekly (Annexure P-22, Page 471-472).

34. That advanced HIV + patients should be treated with a daily dose in the intensive phase of TB treatment (Annexure P-23, Page 473-474).

35. That India violates WHO guidelines; it uses a thrice-weekly model for all (patients), including HIV infected ones, whereas WHO recommends daily treatment, at least during the intensive phase (Annexure P-24, Page 475-476).

36. That a vast research (Annexure P-25, Page 477-479) states:

    a. Relapse is the best estimate of treatment-efficacy.

b. Cavitary tuberculosis is best treated with 6-mo regimens comprising daily IP and thrice-weekly CP, which may be extended when 2-mo culture is positive. (Petitioner's comments: India's DOTS program is primarily sputum smear based. Chest X-ray is not done in sputum positive PTB cases. Hence, who has a cavity is not known. Even in sputum negative PTB cases, which are initially diagnosed through X-ray, repeat X-ray is not done. Follow up is by sputum smear testing alone; continued sputum negative status is taken to mean that patient is responding well).

c. Increasing number of doses (as in daily) may reduce relapse.

d. "You get what you pay for in the treatment of tuberculosis". (Petitioner's comment: India's thrice-weekly DOTS costs minimal, relapse is almost triple; penny wise pound foolish).

37. That Pardesi in Maharashtra (Annexure P-26, Page 480) found that cure rates in new (first time) TB patients is 84% but in Re-treatment (second time) cases it is only 68%, way inferior. [Petitioner's comments: Para 37 & Para 38 prove that first time is best opportunity; next

time means poor outcome. Recurrence is dangerous; it signals that a subtle ominous shift towards incurability has taken place - start of one-way journey to drug-resistant TB].

38. That a Sikkim study (Annexure P-27, Page 481-482) found that cure rates in Retreatment (second time) cases is only 62.4%.

39. That a detailed Legal Notice (March, 2015) and a reminder (May, 2015) were duly served to Respondents giving all scientific reasoning (Annexure P-28, Page 483-490). But Govt. continues thrice-weekly regimen unabated.

It is confessed that in the said notice Petitioner's identity was not disclosed for fear of termination by the government, which would have interrupted the ongoing research, then at a crucial stage.

40. That all researches mentioned above (Para 25 to 38, page 22 to 26) were in effect serial periodic warning to the govt. to switch over to Daily dose regimen. But govt. blindly and stubbornly did not act; missed a series of opportunities; including our PIL filed in 2007.

GROUNDS:

I. BECAUSE when a poor Indian suffers from TB, he goes to a nearby govt. center with total faith; places his life in the hands of the govt. system. There, he swallows ‘7 big tablets, all at once’ thrice a week for initial 2 or 3 months [A more palatable option of 2 tablets (containing requisite doses of all 4 drugs) is very much available in Indian markets and which is used by Nepal etc.]. For the next 4 or 6 months, he is made to ingest 3 to 5 bitter tablets. All along, he entertains a hope that after 6 to 8 months, he shall be healed - for the rest of his life. His expectations seem quite reasonable and justified.

Alas, often, that doesn’t happen!

Firstly, our truncated Indian model of treatment may simply fail to ‘cure’ him. And even if it does ‘cure’ him, the ‘cure’ may not last long. He may soon relapse. So, this was not cure but temporary suppression of symptoms. A Deception!

Now, two-fold damage has occurred. Not only is he ‘not rid of his sickness’, he has turned

permanently in to a ‘difficult to treat’ TB patient; Relapse is more difficult to treat.

In TB, first (maiden) attempt is ideal, as medicines work best (85% cure). Next time (recurrence), drugs become less effective and chances of cure recede (65%) as detailed in Para 37 & Para 38 above (page 25 to 26).

Re-treatment (2nd time) is fraught with higher risks of failure, complications, drug-resistance and death.

So, government’s unscientific model has ruined his only, golden, virgin opportunity, irretrievably, exposing him (needlessly) to recurrence and a bad future.

This is total breach of trust. The innocent sick person remains unaware that the “free-of-cost medication” that he gratefully receives from the government outlet is ‘inadequate’ and ‘hardly the best human option’ available. That it is a low cost, unscientific, truncated, thrice-weekly therapy, largely rejected world-wide.

Patient is put to additional, avoidable suffering. Recurrence is like a slow poison; stepping one-

way into a quagmire. From simple, he turns into a hard core patient; his life-script, takes a malignant turn. Instead of a single 6-month smooth course, he is condemned to at least two messy courses - 14 months of drugging, joblessness and stigma etc.

Thereafter, his nightmares may be endless. Instead of the 60 Injections worldwide in Re-treatment, an Indian by design gets only 24 injections (three per week) - desperately inadequate (Para 23, page 20). Predictably, Re-treatment often fails. He may require a third innings; eventually, he may never truly recover.

This chronicle also exposes him to drug-toxicity like depression, nausea, vomiting, itching, eczema, defective vision, vertigo, deafness, numbness in limbs, jaundice, anemia, kidney failure, joint problems or sometimes even fatal toxicity. Frustrated, some of my chronic patients in Faridabad have even attempted / committed suicide.

II. BECAUSE the true life history of 6 TB patients enclosed (Annexure P-1 to P-6, Page 42-48)

demonstrate the avoidable risk and injury. Each of these six patients underwent several cycles (4 to 7) of therapy! They were ‘cured’ several times! Something is gravely wrong with this therapy. Does it cure or is it a deception? These 6 tragic life-scripts were carefully selected out of vast databank of about 5000 similar condemned cases, found re-registered twice (or thrice or four times) by Petitioner during his day to day routine duties at a district TB hub. Of the 5000 twin-registrations (Repeaters), many are destined to emulate similar tragic fate in years to come. Which ones? Only time will tell. No doubt, some patients may also have themselves contributed to disaster by non-compliance, default, or by violating other “do’s and don’ts”.

The saga exposes his family members to prolonged and repetitive spells of transmission, who too may contract infection and disease, turn by turn, feeding further the family chain of infection (Annexure P-5, Page 47), like India’s merry-go-round.

III. BECAUSE the Patient remains blissfully unaware of universal conspiracy of silence and inaction ongoing against him since decades. Profit oriented modern science ignored to find new cures, tests or vaccines for him. Inept governance has been resulting in wrong, unscientific choices (e.g. thrice-weekly regimen). No accountability whatsoever.

IV. BECAUSE recurrence may turn a patient into a dangerous germ factory; the incurable strains of the germ are increasingly stalking him, his kids and all of us. Indians believe in fate; so, the victim believes that his tragedy was pre-destined. Sick, ignorant and powerless, he will never reach or petition your lordship. No wonder, despite large-scale, avoidable, and hence somewhat UN-NATURAL deaths and (avoidable) destruction, Petitioner has never heard of a single FIR ever! Victim is unaware that his tragedy is iatrogenic (induced by a therapy) and that the catastrophe was so easily avoidable! Only if a handful of powerful central govt. officials had done their routine job dutifully, scientifically, honestly!

V. BECAUSE the Petitioner has on the eve of re-filing (June 20, 2016) identified over 5000 such condemned patients (Annexure P-9 contains 4475 names out of that) who have been registered twice or more often under DOTS - in his own district, Faridabad. The trickle is progressively becoming thicker.

At that rate, of 15 million total registrations in DOTS-era, about 2 million Indians have had to get Re-registered! Mindboggling!

VI. BECAUSE this patient would have lived a better human life, had he been born in another country (with Daily dose regimen).

VII. BECAUSE this tragedy would never have befallen him or his family if he were rich enough to afford a private doctor. Amusingly, India's private sector (which is estimated to manage half the patient-load of India) en-mass uses daily therapy! One country, 2 parallel therapies – yet another burning controversy! With a tacit message within!

VIII. BECAUSE the Petitioner has never seen any VIP's visiting DOTS centers and submitting to or accepting govt.'s own TB therapy.

IX. BECAUSE the Petitioner has often heard anecdotes from insiders that top doctors in premier TB institutes of Delhi (which were instrumental in designing, launching, training and promotion of the current model of DOTS) prefer Daily dose regimen when their own kith and kin fall sick with TB.

X. BECAUSE, God-forbid, if ever Petitioner falls sick himself, your lordship, he swears by his only daughter that he would never submit to thrice-weekly DOTS!

41. Maintainability:

That indeed Petitioner had earlier filed a PIL, CWP No. 185 of 2007 in Delhi High Court praying for wide-ranging reforms in TB-care as well as in public health-care. That was a broad-based and all-encompassing PIL and can never be equated with this specific, single-point PIL by any stretch of imagination.

A copy of the order dated 31.10.2007 in CWP No. 185 of 2007 passed by the High Court of Delhi at New Delhi is being filed herewith vide Annexure P-29, page No. 491-492).

A copy of the order dated 12.03.2008 in CWP No. 185 of 2007 passed by the High Court of Delhi at New Delhi is being filed herewith vide Annexure-P-30 (page No. 493).

Among 11 initial prayers and about 30 more suggestions made later on, it was also pleaded inter-alia to increase weekly doses from 3 to 5 albeit on primitive grounds (Thrice-weekly dose itself was in infancy then).

But since 2008, new and overwhelming scientific evidence has been emerging. TB scenario in India progressively deteriorates and time runs out.

A detailed legal notice and a reminder were duly served to respondents in March 2015, but in vain.

Furthermore, detailed clarifications on maintainability are given in a separate application to the Registrar (Page 504-506).

It is most humbly begged that the issue involved transcends technicalities.

42. That through acts of omission and commission, govt. of India and her technical adviser (WHO) jointly allowed India to be converted virtually into a massive laboratory for the largest, longest and needless human

experiment in history of TB; handling sick people like Guiney pigs.

43. That this PIL may be another opportunity to set things right. However, at such a belated stage, it may not be sufficient for the Hon'able Supreme Court to just briefly intervene, pass appropriate directions and then leave the rest of things to the Respondents. Can we blindly trust an agency (to self-correct), which is possibly responsible for 50 years of repetitive, shameful failures, like:

(i) While other nations controlled TB, we failed.

(ii) Govt. failed to Review her 1st national program for 30 long years - while it kept visibly failing.

(iii) Govt. delayed benefit of newer drugs (REZ) from reaching Indian masses for over 30 years.

(iv) By making one needless, sweeping, unscientific, hasty choice – namely 'thrice-weekly dose' in 1997, govt. snatched defeat from the jaws of victory.

(v) Of the 15 million patients registered under DOTS, about 2 million have had to probably get Re-registered! But for 18 years, govt. slept in

denial, rather unabashedly congratulating itself!

(vi) Despite a PIL in Delhi High Court, it failed to clean up its act or self-correct and Honorable Supreme Court has to devote precious time and effort over yet another PIL.

Past record is more reliable indicator than future promises. Time ticks towards drug-resistance epidemic. Real treatment of drug resistance is its PREVENTION by effective cure at first opportunity. Every single recurrence raises country's drug-resistance-quotient; marks a baby step towards incurability. Seeds (bacilli) sown today in Indian chests shall keep breeding crops in next decades. There are numerous other loose ends in our TB program craving to be tied up; but their mention here may serve only as distraction, your lordship. First things first; this is the root cause.

Having spent an entire professional life studying TB scenario at micro and macro levels, Petitioner solemnly appeals to the Honorable court for a surgical and prolonged intervention; Kindly take complete charge of proceedings and ensure a just process of transition to Daily dose regimen and a definite course-correction

under personal supervision to secure the future of our progeny. Honorable Supreme Court is the last and the only hope. Since TB germ gets transmitted through air, no one is safe till everyone is safe. We and our children, your lordship, share the same air! We all are at risk of resistant (incurable) tuberculosis; of being ferried back to the pre-antibiotic era of our grand-parents when TB used to be incurable!

PRAYER:

It is, therefore, most respectfully prayed that this Hon'ble Court may graciously be pleased to:

I. Issue a writ in the nature of mandamus and appropriate directions to the Respondents to abolish its current practice of administering "three doses of medicines per week" to all patients suffering from tuberculosis (TB).

II. Issue a writ in the nature of mandamus and appropriate directions to the government to replace that ineffective practice with time-tested and traditional "Daily-dose regime" urgently – if possible, with immediate effect; if not, then certainly before the next World TB Day i.e. 24th march, 2017.

III. Issue a writ in the nature of mandamus and appropriate directions to the Government to fix accountability for this historic blunder.

IV. Pass any such other order or orders/directions as this Hon’ble Court may deem fit and proper in the interest of justice.

AND FOR THIS THE PETITIONER SHALL EVER PRAY

Drawn on: Petitioner in Person

03-08-2015

IN THE SUPREME COURT OF INDIA
CIVIL ORIGINAL JURISDICTION

WRIT PETITION (CIVIL) NO. OF 2015

IN THE MATTER OF

Dr. Raman kakar, Government Medical Officer,

Revised National TB Control Program of India…Petitioner

VERSUS

Union of India and Anr. ……Respondents

AFFIDAVIT

I, Dr. Raman Kakar (Medical Officer, Revised National TB Control Program of India, Govt. District Civil Hospital) s/o Late Sh. V.N. Kakar R/o House No. 593, Sector 16, Faridabad 121002, Haryana, presently at New Delhi do hereby affirm and state as follows:

1. That I am the Petitioner in the above Writ Petition and am thus fully conversant of the facts of the present case, and as such I am duly competent to file, sign and affirm the present Affidavit.

2. That the accompanying Synopsis, List of Dates (pages B to G), Writ Petition (page 1 to 39) and I.As. being misc. Applications from pages (494 to 506) have been read and understood and are true to the best of knowledge and belief.

3. That I say that Annexures P-1 to P- 30 annexed along with the accompanying Writ Petition are true copies of their respective originals.

DEPONENT

VERIFICATION

Verified at New Delhi on the day of June 2016 that the contents of the affidavit are true and correct to my knowledge. No part of it is false and nothing material has been concealed therefrom.

DEPONENT

IN THE SUPREME COURT OF INDIA

CIVIL ORIGINAL JURISDICTION

WRIT PETITION (C) NO. OF 2015

IN

I.A. No. of 2015

Dr. Raman Kakar, Government Medical Oficer,

Revised National TB Control Program of India

…….PETITIONER

Versus

Union of India and ANR …….Respondents

IN THE MATTER OF: APPLICATION FOR DIRECTIONS

TO

THE HON'BLE CHIEF JUSTICE AND

HIS COMPANION JUDGES OF THE

HON'BLE SUPREME COURT OF INDIA

THE HUMBLE PETITION OF THE
PETITIONER ABOVE NAMED

MOST RESPECTFULLY SHEWETH:

1. That the Petitioner above named files this Writ Petition before this Hon'ble Court under Article 32 of the Constitution of India. The Petitioner craves indulgence of this Hon'ble Court to refer to and rely upon the contents of the Writ Petition as a part and parcel of this Application for directions.

2. That the instant Writ Petition is being filed by the petitioner-in-person seeking directions under Article 32 to the Government to abolish its current practice of administering ‘three doses per week’ to all patients suffering from tuberculosis (TB) and to replace that with time-tested ‘Daily dose’ regimen.

3. That I have stated all the detailed facts and circumstances of the case in the present petition and which are sufficient for issue of necessary Directions to the Government / Ministry of Health to:

Abolish the current practice of administering ‘three doses of medicines per week’ to all patients suffering from tuberculosis (TB), and to replace it with time-tested ‘Daily dose’ regimen.

4. That this Hon’ble Court may kindly consider issuing the following directions:

(I). Honorable Supreme Court may be pleased to kindly consider if it is necessary to verify the data enclosed (even though Petitioner’s research is duly endorsed by international scientific community). If so, [and as detailed in Para 18 (D) of Petition], a Special Investigation Team (SIT) may kindly be constituted,

operating under Honorable Court's personal supervision. It is most humbly prayed that personnel from Health department may kindly be totally excluded from such an exercise (being an interested party).

(II) It is prayed that Honorable Supreme Court may be pleased to fix accountability for this historic blunder.

a. Primarily, the matter reflects a gross technical failure. Therefore, it is prayed that the role of all concerned officers of the Government may kindly be critically investigated and accountability be fixed.

b. It is prayed that role of officials of World Health Organization (WHO) (the technical advisor to govt. for past several decades) may be scrutinized and their accountably be fixed as well.

(III) If Honorable Court feels that this PIL should be filed in another court, it is prayed that it may kindly be officially transferred there expeditiously or Petitioner may be 'permitted' to do so urgently.

(IV) Soon after filing this petition, Petitioner's services were terminated (age over 62 years). He somehow managed Deputy Commissioner's permission

to continue serving (sans remuneration) since.

Therefore, it is prayed that Honorable Court may be pleased to pass appropriate directions to the government not to disrupt his rare, crucial but precarious research-network by removing or victimizing the petitioner; but rather to proactively facilitate his projects for the next 10 years, or till conclusion of his research or life.

(V) Pass any further order or orders as the Honorable Court may deem fit and proper in view of the facts and circumstances of the case.

AND FOR THIS ACT OF KINDNESS THE PETITIONER-IN-PERSON AS IN DUTY BOUND SHALL EVER PRAY

Drawn on

Filed on

Drawn and filed by:

(Dr. Raman Kakar)
Petitioner-in-person

IN THE SUPREME COURT OF INDIA

CIVIL ORIGINAL JURISDICTION

WRIT PETITION (C) NO. OF 2015

PUBLIC INTEREST LITIGATION

I.A. No. of 2015

IN THE MATTER OF:

Dr. Raman Kakar, Government Medical Oficer,

Revised National TB Control Program of India

…….PETITIONER

Versus

Union of India and ANR …….Respondents

AN APPLICATION FOR APPEARING AND ARGUING BY PETITIONER-IN-PERSON

TO

THE HON'BLE CHIEF JUSTICE AND

HIS COMPANION JUDGES OF THE

HON'BLE SUPREME COURT OF INDIA

THE HUMBLE PETITION OF THE PETITIONER ABOVE NAMED

MOST RESPECTFULLY SHEWETH:

1. That the instant Writ Petition is being filed by the petitioner-in-person seeking directions under Article 32 to the Government to abolish its current practice of administering 'three doses per week' to all patients

suffering from tuberculosis (TB) and to replace it with time-tested ‘Daily dose regimen’.

2. That I have stated all the detailed facts and circumstances of the case in the present petition.

3. That I can hardly afford a senior advocate of the Honorable Supreme Court. Having devoted my entire life to my cherished mission of TB eradication; I could spare little time towards earning money. I do have some savings, which I would prefer to preserve for approaching old age.

4. That I am seeking permission to file documents and also to appear and argue the above captioned Petition as petitioner-in-person because I am well conversant with facts and circumstances of the technical aspect of the case (but not legal or any others).

5. That even if Honorable Court very kindly offers to provide free legal services, Petitioner feels that at such an advanced stage, it may serve to dissipate more time, which is at premium in this matter.

PRAYER

On the forgoing submission, it is most respectfully prayed that the Honorable Court may graciously be pleased to:

a. Grant permission to appear and argue the Writ Petition as petitioner-in-person.
b. Pass any further order or orders as the Honorable Court may deem fit and proper in view of the facts and circumstances of the case.

AND FOR THIS ACT OF KINDNESS THE PETITIONER-IN-PERSON AS IN DUTY BOUND SHALL EVER PRAY

Drawn on

Filed on

Drawn and filed by:

(Dr. Raman Kakar)

Petitioner-in-person

IN THE SUPREME COURT OF INDIA

CIVIL ORIGINAL JURISDICTION

WRIT PETITION (C) NO. OF 2015

PUBLIC INTEREST LITIGATION

I.A. No. of 2015

IN THE MATTER OF:

Dr. Raman Kakar, Government Medical Oficer,

Revised National TB Control Program of India

…….PETITIONER

Versus

Union of India and ANR …….Respondents

AN APPLICATION FOR FILING ADDITIONAL DOCUMENTS AND UPDATED VERSION

TO

THE HON'BLE CHIEF JUSTICE AND

HIS COMPANION JUDGES OF THE

HON'BLE SUPREME COURT OF INDIA

THE HUMBLE PETITION OF THE PETITIONER ABOVE NAMED

MOST RESPECTFULLY SHEWETH:

1. That the instant Writ Petition is being filed by the petitioner-in-person seeking directions under Article 32 to the Government to abolish its current practice of administering 'three doses per week' to all patients

suffering from tuberculosis (TB) and to replace it with time-tested ‘Daily dose regimen’.

2. That I have stated all the detailed facts and circumstances of the case in the present petition.

3. That I am seeking permission to file additional documents and also to file updated versions of ongoing Research and its supportive data.

5. That while extending an unequivocal apology for the delay in curing 32 defects, at the time of re-filing, updated versions of ongoing Research Annexures P-8, P-9, P-10 & P-11 have been submitted, replacing their older versions, filed originally on 03.08.2015.

6. That in order to make Grounds more clear (as instructed in a thorough scrutiny by Mr. Ahuja), additional documents were searched out (from Petitioner’s vast data bank of about 5000 patients who have been taking therapy over and over again). 6 case studies (namely P-1, P-2, P-3, P-4, P-5 and P-6) are being additionally submitted at re-filing.

PRAYER

On the forgoing submission, it is most respectfully prayed that the Honorable Court may graciously be pleased to:

c. Grant permission to file additional documents and also to file updated versions of some of the documents.

d. Pass any further order or orders as the Honorable Court may deem fit and proper in view of the facts and circumstances of the case.

AND FOR THIS ACT OF KINDNESS THE PETITIONER-IN-PERSON AS IN DUTY BOUND SHALL EVER PRAY

Drawn on

Filed on

Drawn and filed by:

(Dr. Raman Kakar)

Petitioner-in-person

IN THE SUPREME COURT OF INDIA

CIVIL ORIGINAL JURISDICTION

WRIT PETITION (C) NO. OF 2015

PUBLIC INTEREST LITIGATION

Letter to the Registrar regarding Maintainability

To

The Registrar,

Supreme Court of India,

New Delhi.

Subject: Maintainability of Petition, Diary No. 25408.

Respected Sir,

Your august office has sought clarification asking when Delhi High Court has already decided a PIL in 2008, why have you now moved the Honorable Supreme Court.

In this matter, I wish to state the following:

1. No doubt, the Petitioner had earlier filed a broad-based PIL (CWP 185 of 2007) in Delhi High Court seeking several reforms in TB control as well as in public health care. Initially 11 prayers and later about 30 more suggestions had been filed. It covered a diverse spectrum of health issues.
2. One of the appeals was to increase the number of weekly TB doses from 3 to 5.
3. However, at that time, it had been made on a primitive basis - anecdotal evidence, gut feeling of insiders and had been on the following lines:
   (i) In Thrice weekly regime, patient visits a health center, receives and swallows 1 dose each on Monday, Wednesday and Friday, in front of a health worker. A missed dose on Monday may lead to a 4 or 5 day gap (Friday till Wednesday).
   (ii) Under routine conditions, missed doses are common occurrence. At times, the multipurpose worker is absent, sick, late or out on tour for polio, antenatal or family planning duties etc. The patient himself may fail to show up, stuck in traffic, job or family problems; countless holidays; monsoon or festival seasons etc.

(iii) When there are only 3 doses in one week, then each dose carries greater significance and a single miss would have more serious consequences. Dose irregularity could prove catastrophic. Besides, perfect supervision of each dose is impossible.

(iv) If 4-day long gaps occur frequently, treatment may fail.

(v) So, increasing doses from 3 to 5 would create a much needed margin for inevitable human error, mitigate the consequences of missed doses.

4. Further, in 2007, thrice-weekly concept itself had been in infancy. Petitioner had lacked contemporary knowledge; he was ignorant of and had failed to quote the 5 relevant scientific studies on issue of doses that had already stood published: Annexure P-18, P-23, P-25, P-26 and P-16 within the petition.
5. Besides, the petitioner acted overzealously and submitted a flurry of suggestions on numerous issues, which clouded and obfuscated the case. He obviously failed to draw even minimal focus on this specific subject. To associate this present petition (which is on a specific pointed matter) with that broad based petition would be unfair and unfortunate and will serve only to lose more time for our sick citizens.
6. After 2008, contemporary research, knowledge and literary evidence on this specific subject have been mounting (Annexure P-14 to P-27). Petitioner's own 6-year ongoing research too is now published and available (Annexure P-8).
7. Petitioner's nightmares which provoked him to take the extreme step of filing a PIL in 2007 seem to have sadly come true - like a prophecy. During past 6 years, every day in his busy TB OPD in a government hub, he has helplessly witnessed patients undergo additional and avoidable suffering and deteriorate despite ingesting DOTS medication properly, and transmit infection to other family members, and eventually turn incurable or die …. As if they were experimental guinea pigs. Petitioner has seen thousands of such cases in 6 years, of which 6 case studies (Annexure P-1 to P-6, Page) demonstrate a tip of the tragic iceberg. Hence, there appears to be no other remedy but to file this PIL – a most agonizing, laborious, arduous, time consuming and an extreme step for an aging and fatigued petitioner.

8. A chain is only as strong as its weakest link. Good quality of each and every brick is critical for the strength of a building. Similarly, ‘efficacy of therapy’ determines the fate of each and every single registered patient. Over 15 million individuals have been registered since inception of the dosing schedule, which is being questioned herein. Therefore, an in-depth review of the current therapy is urgently called for. The matter (and its scale) transcends issues like maintainability and other technical shortcomings that Petitioner’s humble submission may contain. Especially when time is at premium. Every recurrence episode in a citizen is a baby step towards the brewing epidemic of drug resistant (incurable) TB.

   Therefore it is prayed that the present Petition may kindly be allowed and be adjudicated with a sense of urgency.
9. However, if at all, Honorable Court wishes that this PIL should be filed in any other court, it is prayed that it may kindly be officially sent (transferred) to that court expeditiously. Because, if left to a fatigued, lonely Petitioner, the task is likely to waste more time.
10. Petitioner apologizes for the delay in curing defects. Recent turn of events had simply overwhelmed him:

    He was terminated on the basis of age-bar; he had to run around seeking official’s permission to continue serving even though without remuneration; he had to visit South Africa to present his research at world conference; he had to get the manuscript of the research published (and interim data has been replaced with updated data wherever possible, while most defects have been cured); and he has to tend to his very old sick mother. The delay may kindly be condoned and PIL allowed.

Thanking you, sir

Dated

Dr. Raman kakar

Petitioner in person

(Cover of paper book)

IN THE SUPREME COURT OF INDIA

CIVIL ORIGINAL JURISDICTION

WRIT PETITION (C) NO. OF 2015

PUBLIC INTEREST LITIGATION

A PIL FILED UNDER ARTICLE 32 SEEKING ISSUANCE OF WRIT IN THE NATURE OF MANDAMUS AND APPROPRIATE DIRECTIONS TO THE GOVERNMENT TO:

ABOLISH ITS CURRENT PRACTICE OF ADMINISTERING 'THREE DOSES OF MEDICINES PER WEEK' TO ALL PATIENTS SUFFERING FROM TUBERCULOSIS (TB), AND TO REPLACE IT WITH TIME-TESTED 'DAILY-DOSE' REGIMEN.

IN THE MATTER OF:

Dr. Raman kakar, Governement Medical Officer,

Revised National TB Control Program of India .....Petitioner

VERSUS

Union of India and ANR ……Respondents

WITH

I.A. NO. OF 2015

AN APPLICATION FOR APPEARING AND ARGUING BY PETITIONER-IN-PERSON

I.A. No. OF 2015

APPLICATION FOR DIRECTIONS / INTERIM RELIEF

PAPER BOOK

(FOR INDEX PLEASE SEE INSIDE)

PETITIONER-IN-PERSON – DR. RAMAN KAKAR