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ITEM NO.9 COURT NO.3 SECTION PIL

S U P R E M E C O U R T O F I N D I A
RECORD OF PROCEEDINGS

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

SWASTHYA ADHIKAR MANCH, INDORE & ANR. Petitioner(s)

VERSUS

UNION OF INDIA & 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: 30/09/2013 These Petitions were called on for hearing today.

CORAM :
HON'BLE MR. JUSTICE R.M. LODHA
HON'BLE MR. JUSTICE SHIVA KIRTI SINGH

For Petitioner(s) Mr. Sanjay Parikh, Adv.
Mr. Bushra Parvesh,Adv.
Mr. A.N. Singh, Adv.
Mr. Pukhrambam Ramesh Kumar, Adv.

WP 79/2012 Ms. Reshma, Adv.
Ms. Jyoti Mendiratta, Adv.

For Respondent(s) Mr. Siddharth Luthra, A.S.G.
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Mr. Aditya Singhla, Adv.
Ms. Sushma Suri, Adv.
Ms. Supriya Juneja, Adv.
Mr. Anandana Handa, Adv.
Mr. A.K. Kaul, Adv.

NCT of Delhi Ms. Asha G. Nair, Adv.
Ms. Anita Bafna, Adv.
Mr. Rajiv Nanda, Adv.
Mr. Aditya Sharma, Adv. for
Mr. D.S.Mahra, Adv.

NHRC Ms. Shobha, Adv.
Ms. Jyoti Rana, Adv.

ISCR Mr. Manisha Singh, Adv.
Mr. Navnit Kumar , Adv.
Ms. Aruna Gupta, Adv.
Mr. Aalishan Nazvi, Adv.
Ms. Manisha Singh, Adv.

Uttrakhand Mr. AshutoshKr. Sharma, Adv.
Ms. Rachana Srivastava, Adv.

Jharkhand Mr. Anil Kr. Jha, Adv.

Arunachal Pradesh Mr. Anil Shrivastav, Adv.
Mr. Ritu Raj Biswas, Adv.

Assam Mr. Avijit Roy, Adv. for

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	Mr. A.P. Mayee, Adv. Mr. Charudatta Mahindrakar, Adv.
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	Dr. Monika Gusain, Adv. Mr. Abhinav Jain, Adv.
MCI	Mr. Amit Kumar, Adv. Mr. Ankit R., Adv. Mr. Avijit Mani Tripathi, Adv. Mr. Atul Kumar, Adv.
Punjab	Mr. Kuldip Singh, Adv. Mr. Mohit Mudgil, Adv.
Mizoram	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.C. Ghosh, Adv. Mr. S. Bhowmick, Adv. Mr. R.P. Yadav, Adv.
J&K	Mr. Sunil Fernandes, Adv. Ms. Insha Mir, Adv. Ms. Astha Sharma, Adv. Mr. Raghav Chadha, Adv.
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	Mr. M.T.George, Adv.
Nagaland	Ms. K. Enatoli Sema, Adv. Mr. Amit Kumar Singh, Adv.
Sikkim	Mrs. Aruna Mathur, Adv. Mr. Yusuf Khan, Adv.
West Bengal	Mr. Anip Sachthey, Adv. Mr. Mohit Paul, Adv.
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IA 8	Dr. Abhishek Manu Singhvi, Sr. Adv. Mr. Jayant K. Mehta, Adv. Mr. Sukant Vikram, Adv. Mr. Anuj Kapoor, Adv.
IA 9	Mr. Sushil Kr. Jain, Sr. Adv. Mr. Puneet Jain, Adv. Ms. Pratibha Jain, Adv.
	Ms. Sandhya Goswami,Adv.
	Ms. Aparna Bhatt, Adv.

UPON hearing counsel the Court made the following

O R D E R

On 26.7.2013, Mr. Siddharth Luthra, learned Additional Solicitor General submitted that the Secretary, Ministry of Health would 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.

2. In view of the above submission, the matter was adjourned and the Secretary, Ministry of Health was directed to file further affidavit.

3. In pursuance of the above order, the additional affidavit has been filed by Mr. Arun Kumar Panda, Joint Secretary, Ministry of Health and Family Welfare, Government of India. It is stated in the said affidavit that the Secretary, Ministry of Health and Family Welfare was to file the affidavit but he had to travel overseas due to official work and was to resume work on 20.9.2013 and, therefore, he has filed the additional affidavit.

4. In the additional affidavit, it is stated that on 13.8.2013, the meeting of the Chief Secretaries/Health Secretaries of the State Governments and the Administrators of the Union Territories was convened. In that meeting, diverse issues were deliberated. The States also gave their view points. The views expressed by the States of Madhya Pradesh, Rajasthan, West Bengal, Punjab, Andhra Pradesh, Karnataka and Gujarat have been particularly noted in the additional affidavit. Based on the deliberations, the Secretary, Ministry of Health and Family Welfare summed up and made the following observations:

A). Even though the concerns have been raised about the conduct of clinical trials in the country, clinical trials are necessary or the development of new drugs in the country. India has the capacity and knowhow for drug discovery research. However, there should be a robust system for conducting clinical trials in the country to ensure that trials are conducted in a scientific and ethical manner and in compliance to the regulatory provisions.

B). Restricting clinical trials to Government Hospitals alone would not provide a solution. What is required is a robust system for regulating the conduct of clinical trials in the country.

C). The amount of money paid by the sponsor/companies to the investigator for conduct of clinical trial may act as an inducement to the investigator for conducting clinical trials. Sometimes such inducement may lead to bias in enrollment of subjects in the trials.

D). Regulatory provisions may be made so that information relating to the amount of money paid by the companies to investigators for conduct of clinical trials is in the knowledge of the regulatory authorities.

E). There are some concerns on certain clauses of the amendment of Drugs & Cosmetics Rules made on 30.1.2013 regarding compensation in clinical trials. Some amendments in these clauses may be required.

F). A Committee constituted under the chairmanship of Dr. Ranjit Roy Chaudhury for formulating guidelines on clinical trials and new drugs has submitted its report. The report will be helpful in further strengthening of the regulation of clinical trials in the country.

G). States' suggestions and views would be considered for further strengthening of the regulation of clinical trial.

5. The additional affidavit also states that suggestions have

been received from (i) National Human Rights Commission; (ii) Mr. Sanjay Parikh, advocate for the petitioners; (iii) SAMA Resource Group for Women and Health & Locost Standard Therapeutics and (iv) Indian Society for Clinical Research.

6. It is stated in the additional affidavit that the Government of India had already issued three notifications, (i) G.S.R. 53(E) specifying the procedures for payment of compensation to the subjects of the trial in cases of injury or death; (ii) G.S.R. 63(E) specifying various conditions for conduct and inspection of clinical trials and (iii) G.S.R. 72(E) specifying the detailed guidelines for registration of Ethics Committee.

7. The Expert Committee under the chairmanship of Prof. Ranjit Roy Chaudhury to prepare guidelines for approval of clinical trials and new drugs in the country was appointed which has submitted its report on 8.8.2013. It is stated that the said report is under consideration.

8. It has been brought to the notice of this Court that the Drugs & Cosmetics (Amendment) Bill, 2013 (for short "Bill") has been introduced in the Parliament on 29.8.2013. The Bill has a separate chapter containing penal provisions for violation and non-compliance of the provisions relating to the conduct of the clinical trials.

09. It is further stated in the additional affidavit that 577 clinical trial sites have been inspected and notices have been issued to the investigators/sponsors/ethics committees seeking clarifications in 235 cases.

10. In light of the order passed by this Court on 3.1.2013 that until further orders the clinical trials of new chemical entity shall be conducted strictly in accord with the procedure prescribed in Schedule 'Y' of Drugs & Cosmetics Act, 1940 under the direct supervision of the Secretary, Ministry of Health & Family Welfare, Government of India, it is stated that a system of supervision of clinical trials of new chemical entities by constituting Apex Committee and Technical Committee has been put in place.

11. Giving factual details, it is stated that till 31.8.2013, 12 New Drugs Advisory Committees (NDACs) have met 78 times wherein a total number of 1122 applications for approval of clinical trials, new drugs and fixed dose combinations were evaluated. Out of these 1122 applications, 331 were related to approval of Global Clinical Trial (GCT) including clinical trials of new chemical entities. Of these 331 GCT applications, NDACs after deliberations have recommended for approval of 285 applications. For 46 applications, no recommendation has been made. Out of above 285 applications so far, DCG (I) has given approval to conduct clinical trials in 162 cases.

12. With regard to conduct of clinical trials in respect of 162 cases for which approval has been given by DCG (I), we keep the matter for consideration after two weeks to enable the Additional Solicitor General to place on record the report of Prof. Ranjit Roy Chaudhury and also the details of the existing regime which ensures the safety to the subjects of clinical trials and avoid any serious adverse event by such clinical trials.

13. List the matter on 21.10.2013 for consideration of the limited aspect with regard to the conduct of clinical trials in 162 cases as noted above.

14. With regard to the suggestions received by the Central Government from various stakeholders namely; (i) National Human Rights Commission; (ii) Mr. Sanjay Parikh, advocate for the petitioners; (iii) SAMA Resource Group for Women and Health & Locost Standard Therapeutics and (iv) Indian Society for Clinical Research and the Central Government's views thereon shall be considered by this Court on 16.12.2013 along with pending interlocutory applications.

15. For the time being, also issue notice on I.A. Nos. 10 of 2013 and 11-12 of 2013.

(Pardeep Kumar) Court Master	(Renu Diwan) Court Master