

**IN THE HIGH COURT OF DELHI AT NEW DELHI**  
(CIVIL ORIGINAL JURISDICTION)

Writ Petition (Civil) No. .... Of 2009  
PUBLIC INTEREST LITIGATION

A WRIT PETITION IN PUBLIC INTEREST UNDER ARTICLE 226 OF THE CONSTITUTION OF INDIA HIGHLIGHTING HOW IRRATIONAL VACCINES ARE BEING ARBITRARILY INTRODUCED AND PROMOTED BY THE GOVERNMENT AT THE BEHEST OF VACCINE MANUFACTURERS AND OTHER VESTED INTERESTS.

**Memo of Parties**

**IN THE MATTER OF:**

DR. K. B. SAXENA (PH.D)  
FORMER HEALTH SECRETARY, GOVERNMENT OF INDIA  
VISITING PROFESSOR, CENTRE FOR SOCIAL DEVELOPMENT  
53 LODI ESTATE, NEW DELHI-110003 ...PETITIONER No. 1

PROF. S. K. MITTAL (MD)  
FORMER HEAD OF PEDIATRICS, MAULANA AZAD MEDICAL COLLEGE  
DIRECTOR, PEDIATRICS, PUSHPANJALI CROSSLAY HOSPITAL  
VAISHALI, GHAZAIABAD ...PETITIONER No. 2

PROF. DEBABAR BANERJI (MD)  
PROFESSOR EMERITUS  
CENTRE OF SOCIAL MEDICINE & COMMUNITY HEALTH  
JAWAHARLAL NEHRU UNIVERSITY, DELHI ...PETITIONER No. 3

PROF. IMRANA QADEER (MD)  
MEMBER, NATIONAL RURAL HEALTH MISSION  
R/o C-4/111, SAFDARJUNG DEVELOPMENT AREA  
NEW DELHI-110016 ...PETITIONER No. 4

DR. N. J. KURIAN (PH.D)  
S/o CHAKO JOHN  
FORMER ADVISOR TO FINANCE MINISTRY & PLANNING COMMISSION  
VISITING PROFESSOR, COUNCIL FOR SOCIAL DEVELOPMENT  
SANGHA RACHANA, 53 LODI ESTATE, NEW DELHI-110003 ...PETITIONER No. 5

DR. RITU PRIYA (MD)  
PUBLIC HEALTH ADVISOR, NRHM  
MINISTRY OF HEALTH & FAMILY WELFARE  
NIRMAN BHAWAN, NEW DELHI-110001 ...PETITIONER No. 6

DR. MIRA SHIVA (MD)  
FOUNDER COORDINATOR, ALL INDIA DRUG ACTION NETWORK  
D/O LATE MAJOR D S SHIVA  
R/O A-60, HAUZ KHAS, NEW DELHI-110016 ...PETITIONER No. 7

DR. JACOB M PULIYEL (MD MRCP MPhil)  
HEAD, DEPT. OF PEDIATRICS  
ST. STEPHANS HOSPITAL, TIS HAZARI  
NEW DELHI- 110054 ...PETITIONER No. 8

DR. GOPAL DABADE (MBBS, DLO)  
PRESIDENT, DRUG ACTION FORUM (KARNATAKA)  
57, TEJASWINAGAR  
DHARWAD-580002 (KARNATAKA) ...PETITIONER No. 9

**VERSUS**

THE UNION OF INDIA  
THROUGH ITS SECRETARY  
MINISTRY OF HEALTH & FAMILY WELFARE  
NIRMAN BHAWAN, NEW DELHI-110001 ...RESPONDENT No.  
1

NATIONAL TECHNICAL ADVISORY GROUP OF IMMUNIZATION  
THROUGH ITS CHAIRPERSON  
MINISTRY OF HEALTH & FAMILY WELFARE  
NIRMAN BHAWAN, NEW DELHI-110001 ...RESPONDENT No.  
2

INDIAN COUNCIL OF MEDICAL RESEARCH  
THROUGH ITS DIRECTOR GENERAL  
V. RAMALINGASWAMI BHAWAN, ANSARI NAGAR  
NEW DELHI-110029 ...RESPONDENT No.  
3

**NEW DELHI  
DATED:**

**(PRASHANT BHUSHAN)  
ADVOCATE FOR THE PETITIONER**

301, NEW LAWYERS CHAMBERS  
SUPREME COURT OF INDIA  
NEW DELHI-110001

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To,

**THE HON'BLE CHIEF JUSTICE OF DELHI AND HIS COMPANION JUDGES  
OF THE HON'BLE HIGH COURT OF DELHI, AT NEW DELHI**

The Humble Petition of the  
Petitioners above-named

MOST RESPECTFULLY SHOWETH: -

1) That the Petitioners are filing the instant writ petition in public interest highlighting how irrational vaccines are being introduced in the public health system by the Government, under the influence of vaccine manufacturers and international agencies like World Health Organization (WHO), without proper epidemiological and medical studies. Petitioners (who are generally pro-vaccine and pro-modern medicine) are appalled at how in the absence of a rational vaccine policy, newer and newer vaccines are being pushed by the Government into the national immunization programme. Vaccines which are either of little utility or which are not required at all are being introduced and promoted by the Government at the behest of these vested interests and, at the same time, basic vaccines that are the right of every child are not being made available under the Universal Immunization Programme (UIP) to 53% of the population – mostly poor living in rural areas who should be the priority for any immunization program as the poor cannot afford the consequences of disease.

2) Under the Expanded Programme of Immunization (EPI), 6 primary vaccines are covered: BCG, DPT, DT, TT, Measles and Polio. At a time when the Government has utterly failed to ensure that every child receives these vaccines and the country is facing a shortage of these vaccines, new vaccines of

questionable utility and efficacy are sought to be introduced in an arbitrary and irrational manner, and at huge cost. These expensive vaccines, after being introduced, are very likely to be cornered by the urban elite at the expense of the exchequer. The only beneficiaries of this are the vaccine manufacturers. Government has shown little interest to make the EPI vaccines available to the large number of children who are either poor or are in remote rural areas and thereby violating their Fundamental Rights guaranteed under Article 14 and 21 of the Constitution.

3) The Petitioners is highlighting the Government's arbitrary policy on vaccines by using, as case studies, the proposed introduction of Hepatitis B, Haemophilus influenzae Type B (Hib), Pneumococcal and the Pentavalent vaccines which are of doubtful utility, unproven efficacy, expensive and are not required. World over, before a vaccine is introduced in the public health system, a number of studies are carried out with proper methodology and expertise, taking into account a number of factors, and also conflict of interest is strictly guarded against. In India, not only these tests are not being done, adverse studies against these new vaccines are deliberately being ignored. It is of note that the very studies that were done by the WHO to demonstrate the need for the vaccines in India showed that there was very low incidence of the disease and as such there was little sense in introducing the vaccine and these very studies were ignored in the recommendation made to GOI to introduce the vaccine. This practice of selectively ignoring studies (even those done by the ICMR with funding from the WHO) which are inconvenient, goes against the basic tenets of Evidence Based Medicine and results in promoting irrational medicine. This Petition seeks a direction to the Government to formulate a rule-based rational vaccine policy by which vaccines are scientifically evaluated in a transparent manner before they become part of country's UIP. This Petition also seeks an immediate stay against the introduction of Hepatitis B, Haemophilus influenzae Type B (Hib), Pneumococcal and the Pentavalent vaccines till the requisite studies are carried out.

## **THE PETITIONERS**

1) Petitioner No. 1 is Dr. K. B. Saxena (Ph.D). He is the former Secretary in the Ministry of Health & Family Welfare. He is also former Secretary in the Department of Rural Development. He is also former Principal Advisor to the Planning Commission. He is currently a Visiting Professor at Centre for Social Development.

2) Petitioner No. 2 is Prof. S. K. Mittal (MD). He is the former Head of Pediatrics Department in Maulana Azad Medical College, Delhi. He has been a Member of Medical Council of India and President of Delhi Medical Association. He has authored seven books in Pediatrics including two books on immunization. He is a recipient of many awards and is currently Director of Pediatrics at Pushpanjali Crosslay Hospital.

3) Petitioner No. 3 is Prof. Debabar Banerji (MD). He is the Professor Emeritus at the Centre of Social Medicine and Community Health at Jawaharlal Nehru University.

4) Petitioner No. 4 is Prof. Imrana Qadeer (MD), former Professor and Head at Centre of Social Medicine and Community Health at Jawaharlal Nehru University. Prof. Qadeer is Member, PM Advisory Committee and Member, National Rural Health Mission. She is also Member of the Population Council.

5) Petitioner No. 5 is Prof. N. J. Kurian (Ph.D). He is the former advisor to Ministry of Finance and Planning Commission. He has been Director of Public Report on Health and Director of Council for Social Development (CSD). He is currently a Visiting Professor of CSD.

6) Petitioner No. 6 is Dr. Ritu Priya (MD). She is currently an Advisor (Public Health Planning) under the National Rural Health Mission, Government of India.

She has researched extensively on epidemiology, communicable diseases and public health systems.

7) Petitioner No. 7 is Dr. Mira Shiva (MD). For the last 30 years, she has been extensively involved in issues of primary health care, medicine technologies and health safety. She was Chairperson, Consumer Education of Task Force on Safety of Food and Medicine, Government of India. She is Member, Central Social Welfare Board, Government of India and Member, Central Ethics Committee on Human Research, Government of India. She is the Founder Coordinator of All India Drug Action Network, Director- Rational Drug Policy, Director- Initiative for Health Equity & Society. She has won many awards internationally and also by Government of India for her contribution in prevention of misuse of medicines and medical technology.

8) Petitioner No. 8 is Dr. Jacob M Puliyel (MD, MRCP & M.Phil). He is the head of the Pediatrics Department at St. Stephens Hospital in New Delhi. He was vice-Chairperson of the Indian Medical Association's sub-committee on Immunization. He is a well-known expert on the role of vaccines in the public health system and has over 100 publications in indexed national & international medical journals.

9) Petitioner No. 9 is Dr Gopal Dabade (MBBS, DLO). He is the President of Drug Action Forum - Karnataka, which is campaigning for rational drug and vaccines policies. He is also the Co-convener of All India Drug Action Network (AIDAN), which is a national network of civil society members actively involved in promoting the concept of rational drug and vaccines policies.

#### **THE RESPONDENTS**

1) Respondent No. 1 is the Union Ministry of Health and Family Welfare which is responsible for the maintenance and promotion of public health

standards in the country. It is the nodal ministry responsible for the evaluation and introduction of vaccines.

2) Respondent No. 2 is National Technical Advisory Group on Immunization (NTAGI) which is the body responsible for advising the Government on policies and practices for the implementation of the National Immunization Programme. This body is directly under the supervision of the Health Ministry.

3) Respondent No. 3 is the Indian Council of Medical Research (ICMR) which is the apex body in the country for formulation and coordination of biomedical research. It is funded by the Government and its governing body is presided over by the Union Health Minister. The Director General ICMR is also Secretary Health Research under Ministry of Health & Family Welfare.

#### **THE CASE IN BRIEF**

1) Vaccines are vital to avoid unnecessary suffering, disability, and death. Immunization is a proven tool for controlling and even eradicating disease. Just as essential and life saving medicines are needed for medical care, certain vaccines, based on proven utility, are considered essential and they have an important role in health care promotion. India is one of the biggest consumers of vaccines in the world. Under the EPI, six basic vaccines are provided to the children in the country: BCG, DPT, DT, TT, Measles and Polio. These vaccines cost as little as Rs. 30 per child to the exchequer. Yet they are still not made universally available and many children are denied their basic right to immunization. The survey by the Government of India has shown that 53% of the population does not receive these basic vaccines.

2) The Government has in recent times closed down virtually all public sector units that were supplying the essential vaccines at a cost which is a fraction of the cost at which same vaccines are produced by the private sector. There were no complaints against these units and the general view was that these units were

doing exemplary work. No question was ever raised regarding the quality of vaccines produced in these centres. Yet, without any provocation they were closed down on the pretext that they were not following “good manufacturing practices” which related to their building set-up. Even if they required upgrade, government should have sanctioned some funds for the purpose. One of India’s most credible research institution, Centre for Science and Environment (CSE) did a detailed study of vaccine shortage due to the closure of these public sector units which clearly shows how the closure is irrational, unreasonable and malafide. The said study published in their publication is annexed and is marked as **Annexure P1**.

#### Closure of Vaccine Public Sector Units

No.	Current Name & location	Year Estd.	Current status
1	Pasteur Institute of India, Coonor	1907	Suspended in 2008
2	Central Research Institute	1905	Suspended in 2008
3	BCG Vaccine Laboratory (BCGVL), Chennai	1951	Suspended in 2008
4	King Institute of Preventive Medicine	1898	Suspended in 2003
5	Haffkine Institute, Mumbai	1898	Running
6	Institute of Preventive Medicine, Hyderabad	1870	Closed in 2005
7	Pasteur Institute, Shillong	1917	Closed in 2006
8	Vaccine Lymph Department, Belgaum	1904	Closed in 1980
9	Vaccine Institute, Ranchi	1900	Closed in 2003
10	State Vaccine Institute, Patwadanagar	1900’s	Closed in 2005

The said malafide closures in recent times, clearly to benefit private sector manufacturers, are currently under challenge in the Hon’ble Supreme Court of

India where the Hon'ble Court has issued notice to the Government. A news report on this case is annexed and is marked as **Annexure P2**.

Recently, CSE has published the findings of a RTI application which show the shortage of the basic vaccines, caused due to the closure of government's vaccine manufacturing facilities. The said report is annexed and is marked as **Annexure P3**.

3) Within a few months of the said closure, the Government has gone full steam ahead and is on the verge of introducing newer vaccines in the country's Universal Immunization Programme (UIP). These vaccines are of doubtful efficacy, little utility, costly, manufactured only by private sector, have unknown side effects and are being introduced without any proper study. It is to be noted that unlike curative drugs which are given to the few who fall ill, vaccines are given to the entire population. Hence they need a strong economic logic and clear cost-benefit analysis that uses, inter alia, epidemiological data about the disease being sought to be prevented. Clearly, there is a trade off in the number of vaccines one can introduce in a community, depending on costs, number of people affected, the seriousness of the condition, and the consequences - if untreated - for the entire community. A number of research papers have been published showing how the vaccine policy in India is faltering. The said studies are annexed and are marked as **Annexure P4 (colly)**. Frontline, India's most respected fortnightly publication, did a research which warned that vaccines which are not necessary may become a part of nation's immunisation programme as there is a push by global pharmaceutical companies for their introduction. The said research, as published on 29.03.2008, is annexed and marked as **Annexure P5**. Now, the said warning is on the verge of coming true and therefore Petitioners seek urgent intervention of this Hon'ble Court.

4) World over, about 6 factors are seriously studied and researched before a vaccine is introduced:

- a) **Incidence of the disease:** How many people are affected by the disease for a given population in the country or a particular region?
- b) **Severity of the disease:** Whether the disease causes serious discomfort, disability or death? Or is it just a minor ailment in the majority of cases and it results in complication in a very small number?
- c) **Public Health significance:** Which is the population vulnerable to the disease? How is the disease transmitted? What are the health care and economic consequences of the disease?
- d) **Treatment options:** Is the disease untreatable? Does it require expensive or prolonged medication? Is it curable with inexpensive and easily available drugs? Is it naturally curable?
- e) **Efficacy of the vaccine:** If a said number of persons are vaccinated, then what fraction/percentage of them acquire immunity from the disease?
- f) **Cost of the vaccine:** How much will it cost to vaccinate the entire population as against giving medical care to the few who fall ill?
- g) **Side effects:** What are the health side effects of the vaccine that is sought to being given to every child?

5) Clearly, these factors are being ignored and no proper epidemiological and other studies are being carried out, and Government is trying to introduce newer and newer irrational vaccines. The Petitioners are using the proposed introduction of Pentavalent, Hepatitis B, Haemophilus influenzae Type B (Hib) and Pneumococcal as case studies to highlight the totally arbitrary and irrational system of recommendation for introduction of new vaccines. This is being done at the behest of vaccine manufacturers who conduct and promote doubtful studies, and the WHO which, of late, has come under the influence of pharmaceutical industry. It is of note that in the latest recommendation of the NTAGI, important data available from studies done by the ICMR have been conveniently ignored.

**Pneumococcal vaccine:**

6) NTAGI (Respondent No. 2) has recommended that Pneumococcal vaccine be introduced in a phased manner from 2010. This is the Government body responsible for conducting the relevant studies before recommending introduction of any vaccine. The said recommendation is annexed and is marked as **Annexure P6**. The document given to the Petitioner No. 1 under RTI clearly shows that the vaccine would be developed only by 2010. Thus, NTAGI has recommended the introduction of a vaccine in the public health system without any trial. The said recommendation states that results of immunogenicity studies of the Pneumococcal vaccine in Indian children “will be available soon.”

7) Pneumococcal vaccine has been proposed for introduction on the recommendation of WHO which states that this vaccine be included in national immunization programmes in countries where mortality among children aged less than 5 years is more than 50 per 1000 live births *or* where more than 50,000 children die annually. The latter figure has no reference to the birth rate or number of children. In a large country like India, more than 50,000 children die but that figure has little relation to the disease which this vaccine claims to prevent. The first criterion of mortality of more than 50 per 1000 live births is met by 70 countries and the total population to be vaccinated is 316 million. By including the irrational criterion of where more than 50,000 children die annually only 7 additional countries are added but it adds another 161 million to the numbers eligible for vaccination. The WHO recommendations seem dictated by needs of increasing demand for vaccines and profits for manufacturers rather than the needs of public health. This WHO recommendation shows how it is becoming a tool in the hands of pharmaceutical companies who are eyeing major developing countries like India to further their commercial interests. In fact, we would be spending Rs. 1.5 lakh for preventing 1 case of pneumonia which can be treated by spending Rs. 100. This is shown in Petitioners’ letter published in The Lancet. The said letter is annexed and is marked as **Annexure P7**.

8) Also, Pneumococcus is one of the many organisms which cause Pneumonia. And even in the case of Pneumococcus, there are over 90 strains and the Pneumococcal vaccine covers only 1/10<sup>th</sup> of them. Attacking some strains of one or two bacteria, do not make much of an overall impact on bacteria. Even in countries where the disease strains match the prevalent vaccine, it only prevents 3.6 cases of pneumonia per 1000 children vaccinated. It is commonly known medically that if one vaccinates against one strain then other less common strains take its place. ICMR study which was received by the Petitioner under RTI which shows low incidence of meningitis and pneumonia was ignored by NTAGI. The said ICMR study is annexed and is marked as **Annexure P8**. Pneumonia is easily treatable by adequate use of antibiotics and the use of the new vaccines is still unproven. Also, Pneumonia is easily treatable at low cost with use of antibiotics which does not justify that an expensive vaccine be given to all children, especially a vaccine of very little efficacy. Dr. Anuradha Bose (Christian Medical College)'s piece published in The Hindu in this regard is annexed and is marked as **Annexure P9**. Pneumococcus also causes potential side-effects of doubling the incidence of asthma in children. Hence, the actual costs of this vaccine far outweigh its claimed benefits. Research analysis as published in bulletin of WHO are annexed and is marked as **Annexure P10**. A research paper published in prestigious journal of International Society for Vaccines shows how Pneumococcal vaccination is more about commerce and less about science. The said paper is annexed and is marked as **Annexure P11**.

**Hib vaccine:**

9) NTAGI has now shockingly recommended the introduction of the Hib vaccine in the UIP. The recommendation of NTAGI, as published in the journal Indian Pediatrics, is annexed and is marked as **Annexure P12**. It clearly shows that they have selectively quoted from studies favorable to the recommendation and have ignored all studies and material which shows that the vaccine is not required in the country. Also, ICMR (Respondent No. 3) study in Vellore district which was available through RTI has been completely ignored by NTAGI. That

ICMR study showed incidence of all cause pneumonia requiring attention in hospital was only 3/100 and all cause meningitis was only 2/100. Some of the studies that were conveniently ignored are annexed and are marked as **Annexure P13 (colly)**. The evidence available was not favorable for the introduction of the Hib vaccine, and in a totally biased manner it was ignored, reflecting the unscientific nature of the Government's system of vaccine evaluation. Hib vaccine is also known to increase the incidence of Diabetes and hence its costs far outweigh the claimed benefits. A piece in this regard is annexed and is marked as **Annexure P14**.

10) In fact, even without vaccination, the incidence of Hib disease in India is about a tenth of that in the West. The incidence in Asia is 9 per 100,000 compared to 109 per 100,000 in Western countries. A study funded by the WHO published in the Indian Journal of Medical Research suggests that the incidence of Hib meningitis is as low as 0.007% and it speculates that the low incidence may be due to natural immunity in the population or due to low virulence of the organism. The same person (Dr. Thomas Cherian) who was the author of the study is also the author of the NTAGI report. He has also admitted previously in an article that incidence is too low to use Hib vaccine in EPI. The probe studies (Bangladesh) showed that there was no statistical difference between vaccinated and unvaccinated children when properly matched. The said study is annexed and is marked as **Annexure P15**. WHO is pushing the governments to introduce Hib vaccine into the immunization programme irrespective of an individual country's disease burden, irrespective of natural immunity attained within the country against the disease, and not taking into account the rights of sovereign states to decide the use of their resources. Sadly, Indian government has not been able to put forth an internal mechanism which evaluates the need for such vaccines like Hib in the country.

**Hepatitis B vaccine:**

11) Hepatitis B vaccine is a stark example of what is wrong with the current system. It was first wrongly claimed that 250,000 people die of Hepatitis B disease in India, while real figure is somewhat close to 5000. Though the vaccine was not formally introduced in the UIP, but it was given on a large scale for “pilot studies” or “trials” in selected areas which included the city of Delhi. This was done at a huge cost. Also after the Government’s promotion of the vaccine, it was sold and bought in open market on a large scale. Nothing was evaluated in the “trial” and nobody bothered to check as to how many people benefited from the vaccine. A study done by National Institute of Science, Technology and Development Studies in 2002 showed that Hepatitis B vaccination is not cost-effective in India due to low incidence of the disease and the high cost of the vaccine. This was reported in the media, a copy of which is annexed and marked as **Annexure P16**. Yet, the Health Minister said that experiment was a “success” and it must now be introduced nationwide.

12) A number of studies have been done and research papers have been published which clearly show that Hepatitis B vaccine was totally not required in India and the claims of high incidence of the disease in the country were highly exaggerated. A study on Hepatitis B vaccine experience in India published in Economic & Political weekly is annexed and is marked as **Annexure P17**. Even the Indian Medical Association (IMA) was highly critical of the Government’s proposal to put Hepatitis B in UIP calling it “wasteful expenditure” on low priority health issue. IMA also said that rate of chronic carriage is 1.6% and not 4% as originally claimed vaccinating babies is totally a wasteful expenditure. A news report on the IMA report is annexed and is marked as **Annexure P18**. Apparently, the only people who benefited out of this exercise are the vaccine manufacturers.

**Pentavalent vaccine:**

13) The government is now on the verge of introducing a new five-in-one (Pentavalent) vaccine which would be a combination of DPT (diphtheria,

pertussis, tetanus) with Hepatitis B and Hib. Copy of a news report on this Government's move is annexed and is marked as **Annexure P19**. Pentavalent combines the basic DPT vaccine dose which costs Rs. 5 per child with, as is shown above, two unnecessary and expensive vaccines, Hib and Hepatitis B. This would make the Pentavalent cost about Rs. 525 per child. An inexpensive DPT, which is already in short supply after closure of public sector manufacturing facilities, would soon become unavailable. The reason for this is not far to seek. The market for Hepatitis B vaccine in India was in a bad shape since 2005 owing to tepid demand and falling prices. Many manufacturers were in dilemma whether to remain in the business or not. That is when they managed to convince the Health Ministry to come to their rescue which announced that the Hepatitis B vaccine would be included in the UIP. This is expected to increase the demand for the vaccine by more than 300% in the first year and an annual growth of at least 25-30% in the following years. This has been noted by India's most respected business daily Business Standard in a news report. The said report is annexed and is marked as **Annexure P20**. Thus the health ministry decision which came to the rescue of drug manufacturers gives an indication of the financial stakes involved in making such decisions. A basic vaccine for Diphtheria, which is highly contagious and fatal disease, which is already unavailable to 53% of our children, would soon become expensive and hence unavailable. This is also despite the fact that DPT combined with Hepatitis B and Hib vaccine is less effective than vaccines given separately. This has been shown in a comprehensive assessment of various research papers (meta-analysis) published in prestigious Cochrane Library. The said assessment is annexed and is marked as **Annexure P21**. The tendency to combine EPI vaccine with non-EPI vaccines creates an artificial scarcity of affordable EPI vaccines and creates a backdoor method for entry of expensive and unnecessary non-EPI vaccines into the universal immunization programme, riding piggyback on the EPI vaccines.

14) The health ministry's decision to shut down public sector units manufacturing vaccines for the UIP appears to be driven by similar considerations. The ministry has been accused of closing public sector facilities to help provide a huge market of millions of doses of vaccines for private drug companies which they had no access to as long as the government undertakings were manufacturing low cost vaccines. Thus, by switching to the Pentavalent vaccine the ministry would not only ensure permanent closure of the public sector undertakings (which cannot manufacture Pentavalent) but will also lead the country to being totally dependent on the private manufacturers who can then dictate terms. A paper by Y. Madhavi of National Institute of Science, Technology & Development shows how new combination vaccines are providing a backdoor entry to expensive and unnecessary vaccines into the nation's UIP. The said paper is annexed and is marked as **Annexure P22**.

**Role of WHO and other agencies:**

15) WHO is financed by contributions from member states and from donors. Its funding from member countries is only 20% and the rest of the funds come from various sources chief of them being the pharmaceutical industry. In recent years, the WHO's work has involved more collaboration and there are currently around 80 such partnerships with the pharmaceutical industry and NGOs, as well as with foundations such as the Bill Gates Foundation and the Rockefeller Foundation. WHO's role has been criticized in recent times as it has, under the influence of its corporate partners, tried to push newer and newer drugs and vaccines on the developing countries. It has often been stated that to reduce the price of non-EPI vaccines in developed countries (like US) such vaccines should be introduced in the UIP of the developing countries. Countries with huge populations like India are seen as a market for these expensive vaccines. WHO has also in the past tried to increase the market for drug against Osteoporosis by what has now been popularly been termed as 'disease mongering.' A paper on this, published in prestigious bio-medical journal BMJ, is annexed and is marked

as **Annexure P23**. WHO's perverse recommendations on Pneumococcal, Hepatitis B, Hib and Pentavalent, as highlighted in this Petition, are enough reason for the Government to formulate a stringent mechanism for evaluation of the newer vaccines and not take advice of WHO and other such bodies as gospel.

16) Now, Global Alliance for Vaccines and Immunization (GAVI) has agreed to provide subsidy for introduction of Pentavalent vaccine in India. After GAVI subsidy, its price would drop from Rs. 525/child to Rs. 380/child which is still too high. According to its usual practice, GAVI would withdraw its subsidy after 5 years leaving the Government to foot the entire bill. A recent article published in Lancet has also shown that price of combination vaccines has gone up after funding was provided by GAVI. Thus, the developing countries where Pentavalent vaccine has been introduced will have to continue the programme at a much higher cost. 'Save the Children', a noted international organization, has shown that GAVI has managers of pharmaceutical companies on its board. A news report on this is annexed and is marked as **Annexure P24**. Hence, it is important for us to beware of ulterior designs and do our own cost-benefit analysis before a vaccine is sought to be introduced. Conflict of interest in decision making in matters of public policy is becoming a major public health concern.

#### **Indian system of vaccine evaluation**

17) Since vaccines, unlike medicines, are given to all, they need a clear cost-benefit rationale. It must be noted that 'costs' does not only include the cost of the vaccine but also includes the financial and administrative burden of installing the requisite infrastructure (hospitals, clinics, refrigerators, storage), hiring and maintaining staff (doctors, nurses), expenditure on consumables (vaccine containers, syringes), and administrative costs and other overheads. Cost of procuring vaccines is only a small fraction of the total cost of immunization. Also, these new vaccines have potential side effects. Unfortunately, India has in recent

times accepted the advice of WHO, on the basis of doubtful studies sponsored by vaccine manufacturers. This has happened because we have not yet put in place a strong scientific system of vaccine evaluation where requisite studies including epidemiological probes are carried out before a vaccine is recommended for introduction.

18) A long standing demand of public health experts was fulfilled when Government in August 2001 established NTAGI, an advisory committee, for immunization policies. This move was strongly welcomed in the editorial of the noted journal Indian Pediatrics. The said editorial is annexed and is marked as **Annexure P25**. The Secretary to the Government, Department of Family Welfare, is the chairman of this committee, and the Assistant Commissioner, Immunization Program is its Member Secretary. Although not formal members, representatives of UNICEF, the World Health Organization, and the World Bank have a presence in the committee as special invitees. The sub-committees which have made perverse recommendations for introduction of newer vaccines are heavily loaded with persons from WHO and other agencies.

19) There has been little or no transparency in the system of evaluation of vaccines. NTAGI neither calls for civil society participation in its deliberations nor does it put its analysis for public scrutiny and objections. Crucial decisions have huge ramifications on the public health system are taken behind closed doors raising serious eyebrows whether secret deals are being worked out in our top health policymaking bodies. As is shown above NTAGI's bias is evident as it has ignored evidence available, not done proper epidemiological studies, have not quoted from research papers which argued against the introduction and have not done any cost-benefit analysis. Contrast this with the UK system (NICE model), where any intervention that is sought to be made in immunization is first publically announced. Then the requisite clinical and economic evidence is stringently and critically evaluated and then a draft is drawn for circulation among the stakeholders (public health experts, patients, WHO, industry). After that the

draft is revised based on the said reviews and put up before an independent review panel for final assessment. We in India can follow a similar model keeping in mind our needs as a developing country with a huge population.

20) The Petitioners submit that the Government has acted totally arbitrarily and unreasonably by promoting and seeking to introduce irrational vaccines in the UIP and thereby caused serious harm to public interest. Petitioners have used the proposed introduction of Pneumococcal, Hib, Hepatitis B and Pentavalent as case studies to show how the current system of evaluation of vaccines has failed. Government has acted under the influence of vaccine companies, international agencies like WHO and other vested interests, and not on the basis of scientific rationale or the public health needs of the country. Hence, the said proposals for introduction of these vaccines in nation's UIP are arbitrary, perverse and mala fide, and deserve to be stayed.

21) The recent actions of the Government are contrary to National Health Policy, 2002 which inter-alia states:

#### 4.11 USE OF GENERIC DRUGS AND VACCINES

*4.11.1.2 The National programme for Universal Immunization against Preventable Diseases requires to be assured of an uninterrupted supply of vaccines at an affordable price. To minimize the danger arising from the volatility of the global market, and thereby to ensure long-term national health security, NHP-2002 envisages that not less than 50% of the requirement of vaccines/sera be sourced from public sector institutions.*

22) A rational, scientific and evidence-based draft National Vaccine Policy was made under the auspices of National Institute of Science Technology and Development Studies (NISTADS), CSIR New Delhi in consultation with ICMR. Eminent public health experts participated in the process and drafted a policy

framework which was put up for consideration of the Government. The said draft policy is annexed and is marked as **Annexure 26**. In the recent times, Government has violated every basic principle of this draft policy. Therefore, the Petitioners seek urgent intervention of this Hon'ble court.

23) The Petitioners have not filed any other writ, complaint, suit or claim in any manner regarding the matter of dispute. The Petitioners have no other better remedy available.

24) The Petitioners seek liberty from this Hon'ble Court to produce other documents and records as and when required in the course of the proceedings.

#### **GROUND**

A. Government is on the verge of introducing newer and newer vaccines which are irrational, of low efficacy, expensive and are of no real utility. Government's move to introduce new vaccines without first doing proper epidemiological studies is unreasonable, arbitrary and deserves to be quashed. Government's move to introduce non-EPI vaccines of Hepatitis B, Pneumococcal, Hib and Pentavalent into the national immunization programme is arbitrary and mala fide.

B. The current system of vaccine evaluation is arbitrary and promotes the interests of vaccine manufacturers at the expense of health needs of the country and at huge cost to the exchequer. It is also in conflict with the National Health Policy. Government is duty-bound to create a rule-based rational and scientific system of evaluating vaccines and doing epidemiological studies *before* a vaccine is proposed for introduction in the Universal Immunization Programme. A requisite body of experts without any conflict of interest which should then work in a transparent manner and put up its draft recommendation for scientific and public scrutiny before finalizing them. The said vaccine policy should be based

on the fundamental principles of the draft vaccine policy (annexed as Annexure 26).

**PRAYER**

In view of the facts & circumstances stated above, it is most respectfully prayed that this Hon'ble Court in public interest may be pleased to: -

- a. Quash the introduction of Hepatitis B, Pneumococcal, Hib and Pentavalent vaccines in the Universal Immunization Programme until proper trials, epidemiological studies are carried out and a clear cost-benefit analysis is done in a transparent manner by an expert technical body which does not suffer any conflict of interest.
- b. Issue a writ of mandamus or any other appropriate writ to the Government to formulate a rule-based rational vaccine policy which would prescribe mandatory analysis and epidemiological studies which need to be carried out before a vaccine is sought to be introduced into the public health system and will do so in a transparent manner and allow for public and scientific scrutiny.
- c. Issue a writ of mandamus to the Government to ensure that basic EPI vaccines which are the fundamental right of every child are provided to each and every children without discrimination or any constraint of funds.
- d. Issue or pass any writ, direction or order, which this Hon'ble court may deem fit and proper under the facts and circumstances of the case.

Petitioners  
Through

New Delhi  
Dated: December , 2009

Prashant Bhushan  
(Advocate for the Petitioners)