

ITEM NO.8

COURT NO.3

SECTION PIL

S U P R E M E C O U R T O F I N D I A
R E C O R D O F P R O C E E D I N G S

WRIT PETITION (CIVIL) NO(s). 33 OF 2012

SWASTHYA ADHIKAR MANCH, INDORE & ANR.

Petitioner(s)

VERSUS

MIN.OF HEALTH & FAMILY WELF. & ORS.

Respondent(s)

(With appln(s) for directions and extension of time and office report)

WITH W.P(C) NO. 79 of 2012

(With appln.(s) for directions, impleadment and office report)

Date: 26/7/2013 These Petitions were called on for hearing today.

CORAM :

HON'BLE MR. JUSTICE R.M. LODHA

HON'BLE MR. JUSTICE MADAN B. LOKUR

For Petitioner(s)

Mr. Sanjay Parikh, Adv.

Ms. Mamta Saxena, Adv.

Mr. Bushra Parvesh, Adv.

Mr. A.N. Singh, Adv.

Mr. Pukhrambam Ramesh Kumar, Adv.

WP 79/2012

Mr. Colin Gonsalves, Sr. Adv.

Ms. Reshma, Adv.

Ms. Jyoti Mendiratta, Adv.

For Respondent(s)

Mr. Siddharth Luthra, A.S.G.

Mr. Ashok K. Srivastava, Adv.

Mr. Aditya Singhla, Adv.

Ms. Amita, Adv.

Mr Ravindra Kr. Verma, Adv.

Ms. Supriya Juneja, Adv.

Ms. Anondana, Adv.

Mr. Arjun Dewan, Adv. for

Ms. Sushma Suri, Adv.

NCT of Delhi

Ms. Asha G. Nair, Adv.

Mr. Aditya Sharma, Adv.for

	Mr. D.S.Mahra, Adv.
NHRC	Ms. Shobha, Adv.
ISCR	Mr. U.U. Lalit, Sr. Adv. Ms. Krishma Sarmai, Adv. Ms. Manisha Singh, Adv. Mr. Riku Sarma, Adv. Mr. Navnit Kumar , Adv. Ms. Aruna Gupta, Adv.
Uttrakhanad	Mr Atif Suhrawardy, Adv. for Ms. Rachana Srivastava, Adv.
Jharkhand	Mr. Anil Kr. Jha, Adv. Ms. Priyanka Tyagi, Adv.
Arunachal Pradesh	Mr. Anil Shrivastav, Adv. Mr. Ritu Raj, Adv.
Assam	Mr. Avijit Roy, Adv. for M/s. Corporate Law Group
Madhya Pradesh	Ms. Vibha Datta Makhija, Adv.
Goa	Mr. Pratap Venogopal, Adv. Ms. Meenakshi Chauhan, Adv. Mr. Gaurav Nair, Adv. for M/s. K.J. John & Co.
HP	Mr Ajay P.S. Mandyal, Adv. Mr. H.C. Aggarwal, Adv. Ms. A. Subhashini, Adv. Ms. C.K. Sucharita, Adv.
UT-Chandigarh	Ms. Vimla Sinha, Adv. for Mr. Gopal Singh, Adv. Mr. Sapam Biswajit Meitei, Adv. Mr. Khwairakpam Nobin Singh, Adv. Dr. Monika Gusain, Adv. Mr. Abhinav Jain, Adv.
MCI	Mr. Amit Kumar, Adv. Mr Atul Kumar, Adv. Ms. Rekha Bakshi, Adv. Mr. Ashish Kumar, Adv.

Punjab Mizoram	Mr. Kuldip Singh, Adv. Mr. P.V. Yogeswaran, Adv.
Tripura	Mr. Gopal Singh, Adv. Mr. Ritu Raj Biswas, Adv.
Chhattisgarh	Mr. Atul Jha, Adv. Mr. Sandeep Jha, Adv. for Mr. Dharmendra Kumar Sinha, Adv.
Karnataka	Mr. V.N. Raghupathy, Adv.
Puducherry	Mr. V.G. Pragasam, Adv. Mr. S.J. Aristotle, Adv. Mr. Prabu Ramasubramanian, Adv.
Meghalya	Mr. Ranjan Mukherjee, Adv. Mr. S. Sangal, Adv.
J&K	Mr. Sunil Fernandes, Adv. Ms. Insha Mir, Adv. Ms. Astha Sharma, Adv. Mr. Raghav Chadha, Adv.
Haryana	Mr. Raktim Gogoi, Adv. Ms. Anitha Shenoy, Adv.
Bihar	Mr. Abhinav Mukerji, Adv. Mr. A. Kochhar, Adv.
UP	Mr. Shakeel Ahmad Syed, Adv. Mr. Abhish Kumar, Adv.
Rajasthan	Mr. Manish Singhvi, Adv. Ms. Pragati Neekhra, Adv.
Tamil Nadu	Mr. R. Rakesh Sharma, Adv. Mr. B. Balaji, Adv. Ms. Aruna Gupta, Adv. Mr. M.T. Georg, Adv.
Nagaland	Ms. K. Enatoli Sema, Adv.

	Mr. Amit Kumar Singh, Adv.
Sikkim	Mrs. Aruna Mathur, Adv. Mr. Yusuf Khan, Adv. Ms. Movita, Adv.
WB	Mr. Avijit Bhattacharjee, Adv. Mrs. Sarbani Kar, Adv. Ms. Debjani Das Purkayastha, Adv.
IA 8	Dr. Abhishek Manu Singhvi, Sr. Adv. Mr. Jayant K. Mehta, Adv.
IA 9	Mr. Sushil Kr. Jain, Adv. Mr. Puneet Jain, Adv. Ms. Sandhya Goswami, Adv. Mr. Aniruddha P. Mayee, Adv.

UPON hearing counsel the Court made the following

O R D E R

Pursuant to the order dated October 8, 2012, an affidavit has been filed by the Secretary, Ministry of Health and Family Welfare, Government of India (for short "Secretary, Ministry of Health").

2. Mr. Siddharth Luthra, learned Additional Solicitor General submits that certain measures have been taken to strengthen regulation of clinical trials that include amendment in G.S.R. 53(E) dated 30.01.2013, G.S.R. 63(E) dated 01.02.2013 and G.S.R. No. 72E dated 08.02.2013. G.S.R. 53(E) specifies procedure to analyze the reports of serious adverse events including deaths occurring during clinical trials and procedures for payment of compensation in case of trial related injury or death.

3. G.S.R. 63(E) specifies various conditions for conduct of clinical trials, authority for conducting clinical trial inspections and actions in case of non-compliance.

4. G.S.R. 72(E) provides for requirements and guidelines for registration of Ethics Committee. By amendment, it is proposed that no Ethics Committee can review and approve any clinical trial protocol unless it is registered with the Central Drugs Standard Control Organization and that in case of non-compliance, the registration can be suspended/cancelled.

5. Learned Additional Solicitor General also informs us that Drugs and Cosmetics (Amendment) Bill, 2013 has been approved by the Government. The Bill has a separate chapter containing strict penal provisions relating to payment of compensation, Ethics Committee etc.

6. Certain other measures, which have been taken to strengthen regulation of clinical trials, were also orally stated by the learned Additional Solicitor General.

7. However, Mr. Sanjay Parikh, learned counsel for the Petitioners submits that the measures, which have been taken after 3.1.2013 as noted above, and the proposed measures do not answer many issues particularly, with regard to the clinical trials in respect of new chemical entities and so also the controlling and monitoring measures.

8. Ms. Shobha, learned counsel for the National Human Rights Commission (for short "Commission") submits that the Commission has specific suggestions to offer that may help strengthening regulation of clinical trials.

9. Ms. Vibha Dutta Makhija, learned counsel for the State of Madhya Pradesh submits that no consultation with regard to the measures that are necessary for strengthening regulation of clinical trials has taken place with the State Government. The State Government is directly concerned with the matter.

10. As a matter of fact, the stand of State of Madhya Pradesh, as stated by Ms. Vibha Dutta Makhija, is the stand of almost all the States/Union Territories.

11. Having regard to the above, learned Additional Solicitor General submits that the Secretary, Ministry of Health shall convene the meeting of the Chief Secretaries/Health Secretaries of the State Governments and the Administrators of the Union Territories to discuss all the facets and aspects concerning the legal framework for strengthening the regulation of clinical trials and other incidental matters.

12. We accept the statement of the learned Additional Solicitor General and expect that a meeting for the purposes, as noted above, shall be convened by the Secretary, Ministry of Health expeditiously and positively within four weeks from today. The petitioners, National Human Rights Commission, NGOs/bodies and proposed intervenors may also submit their suggestions to the Secretary, Ministry of Health in respect of regulation and monitoring of clinical trials within two weeks from today.

13. Further affidavit, in compliance of this order, shall be filed by the Secretary, Ministry of Health within six weeks from today. The copy of such affidavit shall be given to the counsel for the petitioners, counsel for the

States Governments/Union Territories, Commission and proposed intervenors.

14. For further consideration, list the matter on September 24, 2013. I.A. Nos. 8 and 9 shall be considered on the next date.

|(Pardeep Kumar)
|Court Master

| |(Renu Diwan)
| |Court Master