श्री अवतार सिंह करीमपुरी (उत्तर प्रदेश) : सर, दलितों पर हमला हुआ है। ...(**व्यवधान**)...

श्री प्रकाश जावडेकर (महाराष्ट्र) : कांग्रेस के राज में दलितों को जिंदा जलाया जा रहा है। ...(**व्यवधान**)...

MR. DEPUTY CHAIRMAN: You give a notice. ...*(Interruptions)*... Calling Attention. ...*(Interruptions)*... Shrimati Brinda Karat to call the attention of the House regarding the vaccine programme ...*(Interruptions)*... For your information, there are other speakers also. ...*(Interruptions)*...

श्री बलबीर पुंज : सर, लोगों को जिंदा जला दिया गया है। ...(**व्यवधान**)...

SHRIMATI BRINDA KARAT (West Bengal): Sir, please can't hear. ...*(Interruptions)*... Please, Sir. ...*(Interruptions)*...

श्री बलबीर पुंज : सर, हरियाणा के अंदर ...(**व्यवधान**)...

CALLING ATTENTION TO THE MATTER OF URGENT PUBLIC IMPORTANCE

HPV Vaccine Programme by path in certain States of India and Government's Policy on Introduction of such vaccines

SHRIMATI BRINDA KARAT (West Bengal): Sir, I beg to call the attention of the Minister of Health and Family Welfare to the HPV vaccine programme by PATH in certain States of India and Government's policy on introduction of such vaccines. ...*(Interruptions)*...

श्री उपसभापति : आज जीरो ऑवर नहीं है, इसलिए नहीं लिया जाएगा। ...(**व्यवधान**)... मैं बता रहा हूं। ...(**व्यवधान**)... आज जीरो ऑवर नहीं है। ...(**व्यवधान**)... पुंज जी, आप सीनियर मैम्बर हैं, ऐसा मत करिए। ...(**व्यवधान**)... आपने नोटिस दिया? ...(**व्यवधान**)... आज जीरो ऑवर नहीं है। ...(**व्यवधान**)... कल लिया जाएगा ...(**व्यवधान**)... कल लिया जाएगा। ...(**व्यवधान**)...

श्री रवि शंकर प्रसाद (बिहार) : सर, दलितों की हत्या हुई है। ...(**व्यवधान**)...

MR. DEPUTY CHAIRMAN: You may bring it up tomorrow. Nothing will happen. ...*(Interruptions)*... Bring it up tomorrow. ...*(Interruptions)*... I am telling you; bring it up tomorrow. ...*(Interruptions)*... देखिए ...(**व्यवधान**)... कल लीजिए। ...(**व्यवधान**)... Please take it up tomorrow. ...*(Interruptions)*... प्लीज, आप बैठिए ...(**व्यवधान**)... देखिए, आज जीरो ऑवर नहीं है, कल लेंगे ...(**व्यवधान**)...

श्री बलबीर पुंज (उड़ीसा) : जांच-पड़ताल की जाएगी ...(**व्यवधान**)... तब तक इसका आश्वासन तो आना चाहिए ...(**व्यवधान**)...

श्री उपसभापति: क्या आश्वासन देंगे? ...(**व्यवधान**)... देखिए, आप जो कह रहे हैं, वह रूल्स के खिलाफ है, आज जीरो ऑवर नहीं है ...(**व्यवधान**)... जिस दिन जीरो ऑवर होगा ...(**व्यवधान**)... कल है ...(**व्यवधान**)... I am on my legs. ...*(Interruptions)*... प्लीज सुनिए ...(**व्यवधान**)...

श्री रवि शंकर प्रसाद : सर, ...(**व्यवधान**)...

श्री उपसभापति : सुनिए ...(**व्यवधान**)... प्लीज सुनिए ...(**व्यवधान**)...

श्री बलबीर पुंज : आश्वासन मिलना चाहिए ...(**व्यवधान**)...

SHRI NARESH GUJRAL (Punjab) **:** Sir, please give us an assurance that it will be taken up tomorrow**. ...***(Interruptions)***...**

श्री उपसभापति : जरा सुनिए, पुंज जी ...(**व्यवधान**)... I am on my legs**. ...***(Interruptions)***...** Please listen to me**. ...***(Interruptions)***...** देखिए, जब भी कॉलिंग अटेंशन होगा, उस दिन जीरो ऑवर नहीं होगा। आज कॉलिंग अटेंशन है, कल जीरो ऑवर होगा, यह मैटर कल लिया जाएगा ...(**व्यवधान**)...

श्री बलबीर पुंज: सर ...(**व्यवधान**)...

श्री उपसभापति : यह क्या है? ...(**व्यवधान**)... अगर सभी आदमी बोलना शुरु कर देंगे तो कैसे होगा ...(**व्यवधान**)... आप बैठिए ...(**व्यवधान**)... प्लीज़, आप बैठिए ...(**व्यवधान**)... ढींढसा जी बोल रहे हैं ...(**व्यवधान**)... आप बैठिए ...(**व्यवधान**)... इनको बोलने दीजिए, मैं किसी एक को सुन सकता हूं ...(**व्यवधान**)... सबको नहीं सुन सकता हूं ...(**व्यवधान**)...

श्री बलबीर पुंज : चौबीस घंटे में उनको सुरक्षा प्रदान की जाएगी ...(**व्यवधान**)... आप सरकार से इतना कहलवा दीजिए ...(**व्यवधान**)...

श्री अवतार सिंह करीमपुरी (उत्तर प्रदेश) : जो मार दिए गए हैं ...(**व्यवधान**)... उनके बारे में बोलना चाहिए ...(**व्यवधान**)...

सरदार सुखदेव सिंह ढींढसा (पंजाब) : उपसभापति जी, टाइम्स ऑफ इंडिया में यह आया है कि मि. सज्जन कुमार के खिलाफ दो केस थे ...(**व्यवधान**)...

श्री उपसभापति : देखिए, क्या आपने नोटिस दिया है?

सरदार सुखदेव सिंह ढींढसा : मैंने नोटिस दिया था ...(**व्यवधान**)...

SHRI RAVI SHANKAR PRASAD **:** Sir, the Delhi Police is in collusion to save Sajjan Kumar**. ...***(Interruptions)***...**

श्री उपसभापति : कल लिया जाएगा ...(**व्यवधान**)...

श्री रविशंकर प्रसाद : सर, यह विषय बहुत गंभीर है ...(**व्यवधान**)... कालिंग अटेंशन ...(**व्यवधान**)... हमने नोटिस दिया था ...(**व्यवधान**)...

श्री अवतार सिंह करमीपुरी : मान्यवर, आप बात सुनिए ...(**व्यवधान**)...

श्री उपसभापति : मैं कह रहा हूं कल लिया जाएगा ...(**व्यवधान**)... बात कैसे सुन सकते हैं ...(**व्यवधान**)... आप नोटिस ...(**व्यवधान**)...

श्री प्रकाश जावडेकर (महाराष्ट्र) : हमने नोटिस दिया है ...(**व्यवधान**)... आप दलितों के मामले में ...(**व्यवधान**)... एक मिनट ...(**व्यवधान**)... जिस तरह से यह हुआ है...(व्यवधान)...

श्री उपसभापति : देखिए, आज जीरो ऑवर नहीं है, कल लिया जाएगा, मैं एश्योरेंस दे रहा हूं ...(**व्यवधान**)... आप बैठिए ...(**व्यवधान**)...

श्री बलबीर पुंज : हमारा यह निवेदन है कि यह आश्वासन दिलवा दीजिए कि उन्हें सुरक्षा प्रदान की जाएगी ...(**व्यवधान**)...

श्री उपसभापति : कल लेंगे ...(**व्यवधान**)...

एक माननीय सदस्य : कल लिया जाएगा ...(**व्यवधान**)... उसमें हमें क्या करना है ...(**व्यवधान**)...Yes, hon. Minister. ...*(Interruptions)*...

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD): Mr. Deputy Chairman, Sir, two imported brands of HPV vaccine that is GARDASIL, imported by Merck, and CERVARIX, manufactured by GSK; which have been approved in more than 100 countries each respectively were allowed to undergo clinical trial, Phase III in India, and were thereafter, granted permission to import and market authorisation by the Drug Controller General of India, in accordance with the provisions of the Drugs & Cosmetic Act 1940. These vaccines are available in the Indian market since 2008.

PATH, Programme for Appropriate Technology in Health, an international NGO, was granted permission to carry out a post-licensure, operational research, study of HPV vaccination in three blocks each of Khammam District of Andhra Pradesh and Vadodara District of Gujarat, with the State Governments of Gujarat and Andhra Pradesh. The objectives of the study are to demonstrate the suitability of vaccine delivery strategies for HPV in the 10-14 year adolescent girls, to raise community awareness on HPV, cancer of cervix and its prevention; gaining experience in HPV vaccination and to build evidence based vaccine delivery strategy for future introduction of HPV in the Universal Immunisation Programme.

The Indian Council for Medical Research has signed an MoU to provide technical support for the development of protocols and criteria for site and partner selection and advise on ethical issues as per the Government of India guidelines. ICMR would also be reviewing the results and advising on plans for dissemination of results.

Four deaths have been reported in a population of 14,091 vaccinated girls in Andhra Pradesh. The District Medical and Health Officer in his letter dated 17th March, 2010 to Commissioner of Family Welfare, Hyderabad has given the cause of death as suicide (2), drowning (1) and viral fever (1). In the case of Gujarat also there were two deaths reported in a population of 10,686 vaccinated girls. The cause of these deaths were reported as suspected snakebite and severe anaemia with malaria.

Although, prima facie, there does not appear to be a connection between the deaths and the vaccination, but, for our satisfaction and to allay the apprehensions of the hon. Member, the States have been advised not to carry out any further vaccinations till further orders.

Moreover, to also investigate the allegations of ethical violations, the Ministry has already ordered an independent enquiry and constituted a committee consisting of eminent persons, that is, Dr. Ranjit Roy Chaudhury, former Emiratus Scientist, National Institute of Immunology, New Delhi, Dr. S.P. Aggarwal, Secretary General, Indian Red Cross Society and former DGHS, and Dr. Sunita Mittal, HOD Obstetrics and Gynaecology, All India Institute of Medical Sciences. The committee has been asked to submit its report within two months.

SHRIMATI BRINDA KARAT: Sir, thank you. The reason I thought it was important to have a calling attention on this issue is because the target group of the vaccine is chosen - children between the ages of 10-14.

Since the target group for the vaccine is children, I felt that it was very important that we raise the question in this House as to whether we are going to allow Indian children to be made guinea pigs for the interests of multi-national companies who want to sell their vaccine. This particular case is on a vaccine, but the questions which arise pertain to the entire system of clinical trials in this country.

I believe that a system, which predates on the most vulnerable and socially disadvantaged sections as a system has to be changed. Therefore, the questions I raise today are not against this or that company or against this or that NGO. I want to make it absolutely clear. Just because a vaccine is produced by a particular company, there is no reason to oppose that vaccine.

The question is, are these companies manufacturing and selling that vaccine in India being given any special benefit? Have the stringent guidelines in India been violated at any stage? Which are the institutions who are accountable?

What is the accountability of the Central Health Ministry itself? In his reply, the Minister has clearly stated that clinical trials were permitted on this vaccine. I believe that there are questions about the veracity of this statement. Sir, at the outset, I want to make it very clear that I have absolutely full confidence in the Minister; absolutely whatever he says is what he believes to be true. But unfortunately, there are such high stakes in clinical trials in this country and we have seen how the system can be manipulated, so, I request the Minister to look into the following points. One, in a

letter to me dated 8th April, 2010, the Minister categorically said these vaccines were approved by the DCGI in India by following standard procedure and after carrying bridging studies as they were already approved in their country of origin. In other words, from the Minister's letter it is clear that there are no clinical trials because I asked specifically a question whether there were clinical trials. The Minister in his letter says that there are bridging studies. In his statement today he says that there were clinical trials. I would like to know what is correct, whethe the letter to me or the statement that is before the House. There is no such thing like bridging studies in any of our protocols for clinical trials or in other any type of study. There is nothing like a bridging study. This is a new terminology which is brought into our system. Sir, I have looked up all the clinical registry guidelines and I have looked up where the protocols and where the clinical trials are registered. At least, I could not find any Phase-III trial completed with published data. Yes, I could find it in the US Government website where the company says that they have done this or that trial in India.But I could not find it on the ICMR website in India. So, the first question is, what is the published data because according to the ICMR guidelines, before you do trial on children, you have to do trial on adult population. What were the trials done? How many women were given this who were screened for HPV that they do not have that virus? Following that how many children were subject to clinical trial? Where were these trials conducted? Where has such published material been given? If anything which is there on the ICMR website it is this that two clinical trials, Phase-III, are going on and not completed. When market approval is given, why are phase-3 trials being conducted now? That is the first question. My contention is and I am going to say it with full responsibility, the Drugs Controller of India has violated the guidelines, he has not shown any due diligence in looking at the vaccine, in looking at its efficacy and looking at the guidelines. This is the first point I want to make. Please inform the House about that. The second point I want to raise, Sir, which is not at all mentioned in the statement of the Minster, is what were the grounds, what is the efficacy of the vaccine. Sir, you will be surprised to note that the company itself has said that till now we can say that this vaccine is only effective for three to five years. The Minister has not explained to the Members that this virus, HPV, is sexually transmitted from male to female and, therefore, you have to screen a women. The HPV virus does not always lead to cancer, but, yes, it is a fact that it is a major cause for cancer. Therefore, prevention of HPV is not something that we can dispute or we can say that it is not required but this particular vaccine's efficacy is proved only for three to five years. What the company is saying that give all the children this vaccine to prevent cancer. First of all, that is a lie and it seems the Drugs

Controller General of India, for whatever reason, has bought a lie. The second question here is, if, for example, we vaccinate a child of ten with a vaccine which is effective only for five years, how many booster doses are you going to give her? Cancer usually sets in after the age of 40, 50 or 60. What is the research on the booster doses? There is no global research on it whether the booster doses are required, what effect the booster does will have. For the information of the House, Sir, I would like to submit that one of the major researches on this by Merck, an American company, a very well know researcher called Dr. Dianne Harper, this is what she has to say in an interview that if we vaccinate an eleven year old and the protection does not last, we put them at harm with side effects, small but real for no benefit.

"The benefit of public health is nothing. There is no reduction in cervical cancers. They are just postponed unless the protection lasts for at least 15 years and 70 per cent of women before sexual activity are vaccinated." Obviously, this is not going to be possible in our country. Therefore, Sir, the question, why the DGCI was in such a hurry to given permission to this vaccine, is something which, I think, requires to be answered because this vaccine is not proved to be effective beyond three to five years. Now, the third point that I want to raise, again, is not mentioned in the Minister's Statement, and, therefore, unfortunately, with due respect to the Minister - this statement Sir, conceals more than what it reveals. Who is PATH? PATH is an American NGO which has partnered this very company which is selling this vaccine and you are allowing PATH to lead this project. At present, PATH is being funded by Melinda and Bill Gates Foundation. I want to state it on record; I do not question the intentions or integrity of this or that leader individual in PATH. However, the question I have raised is: what is the ICMR doing? How does the ICMR allow a foreign NGO to vaccinate 32000 Indian children? Who is accountable for that? Four children have died in Andhra Pradesh. Naturally, they are going to say, 'no, the deaths are not related to vaccine'. Is there any example in the whole world where any multi-national company is going to take responsibility for a death? I don't think, there are many examples. It is certainly not in my knowledge. Therefore, the question is outside the public health system, how did the ICMR get involved in giving permission and designing protocols for a foreign NGO to vaccinate our children? What does the ICMR guideline say? It is very clear, you cannot use socially disadvantaged sections for any type of study. Now, I ask the

Government, what is this study. Is it a clinical trial? Is it a post-marketing surveillance study which is allowed in our country under certain conditions? What is it? What is the Minister's reply given to me? "This is an operational research study". Sir, there is no operational research study in our laws. The company says, it is a demonstration. Demonstration for what? For whom? Another company release from Andhra Pradesh says, this is extremely important for the health of the children. Who decides that? Who are the children? I went to Andhra Pradesh. In this, I am very clear. I do not hold the State Governments of Andhra Pradesh and Gujarat, primarily, responsible for this. I spoke to the officials. They said, they simply went by what the Central Government had said, the permissions they had given, the protocols they had designed. And what did I see there, Sir? I went to Bhadrachalam. I went to Scheduled Tribes girl students' hostel. I went to five different villages. I went to bastis in the slums. And look at the way the Government answers me. I found every single child who was vaccinated was a poor child. Sir, I saw children who say they are eleven years old. They don't look more than seven or eight because they are victims of mal-nourishment. There are a plethora of health ailments, which unaddressed and yet, this Central Government is not able to give vaccines of Diphtheria to our children and allows the foreign NGOs to go and vaccinate when the effectivity of the vaccine itself is under a cloud. This is the situation. What does the ethical guideline say? "You cannot vaccinate socially disadvantaged sections." But they have done it, and to conceal that, they say, 'No, we have done it on all sections, rural and urban'. Which urban children? I went there and saw. Apart from the Scheduled Tribe children in the Scheduled Tribe hostel, in other words, using an educational institution, the vulnerability. You go to a hostel. Can anybody's child say,'no'? But, in the basti that I went to there were Muslims, there were Scheduled Castes and there were very poor slum children. It was an urban slum in which all sections, mainly, Muslims and SC children all from socially disadvantaged sections had been vaccinated. So, this was violation of guidelines.

The other guideline which was violated was that of informed consent. The House will be shocked to hear, in the ST girls hostel that I went to, one warden gave the consent for all the 278 children who were vaccinated without even referring it to their parents! Is this possible in any society? Can anybody go to one of the public schools in Delhi and dare to vaccinate children without taking the permission from their parents? Does the life of our poor children have no value? There is no price on it. There is no dignity for them that parent is not even consulted. And, Sir, I tell you with

full responsibility again that I saw three types of examples. The first one is, the warden gave the consent. The second one is, the children were given forms and told, 'go home and get the signature of your parents, because this is going to be good for you.' The third one is, the illiterate and poor parents who rush to the fields to pluck chilies or do agriculture work were told suddenly that this is the form and this is what the Government is doing. And the most horrible thing they - the project people there - did is that they used the Logo of the National Rural Health Mission! It is totally illegal. The NRHM has no mandate for any type of trial, for any type of study on any vaccine. But, they have used the Logo of the NRHM.

Therefore, Sir, on all these aspects, there is a gross violation of guidelines and laws concerning clinical trials in our country. The Government has set up a Committee after my letters and that of many other organizations and public health activists. However, I regret to say, since this Committee has to enquire into people holding high office, including the Drug Controller General of India, ICMR officials at that time who had given these permissions, the present composition of the Committee, with due respect to the integrity of Members, cannot do it. The AIIMS itself is doing clinical trials for this very vaccine the Head of the Department of which has now being asked to enquire into. It is not possible. However good she may be, it is not possible. You have a retired Government official. Whatever is his integrity, he is not going to be in a position to do it. Therefore, Sir, I would request you to change the composition of the Committee, bring senior people who know about violation of ethical guidelines and who studied it. Bring senior public health experts onto this Committee and have a proper enquiry and till then, Sir, 1 would say...

MR. DEPUTY CHAIRMAN: Please conclude.

SHRIMATI BRINDA KARAT: ...the marketing permission given to these vaccines is wrong and is beset with so many issues. Therefore, reconsider the permission that you have given, go through all the proper procedures, because it concerns children. Concern about loss of profit can wait and see that, at least, our children's security is protected.

Lastly, as far as PATH is concerned, please make sure that no such vaccination programmes are given to PATH or any NGO since a large number of children in our country are involved, because

there is a deep conflict of interest which goes against India's interest. Thank you.

SHRIMATI VASANTHI STANLEY (Tamil Nadu): I thank you very much, Mr. Deputy Chairman, for giving me this opportunity. I would also thank Madam Brinda Karat for brining this Calling Attention. The Government, according to the statement made by the hon. Minister, has given permission for vaccination to children between 10-14 years of age to prevent cervical cancer. This means that this has to be given before sexual activity. The same issue had been raised by the hon. Member, Shrimati Brinda Karat, in the Standing Committee also. She had raised the same questions over there also. A unanimous decision had been taken by the Committee that this vaccination programme should immediately be stopped. And, it had, consequently, been stopped too. A decision had also been taken by the Chairman of the Standing Committee, Shri Amar Singh, that after stopping this vaccination programme inquiries should be initiated against the people who were involved in getting this MoU signed, whether it is the Secretary or the Drug Controller of India or anybody else. And, when this decision was taken we were all told that this should be kept as a secret and we should not disclose it anywhere. The vaccination programme was immediately stopped so that this programme does not enter into other States. Whatever programme is taken up by the Government, it is taken up for a good cause. I appreciate the hon. Member's intention for bringing into notice the wrong things which have been done through this vaccination programme. But when it had already been brought to the notice of the Standing Committee and a decision had already been taken by the Chairman of the Committee and when the officials had also consented to immediately stop the vaccination programme, what was the necessity for bringing forward this 'Calling Attention'? That is my question.

SHRIMATI JAYANTHI NATARAJAN (Tamil Nadu): Sir, this is a very, very important issue, which has been raised before the House. Actually it concerns every single one of us. Every single citizen of India is concerned with this issue. At the outset, I would like to say that every single one of us, most certainly the Government of India, the Minister, the Parliament, all of us over here, are absolutely determined and committed that in our democracy, in our developing country, our citizens, especially our socially and economically disadvantaged citizens, our children should not be exploited, should not become guinea pigs; should not, in any event, be used by anybody for their own profit or

for any other end. We are not a banana republic that the Government of India is going to allow some one multinational or two or ten or hundred multinationals to come over here and exploit Indian children. No Indian Government, not just the UPA Government, of any party would ever allow Indian citizens to be used as guinea pigs. I think, that is the first confidence that we should have in our Government. Certainly, Sir, if mistakes have been committed, if distortions have occurred, if illegalities have occurred, if protocols have been violated, if certain steps have been taken that put our children at risk, then, people should be called to account. I would, first of all, like to appreciate the hon. Minister for immediately stopping the programme and instituting an inquiry into it. I also appreciate the Government for having the courage to immediately accept that this is a transparent process and they will inquire into it and will find out what went wrong and, then, will take whatever steps are necessary to set the matter right. Sir, you gave twenty-five minutes to the hon. Member, Shrimati Brinda Karat, because she gave Calling Attention Notice. But please do not ring the bell now.

MR. DEPUTY CHAIRMAN: I have not yet ringed the bell.

SHRIMATI JAYANTHI NATARAJAN: Please give me, at least, five minutes to make my point. I was seeing that you were about to ring the bell.

MR. DEPUTY CHAIRMAN: No; no. You have two more minutes.

SHRIMATI JAYANTHI NATARAJAN: Sir, the hon. Member, Shrimati Vasanthi Stanley, took only two minutes. I am taking her time also.

Sir, I am going to give a little perspective of the cervical cancer because this is a very important issue. I ask the Government to look at the perspective of the cervical cancer. I have some details. The cervical cancer case is a classic case of inequality in our public health, that is, in the health of women in this country. It is the second most common cancer amongst women. Half-a-million new cases are detected world-wide each year. One-fourth of these are in the developing world. India, our country, our women, bear one-fourth of the world burden. 1,20,000 women, in our country, are diagnosed with cervical cancer every year. About 78,000 fatalities occur every year due to cervical cancer. India is home to more cervical cancer cases than any other country in the world. And,

cervical cancer is the number one cause of cancer-related death among women. In India, the most prevalent is cervical cancer followed by breast, ovary and other forms of cancer. Sir, it is a peculiar logistical threat. You need screening - the hon. Member spoke about screening - which is, virtually, non existent in our public health system or in any other system. There is no-screening. The possibility of sophisticated lab equipment, human expertise for the pap-smear, the human expertise required, the knowledge required, the equipment required and a very rigid and vigorous follow-up regime which is required after the pap-smear to screen women for cervical cancer is simply not there. Therefore, I feel that this is a very neglected area which needs the concern of the Government. The Government, perhaps, in that concern, should find the ways by which cervical cancer can be stopped. Sir, there are two parts of vaccines. Vaccines are a tremendous boon to mankind. There are vaccines like Hepatitis B vaccine which came to developing countries like India fully 20 years after they were first given in other countries, for various reasons, because they were very expensive, because we could not import them, etc. Sir, we should not now be in a situation where we are not able to get latest medical technology for our poor people just because we are not able to afford these technologies, for various other reasons and for reasons because we do not understand how these technologies play out in our country. So, Sir, this is the background. Sir, as for the screening factor, we are a very young country. Of course, the fact remains. Sir, there are more than 100 types of HPV virus. A vaccine is, apparently, available for only HPV 16 and HPV 18. All the others are not yet protected. Out of these, if two out of five women in the 20 -24 age group are married by 18, if there are 27 million babies per year and 15 per cent of mothers are between 15 and 19 years of age, the greatest risk of having cervical cancer is in that age group. The entire family can be destroyed by the death of that mother or if she is affected by cervical cancer. Sir, Brinday*ji* raised a very important question. Is this a clinical trial? If it is a clinical trial, what are the guidelines? These are basics. Nobody can, possibly, disagree with her. If it is a clinical trial, the most fundamental requisite of a clinical trial is people should not be exploited. If they come from the most poverty-stricken background, or if they are given some consideration for which their bodies are used, it will become akin to selling their kidneys or parts of their bodies. That should not be allowed by the Government. People cannot be exploited by the Government. Therefore, the most fundamental rule of a clinical trial is that our people should not be exploited or used as guinea pigs. If that has been violated, the

Government should take absolutely stringent action against that. But, here, in this case, this vaccine is available over the counter. It is available for the people who are wealthy. It is being licensed by the Government. If I had a daughter, I would have gone to the pharmacy, bought the vaccine and got my daughter vaccinated. So, in a very peculiar inverted way, this is a technology for prevention of cervical cancer. I agree it is not confirmed as to how long it will be efficacious. Whether it will not be efficacious after five years? ...(Time-bell rings)... Just one minute more, Sir.

MR. DEPUTY CHAIRMAN: You have taken the time you had asked for.

SHRIMATI JAYANTHI NATARAJAN: But these are all issues that follow up on every new technology, Sir. We cannot throw the baby out alongwith the bath water. So, the strict paradox, Sir, here is, wealthy people, those who can afford it, can go to Pharmacy and buy this vaccine in Delhi. If you talk about Delhi, I can go and buy the vaccine today. Private doctors are injecting the vaccine to the children who belong to wealthy families. This is what I believe. I would like to ask the Minister, if it was so, a well-intentioned effort by the Government to try and introduce in our public health system, something which was not available for those who cannot afford it, is required to see that the, delivery of this vaccine is possible at that level. ...*(Interruptions)*... ...(Time-bell rings)...

Sir, please allow me to complete. ...*(Interruptions)*... Sir, it would be wrong, if ICMR, the State Governments. ...*(Interruptions)*... I don't care and I don't hold a brief for any private NGO or any other organization or any vaccine manufacturing company. I, only care about the children of this country. I want to put my faith in the Government. All these statements were made by ICMR, Central Government and the State Governments. The fact is that it was the Government of Andhra Pradesh and Government of Gujarat which administered these vaccines. All these statements said that those deaths occurred for various other reasons and not because of the vaccine. Were they wrong or were they right? Let the Minister clarify. And I would like to appeal to the House, Sir, to see this thing in perspective to appreciate Government's intention. Sir, this is now available in the public health system of 10 countries, including the U.K. and the U.S.A. Should it be available in our public health system or not? ...(Time-bell rings)... It is available in 105 countries...

MR. DEPUTY CHAIRMAN: Shri Shantaram Laxman Naik.

SHRIMATI JAYANTHI NATARAJAN: One minute, Sir.

MR. DEPUTY CHAIRMAN: This is not clarification. ...*(Interruptions)*... This is not clarification. ...*(Interruptions)*...

SHRIMATI JAYANTHI NATARAJAN: In 103 countries, there is another vaccine. Sir, the Committee has been constituted. So, we should wait. I would not like to question the credibility of a Committee. It is Brindaji's privilege. She has questioned it. ...(Time-bell rings)... I would say, wait for the Committee's report.

MR. DEPUTY CHAIRMAN: Why are you repeating it?

SHRIMATI JAYANTHI NATARAJAN: Sir, I am saying, wait for the Committee's report to come out. Please don't throw the baby out along with the bath water.

SHRI SHANTARAM LAXMAN NAIK (Goa): Sir, in the olden times, the vaccines were opposed in rural areas and doctors and nurses were driven away. Even those who went for normal vaccines for fever, etc., were treated like that. Doctors and nurses were driven away for years together. Are we going to return to that age, old-age or stone-age? It is a question that we have to consider. People prefer to go to quacks, jadoowalas, tonawalas, but they will never entertain a person who treats with vaccines. I am speaking of broader things because Jayanthiji has covered most of the details and specifics.

With due respect to Brindaji, I would like to mention one thing. The reason why I am specifically mentioning it is because this is the view of many people. If there is anything which comes from the United States, certain Members, including the hon. Member, always object to that.

MR. DEPUTY CHAIRMAN: Are you seeking clarification or are you replying to Brindaji? ...*(Interruptions)*... Please seek clarifications.

SHRI SHANTARAM LAXMAN NAIK: If this programme had been coming from China, if PATH had been an NGO from China, would the hon. Member have ever objected to it? This is the question. The hon. Member has to show ...

MR. DEPUTY CHAIRMAN: Mr. Naik, I am suggesting, please seek the clarifications from the statement.

SHRI SHANTARAM LAXMAN NAIK: Sir, I am seeking the clarification in the same manner as the Brindaji or Jayanthiji or for that matter any other Member has sought.

MR. DEPUTY CHAIRMAN: That means everybody should follow his own rules and not the rules which we have mentioned here. ...*(Interruptions)*... If somebody has not followed it, don't say that 'I am also going to do the same thing.'

SHRI SHANTARAM LAXMAN NAIK: Sir, who seeks clarifications that way? The main speech is submissions. If it is only related to clarification, then it can be done in only one minute. Finish. Whoever sought clarifications made a speech. She had made a speech. Jayanthiji had made a speech. She has also made a speech.

MR. DEPUTY CHAIRMAN: Then it will be free for all. It means, there are no rules. ...*(Interruptions)*...

SHRI SHANTARAM LAXMAN NAIK: I should not be discouraged.

MR. DEPUTY CHAIRMAN: It is not correct. It is my duty to remind it to every Member. I have been reminding them also and reminding you also that the rules are very clear that once a statement is made by the Minister, one should seek only clarifications and not reply to other Members.

SHRI SHANTARAM LAXMAN NAIK: Okay; Sir. Operational research is a widely known term. So, why should anybody object to any operational research done in respect of vaccine? This is the question. The hon. Member is questioning the technical term, 'operational research'. The 'operational research' term is a widely understood term and therefore there should be no objection to that.

Tomorrow, if a drug is found for the treatment of Cancer, what will be our attitude? Are we going to have the same approach, that this should not be experimented in India, that it will come from some other country for which we may have some sort of an allergy? Tomorrow, it may happen that a cure for Cancer is found and if at that time we have the same approach, we would be lagging behind.

Secondly, I would like to know from the hon. Minister whether there is any policy to decide what type of objections in case of such programmes should be entertained. There should be a policy because nobody has pointed out if any particular guideline or those issued under the Drug Control Act have been violated. So, either it should be shown that a particular guideline has been violated or there should be a policy under which these curbs could be imposed.

Then, Sir, whenever objections are made, bonafides of such objections must be determined. I think the hon. Minister has taken the right decision in the circumstances, but the bonafides of such objections must always be considered. Political motives must also be considered. The society is sought to be divided by referring to tribals.

These are the issues that need to be considered while considering whether a research programme should be brought to a halt. Will the Minister consider these aspects in future?

श्री आर.सी. सिंह (पश्चिमी बंगाल) : महोदय, मैं आपका धन्यवाद करता हूं कि आपने मुझे कुछ सवाल करने का समय दिया है। यह बात सच है कि World Health Organization के अनुसार हर साल हमारे देश में 1 लाख 30 हजार महिलाएं cervical cancer से ग्रसित होती हैं, जिनमें से 74 हजार महिलाओं की मौत हो जाती है। इसको रोकना बहुत जरूरी है। लेकिन इसके लिए हमारी जो बच्चियां हैं, कमसिन लड़कियां हैं, उनको 'guinea pig' के रूप में इस्तेमाल करने की अनुमति क्यों दी गई, इसके बारे में मंत्री महोदय से जानना चाहता हूं? एक बात बताई गई है कि इसके इस्तेमाल से जोड़ों और मांसपेशियों में दर्द, थकान, शारीरिक कमजोरी आदि कुछ साधारण बीमारियां होती हैं। लेकिन जो घटनाएं घटीं, जिनमें चार बच्चियों की मौत हुई, उनसे पता चला कि उनके पाचन तंत्र में गड़बड़ी थी, उनको epilepsy थी, उनका सर दर्द होता था और उनका जल्द मासिक स्राव हुआ है। इसकी जांच नहीं की गई। इसकी जांच करना बहुत जरूरी थी। इसमें हमारा तंत्र क्यों फेल रहा, इसके बारे में हम जानना चाहेंगे? महोदय, ICMR और दूसरी एजेंसियों के द्वारा मानव परीक्षण की अनुमति से पूर्व इस प्रकार की संभावित प्रतिक्रियाओं के बारे में उचित विचार किया गया था कि नहीं, इसके बारे में मैं मंत्री महोदय से जानकारी चाहूंगा? मैं जानना चाहूंगा कि इसके पीछे क्या कारण थे - विदेशी कम्पनियों को लाभ देने के लिए या उनकी जांच करने के लिए - क्यों उनको अनुमति दी गई थी? महोदय, एक सामान्य प्रक्रिया है कि किसी भी दवा के इस्तेमाल से पहले इसे clinical trial की कई अवस्थाओं से गुज़रना पड़ता है। मैं माननीय मंत्री जी से यह जानना चाहता हूं कि क्या यह सत्य है कि गार्डासिल ने इस संबंध में केवल एक परीक्षण किया है कि वह भी करीब 100 बच्चियों के समूह पर? क्या यह सत्य है कि इस वैक्सीन को 25-30 वर्ष की आयु की व्यस्क महिलाओं के लिए भी स्वीकृति दी गई थी और वह भी बिना इस आयु समूह के ऊपर परीक्षण किए? अगर हां, तो इन्हें इस पर परीक्षण करने की अनुमति क्यों दी गई? मैं यह भी जानना चाहता हूं कि क्या कम्पनी ने अपने vaccination card "HPV Immunization Card" के ऊपर NRHM का logo लगाया है? अगर हां, तो क्या सरकार ने इस logo के इस्तेमाल की स्वीकृति दी थी? अगर दी थी तो क्यों दी थी? इसके बारे में भी मैं जानकारी चाहूंगा।

मैं माननीय मंत्री जी से यह भी जानना चाहता हूं कि क्या यह सत्य है कि HPV 100 strains में से केवल 4 strains के cervical cancer की रोकथाम में ही मदद करता है? अगर यह सही है तो भारत में 4 strains से ऊपर के cervical cencer से ग्रसित महिलाओं की परसेंटेज बताई जाए और यह भी बताया जाए कि यह वैक्सीन किस हद तक केवल 4 strains तक के cervical cancer को रोकने में मदद कर पाती है तथा अगले कदम सरकार उठा रही है? मैं यह भी जानना चाहूंगा कि इससे जो लोग ग्रसित हुए हैं, सरकार क्या उनकी मदद के लिए कितनी दूर तक आगे गई है तथा उनको आर्थिक रूप से क्या मदद दे पाई है?

DR. (SHRIMATI) NAJMA A. HEPTULLA (Rajasthan): Sir, in Western countries where these drugs are manufactured by the multi-national companies are covered by very strict rules and regulations of FDA and because of those restrictions many of the multi-national companies are making poor population of developing countries as their field of experiment. So, we are the guinea pigs for the rest of the developed world from where they come and experiment on us. This is not the first incident. Day before yesterday and today, a mention of Bhopal Gas Tragedy was referred to. Tiwariji mentioned about it. I would mention it again here. At that time when that tragedy took place, there was a study in the Time Magazine that those people who manufactured these pesticides were spraying these pesticides on African children in the rural areas and in Egypt to find out the effect of those pesticides on human beings. So, it is a known fact that these trials were done in India, as Brindaji has mentioned and the Minister also said it in his statement, by a company which is a NGO. Can we allow NGOs in our country to take such experiments on our people? What is the *locus standi* of that NGO? However good they might be, but what is the *locus standi* of that NGO? This is the first question that I would like to ask the hon. Minister? The second thing is that two districts were selected. Why were these two districts selected? Was there any survey done in those districts that there are complaints of cervical cancer in that area? Why were these two particular districts selected?

DR. K. KESHAVA RAO (Andhra Pradesh): It was ...*(Interruptions)*...

डा. (श्रीमती) नजमा ए. हेपतुल्ला : आप जवाब दे रहे हैं या मंत्री जी देंगे। ...(**व्यवधान**)... आपको कोई एलर्जी हो गई है कि जब भी कोई सवाल मंत्री से पूछो तो आप जवाब देने लगते हैं। You better to have some vaccine for it. एलर्जी के लिए वेक्सीन की जरूरत है। I ask the hon. Minister: Why were these two districts selected? If there is any epidemic, only then we apply vaccine in that area. Was any survey conducted to select them? Why was it not done in Delhi or in any urban area? When anything of that sort is done, only tribals and poor slum children are selected because they don't know anything and their parents don't know anything and they become keep quiet on these issues and become guinea pigs. I also want to remind the hon. Minister that during Rajiv Gandhi's time - don't get allergic, I am saying good things about him - there were five Technology Missions. One of them was on Universal Vaccination. At that time, certain vaccines were used for polio. There was also a cluster of vaccines used for HIV AIDS. It was discovered that they were not effective.

Or, they were harmful. So, they were immediately withdrawn. Now, the Minister has admitted. If he had not understood the bonafide of it, he would not have made an inquiry about it. Definitely, there is a bonafide into it and this is clear from your statement only. So, I will ask the hon. Minister whether he did any survey for this vaccine that in the countries where this vaccine is manufactured - the western countries, there are two companies manufacturing - as to what are the FDA trials over there, what are the reports of clinical trials. Do you have any report of the clinical trial? Do you know what the side-effects are? One hon. Member mentioned that those people, who had been vaccinated, complained about headache or some problems. So, do you have a report? Can you bring it to the Parliament and let the Members of Parliament know that these were the reports of the clinical trials in America, or in Europe, or in those hundred countries where they said that this had been used, or forty countries, where this had been used? What are the reports? Have those reports been studied and compared? When you give a vaccine, you have to try.

The other thing, which I would like bring to your notice, is that without any control, anybody can advertise anything on the television. There was an advertisement on a family planning pill, I-Pill, or some such name was there, which has now been withdrawn because there were complaints about it.

DR. C. P. THAKUR (Bihar): They have introduced again.

DR. (SHRIMATI) NAJMA A. HEPTULLA: So, these kinds of advertisements are coming on the television, and people are buying those vaccines on the counter; Jayanthiji mentioned about it. Is there any control of the Government over these advertisements or not? Or, anybody can manufacture anything and put it on the counter without even trials.

Sir, I would like these four questions to be answered. I have confined myself to the statement only. I have not taken too much time and I have only pertinent questions. I hope the hon. Minister is very capable and will be able to answer them.

DR. C. P. THAKUR: Thank you, Mr. Deputy Chairman, Sir, for giving me this opportunity to speak on this very important issue. I also thank Shrimati Brinda Karat who has raised this issue of clinical trials in India. I also thank the hon. Minister who has stopped the further trials. I start with the second page of the statement which mentions about the cause of deaths. In one place, it was 'Viral

fever'. So, was this 'viral fever' caused by the same virus of the vaccine? It can be caused. Were viral studies done in this case or not? That has to be clarified. Then, in other place, cause of death is anaemia with malaria. Was it justified that you give this trial vaccine in a case of anaemia? So, these two important causes of deaths have been given.

Sir, when I was the Minister, I also had to face a similar hazardous trial of cancer vaccine in Kerala under the Cancer Treatment Programme. At that time, we made Ethical Guidelines. Now, the Minister is better equipped than I was because he has got a full-fledged Department of Medical Research as a separate Department headed by an officer of the rank of Secretary, Government of India. Now, guidelines relating to clinical trials should be more strictly followed in India.

Then, Sir, India is emerging as a major centre for clinical trials. The one reason is that a trial in India is cheaper than in America. The cost is one-third or something like that. It costs much less here than in America. So, every company, coming up with a new drug, rushes to India. Proper guidelines have been framed. But, have those guidelines been given the shape of some statutory Act or something like that? That has to be made. The guidelines for trial in India should not be less stringent than what it is in America. That should be the motto of the Department. Then, it will be helpful for our population.

Sir, the effect of this vaccine lasts for only four to five years. So, how will it protect our population from cancer? That is another problem. Recently, there was flu, an epidemic. And, there was a news item in the Press that the company, which made this tamiflu and other vaccines, spread this epidemic of flu so that their vaccine of tamiflu could sell in the market. Many such articles were published.

In the morning hours also, the hon. Minister was saying that India is a developing country. Now, stop saying that India is a developing country and behave as if India is a developed country. Whether it is clinical trial or any other trial, it should be done as it is done in any developed country. There are rules, there are ethical guidelines. Now, it can go to a department. It should not be done in a hurry as it was done in this case. It was done very hurriedly but, rightly, it has been stopped.

Regarding cervical cancer, awareness should be spread. Besides the trial of the vaccine, awareness should be spread as to how it can be prevented. There are many other methods of prevention. So, I think, the Government should now formulate very strict principles for doing clinical

trials. This is not the rule that some foreign company comes to India and starts the trial. It should be done in India by an Indian company, Indian people or Indian research institutions. So, all these factors should be standardized. So, Sir, I call the attention of the Minister towards these aspects.

SHRI H. K. DUA (Nominated): Thank you, Mr. Deputy Chairman, Sir. Mrs. Brinda Karat has raised some vital questions about the whole project, which certainly need answer. I would like to know, in brief, has the Government made some enquiries about the antecedents of this NGO. Secondly, has some enquiry been made about the funding of this particular project? Often, it has been seen that the pharmaceutical companies float or assist the kind of research that they want about the products they are selling for profit. Thank you.

SHRI MOINUL HASSAN (West Bengal): I have two questions arising out of the statement given by the Minister. When this clinical trial - phase 3 is going on and the safety and efficacy is not proved hundred per cent or is not up to the mark, then, why is this type of vaccine being marketed in the Indian markets right from 2008 as an anti-cancer vaccine? They have advertised it as anti-cancer vaccine. It is very much unwanted and it is against the ethics which we follow in our country. My second question is about this foreign-based NGO. Why and how was this chosen to do this work and conduct survey in our country? Thank you.

PROF. P.J. KURIEN (Kerala): Sir, this is a very important Call Attention. I must thank Brindaji for raising it and bringing it to the notice of the Government. I must also thank the hon. Minister that he has taken action in advance. I think, he had premonition that Brindaji is going to raise it. ...*(Interruptions)*... It is not that. Anyhow, the Minister has taken prompt action and I thank the Minister for that. However, Sir, being an absolute layman in this regard, I have some doubts. Firstly, he mentioned above clinical trial and operational research. I would like to know the difference between the two, and, therefore, I would like to know whether this vaccine had been put for trials anywhere. He said, 105 countries are using it; more than 100 countries. Whether trials were conducted in those countries, and, if they have conducted trials, well, I would like to know the details thereof.

Another question I would like to know is that, Brindaji herself alleged that these trials were conducted on the tribals only. I would like to know whether it is true. How many districts were put under these trials? And, is there any direction from the Government that the trials should be restricted to the tribals only?

SHRIMATI BRINDA KARAT: I did not say 'tribals' only. I said, the 'poor people'.

PROF.PJ.KURIEN: Okay. Now, whether these three districts are rural districts or tribal districts? I do not know about the composition. If so, in those districts, was there any discrimination that only the tribals and the poor sections would be put under trial? Is there any such direction given by the Government?

The next question I would like to know is this. Is there any procedural violation by the concerned authorities because the ICMR should know about this, the Director General of Drugs should know about this? Then, as has been mentioned by the hon. C.P. Thakur, during his regime, they have already found some ethical committees. Is there any violation on the part of the ethical committees or the ICMR or the Director General? I would like to know this.

Then, there were some deaths, and you said that those deaths were not due to this vaccination, which has been disputed also. I would like to know whether you will conduct an inquiry on the real cause of the deaths. Or, have you already conducted an inquiry on the real cause of the death?

Lastly, I would like to state that, in any case, no new medicine can be introduced without trials. It is a must. No inventions are there and India has to use those medicines. Is there any guideline in our country with regard to such clinical trials? Is there any law regarding that? If there is no such law as on today, why don't you consider bringing a new law? I conclude by thanking the Minister once again for taking the steps and stopping the clinical trials and also appointing a Committee for inquiry. I thank the Minister for that. But, however, I hope that he will give a reply to all these questions.

SHRI GHULAM NABI AZAD: Hon. Deputy Chairman, Sir, first I would like to answer some general questions and may be then some specific ones. This will also cover most of the specific questions put forth by the hon. Members. I think, first of all, it has also been asked here that what this PATH is. So, I would like to mention that this is one of the 200 largest United States Charities which receives funding from foundations, the United States Government, other Governments, non-Governmental organizations, multilateral agencies and individuals. PATH's budget for 2008 was 281 billion US dollars. The Charity Navigator, America's largest independent evaluator of non-profits, awarded PATH its highest rating. This is the background of the PATH. The PATH, an international NGO, as I have mentioned, approached ICMR for conducting a licensure, operational research study

to demonstrate the suitability of vaccine delivery strategy for HPV in 10-14 year old adolescent girls. And to build evidence based vaccine delivery strategy for future introduction of HPV under Universal Immunization Programme and monitoring of adverse reactions and side-effects. Accordingly, an MoU was signed between the ICMR and PATH in February, 2007.

The study would also provide important inputs on wastage of vaccines apart from other things which I have already mentioned, frequency of non-compliance, protocols for temperature monitoring, frequency of stock out of vaccines, and other implementation issues relating to the administration of the vaccine on a wider scale and a large population.

Based on these facts, the ICMR permitted PATH, an international NGO, to carry out this research.

SHRIMATI BRINDA KARAT: Where are the facts? There are no facts; these are only assertions.

SHRI GHULAM NABI AZAD: Let me complete.

MR. DEPUTY CHAIRMAN: Let him complete.

SHRI GHULAM NABI AZAD: For your information, I would like to tell you that this is not the only international NGO. There are some other NGOs also. ...*(Interruptions)*...

DR. (SHRIMATI) NAJMA A. HEPTULLA: There are many NGOs working in the country. Are there any other NGOs which have been given permission to conduct clinical trial? ...*(Interruptions)*...

SHRI GHULAM NABI AZAD: We are talking about the MoU with the ICMR. There are two other international vaccine initiatives on HIV/ADS. The International Vaccine Institute, Korea, is working on cholera and typhoid.

The DCGI, the statutory authority, gave the approval for conducting the study in two States, namely, Andhra Pradesh and Gujarat.

As per Schedule-Y of the Drugs & Cosmetics Act, Phase-IV, post-market trials are allowed by the licensing authority, i.e., the DCGI for optimizing the drug use.

Phase-IV trials also include additional drug-drug interactions, those responsible for safety study and trials designed to support use under the approved indications, namely, mortality, morbidity studies, epidemiological studies, etc.

Questions have been raised about it. Here I am going to make it clear why I am saying trial as well as study. This can be categorized as epidemiological study which needs to be carried out on a bigger population and a larger number of subjects. ...*(Interruptions)*...

DR. (SHRIMATI) NAJMA A. HEPTULLA: Was there any case of cervical. ...*(Interruptions)*...

SHRI GHULAM NABI AZAD: Let me complete. ...*(Interruptions)*...

MR. DEPUTY CHAIRMAN: If you go on interrupting, how will he finish it? ...*(Interruptions)*...

SHRI GHULAM NABI AZAD: Let me complete. अभी आपने सुना नहीं, आप ध्यान से सुनिए Don't try to find fault before you listen anything.

SHRIMATI BRINDA KARAT: What did you say earlier?

SHRI GHULAM NABI AZAD: As I said, Phase-IV trials also include additional drug-drug interactions, those responsible for safety study and trials designed to support use under the approved indications. What are those indications? These are: mortality, morbidity studies, epidemiological studies, etc. This can be categorized as epidemiological study which needs to be carried out on a bigger population and a larger number of subjects.

Now I come to Phase-III clinical trial. Here, you will say that I am saying it study as well as clinical trial. So, in this case, Phase-III clinical trial and bridge study is one and the same thing. ...*(Interruptions)*... I am coming to that. For any vaccine, which is already operating in any part of the world and which has already got the permission or maybe, is in public health or otherwise - well it is not the only vaccine which we are bringing from outside, there are a number of other vaccines - we are supposed not to do the trial on a large number. ...*(Interruptions)*... Just listen to me. The hon. Member has said that the Indians will be made the guinea pigs. I totally agree that nobody will be allowed to make the Indian children or women or any human being for that matter as guinea pigs. But, I think, you should have been also very much sure before putting that question across that in America, where it is very difficult to find a large number of subjects for trial for various reasons, this trial has been done on 21000 girls and women. I don't find any clinical trial being done in the United States of America before getting the FDA approval on 21000 individuals. So, it is not that somebody

said and somebody started trials here. As I said, at the moment, both these vaccines are being used - one in 115 countries and another in more than 120 countries. At the same time, I would also like to mention that this is in the national immunization programme in the United States, the United Kingdom, etc. and in almost all the developed countries, this is part of the national immunization programme. So, I think, you should not dismiss it totally on the basis of what some paper writes, without going into the history and study. I don't think the Americans would have done this study on 21000 individuals without any preparation and then allow it into the national immunization programme. Now, having been done so by many developed countries, the WHO has also suggested to other countries, which can afford and show whether it is cost effective and where it is prevalent, to also launch it. In so far as our country is concerned, it is very prevalent in our country. I wanted to first read it and then go into all these things. But, I can do mix up of both. In 2006 alone, we had 1,32,000 girls suffering from this disease. Do you know how many of them died? Seventy-six thousand of them died. So, you can see how deadly and how prevalent this disease is in our country. And, every year, the prevalence is increased by additional one lakh cancer patients of this type. So, do you want that if a disease is being increased by one lakh every year, we should hold our hands like this? And, when the entire globe of 115 or 120 countries right from the United States, from North to South, from East to West are making use of it, we say that we will not do it here and we will not do it there because somebody has written something. So many people write so many things everyday. We don't stop functioning. We do function as a democracy. And I assure the House that we will not allow anybody to play politics or gain any extra benefit for doing this. But, I think, if you would have done study on this particular subject that how far this vaccine has already gone across the globe, maybe, you would not have come forward here to raise all these questions.

Now, what is the clinical trial? Let me clarify that. Normally, a drug vaccine is introduced in the market as per the Drugs and Cosmetics Act after it undergoes the clinical studies as prescribed in Schedule-Y of the Drugs and Cosmetics Act. It involves four phases. So, you should be very clear. Any new drug goes through four phases. Number one, trial for establishing safety and tolerability; number two, trial for effectiveness; number three, trial for demonstrating or confirming the clinical and therapeutic benefit; and number four, trials on a large population after post-market approval. The market approval has been given about two years ago, in 2008, after the third phase was over on

a limited number. In one case it was 100 or something like that and in the other case it was 300. In the case of an imported medicine, which has already been cleared by the respective Governments, you are supposed to do a bridging trial, which is called Phase-III, on a very limited number. It is not done on a large number. Then it is given the market approval. So, it is only after the market approval is given for two years, the fourth phase starts on a large population. This is what we are doing after two years, in the fourth phase, on a large population. We are doing this according to the Act. So, we are not doing anything wrong. Whether the PATH is there or not, somebody has to carry out this exercise of Phase-IV trial in our country on a large population.

Again, I would like to talk about research. We have three types of research. One is basic research; second is clinical research; and third is epidemiological research. The basic research is done in the lab. It is cell based or, maybe, otherwise. The clinical research is done on animals and human beings. The third, that is, this particular research which is going on, is epidemiological research which Madam has mentioned. Epidemiology is a branch of science. Both of us, you and I, are science students. This branch of science deals with the study of causes, which we are doing, distribution and control of disease in population. Now, this research has three further components. One is descriptive research, that is, morbidity, mortality and geographic distribution. So, what we are doing is geographical distribution. If some research is going on in Gujarat, geographically it is one part of the country. If some research is going on in Andhra Pradesh, geographically it is another part of the country. Then, in the descriptive we have taken the urban population, the rural population and the rural population in remote areas. Second is analytical research which involves verifying the risk factors, direct causes, age factor, diet habit and socio-economic status. We have considered all this when we have selected different States. For your information, meanwhile a study was going on, which, I think, no hon. Member has mentioned, in Mumbai, Kolkata, Ghaziabad and other parts of the country, which has, at the moment, come to an end. So, it is not that only the tribal areas or difficult areas have been mentioned.

डा. (श्रीमती) नजमा ए. हेपतुल्ला : क्या आपने अपने statement में इसे mention कर रखा है?

एक माननीय सदस्य : यह आपके statement में mention नहीं है। ...(**व्यवधान**)...

श्री गुलाम नबी आज़ाद : वह मैं अभी बता रहा हूं। ...(**व्यवधान**)... जवाब तो मैं आज दे रहा हूं। कोलकाता और मुम्बई जैसे और भी बड़े-बड़े शहरों में यह co-ordination बड़े institutes के साथ चल रहा है, जिसको भी अभी रोक

दिया गया है। मकसद यह है कि इसमें geographical distribution आ जाए, causes आ जाएं, drug habits आ जाएं और socio-economic status पर study भी हो जाए। Epidemiological research का जो तीसरा component है, that is intervention research. That is called operational research. इस research में तीन-चार चीजें हैं, that are: use of vaccination and drugs, counselling of bad habits, counselling of lifestyles. Under epidemiological research - research for morbidity, mortality, risk factors and operational research for feasibility of implementation is undertaken. I would like to make it clear to the hon. Members that the demonstration project in a working model to study the impact of public health and management of a particular illness in this age group is part of the operational research. Shouldn't we think at any given point of time that this has to be introduced as part of the National Immunisation Programme? If a country like the United States, a country like Britain, a country like France or a country like Australia have made it a part of National Immunisation Programme; when this disease is so prevalent in our country, don't you think that we should rise to the occasion and make some efforts also in our country to do more trials? Otherwise, according to the Act, in Phase-IV, we are supposed to do clinical trials on geographic basis, on number basis, on bigger population, to see the morbidity, see other actions and reactions before we take the final step. Shrimati Brinda Karat has rightly talked about the duration of protection. It has been mentioned that this is for two years, three years or four years. I totally agree with you. But we should also keep this in mind that this particular vaccine is hardly four years old. So how can you talk of 20 years, when it is not 20 years old? Had this been 20 years old, anybody would have seen its effect for 20 years. Had this vaccine been 15 years old, then the outcome could have been seen, or you could have said that okay it would last for 13 years or 14 years. The vaccine itself was launched in 2006. I do not know in which month of 2006 it was launched. But it has not completed five years. So it will depend as and when we complete five years or six years or seven years. All the international agencies and scientists, those who have invented this vaccine, definitely, hundreds of them are working on it and seeing the efficacy and longevity of this, to see how long it will last. But at this stage it is not possible to say whether it will last for five years or beyond six years. That will be seen only after five years or six years of the launch of this particular vaccine. Sir, I have too many things. I do not know whether I should. ...*(Interruptions)*...

MR. DEPUTY CHAIRMAN: If you have an exhaustive reply, then I think there is no need for any clarification.

SHRIMATI BRINDA KARAT: It is a critical issue. I just want to raise...

MR. DEPUTY CHAIRMAN: Please be pointed.

SHRIMATI BRINDA KARAT: I am being very pointed. The Minister has made a statement in the House that according to him, a bridge study is the same as a Phase III trial...

SHRI GHULAM NABI AZAD: In this case.

SHRIMATI BRINDA KARAT: There is no 'in this case or that case'...

SHRI GHULAM NABI AZAD: In this case because the trial III for the new drugs is totally different. If the drug is already in use, then, this may not hold good.

SHRIMATI BRINDA KARAT: Thank you, Ghulamji. You have made my task even easier. There are no exceptions allowed in the present Indian legal framework. I have here the Therapeutic Confirmatory trials, Phase III. It is very clear, "Phase III trials are designed to confirm the preliminary evidence accumulated in Phase II that a drug is safe and effective for use. These studies should be intended to provide an adequate basis for marketing approval."

SHRI GHULAM NABI AZAD: You are reading for the new drug. You are not reading for the drug which is already there. ...*(Interruptions)*...

SHRIMATI BRINDA KARAT: Please, I know that. For new drugs approved outside India, Phase III studies need to be carried out to generate evidence of efficacy and safety of the drug in Indian patients when use is recommended in the prescribing information. At present, according to the Clinical Trials Registry of my Government, of my country, not by the American Government or any other Government, there are two trials which are phase III trials. What is the period? The duration is three years. What is the target? One is, five years, and the target sample is 20,000 people. And, today, you are trying to convince this House, and I am very, very sorry that I have to say this to Ghulam Nabiji because of his sympathetic attitude towards public health. He is being misled by his officials. I put this on record. How can safety be proved on 110 subjects, and that too by a study done by the company itself? And the second study, I have it here. You said, "You should have studied it." I studied this entire thing in great detail. And, I can tell you that this is immunogenicity,

safety in humans. And this has been done by whom? One is GARDASIL and the other is Glaxo. They are having a competition amongst themselves as to who is going to capture which market. And where is it? This was not registered in India. This was done by Indians. It was for how many! It was for 354. Sir, only 177 were given the vaccine. The others were given placebos. This is, obviously, what you mean. That is, obviously, to check the immune bodies, whether these are being generated in the body or not. But these cannot be equated with Phase III trial. And I reiterate today that if you want to change the ICMR guidelines, change them; bring it before the House. But we will not accept tiny population studies to say that they are Phase III trials in India. They are not Phase III trials. Therefore, on this, I require the Government to consider this. I do not want to blame the Minister. This is something which is duly being concocted by certain sections here. Therefore, I say, it is very, very clear; Phase III trials have to be done on Indians. We cannot go by other countries, however great they are, however scientific they are. That is the present law. If you want to change the law and you want to change the guidelines, please change it and bring it to the House. But don't try and say that a trial on 110 people is a Phase III trial. It cannot be accepted.

DR. CP. THAKUR: Sir, actually, there are definite guidelines for Phase II and Phase III trials...

SHRIMATI JAYANTHI NATARAJAN: Are we going to have further clarifications? Then, all of us can speak.

MR. DEPUTY CHAIRMAN: What do I do?

DR. C.P. THAKUR: According to the statement of the hon. Minister, it appears to be justified that India should strictly take Phase III trials for this vaccine. It is said that it has been tried in America. Certain drugs which are good in America are not good in other parts of the world. Take the anti-diabetic oral drug. It was used everywhere. Americans did not use it for quite a long time. They said it might be good in England, but it was not in America. They did not use it even after a great pressure. So, for our country, at least, Phase-III and good Phase-IV trials should be conducted, and not very small ones; Americans also do trials but they do very large ones. In a country like India where this disease is very common, I think a new study should be done and the hon. Minister should undertake that study so that it is useful for the whole country.

SHRI GHULAM NABI AZAD: Sir, as I have made it very clear, each drug has to undergo four trials - first, second, third and fourth-and the third phase depends on whether it is a tried one or a new drug. If it is a totally new drug, not tried in any part of the country, not made available in any part of the country, not given permission by the permitting agencies...

DR. C. P. THAKUR: Sir, this is a new drug.

SHRI GHULAM NABI AZAD: This is not a new drug. It is there in 120 countries. How is it a new drug? ...*(Interruptions)*...

MR. DEPUTY CHAIRMAN: Now, let us not open a new debate. ...*(Interruptions)*...

SHRI GHULAM NABI AZAD: This is not a new drug. ...*(Interruptions)*...

MR. DEPUTY CHAIRMAN: He has made it very clear. Now, let us not open a new debate. ...*(Interruptions)*...

DR. C.P. THAKUR: It's a new drug.

SHRI GHULAM NABI AZAD: A new drug is one which has been invented for the first time by ...*(Interruptions)*... डॉक्टर साहब, आप नया interpretation नहीं निकालिए ...(**व्यवधान**)...

DR. C. P. THAKUR: No, I am not arguing.

SHRI GHULAM NABI AZAD: This is so simple. Any drug which is in vogue in 120 countries cannot be a new drug.

DR. C P. THAKUR: No.

SHRI GHULAM NABI AZAD: We haven't made any new drug here. It is the same. ...*(Interruptions)*...

SHRIMATI BRINDA KARAT: Look at the rules, Sir. Nowhere is it said. ...*(Interruptions)*... Sir, they are misleading you. ...*(Interruptions)*...

SHRIMATI JAYANTHI NATARAJAN: What is happening, Sir?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI DINESH TRIVEDI): Sir, are they interested in the answer or not? It can't go on like this.

SHRI GHULAM NABI AZAD: I would request my hon'ble friend that nobody can mislead us.

DR. C. P. THAKUR: Sir, it is not a question of debate. The question is whether it is good for our country...

श्री गुलाम नबी आजाद : आप सुनने से पहले जवाब दे रहे हैं ...(**व्यवधान**)...

डा. सी.पी. ठाकुर : नहीं, मैं जवाब नहीं दे रहा हूं। ...(**व्यवधान**)...

श्री गुलाम नबी आजाद : कृपया मेरी बात सुनिए। हमारी जो drug दुनिया में जाती है, वे भी यही करते हैं। ...(**व्यवधान**)... अब वह पुराना जमाना नहीं है। हमारे भी बहुत से drugs दुनिया भर में जाते हैं ...(**व्यवधान**)...

SHRIMATI BRINDA KARAT: Sir, just a second.

MR. DEPUTY CHAIRMAN: No, no. ...*(Interruptions)*... I can't allow this. ...*(Interruptions)*... What is this? ...*(Interruptions)*... No, no. Your point of view. ...*(Interruptions)*...

SHRIMATI BRINDA KARAT: Sir, I will take just a second.

MR. DEPUTY CHAIRMAN: Then, you write to the Minister. ...*(Interruptions)*...

SHRI GHULAM NABI AZAD: I am not yielding.

SHRIMATI BRINDA KARAT: Just for a second, Sir.

MR. DEPUTY CHAIRMAN: He is not yielding, Brindaji.

SHRIMATI BRINDA KARAT: Sir, just for one second.

MR. DEPUTY CHAIRMAN: Brindaji, what is this?

SHRIMATI BRINDA KARAT: Just for one second, Sir.

SHRI GHULAM NABI AZAD: All right.

SHRIMATI BRINDA KARAT: Thank you very much, Sir. Sir, apart from what I read, what it says is, "...to verify that a data generated in Indian population is in conformity with the data already generated abroad.". If the data in America is on the basis of 21,000 people, how can you, in India, say we have the same data generated by 110 people, that also through a study not registered in India?

श्री गुलाम नबी आजाद : आप भी वही बात कह रहे हैं, जो बात अभी डॉक्टर साहब कह रहे थे ...(**व्यवधान**)... That is why there is the fourth phase. So, we are in the fourth phase; on 26,000 people. ...*(Interruptions)*

श्री उपसभापति : यह क्या हो रहा है? ...(**व्यवधान**)...

SHRI GHULAM NABI AZAD: That is why they have put it in the fourth phase. If it is not sufficiently done in the third phase, there is a fourth phase which you have to do on a large population. We have done 14000 and 10000, that is, 24000 trials. I don't know, डॉक्टर साहब, आप कह रहे हैं कि ज्यादा पर कीजिए, पर क्या 24,000 कम है? ...(**व्यवधान**)...

MR. DEPUTY CHAIRMAN: The Calling Attention is over now. Bills for introduction now.

GOVERNMENT BILL

The Personal Laws (Amendment) Bill, 2010

THE MINISTER OF LAW AND JUSTICE (SHRI M. VEERAPPA MOILY): Mr. Deputy Chairman Sir, I move for leave to introduce a Bill further to amend the Guardians and Wards Act, 1890 and the Hindu Adoptions and Maintenance Act, 1956.

The question was put and the motion was adopted.

SHRI M. VEERAPPA MOILY: Sir, I introduce the Bill.

MR. DEPUTY CHAIRMAN: The House is adjourned for one hour for lunch.

The House then adjourned for lunch at forty-five minutes past one of the clock.

The House re-assembled after lunch at forty-six minutes past two of the clock,

THE VICE-CHAIRMAN (PROF. P. J. KURIEN) in the Chair

DISCUSSION ON WORKING OF MINISTRY OF YOUTH AFFAIRS AND SPORTS

THE VICE-CHAIRMAN (PROF. P.J. KURIEN): We shall now take up discussion on the working of the Ministry of Youth Affairs and Sports. Smt. Jayanthi Natarajan.

SHRIMATI JAYANTHI NATARAJAN (Tamil Nadu): Sir, I would like to thank you for giving me this opportunity to initiate the discussion on the working of an extremely important Ministry, the Ministry of Youth Affairs and Sports. Sir, I am quoting from Benjamin Disraeli, "We live in an age where to be young and indifferent can no longer be synonymous. The youth of the nation are the