

SHRI DIGVIJAYA SINGH: Please give.

MR. CHAIRMAN: Take your seat. Hon. Members, a very senior Member of this House, Shri Digvijaya Singh, wants my ruling immediately. As a senior Member of this House, he should be fully aware. It is the discretion and prerogative of the Chair to reserve the ruling and you will have it in detail. I have done it on earlier occasions also. You will get a detailed, reasoned, informed ruling on this issue. And, since it emanates from another Member's observation, we will keep that also in mind.

Hon. Members, I have given consideration to the notices received under Rule 267 and I have gone through them carefully. I find these notices neither conform to the requirements of Rule 267 nor of the directives that have emanated from the Chair and the same are not accepted. ...*(Interruptions)*...

SHRI SANJAY SINGH: Sir, *

MR. CHAIRMAN: Nothing will go on record. ...*(Interruptions)*...

MATTERS RAISED WITH PERMISSION

MR. CHAIRMAN: Now, matters raised with permission of the Chair. Dr. Kanimozhi NVN Somu - 'Concern over rising cases of dubious drug trials having serious repercussions on the healthcare sector in the country'. Please go ahead.

Concern over the rising cases of dubious drug trials having serious repercussions on the health care sector in the country

DR. KANIMOZHI NVN SOMU (Tamil Nadu): Sir, it is my prime duty to bring to the notice of this House, a very serious issue raised by the Ethical Committee of the National Institute of Virology about the rising cases of dubious drug trials in India which have serious repercussions on the whole health sector. It also raise serious questions about the monitoring and quality control of the clinical studies in our country. Recently, the Drug Controller General of India (DGCI) has received an appeal to investigate the critical gaps in clinical trials by a pharma company to

* Not recorded

develop a biosimilar product for treatment of breast cancer. For a company to conduct trials, all trials have to be registered with the Central Trial Registry of India.

(MR. DEPUTY CHAIRMAN *in the Chair.*)

The most important factor in such trial is the genuineness of the original product which is considered the gold standard. Any doubt about the authenticity of the gold standard is bound to give misgivings about the integrity of the whole trial and the effectiveness of the biosimilar copy being tested. Sir, the allegation is that the trials are being conducted just four months before the procurement of the gold standard drug from the original manufacturer. A principal assessor at the National Accreditation Board of Hospitals and the Quality Control of India had called the ethics committee of the medical colleges and the big hospitals as dysfunctional as they are just namesakes and do not scrutinize medical research properly in many instances. This spurious thing is going undetected by the IECs and the IRBs of the 40 premier institutions of the country. It illustrates the porosity of the checks and balances on the ethical conduct of clinical trials. This raises a serious question about the authenticity of the trial data. By no sleight of hand can this anomaly be brushed under the carpet. Human lives are at the stake if this drug sees the light of the dubious trial. Unfortunately, the same pharma company has a substantial large contribution through electoral bonds. The data released by the Election Commission on 14th March has revealed that 35 pharma companies in India have contributed nearly 1000 crores to political parties across the State and Centre through the companies which are being investigated for poor quality drugs which they have purchased through the bonds. As a member of the medical fraternity, Sir, I caution the Union Government to take stringent action against all those involved in these unethical practices in clinical trials and not to play with the life of the innocent people by supporting and facilitating those who conduct dubious unethical drug trials in the country. Sir, through the Chair, I request the hon. Minister of Health. I will also give a personal writing to him on this issue with all the data. Kindly ask him to do the needful. Thank you, Sir.

MR. DEPUTY CHAIRMAN: The following hon. Members associated themselves with the matter raised by the hon. Member, Dr. Kanimozhi NVN Somu: Dr. Fauzia Khan (Maharashtra), Shrimati Mahua Maji (Jharkhand), Shri K.R.N. Rajeshkumar (Tamil Nadu), Shri Sanjeev Arora (Punjab), Shri Niranjan Bishi (Odisha), Shri Jawhar Sircar (West Bengal), Shri Ramji (Uttar Pradesh), Shri Tiruchi Siva (Tamil Nadu), Shri Sujeet Kumar (Odisha), Dr. V. Sivadasan (Kerala), Shri Imran Pratapgarhi

(Maharashtra), Shri Saket Gokhale (West Bengal), Dr. Sasmit Patra (Odisha), Shri P. Wilson (Tamil Nadu), Shrimati Priyanka Chaturvedi (Maharashtra), Shrimati Jebi Mather Hisham (Kerala), Shrimati Sulata Deo (Odisha), Shri Ajit Kumar Bhuyan (Assam), Dr. John Brittas (Kerala), Shri Sandosh Kumar P (Kerala), Shri R. Girirajan (Tamil Nadu), Shri M. Shanmugam (Tamil Nadu), Shri Jose K. Mani (Kerala) and Shri A. A. Rahim (Kerala).

The next speaker is Shri A. A. Rahim - 'Concern over mismanagement of Railways in Kerala causing distress to the railway workers/passengers in the region'.

Concern over mis-management of Railways in Kerala causing distress to the railway workers/passengers in the region

SHRI A. A. RAHIM (Kerala): Sir, no one seems to be able to understand the plight of train passengers in Kerala. Sir, it is beyond our imagination. A couple of weeks ago, six passengers fainted due to an uncontrolled rush in Parasuram Express. A lot of similar incidents have been happening in Kerala every day. Sir, the train journey has become a nightmare for Kerala passengers. We do not have adequate train services. The Union Government is very much interested in the 'renaming process'. They are changing the names of roads. They are changing the names of buildings and everything. The same trend is continuing with the Railways also. The name of passenger trains has been changed as Express special trains. Sir, the aftermath of this Tughlaqian reform, the ticket fare has increased.

The automatic signalling system is not implemented in Kerala. From Thiruvananthapuram to Ernakulum, the maximum speed of a train can only be 100 kilometre per hour. From Ernakulum to Shornur, the maximum speed is only 90 kilometre per hour. Sir, Kerala is a leading State in the country in terms of Railway passenger numbers and revenue. However, the Railway is not ready to improve infrastructure in Kerala and also, not even allowing the Kerala Government to do so. The Union Government is putting red tape on the dream project of Kerala K-Rail for mere vested political interests.

I would like to urge the Government that do not scrap the K-rail project, do not scrap the future development of Kerala. Sir, moreover Indian Railway is yet to come out of its colonial hangover. Their attitude is extremely inhumane. In the last week, in Thiruvananthapuram, a heart-breaking incident happened. Joy, a Railway contract worker from a poor family died when he was cleaning a canal for Railways. Not even a senior official of the Railways came to the spot to properly inspect the situation or