

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 intervention and extension of time and impleadment and office report)

WITH

W.P(C) NO. 79 of 2012

(With appln.(s) for directions, permission and impleadment and permission to file additional documents and office report)

W.P(C) NO. 91 of 2004

Date: 10/03/2014 These Petitions were called on for hearing today.

CORAM :

HON'BLE MR. JUSTICE R.M. LODHA

HON'BLE MR. JUSTICE KURIAN JOSEPH

For Petitioner(s)

WP 33/2012

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WP 79/2012

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WP 91/2004

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For Respondent(s)

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Mr. Shekhar Kumar, Adv.

UPON hearing counsel the Court made the following

O R D E R

From the rejoinder affidavit filed on 06.03.2014 by the petitioners in Writ Petition (Civil) No. 33 of 2012, inter alia, as regards approval of 475 trials including New Clinical Entities (NCEs) from January 2005 to June 2012 the following situation emerges :

506 subjects had serious adverse effects arising from clinical trials that occurred from January 2005 to June 2012.

It transpires that for these subjects neither any compensation has been provided nor paid.

Mr. Siddharth Luthra, learned Additional Solicitor General for the Union of India, prays for time to seek instructions in this regard and to state on affidavit about the quantum of compensation and the time within which such compensation shall be paid to these subjects.

The table at page 28 of the rejoinder affidavit indicates the total number of deaths and so also the total number of subjects who had serious adverse effects in the clinical trials. The table

refers to approval of 475 New Clinical Entities (NCEs) from January 2005 to June 2012. As to whether or not the new regime has been successful in reducing deaths and serious adverse effects in clinical trials needs to be evaluated. We, accordingly, direct the Union of India to give information with regard to deaths and the number of subjects who received serious adverse effects in clinical trials due to approval of NCEs for the period from 1st of July 2012 to 31st of December, 2012 and from 1st of January, 2013 to 31st of December, 2013. The necessary information shall be furnished by Union of India on affidavit within four weeks.

Mr. Sanjay Parekh, learned counsel for the petitioners in Writ Petition (Civil) No. 33 of 2012 has raised the grievance that three parameters, namely, (i) assessment of risk versus benefit to the patients, (ii) innovation vis-a-vis existing therapeutic option and (iii) unmet medical need in the country, indicated by this Court in the order dated 21.10.2013, have not been followed in letter and spirit in granting approval to 157 NCEs.

Mr. Siddharth Luthra, learned Additional Solicitor General, submits that in the affidavit which is to be filed by the Union of India, this aspect too shall be responded.

List the matters on April 21, 2014.

Interlocutory Application No. 13 of 2014  
in  
Writ Petition (Civil) No. 33 of 2012

Issue notice returnable on April 21, 2014.

Union of India may respond to the application in the  
meanwhile.

Interlocutory Application Nos. 11-12 of 2013  
in  
Writ Petition (Civil) No. 33 of 2012

We record and accept the statements of Mr. Siddharth Luthra, learned Additional Solicitor General for the Union of India and learned counsel for the I.C.M.R. that reply to these applications shall be filed within four weeks.

List these interlocutory applications along with the main  
matter.

|(Rajesh Dham)  
|Court Master

|(Renu Diwan)  
|Court Master

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