In the High Court of Judicature at Madras

(Special Original Jurisdiction)

W.P.No. 7558 of 2020

M.L.RAVI, (M/54)
President, Desiya Makkal Sakthi Katchi
No.21/11, Venkatraman Street,
Chennai, TN – 600 079 ….Petitioner

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1. The Secretary,
   Ministry of Health and Family Welfare,
   Government of India,
   'A' Wing, Nirman Bhavan,
   New Delhi, DL – 110001

2. The Secretary
   Ministry of Health and Family Welfare
   Government of Tamil Nadu
   Fort St.George
   Chennai, TN – 600009

3. Director General,
   Indian Council of Medical Research,
   V. Ramalingaswami Bhawan,
   Ansari Nagar,
   New Delhi, DL – 110029.

4. Director
   ICMR – National Institute of Virology
   20/A, Dr.Ambedkar Road
   Pune, MH – 411001 ….Respondents

AFFIDAVIT FOR AMENDMENT filed by M.L.RAVI

1. I am the Petitioner herein and am well aware of the facts and circumstances of the case and am competent to file this Affidavit.

2. I submit that I had filed this Writ Petition WP 7558 of 2020 on 24-04-2020 through e-mail to regrgenl@tn.nic.in with a Common Affidavit, Writ Petition, and Writ Miscellaneous Petition and all other procedural requirements. The same was taken up for hearing by video-conferencing on 30-04-2020. The presentation of the

case through arguments by Counsel before this Hon'ble Court was based on learnings subsequent to the filing of the case that the newly manufactured or imported Medical Devices including In-Vitro Diagnostic Kits for COVID-19 require approval from the licensing authority under Drugs and Cosmetics Act, 1945 and Drugs and Cosmetics Rules, 1945 and that those Test Kits including the Rapid Test Kits being procured and used by the Respondents are without approvals. In the circumstances, and after craving leave of this Hon'ble Court in the hearing on 30-04-2020, I am filing this as an Amended Affidavit incorporating the additional and necessary averments for a fuller consideration of facts and applicable law.

3. I submit that I am the President of Desiya Makkal Sakthi Katchi, a registered Political Party, registered with Election Commission of India with the objective of upholding the Constitution and its values, Social Justice with equal opportunities to all and a Corruption-free and transparent administration for Good Governance. I am also a Practicing Advocate, Social Activist and Charter President of Lions Club of Chennai Mint. I have contested in the Elections held for Lok Sabha as Desiya Makkal Sakthi Katchi's Candidate for North Madras Constituency.

4. I submit that in furtherance of the stated objectives, I have been working on several issues affecting the public by taking it up with the Authorities and, if necessary, by moving appropriate legal proceedings for relief including many earlier filed Writ Petitions in Public Interest before this Hon'ble Court. In the present COVID-19 Pandemic, I have, through Desiya Makkal Sakthi Katchi, provided COVID-19 distress relief to the needy by way of organizing distribution of relief materials and essential supplies in Vyasarpadi, R.K.Nagar and Eranaavur in Chennai at various times and occasion during the lockdown period including the below occasions that have a digital record regarding

    a) Spraying Disinfectant, on 08-04-2020, in Sithalapakkam, near Tambaram

b) Distribution of protective gear like hand-gloves and face-masks on 11-04-2020 in Sendhamangalam village, Namakkal District.

c) Distribution of groceries and vegetables, on 25-04-2020, to families in Vellaarai Village, Sriperumbudur Union, Kancheepuram District

d) Distribution of Rice, on 01-05-2020, to families in Ceylon Colony of Naanjikkottai, Thanjavur District.

And, this present Writ Petition filed in Public Interest is also no less for the benefit of millions of lives and livelihoods affected by acts of the Respondents in disregard to the Rule of Law, detailed infra, that is demonstrably a reason for the un-detected spread of COVID-19, detailed infra.

5. I submit that in the course of serving the public during COVID-19, it has come to my knowledge that the Government of India ("GoI") and Government of Tamil Nadu ("GoTN") are carrying out the Testing for COVID-19 in their Healthcare Systems with In-Vitro Diagnostic ("IVD") Kits that have not been approved by the concerned Regulatory Authority under statute, i.e. the Drug Controller General of India ("DCGI") under the Drugs and Cosmetics Act, 1940 ("DC Act") and the Drugs and Cosmetic Rules, 1945 ("DC Rules"). Moreover, it has also been publicly evident that the Antibody Rapid Test Kits procured by GoI and GoTN in these times have been defective. Aware of the consequences of testing with un-approved and defective Test Kits in the circumstances where the GoI and GoTN have had total disregard to compliance with regulatory requirements, I am moving this Writ Petition in the larger interest of the public, millions of whom will be affected with un-detected spread of COVID-19 by ineffective testing with defective testing kits that haven't been approved by DCGI.

6. I submit that I am filing this writ petition as Public Interest Litigation out of my own funds. My PAN No. is AAFPR1527G. My Income per annum is Rs.2,50,000/-. I have no personal or vested interest in the case and I undertake to abide by any condition and / or to pay costs that may be imposed by this Hon'ble Court if this

PIL is found to be intended for personal gain or other motives devoid of public interest. The averments in the above affidavit are all my personal knowledge and the enquiries made by me personally and also by my counsel deriving it from various public documents and sources in the public domain. I crave leave of this Hon'ble Court to treat the contents of the volumes of the Typed Set of Papers as part and parcel of this Affidavit and to permit me to file Additional or Rejoinder Affidavit if required in response to Counter / Reply Affidavit of the Respondents.

7. I submit that with China first reporting of cases of pneumonia from of unknown etiology (unknown source) to WHO on 31-12-2019 and detection of first cases in neighbouring Thailand on 13-01-2020, Japan on 15-01-2020, South Korea on 20-01-2020 and India on 30-01-2020 and to almost all countries at around these times, the WHO has declared it to be an international pandemic. The novel Corona virus now named SARS Cov-2 and the disease / infection as COVID-19 is yet without any drug invented for treatment or vaccination and in the circumstances is treated by increasing immunity through certain drugs in existence, appropriate nutrition and traditional knowledge.

8. I submit that, on 24-03-2020, the Government of India announced a 21-day lockdown throughout country due to COVID-19 epidemic beginning from 25-03-2020 and ending on 14-04-2020, after the advisory notification issued by WHO. An Order "No. 40-3/2020-DM-I(A)" dated 24-03-2020 was issued by the Home Ministry in this regard, for a period of 21 days up to 14-04-2020 and which was later extended till 03-05-2020 and which now stands extended up to 17-05-2020 through subsequent Notifications.

9. I submit that with many "Asymptomatic" cases reported in India (cases where there are no symptoms of the virus on the carrier for upto 21 days and yet the person continues to infect others) the spread of virus through such Asymptomatic carriers will continue undetected and be the source of infection for a multitude of others. Further, erroneous and ineffective testing using defective test kits

and such test kits that have not been approved for quality by the Regulator DCGI will not have properly detected the virus affected persons to be kept in isolation for COVID-19 treatment and thus further add to the spread of COVID-19 by un-detected carriers.

10. I further submit that SARS Cov-2 spread will continue despite the implementation of lockdown due to

    a) ineffective and erroneous testing done with defective test kits or test kits not approved for quality by DCGI

    b) Asymptomatic nature of SARS Cov-2 for up to 21 days

    and therefore the spread of COVID-19 can be controlled only by extensive testing and effective testing followed by treatment to the infected.

11. I further submit that it is evident that nations have been relatively unaffected by COVID-19 or those nations that had better controlled COVID-19 spread are those nations that had done extensive testing and effective testing. This cannot be better demonstrated than by taking the example of South Korea that is, in relative terms to India, a nation geographically closer to the COVID-19 epicenter in China, a nation with a higher population density than India, a nation that had its first case of COVID-19 much earlier than India and a nation that had never implemented a lockdown for the purpose of dealing with the spread of COVID-19. And yet, with extensive testing done on its populace (12204 tests done per million population as on 03-05-2020) with effective testing kits (approved by its Regulator), South Korea is a clear evidence that only effective testing and extensive testing followed by available treatment will be the solution to control the spread of COVID-19.

12. I further submit that similar to South Korea, countries with an even higher population density like Taiwan (652 per Sq.Km) and Hong Kong (6782 per Sq.Km.) have managed to control the spread of COVID-19 without a lockdown with effective testing and extensive testing (2715 tests per million people in Taiwan as on 03-05-2020 AND 20714 tests per million people in Hong Kong as

on 27-04-2020) followed by available treatment further substantiating the fact that effective testing and extensive testing alone is the best step forward.

13. I further submit that between countries that have done "extensive" testing with closely similar rates of testing (persons tested per million population) like South Korea (12204 tests per million people as on 03-05-2020) and USA (20850 tests per million people as on 02-05-2020), the difference has been "effective" testing. A recent research report on test kits being used in the US has found most Test Kits to be without US-FDA approval and confirmed that Test Kits with even a 3% false result is not interpretable and a 13% false result is useless. However, in India, Test Kits in use haven't been approved by DCGI and they have also demonstrated an unimaginable upto 94% false results and thus compounding the possibilities of un-detected and un-fettered spread of COVID-19 attributable to faulty testing by defective test kits unapproved by Regulator DCGI.

14. I further submit that while overly relying on Lockdown as a solution to prevent the spread of COVID-19, the GoI and GoTN have failed to appreciate the importance of extensive testing and effective testing, with Regulator DCGI approved Test Kits, as the most important tool to control the spread of COVID-19 as seen from the experience of countries that have succeeded in controlling COVID-19 even without a Lockdown (South Koreas, Taiwan, Hong Kong) and from the experience of countries that faced the consequences of wide-spread COVI-19 with usage of defective Test Kits that weren't approved the Regulator (US-FDA, in this case of USA). These lessons from international experiences effectively imply that the way forward to control the spread of COVID-19 is

    a) Extensive Testing for more people per million population
    b) Effective Testing with Quality Test Kits approved by Regulator
    c) Treatment in isolation for improving immunity with existing drugs, nutrition and traditional knowledge.
    d) Lockdown, at best, only slows the initial spread and does not prevent spread of COVID-19

e) Social Distancing & Hygiene is a necessity to stop contagion.

15. I respectfully submit that under the Drugs and Cosmetics Act, 1945 ("DC Act"), per Sec.3(b)(ii), a "Drug" includes Devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings. And, the COVID-19 Diagnosis Test Kits that use nasal and throat swab samples extracted from human bodies (RT-PCR Test Kits) and Test Kits that use blood samples extracted from human bodies (Antibody Rapid Test Kits) are "In-Vitro" Diagnostic ("IVD") Medical Devices and come within the definition of "Drug" under the Drugs and Cosmetics Act, 1945 for the Act to apply to IVD.

16. I respectfully submit that the DC Act provides for making rules with respect to those including Licensing, Standards, Testing and Analysis, Labeling, etc. for Imported Drugs including In-Vitro Diagnostics (per Sec.12) and Manufactured Drugs including In-Vitro Diagnostics (per Sec.33).

17. I respectfully submit that under the DC Rules, in "Part X A" that relates Rules on Import or Manufacture of New Drugs for Clinical Trials or Marketing, Rule 122-A prescribes that No new Drug (including In-Vitro Diagnostics by implication) shall be "Imported" except under and in accordance with the permission granted by the Licensing Authority appointed under Rule 21(b). And, Rule 122-B prescribes that No new Drug (including In-Vitro Diagnostics by implication) shall be "Manufactured" for Sale unless it is approved by the Licensing Authority appointed under Rule 21(b).

18. I respectfully submit that the Drug Controller General of India ("DCGI") is the Authority appointed by the Central Government to perform the duties of the Licensing Authority per Rule 21(b). And a total of 7 Labs notified to be Central Drugs Laboratory, for the purpose of testing and analysis of Drugs (including In-Vitro Diagnostics) amongst other purposes, that come under the Central Drugs Standard Control Organization ("CDSCO") as well as other statutorily required Drugs Consultative Committee ("DCC") and Drugs Technical Advisory Board ("DTAB") are all headed by DCGI.

19. I respectfully submit that Rule 69(2)(c) provides for an Application for a Licence to "Manufacture" In-Vitro Diagnostics and Rule 81(1) provides for the grant of the Licence thereto. Likewise, Rule 24 provides for an Application for a Licence to "Import" Drugs (including In-Vitro Diagnostics by implication) and Rule 27 provides for the grant of the Licence thereto.

20. I respectfully submit that the conditions for Licence to "Import" Drugs (including In-Vitro Diagnostics by implication) prescribed under Rule 26 for grant of Import Licence under Rule 27 and the conditions for Licence to "Manufacture" Drugs (including In-Vitro Diagnostics by implication) prescribed under Rule 78 and Schedule 'F' or Schedule 'F(1)' for grant of Manufacturing Licence under Rule 81(1) require among other conditions the adherence to standards of quality. The standards of quality are specified in Rule 125A and "Schedule R-I". And the Quality Management System to be followed in case of manufacture of Medical Devices and In-Vitro Diagnostics are specified in "Schedule M – III".

21. I further submit that in the context of the aforementioned applicable provisions of the DC Act and DC Rules, it is noticed that the Respondents have acted in total disregard to the same by implementing testing for COVID-19 in their Healthcare Systems (Hospitals, Diagnostic Labs, etc.) with imported as well as locally manufactured In-Vitro Diagnostics Medical Devices for diagnosis of COVID-19 through the 2 types of testing done with

    a) RT-PCR Test Kits (that use nasal or throat swab to extract RNA of the virus therein to check if it shares the same genetic sequence of SARS Cov-2 virus), and
    b) Antibody Rapid Test Kits (that use blood sample to detect presence and quantity of antibodies to determine if the immune system has encountered the virus)

    that have NOT been approved (with grant of Licence) by the Regulator, DCGI.

22. I submit that the Indian Council of Medical Research ("ICMR") has taken upon itself the role of Approving COVID-19 Test Kits for use

in Healthcare Systems even without those Test Kits being approved for Quality Standard by DCGI. This has resulted in GoI and GoTN and other states, through the different arms/agencies of the Government, procuring numerous COVID-19 Test Kits that have not been approved by DCGI and which has eventually turned out to be defective Test Kits providing erroneous test results (False Positives and False Negatives for infection of SARS Cov-2 virus) that will now add to the "un-detected" spread of COVID-19.

23. I submit that ICMR had, on 23-03-2020, issued a Press Release about ICMR having operationalized a Fast-track Approval Mechanism for COVID-19 Testing Kits and completed evaluation of 9 COVID-19 Test Kits at ICMR-National Institute of Virology, Pune ("NIV-Pune") until then and the approval of 2 COVID-19 Testing Kits for commercial use in India. Thereafter, ICMR had, on 16-04-2020, issued a Guidance on Antibody Rapid Test Kits for COVID-18 stating that ICMR had till that date validated 23 Rapid Test Kits at NIV-Pune and found 14 Rapid test Kits to be "Satisfactory for use" including 9 of those Rapid Test Kits that were manufactured in India. However, this Guidance of ICMR was with a Disclaimer that
    a) Positive result of virus presence comes only after 7–10 days of infection
    b) Positive result of virus presence indicates exposure to SARS Cov-2 (the virus)
    c) Negative result of virus presence does not rule out COVID-19 (the disease)
    d) The Guidance limited to the specified batch of Rapid Test Kits
    e) That these Antibody Rapid Test Kits are NOT Recommended for diagnosis of COVID-19 infection.

24. I submit that it was based on these on-going approvals by ICMR that GoI, through National Institute of Cancer Prevention and Research ("NICPR"), issued a Purchase Order ("PO") to Aark Pharmaceuticals, New Delhi ("Aark Pharma"), on 28-03-2020, for procuring 5,00,000 Antibody Rapid Test Kits manufactured by Wondfo Biotech, Guangzhou, China ("Wondfo"). Likewise, GoTN, through Tamil Nadu Medical Services Corporation Limited

("TNMSCL"), issued a PO, on 06-04-2020, to Shan Biotech & Diagnostics ("Shan Biotech") for 50,000 Antibody Rapid Test Kits manufactured by Wondfo.

25. I submit that Newspaper reports suggest that GoI has further ordered about 3 million Rapid Test Kits and 3 million RT-PCR Test Kits and it is not known if those Kits ordered are ones approved (with grant of Licence) by the Regulator, DCGI. Neither the process for those procurement nor the vendor for supply has been made available to the public and shrouded in secrecy. However, it is noticed from data available in the public domain that India's DCGI has approved only 4 COVID-19 Test Kits (2 – PCR and 2 – Rapid Test Kits) of the following manufacturers
    - 3B Blackbio Biotech India Ltd. (RT-PCR based)
    - Molbio Diagnostics Pvt. Ltd. (RT-PCR based)
    - CTK Biotech Inc. (Antibody Rapid Test Kit)
    - Medsource Ozone Biomedicals (Antibody Rapid Test Kit)

26. I submit that a number of States that put to use the Rapid Test Kits, imported by GoI or by the States themselves, in their Healthcare Systems, based on the Guidance issued by ICMR, found their working in the diagnosis of CIVID-19 to be erroneous and ineffective due to defect in design and / or manufacture with error rates going up to even 94%. Thereafter, on 27-04-2020, ICMR issued a Revised Advisory to all States asking them to stop using the Antibody Rapid Test Kits manufactured by Wondfo Biotech and Zhuhai Livzon Diagnostics, China without any say on the lack of quality approval of the Regulator, DCGI.

27. I respectfully submit that the aforementioned acts of the Respondents are only contributing to the further spread of COVID-19 as evident from the interpretation of data available in public domain and as such are irrational acts of negligence, arbitrariness with non-application of mind that has been affecting, compromising and jeopardizing the lives and livelihoods of millions of people and thus a direct affront to the right to life guaranteed

under the Constitution which I endeavor to challenge on the following amongst other

GROUNDS

A. That Purchase Orders by the 1st Respondent and 2nd Respondent, through the different arms/agencies of the Government, ought not to have been for purchase of COVID-19 Diagnosis Test Kits that are not approved (with grant of Licence) by the Regulator, DCGI under the Drugs and Cosmetics Act, 1940 and Rules thereunder.

B. That any Request for Proposal, Call for Tender, Invitation to Offer, Expression of Interest, and the likes for the supply of COVID-19 Diagnosis Test Kits as called for by the 1st Respondent and 2nd Respondent, through the different arms / agencies of the Government, ought to have specifically limited the call for supplying only such of those COVID-19 Diagnosis Test Kits that are approved (with grant of Licence) by the Regulator, DCGI.

C. That 3rd Respondent taking upon itself the role for Approving COVID-19 Test Kits for use in Healthcare Systems even without those Test Kits being approved for Quality Standard by DCGI is a blatant violation of the provisions under the Drugs and Cosmetics Act, 1940 and the Rules thereunder.

D. That the decision of the 1st Respondent and 2nd Respondent, through the different arms / agencies of the Government, to procure COVID-19 Diagnosis Test Kits from Wondfo Biotech and Zhuhai Livzon Diagnostics to the exclusion of other suppliers who have DCGI Approval or International Certifications specific to Quality of In-Vitro Diagnostic Kits like "CE-IVD" Certification, is an arbitrary exercise of power.

E. That the decision of the 1st Respondent and 2nd Respondent, through the different arms / agencies of the Government, to procure COVID-19 Diagnosis Test Kits without factoring in the fact known to them even before issuing Purchase Orders, that Chinese manufacturers have been supplying such defective Test Kits to Spain and Turkey and which has been in the news as early as 26-

03-2020, is a clear act of Non-application of mind, lack of prudence and without any due-diligence.

F. That the failure to learn from the experiences of other countries relating to extensive testing and effective testing as the path to take for controlling the spread of COVID-19 even in a country with higher population density, earlier 1st case of COVID-19 and even without a lockdown imposed, and instead going on to procure defective COVID-19 Diagnosis Test Kits in miniscule numbers at a total cost that is relatively only a fraction of the economic loss to the nation due to COVID-19, can only further the "un-detected" spread of COVID-19 and as such has gone on to affect the lives and livelihood of millions of people in a direct affront to the right to life guaranteed under the Constitution.

G. That the 1st Respondent and 2nd Respondent continue to use only COVID-19 Diagnosis Test Kits that have not been approved (with grant of Licence) by the Regulator, DCGI is an affront to the Rule of Law that ought to be acted against to prevent the "un-detected" spread of COVID-19 that will affect the lives and livelihood of millions of people as seen from experiences of other countries.

H. That the analysis and interpretation of empirical data available in the public domain has only substantiated the fact that the steps taken by the Respondents have not had any inspiring effect in the control of spread of COVIFD-19 which could have been otherwise achieved with extensive testing and effective testing using COVID-19 Diagnosis Test Kits that are approved (with grant of Licence) by the Regulator, DCGI and as such needs Judicial Intervention when elected representatives and executive authorities have failed to act swiftly, astutely and diligently.

I. That further and continued use of COVID-19 Diagnosis Test Kits that are Defective and / or NOT approved (with grant of Licence) by the Regulator, DCGI will only result in mass mismanagement of a pandemic of epic proportion leaving a catastrophic effect on public health and economy and pushing millions into poverty,

deprivation and deaths as evidenced in other parts of the globe in other countries like USA, Spain, Italy, etc.

And, it is in these circumstances that this Writ Petition has been filed as there is no other effective or alternate remedy, given the gravity of the situation and the need to act swiftly, except by invoking Art.226.

It is prayed that this Hon'ble Court may be pleased to permit me to amend the Affidavit, Writ Petition and Writ Miscellaneous Petition filed on 24-04-2020 in WP 7558 of 2020 and thus render Justice.

It is prayed that this Hon'ble Court may be pleased to pass an Order of ad interim Injunction restraining the 1st Respondent and 2nd Respondent from procuring and using in their Healthcare Systems such COVID-19 Diagnosis Test Kits that are NOT approved (with grant of Licence) by the Regulator, DCGI, pending disposal of this Writ Petition and thus render justice.

I therefore pray that this Hon'ble Court may be pleased to Issue a Writ of MANDAMUS or any other Order or Orders or Direction in the nature of Writ, to direct the 1st and 2nd Respondents to fully implement testing for COVID-19 in their Healthcare System using only such COVID-19 Diagnosis Test Kits approved (with grant of Licence) by the Regulator, DCGI, and pass such further and / or other Orders as this Hon'ble Court may deem fit and proper in the circumstances of the case and thus render justice..

Solemnly affirmed at Chennai on this the 4th day of May 2020 and Signed his name in my presence.

BEFORE ME,

ADVOCATE, CHENNAI

CHENNAI :: DISTRICT

HIGH COURT :: MADRAS

W.P.No. 7558 of 2020

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-v-

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& 3 Others
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ADDITIONAL AFFIDAVIT

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