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Title: Dr. Laxminarayan Pandey called the attention of the Minister of Health and Family Welfare regarding sale of spurious drugs in the country causing serious health hazards to the people and steps taken by the Government in regard thereto.

**डॉ. लक्ष्मीनारायण पाण्डेय (मंदसौर) :** अध्यक्ष महोदय, मैं स्वास्थ्य मंत्री का ध्यान अविलम्बनीय लोक महत्व के निम्न विषय की ओर दिलाता हूं और प्रार्थना करता हूं कि वे इस संबंध में वक्तव्य दें :

"देश में नकली दवाओं की बिक्री जिसके परिणामस्वरूप लोगों के स्वास्थ्य को गंभीर खतरा उत्पन्न हो रहा है, से उत्पन्न स्थिति और इस संबंध में सरकार द्वारा उठाए गए कदम "

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. ANBUMANI RAMADOSS): Sir, the manufacture, sale, distribution of spurious drugs is a clandestine activity generally indulged by anti-social elements and generally carried out by unlicensed manufacturers. The State Governments are responsible to monitor the quality of drugs moving in the market as they are the licensing authorities for the establishments engaged in the wholesale and retail sale. ...(*Interruptions*)

SHRI BRAJA KISHORE TRIPATHY (PURI): Sir, let it be laid on the Table of the House.

MR. SPEAKER: Are you for that?

SOME HON. MEMBERS: Yes, Sir.

MR. SPEAKER: Mr. Minister, you can lay the rest of the statement on the Table of the House.

DR. ANBUMANI RAMADOSS: This is an elaborate answer, Sir.

MR. SPEAKER: Very well, they will ask questions and you can answer them.

DR. ANBUMANI RAMADOSS: I would like to lay the rest of the statement on the Table of the House.

*As a part of their function, the Inspectors appointed by the States carry out market surveillance by drawing samples from sales establishments, hospitals and manufacturers and get them tested at their respective Government laboratories.

Trading of counterfeit drugs is reported the world over. The extent of counterfeit drugs in the country is difficult to assess. As per the information available, on an average 40,000 samples are got tested by the States from their laboratories and the incidence of spurious drugs reported for the years 2004-05, 2005-06 and 2006-07 is between 0-.182 and 0.29 per cent. The media reports and figures quoted in media in this regard are exaggerated and not substantiated by facts.

Two pilot studies were conducted – one by the Government and the other by a Private Professional Body – and both do not indicate any significant incidence of spurious drugs.

In view of the concerns expressed in Parliament, public and media in the year 2003, the Government of India constituted an expert committee under the Chairmanship of Dr.R.A. Mashelkar with two main objectives – one to upgrade the regulatory system at the States and the Centre to that of global standards and, two, to assess the counterfeit drugs and initiate action to curb the trade of counterfeit drugs.

Government has taken many steps to contain this social evil. In pursuance of the recommendations of the Expert Committee set up under the Chairmanship of Dr. R.A. Mashelkar, Director General and Secretary, CSIR, Government had introduced a bill in the Parliament for the amendment of the Drugs and Cosmetics Act, 1940, to provide for stricter penalties, provision for special courts for speedy trial of drug related offences, compounding of offences, authorizing the police also to file prosecution for drug related offences and making all drug related offences cognizable and non-bailable. The draft Bill was referred to the Parliamentary Standing Committee and the recommendations of the Committee have been incorporated and the revised Bill is expected to be introduced in the current session of the Parliament. The proposed punishment for counterfeit and spurious drugs in this Bill has been made more stringent with life imprisonment and/or fine of Rs. 10 lakh.

Government of India is also implementing a 5-year World Bank Aided Capacity Building Project for Food Safety and Quality Control of Drugs with a total project cost of Rs. 354.25 crore. Under this project, 23 States and 7 Central drug laboratories are being strengthened by new laboratories, renovations and extensions and providing the latest sophisticated equipment. This would enhance the capacity of the laboratories to deal with larger number of samples speedily. Assistance is also provided to States for providing National Acreditation Board for Laboratories (NABL) accreditation of the laboratories,

funding for manpower and training of drug regulatory staff under the project and a strong media campaign for the education of the consumers in Drug Purchase and Use has also been initiated.

Since the success of eradicating the problem of spurious drugs depends upon adequate measures taken by State Governments, I have taken up this issue in detail with all Chief Ministers in national level meetings. Detailed guidelines have been issued to the State Governments to undertake focused surveillance over possible movement of spurious drugs. Specific training programmes for regulatory officials of State Governments on the logistics of intelligence work, prosecutions, etc., have been conducted. Schedule – M of the Drugs and Cosmetics Act has been amended to make it at par with international standards and it has been made mandatory for the manufacturers of drugs to comply with the requirements of the schedule for quality control of products manufactured by them.

A Bill is being introduced in this session of Parliament providing for the creation of a Central Drug Authority for strengthening the regulatory system for licensing and control of drugs.

The Government is taking all possible steps to check and mitigate this social evil and I appeal to all the hon. Members t ensure quick and smooth passage of the proposed legislations in this regard.*

**डॉ. लक्ष्मीनारायण पाण्डेय (मंदसौर) :** अध्यक्ष महोदय, मैंने इस वक्तव्य को एक बार नहीं तीन-चार बार ध्यान से पढ़ा है और मुझे बड़ा खेद है कि माननीय मंत्री जी द्वारा इस विषय को जिस गम्भीरता से लेना चाहिए था, उस गम्भीरता से नहीं लिया है। शायद उन्हें देश के आम लोगों के स्वास्थ्य के प्रति जो चिन्ता होनी चाहिए, वह नहीं है। नकली दवाएं बनाने का धन्धा अवैध रूप से चल रहा है और इसमें हजारों करोड़ रूपये का व्यापार हो रहा है, उसके बारे में उन्होंने जो अपनी बात कही है, उसमें राज्य सरकारों पर बहुत कुछ डाला गया है। मैं नहीं समझता हूं कि इस राष्ट्रीय विषय पर, जो कि राष्ट्रीय स्वास्थ्य नीति से संबंधित है, उसको केवल राज्य सरकारों के भरोसे डालना, उनके उत्तरदायित्व के लिए कहां तक न्यायसंगत हो सकता है, कहां तक ठीक हो सकता है? मैं चाहूंगा कि माननीय स्वास्थ्य मंत्री इस विषय को जिस गम्भीरता से देखा जाना चाहिए, उसी गम्भीरता से देखें। यह एक सामूहिक नरसंहार जैसा मामला है। इस विषय को गम्भीर समस्या मानकर उन्होंने जिन उपायों की चर्चा की है, उन उपायों की किस तरह से पूर्ति हो सकती है और कब हो सकती है? इसकी चिन्ता लेंगे, तभी मैं समझता हूं कि यह काम ठीक तरह से और समय पर हो सकता है।

स्वास्थ्य मंत्री महोदय ने डॉक्टर माशेलकर की अध्यक्षता में बनी एक समिति की भी चर्चा की है। उन्होंने यह भी कहा है कि उस समिति ने कुछ सिफारिशें की हैं। मैं उन सिफारिशों के बारे में जानता हूं और संसदीय समिति ने उन सिफारिशों पर जो अपनी सिफारिशें दी हैं, उन पर मंत्री जी एक विधेयक प्रस्तुत करना चाहते हैं। मैं जानना चाहता हूं कि वह विधेयक कब प्रस्तुत किया जाएगा? क्या उस विधेयक का मसौदा पुन : तैयार हो गया है? क्योंकि पूर्ववर्ती सरकार द्वारा भी ऐसा विधेयक लाया गया था। क्या उन सभी बातों का उस विधेयक में समावेश होगा, जिनके बारे में चिन्ता की गई है कि ऐसी कम्पनियां जिनके बारे में यह मालूम हुआ है कि वे नकली दवाओं के बनाने और परिचालन में लगी हुई है। यह एक महत्वपूर्ण विषय है। जैसा कि माननीय मंत्री जी ने कहा है कि वह यह विधेयक इसी सत्र में लाना चाहते हैं। मैं चाहता हूं कि मंत्री जी इस बात का आश्वासन देने की कृपा करें कि यह विधेयक इसी सत्र में प्रस्तुत किया जाएगा।

अध्यक्ष महोदय, मैं आपके ध्यान में एक बात और लाना चाहता हूं। माननीय मंत्री जी एक केन्द्रीय औषध प्राधिकरण बनाना चाहते हैं। यह बहुत ही अच्छी बात है। लेकिन इसी प्रकार के प्राधिकरण की व्यवस्था पहले से की हुई है। इसके अलावा एक केन्द्रीय औषध नीति भी है, उस नीति को आप कितना क्रियान्वित कर पा रहे हैं? उस नीति के क्या परिणाम सामने आए हैं? क्या केन्द्रीय औषध नीति को फिर से पुनरीक्षित करते हुए, कोई ऐसी नीति, जो समेकित हो, जो काप्रेहेंसिव हो को लाने का प्रयास करेंगे ताकि एक समेकित औषध नीति पूरे देश के लिए बन सके। विधेयक अपनी जगह है और औषध नीति अपनी जगह है। चूंकि विधेयक के अन्तर्गत आप पुलिस और राज्य सरकारों को अधिकार देने वाले हैं, उसे स्पष्ट करें लेकिन केन्द्रीय औषध नीति में दवाओं की गुणवत्ता, उनके फार्मुले वगैरह पर किस तरह से काम किया जाए, इस पर विचार किया जाता है। उनकी क्रियान्विती ही कहो।

अध्यक्ष महोदय, मैं बताना चाहता हूं कि किस तरह से देश में नकली दवाओं का व्यापार चल रहा है। किसी भी दवा का फार्मूला एक ही होता है और उसके अन्तर्गत ब्रांड नाम का रजिस्ट्रेशन प्राप्त किया जाता है। एक दवाई जिसका नाम एनॉलजिन है, वह रजिस्टर्ड है, नोवालजिन रजिस्टर्ड है, एटोनॉल रजिस्टर्ड है, लेकिन उस रजिस्टर्ड दवा के साथ एक दवा और मिलाकर किसी अन्य नाम से बना दी जाती है। वह बाजार में धड़ल्ले से बिकती है। सामान्य व्यक्ति इससे अपरिचित होता है क्योंकि 'रेपर ' तक एक सा होता है।

अध्यक्ष महोदय, मैं माननीय स्वासथ्य मंत्री का एक अन्य बात की ओर ध्यान आकर्षित करना चाहता हूं। दवा बेचने के लिए फार्मिसिस्ट का लाइसेंस तो एक ही को मिलता है, लेकिन दवा का विक्रय 5-6 लोग करते हैं। फार्मासिस्ट तो एक ही होता है और बाकी लोग दवाओं के संबंध में प्रशक्षित नहीं होते हैं। इसलिए जिस दुकान से औषध का विक्रय होता है, वहां भी गलती हो सकती है और नकली दवाएं वहां से सहज रूप में बेची जा सकती हैं और प्राप्त की जा सकती हैं। फार्मासिस्ट को नियुक्त करना और उन्हें लाइसेंस देना राज्य सरकार का विषय है, लेकिन केन्द्र सरकार भी राज्य सरकारों को निर्देशित करे कि उन दवा विक्रेताओं के यहां वही फार्मासिस्ट काम करेंगे जो प्रशिक्षित होंगें । जो प्रशिक्षित हैं या उस प्रकार से उन्होंने इस बारे में कोई प्रशिक्षण प्राप्त किया है। मैं एक और निवेदन इस सम्बन्ध में करना चाहता हूं और स्पष्टीकरण जानना चाहता हूं कि आप जो एक विशेष न्यायालय की व्यवस्था करने वाले हैं और जो पुलिस बल को विशेष अधिकार देने वाले हैं, वह किस प्रकार से होगा। न्यायालय की व्यवस्थाओं के अन्तर्गत यह किसके अधिकार क्षेत्र में होगा और यह पुलिस की व्यवस्था किसके अधिकार में होगी? क्या केन्द्रीय सरकार के अधीन होगा या फिर न्यायालय की रचना का प्रकार क्या होगा, स्वरूप क्या होगा, इसके बारे में भी माननीय स्वास्थ्य मंत्री महोदय स्पष्ट करने की कृपा करेंगे। मैं इस विषय में आपका ध्यान और आकर्षित करना चाहूंगा कि कई बार हमें चिकित्सक एक प्रैस्क्रिप्शन देता है और उसके आधार पर हम जाकर दवाएं लेते हैं, लेकिन आजकल जो प्रचलन है, देखने में आया है कि किसी भी दवा विक्रेता के यहां जाकर खड़े हो जायें और उससे मांग लें कि मुझे ब्लड प्रैशर की कोई दवा चाहिए, तो एटनेलोल वगैरह जो दवा चाहिए, वह झट से उठाकर उसी वक्त दे देता है। इसको भी सुनिश्चित किया जाना चाहिए कि बिना चिकित्सक के प्रमाणीकरण या प्रैस्क्रिप्शन के कोई दवा न मिले, तब तो ठीक है, अन्यथा जब दवा दी जाती है तो कौन सी दवा दी जा रही है, किस प्रकार की दवा दी जा रही है, इस प्रकार की कोई जानकारी नहीं होती है और आज जो इन निकली दवाओं के जो दुष्परिणाम सामने आ रहे हैं, मैंने कई परिणामों को देखा है, मैं स्वयं भी इसका

अनुभवी हूं कि किस प्रकार से दुष्परिणाम होते हैं और किस प्रकार नकली दवाएं, जो एण्टी एलर्जिक दवाएं हैं, वही एलर्जी पैदा कर देती हैं, इसलिए कि वे नकली हैं और इस कारण लोगों को परेशान होना पड़ता है। मैंने उन बीमारों को, रोगियों को भी देखा है, जो एण्टी एलर्जिक दवा लेने के बाद एलर्जी से इतने पीड़ित हुए कि कम से कम 15-15, 20-20 दिन उनको परेशान होना पड़ा। इसके बारे में आप कौन सी ऐसी व्यवस्था कर रहे हैं, ताकि इनकी गुणवत्ता के बारे में देखा जा सके? माननीय स्वास्थ्य मंत्री महोदय ने जो प्रारम्भ में कहा है कि नकली औषधियों का निर्माण, बिक्री, वितरण एक गुप्त कार्यकलाप है, मुझे समझ में नहीं आता कि गुप्त कार्यकलाप किस प्रकार से है, जबकि धड़ाके से दवाइयां बिक रही हैं। पिछले वर्षों में मध्य प्रदेश, आंध्र प्रदेश में हाल ही में उडीसा का रैकेट सामने आया है। अगर गुप्त कार्यकलाप है तो क्या केन्द्रीय सरकार के पास कोई ऐसी एजेंसी नहीं है? लोग गुप्त रूप से किस प्रकार से औषधि निर्माण करते हैं, इस कार्य में समाज विरोधी तत्व लगे रहते हैं, जो समाज विरोधी तत्व हैं, उनके बारे में, मैं समझता हूं कि केन्द्रीय सरकार का यह विषय भी है और ये सामान्यतया गैर लाइसेंसशुदा लोग निर्मित करते हैं। राज्य सरकारें बाजार में आने वाली औषधियों की गुणवत्ता को मोनीटर करने के लिए उत्तरदायी हैं। राज्य सरकारें ही नहीं, केन्द्र सरकार भी उत्तरदायी इसलिए है कि वह इन औषधियों के नियंत्रण पर और उनकी सारी गुणवत्ता पर, उनके फार्मूलेशन पर उसका भी एक केन्द्रीय अधिनियम है, उसके अन्तर्गत वह कार्रवाई करती है और इन बातों को देखती है। मैं माननीय मंत्री महोदय से जानना चाहूंगा कि क्या सरकार ने इस बात की जानकारी प्राप्त की है कि नकली औषधि व्यापार में जो सामान्यतया कहा जाता है कि तीन हजार करोड़ का है, कोई कहता है कि चार हजार करोड़ का है, कोई कहता है कि दस हजार करोड़ का है, कोई इसे पूरे औषध व्यापार का पचास प्रतिशत कहता है । आखिर इसमें कितना व्यवसाय होता है और उसको रोकने के लिए अन्य कौन से उपाय हो सकते हैं, उसके बारे में आप कृपया स्पष्ट करें?

**श्रीमती सुमित्रा महाजन (इन्दौर):** माननीय अध्यक्ष जी, मंत्री जी का जो पूरा स्टेटमेंट है, उसके फर्स्ट पैराग्राफ को भी अगर आप पढ़ें तो उससे मालूम होता है कि कितने गैर-जिम्मेदार, मैं बिल्कुल यह शब्द यूज़ कर रही हूं कि कितने गैर-जिम्मेदार हमारे स्वास्थ्य मंत्री जी हैं कि पूरी जिम्मेदारी जिस तरीके से स्टेट गवर्नमेंट पर टाल दी है, इतना ही नहीं, मंत्री जी का स्टेटमेंट ही शुरू होता है कि यह एण्टी सोशल एलीमेंट्स कर रहे हैं, "generally carried out by unlicensed manufacturers." लाइसेंस देने की आपकी प्रक्रिया भी क्या है और बाद में ऐसे अन्नोथोराइज्ड लोग, जो मैन्युफैक्चरर कर रहे हैं, उनको रोकने के लिए सैण्ट्रल गवर्नमेंट क्या कर रही है, यह भी मैं जानना चाहूंगी? दूसरी बात मैं कहना चाहूंगी, इन्होंने जो स्टेटमेंट दिया, उसी पर मैं बात कर रही हूं। बाद में ये कहते हैं, जो फीगर्स मीडिया में दी हैं, "which are exaggerated and not substantiated by facts." पहली बात तो है, केवल मीडिया ही यह रिपोर्ट नहीं दे रहा है, आपके आई.एम.ए. के अध्यक्ष भी यही बात बोल रहे हैं, जो एक जिम्मेदार व्यक्ति माने जाते हैं। मगर आप जैसा कर रहे हैं कि सब्सटेंशिएटिड नहीं है तो सब्सटेंशियट होने के लिए जो ड्रग इंस्पैक्टर्स हैं, जो नमूने अगर लेते हैं तो लैब से बाद में उसको कन्फर्म कराना होता है, टैस्टिंग कराना होता है। मैं जानना चाहूंगा कि क्या पर्याप्त मात्रा में आपकी लैब काम कर रही हैं, क्या जो लैब काम कर रही हैं, क्योंकि केवल सात काम कर रही हैं, सैण्ट्रल लैब की भी मैं बात कर रही हूं और जो सैण्ट्रल लैब हैं, क्या वे वैल इक्विप्ड हैं? मैंने मुंबई और दिल्ली दोनों लैब्स देखी हैं। एक समय मैं एक उप-समिति की अध्यक्षा थी और उस समय मैंने ये दोनों लैब्स देखी। They are not well equipped.

**13.00 hrs.**

तीसरी बात, क्या ये लैब मानद के अनुसार हैं? क्या वहां पर टेस्टिंग को दिए हुए नमूनों की समय के अंदर जांच करके रिजल्ट्स आते हैं, इसके बारे में भी मंत्री जी उत्तर दें।

MR. SPEAKER: There will be no lunch recess today.

**श्रीमती सुमित्रा महाजन (इन्दौर) :** महोदय, अब बिल आ रहा है, मैं इसका स्वागत करती हूं और यह बिल जल्दी आए। लेकिन एक और बात मंत्री जी के स्टेटमेंट में लिखी है, उसे पढ़कर मुझे बहुत दुख हो रहा है, क्योंकि स्पूरिअस ड्रग्स के कारण गरीब लोगों की ही ज्यादा मौत हो, ऐसी बात नहीं है। किसी के भी पेट में यह जाए, तो उसकी मौत होनी है। लेकिन माननीय मंत्री जी ने कहा कि the Government is also implementing a five-year World Bank aided Capacity Building Project, etcâ€¦उसमें बहुत सारी चीजें दी गयी हैं और यह कई करोड़ का है। मैं जानना चाहूंगी कि क्या जब वर्ल्ड बैंक मदद दे, तभी गवर्नमेंट आफ इंडिया हमारे हिन्दुस्तान के लोगों के स्वास्थ्य का ध्यान रखेगी, तभी हमारे यहां की लैब्स अपग्रेड होंगी, तभी यहां पर आज जो वह ट्रेनिंग की बात कह रहे हैं, जनजागरण की बात कह रहे हैं, तभी यह होगा? अगर गवर्नमेंट आफ इंडिया अपनी तरफ से कुछ नहीं करेगी, तो मंत्रालय किस बात के लिए है?

महोदय, मैं एक और बात जानना चाहूंगी। अब प्राधिकरण बनाने की बात कह रहे हैं, इस प्राधिकरण की सिफारिश सन् 1975 की है। वह कह रहे हैं कि अब बिल आएगा और हम इसे बनाएंगे। क्या इसके लिए आपने कुछ टाइम बाउंड प्रोग्राम बनाया है?

मैं एक बात और जानना चाहूंगी कि जो स्पूरिअस ड्रग्स आते हैं, क्योंकि आज हम देखते हैं कि दवाओं की कीमतें इतनी बढ़ गयी हैं कि यह वास्तव में आम-आदमी की पहुंच के बाहर हो गयी हैं, क्या यह भी एक कारण है कि सस्ती और नकली दवाएं बाजार में आ रही हैं और ऐसी नकली दवाएं बनाने वाले जो लोग हैं, क्या वे कहीं न कहीं प्रभावशाली तरीके से हमारी रीति-नीति को अफेक्ट कर रहे हैं? कहीं ऐसी बात तो नहीं है, इन सब बातों का जवाब मैं माननीय मंत्री महोदय से जानना चाहूंगी।

MR. SPEAKER: Shri Basu Deb Acharia, you are entitled to put only questions.

SHRI BASU DEB ACHARIA (BANKURA): The State of the Minister does not show the situation is so serious. In a State of our country, Orissa, the situation has become so serious in regard to the circulation of spurious and counterfeit drugs. The Opposition Parties in the State have decided to observe a day's bank demanding the CBI Inquiry on certain incidents which have taken place in Orissa resulting in deaths because of the use of spurious and counterfeit drugs. ...(*Interruptions*) They are coming from various States. It is not only pertaining to one State. ...(*Interruptions*)

MR. SPEAKER: You are holding a meeting between yourself.

...(*Interruptions*)

SHRI BASU DEB ACHARIA : This is not pertaining to one State. The situation is same in almost in every State. Drugs are the essential components meant for the healthcare of the public. Quality of drugs is of paramount importance as these are consumed mostly by ailing patients. Circulation of spurious drugs is of great concern to everybody, namely, drug industry, regulator, those who are in medical profession and the general public. The IMA, the World Health Organisation and the Federation of Medical and Sales Representatives of the country have been campaigning for several years against circulation of spurious drugs but no concrete action has been taken to stop the circulation of spurious and counterfeit drugs.

Hon. Minister has described the circulation of spurious drugs as a social evil. We do not consider it as a social evil but as a criminal act. When a criminal act is being perpetrated in our country continuously for several years, why has no concrete action yet been taken? There is no stringent law prevailing in our country today. A number of Committees were appointed by the Government of India, starting from Hathi Committee to Dr. Mashelkar Committee. But the recommendations of those Committees are yet to be implemented.

Today, the total turn over in pharmaceutical industry is more than Rs.30 crore; in one report, it is said that the percentage of the spurious and counterfeit drug is 30 per cent and some other report says that it is 40 per cent. If 40 per cent of the drugs are counterfeit and if they are consumed by the patients, you can imagine what will happen to the patients. There have been deaths every year because of prescription of these drugs not only by the rural quacks but also by the Government hospitals, which are being supplied to the patients.

The hon. Minister has stated that several measures are to be taken. May I know from the hon. Minister whether the Government has ascertained the percentage of spurious drugs? What he has stated in his statement is that the figures stated by various organizations are exaggerated. How can the Government come to the conclusion that the figure is exaggerated?

MR. SPEAKER: Please put your question.

SHRI BASU DEB ACHARIA : Even the WHO has stated that the drugs which are coming from outside, up to 30 per cent of the drugs which are imported into this country, are spurious. If the production cost of one tablet is Re.1, it is sold to the people at Rs.10. The UPA Government, in its programme, is committed to reduce the price of drug so that the price will be affordable to the poor patients. So, I would like to know what action has been taken to reduce the price of drug. This issue of price does not pertain to the Ministry of Health and Family Welfare, but the Government is answerable to this House.

Secondly, as the situation has become so serious, what stringent measures – in addition to enactment of a legislation – the Government proposes to take to cut the circulation of drugs and also to take action against those who are manufacturing them. Sir, you will be surprised to know that the number of manufacturers has increased enormously, whereas the testing facility in our country, since 1995 has remained the same.

MR. SPEAKER: You are entitled to put question only. Please put your question. Please cooperate. Prof. Malhotra.

SHRI BASU DEB ACHARIA : There has not been any augmentation in regard to testing facilities, commensurating with the increase in the number of manufacturers. Thank you.

MR. SPEAKER: Please conclude. You know the rules very well. You have to ask a clarification.

Thank you very much for your cooperation. Prof. Malhotra.

**प्रो. विजय कुमार मल्होत्रा (दक्षिण दिल्ली):** अध्यक्ष महोदय, यह न राजनीतिक विषय है और न यह मामला ऐसा है जो किसी एक राज्य सरकार, दूसरी राज्य सरकार, केन्द्र सरकार या अभी का विषय है। यह बहुत ही गंभीर विषय है। मुझे केवल इस बात का अफसोस है कि मंत्री महोदय, जिनकी मैं इज्जत करता हूं, उन्होंने इस विषय को रखते हुए जो बयान दिया है, उन्होंने समस्या को लापरवाही से देखा है। उन्होंने कहा है -

> "The incidence of spurious drugs reported for the years 2004-05, 2005-06 and 2006-07 is between 0.182 and 0.29 per cent."

इसका मतलब एक परसेंट का भी पांचवा हिस्सा है। अगर यह हालत है कि 100 में से 99 प्रतिशत, आठ दवाइयां बिल्कुल ठीक हैं, तो आप एक्शन क्या लेंगे? 'Media Reports, and the figures quoted in Media are exaggerated' आपको यह कहने की आवश्यकता नहीं थी। आपने ड्रग इंसपेक्टर्स के बयान को ले लिया है। अब स्पूरियस ड्रग्स वालों से ड्रग इंसपेक्टर्स मिले हुए हैं। इस तरह अरबों-खरबों रुपये के धंधे में उनकी मिलीभगत है। बजाय इसके कि आप उन पर एक्शन लें, आप यह कह रहे हैं कि कोई समस्या ही नहीं है। इसमें आगे कहा गया है कि 19 हजार करोड़ रुपये का अगर बिजनेस है, तो चार हजार करोड़ रुपये

स्पूरियस ड्रग्स का बिजनेस है। अभी यू.पी. के बारे में वहां की चैम्बर में यह बयान दिया गया है कि twenty per cent of the drugs sold in Uttar Pradesh are fake. This is the study made. कोई 40 परसेंट कह रहा है, कोई 20 परसेंट तो कोई 30 परसेंट कह रहा है। They are mass murderers. ये सामूहिक नरसंहार कर रहे हैं। देश में आज भयंकर स्थिति है। आप इस मामले को, बजाय इसके कि यह होता कि कोई स्पूरियस ड्रग्स बनाने वाले को फांसी दी जायेगी, खंभे से बांध कर लटका दिया जाये, आप कह रहे हैं कि समस्या ही नहीं है, हालात ही कुछ नहीं हैं। प्वाइंट टू परसेंट मामले ही केवल पता लगे हैं और कोई समस्या नहीं है और यह भी कह दिया कि हम कानून की व्यवस्था पांच साल से दस साल करने जा रहे हैं।

अध्यक्ष महोदय, मैं मंत्री जी से कहना चाहता हूं कि यह स्टेट्स का मामला है, इसमें कोई शक नहीं है। परन्तु आयुर्वेदिक दवाइयों के साथ-साथ दूसरी दवाइयों में भी यही हो रहा है। आयुष की दवाइयों में यही हो रहा है और ऐलोपैथिक दवाइयों में भी यही हो रहा है। ये जो मॉस मर्डर, अभी पीछे एक चैनल पर सारी जगह पर कैसी दवाइयां खुले आम बनाई जा रही हैं, उसका पूरा स्टिंग आपरेशन करके दिखाया है। हम यह कह दें कि वे केवल एग्जेरेटिड हैं, जगह-जगह पर खुले आम फैक्टरियां चल रही हैं। इस बारे में सख्त कदम उठाने की जरूरत है। इसलिए मंत्री महोदय सिवाय समस्या को छोटा करने की बजाय राजनीतिक मामले से ऊपर ...(व्यवधान)

SHRI GURUDAS DASGUPTA (PANSKURA): Is it fit for liberalization?

**प्रो. विजय कुमार मल्होत्रा :** बाहर से भी दवाइयां आ रही हैं। बाकी चीजें भी हो रही हैं। हमारा मंत्री महोदय से कहना है कि वे इस मामले को बहुत गंभीरता से लें, सख्त कार्रवाई करें और देश को इनसे बचाया जाये।

SHRI BRAJA KISHORE TRIPATHY (PURI): Sir, the Statement made by the Minister, on behalf of the Government, is very much evasive and contradictory. It intends to shift the Central Government's responsibility to the State Governments. The Statement says that the State Governments are responsible to monitor the quality of drugs moving in the market. In another sentence the Statement says that the trading of counterfeit drugs is reported the world over. On the one hand the Government says that there is no such alarming situation and on the other it says that it is reported the world over and hence the Government is completely helpless to control this world over drug trading in the country. This has created confusion in the minds of entire country. In my opinion this spurious drug trade is spreading because of lack of stringent laws in the country.

Sir, the hon. Minister is supposed to be the Member of Indian Medical Association which has assessed that 35 per cent of the drugs sold in India are fake drugs. This is the statement of Indian Medical Association and not mine. The hon. Minister is supposed to be a Member of this Association. Data collated by the Health Ministry for the past decade shows that of the less than 40,000 samples tested every year, between 8 and 10 per cent did not meet quality standards. This is the statement of the Health Ministry. The Ministry has also stated the same before the Parliamentary Petitions Committee. How can the Minister say in the Parliament that it is between 0.182 and 0.29 per cent when the representatives of the Ministry have stated before the Petitions Committee of the Parliament that 8 to 10 per cent of the medicines available in the market are fake medicines or below quality standard? According to the World Health Organisation, the fake drugs market in India...(*Interruptions*)

MR. SPEAKER: What he said was that out of the samples tested, the fake drugs reported are between 0.182 and 0.92 per cent.

SHRI BRAJA KISHORE TRIPATHY : Below quality standard medicines are fake medicines and are not good for the health care.[R17] The Government has itself admitted it. It is also injurious.

MR. SPEAKER: I agree with him that it is mass murder.

SHRI BRAJA KISHORE TRIPATHY : According to the World Health Organisation, the fake drug market in India is worth Rs.4000 crore and one in four drugs is spurious. This is WTO's own survey.

Sir, the European Commission, Taxation and Customs Union has alleged that India is the biggest supplier of counterfeit drugs to the European Union. This is a shame to us. We are ashamed of it. Nearly one-fourth of Indian drugs export revenues worth over one billion dollar come from European Union market.

MR. SPEAKER: Come to your question now.

SHRI BRAJA KISHORE TRIPATHY : I am not exaggerating it. This is the statement of World Health Organisation and the European Commission. So, we must take it seriously.

Now India is seeing the epidemic of counterfeits of life saving drugs. We will make no apology for the use of the term manslaughters to describe this criminal and lethal trade. Indeed, we may call it murder. The Minister is not taking it seriously. His own statement says that it is not so much serious. The former Health Minister in the NDA Government, Mrs. Sushma Swaraj, had rightly proposed death penalty for these merchants of death. The call for death penalty for the makers of spurious drugs has long been given silent burial.

MR. SPEAKER: Now please come to your question part.

SHRI BRAJA KISHORE TRIPATHY : Sir, once this Bill was introduced in the Lok Sabha in 2003 but unfortunately the Lok Sabha was dissolved in 2004. A Committee was constituted under Dr. Mashelkar. It has also recommended certain good things. But the Minister is sitting over the Bill. I charge that the Minister is ...* sitting over the Bill for the last three and a half years.

MR. SPEAKER: That word will be deleted.

SHRI BRAJA KISHORE TRIPATHY : He is not introducing the Bill for the stringent measures which are necessary for the country to control the spurious drugs market.

MR. SPEAKER: You put your question.

SHRI BRAJA KISHORE TRIPATHY : Sir, when is the Government going to introduce the Bill regarding amendment to the Drug and Cosmetic Act, 1940? He could say that the Standing Committee is considering it but all these things have

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* Not recorded

been considered long ago. He is sitting over the Bill. He should tell us when he is going to introduce the Bill...(*Interruptions*)

MR. SPEAKER: If you want, I am prepared to have a proper discussion.

SHRI BRAJA KISHORE TRIPATHY : The country requires a legislation for strict penalties in pursuance of the recommendation of Dr. Mashelkar Committee with provision of special courts for drug related offences, compounding of offences, authorising the police also to file prosecution, making all drug related offences cognizable and non-bailable. We would like to know whether he is considering all these aspects of the recommendation...(*Interruptions*)

MR. SPEAKER: Now no more Mr. Tripathy. You see the rule about the Calling Attention Motion.

...(*Interruptions*)

MR. SPEAKER: I am sorry. Now, I would not allow. We are violating all the rules.

...(*Interruptions*)

MR. SPEAKER: Nothing more will be recorded now. The hon. Minister to reply now.

*(Interruptions) â€¡**

MR. SPEAKER: Mr. Tripathy, you have spoken for more than five minutes. You are entitled to put one question only.

...(*Interruptions*)

MR. SPEAKER: Now, do not record anything more.

*(Interruptions) â€¡**

SHRI ANIL BASU (ARAMBAGH): Sir, I also want to speak on this...(*Interruptions*)

MR. SPEAKER: As directed by me, you send your name to be associated.

...(*Interruptions*)

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* Not recorded

MR. SPEAKER: I will not allow, Mr. Basu.

...(*Interruptions*)

MR. SPEAKER: Then, I will ask the Minister not to reply and go away. I will not allow.

...(*Interruptions*)

MR. SPEAKER: You have never bothered even to give a notice.

SHRI ANIL BASU : Sir, I have given notice.

MR. SPEAKER: Your name has not come.[R18]

...(*Interruptions*)

MR. SPEAKER: If the hon. Members always disturb the House, then I am very sorry about it. Anybody has the right to disturb the House any time they like.

...(*Interruptions*)

MR. SPEAKER: Shri Basu, I have said that I will not allow you. You even did not bother to give a notice.

...(*Interruptions*)

SHRI ANIL BASU : Sir, I had given a notice at 9.40 a.m. ...(*Interruptions*)

MR. SPEAKER: Your name has not come in. Moreover, five Members are allowed to speak in a Calling Attention and I have allowed five hon. Members.

...(*Interruptions*)

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. ANBUMANI RAMADOSS): Firstly I would like to thank all the hon. Members, especially the senior Members for bringing this issue to the notice of the Government...(*Interruptions*)

MR. SPEAKER: Shri Deo, you come up with another notice, I will allow it.

...(*Interruptions*)

DR. ANBUMANI RAMADOSS: This issue of spurious drugs is a very serious, very critical and a very crucial issue in this country. I would like to assure you and through you the hon. Members of the House that the Government is taking all the steps necessary and the Government considers this as a very important issue. The Government is taking all steps necessary to eradicate the issue of spurious drugs and drugs related with this.

Sir, firstly I would just like to define very shortly the parameters. There are different types of drugs. One is the standard drugs, which is the normal drug. Then, we have sub-standard drugs; adulterated drugs, misbranded drugs; and then we have spurious drugs. These are the different types of drugs prevalent. All standard drugs are normal drugs. Sometimes a drug could be sub-standard because of the loss of refrigeration with a pharmacist, in which case the manufacturing could have been all right but when the drug reached the pharmacist there may not have been proper refrigeration owing to which the drug became sub-standard by way of temperature change and such other things. A lot of issues are there. But whatever be the reason it is not considered as a standard drug.

Sir, the Government in the last few years has taken a number of steps. First is to increase the penal and legal punishment which the Bill that I intend to introduce in this Session of Parliament envisages. Second is to improve upon the enforcement authority. We are setting up a Central Drug Authority. I would have introduced this Bill in the last Session of Parliament itself, but I was not given the opportunity to do so because the House got adjourned earlier. But I wanted to do it in the last Session itself...(*Interruptions*) Allow me to finish my reply and then you can ask your questions and I will reply then...(*Interruptions*)

MR. SPEAKER: Shri Basu, I have disallowed your question but even then you are insisting on this.

SHRI ANIL BASU : Sir, you are a legal luminary.

MR. SPEAKER: But I have to be an illegal person to deal with you!

DR. ANBUMANI RAMADOSS: Sir, this is a very serious issue. I am prepared to listen to the hon. Members and as I promised I would reply to all their queries...(*Interruptions*)

MR. SPEAKER: Mr. Minister, you may please carry on. You can ignore him. His submissions are not being recorded.

*(Interruptions) â€¦ **

DR. ANBUMANI RAMADOSS: Sir, the next point was about upgrading the enforcement authority. But then this is a Concurrent subject where both the Central and the State Government are part of it. I am not shying away from my responsibility but we have to work in tandem. Licensing, monitoring, enforcement, drug inspectors are all part of the State Government. Nevertheless we are trying to improve the enforcement authority at the State as well as at the Central Government level.

Sir, on this issue hon. Member, Shrimati Mahajan asked as to why World Bank funded money was being used for this enforcement. World Bank funded money was brought in by the last NDA Government. It was started during the NDA Government. There was a sum of Rs. 350 crore for capacity building. In fact, my predecessor Shrimati Sushma Swaraj was doing a very good work on this and during her tenure there was a very important Bill on this for discussion in the Parliament. I am continuing from what she had been doing. It is a continuous process.

Some hon. Members have said that the reply given is very evasive. But going by the reply I would say that it is a very elaborate reply wherein the Government has said what all steps are being taken. We are also training personnel at the State as well as the Central Government in consonance with the global regulatory pattern. This is a very important point. We have set up a new Pharmaco Vigilance Committee to monitor the adverse impact of drug and drug reaction all over the country. Then, we have modified Schedule M to make it monitoring mandatory for all units in this country and all units should have good manufacturing practice in consonance with global standards. These are so[MSOffice19]me of the things which we have taken up which I would not go into depth. But very briefly, I would like to say the other side of the drug industry in our country, namely, the goods side.

* Not recorded

Sir, the Indian drug industry is the fastest growing one in the world.

...(*Interruptions*) Please give me a few minutes to explain. Sir, he is such a senior Member. Why does he not give me a few minutes to speak?...(*Interruptions*)

MR. SPEAKER: Most reluctantly and painfully, with great sorrow, I had to take

action against an hon. Member who is like my own brother. I know him so well. But for the sake of the House, I had to do so. I am not threatening but let me not repeat it. Right or wrong, until you get me out of here, I will go on enforcing the rules . Therefore, please cooperate. Whether I give you an opportunity or not, you will find that I have followed the rules. I have also allowed, with your kind cooperation, two important issues to be raised. Now if any Member wants to do whatever he or she likes, then there is neither the necessity of the Chair nor the List of Business nor the rules. ाषEछ कहने की जरुरत नहीं है, हम तो डॉ पांडे को यहां बैठाकर चला जाएगा।

Give me a proper notice and I will try to give you an opportunity. .

DR. ANBUMANI RAMADOSS Sir, in fact, India has the fourth largest volume of pharmaceutical produces in the entire world and India has the highest USFDA approved pharmaceuticals outside the United States. The USFDA is one of the biggest and the most credible bodies in the entire world. It is the Food and Drug Administration Authority. It is the enforcement authority and nearly about 105 of our drugs are approved by the USFDA and EU has approved about 265 bulk items and 60 formulations. Initially, there were only two generic formulations from India approved by the United States. Today, there are about 350 generic formulations approved by the USFDA. Our pharmaceutical domestic growth last year was about 10 to 15 per cent and export was about 15 to 20 per cent.

And as regards the value of GDP, nearly about 2.5 per cent of the GDP is due to Indian pharmaceutical growth. In monetary terms, I could say that the domestic growth is nearly Rs. 36,000 crore and the export is about Rs. 24,000 crore This is the goods side of the industry and we are really doing well in the industry.

Sir, I am not denying that there is a problem. But the problem is not to the extent which has been created in the media saying that 30 per cent or 40 per cent or 50 per cent of the drugs are spurious drugs. It is not to that extent definitely. And the Government also has gone into the issue. We are going into it scientifically and we are getting a lot of inputs from the associations, the manufacturers themselves and also research studies.

MR. SPEAKER: The matter is serious. I am sure that the Government will take care of it.

DR. ANBUMANI RAMADOSS: Sir, I accept it. I am also a doctor and I also know the seriousness of the issue and what a spurious drug could do to a patient. â€¦ (*Interruptions*)

MR. SPEAKER: Certainly, even if it is 0.1 per cent.

...(*Interruptions*)

DR. ANBUMANI RAMADOSS: Sir, I share the concern of the hon. Member of the seriousness of the issue.

MR. SPEAKER: You agree with all that the hon. Members have said and then deal with it.

DR. ANBUMANI RAMADOSS: I share the concern of the hon. Member.

MR. SPEAKER: Shri B.K. Deo, no clarifications are allowed. I am sorry. Nothing will be recorded.

*(Interruptions) â€¦**

DR. ANBUMANI RAMADOSS: Sir, two Bills are going to be introducedâ€¦ (*Interruptions*) I will come to Orissa.

MR. SPEAKER: Please do not respond to him. I have not allowed him.

DR. ANBUMANI RAMADOSS: In the two Bills which are going to be

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* Not recorded

introduced, penal and legal punishment are dealt with. We have proposed life imprisonment for anybody found to be selling spurious drugs.

SHRI BRAJA KISHORE TRIPATHY : Why not death penalty?

MR. SPEAKER: You may bring an amendment to the Bill in the House.

DR. ANBUMANI RAMADOSS: That is the policy of the Government. The Government says that we will have life imprisonment and a fine for the person. Earlier, the fine was Rs. 10,000 and now we are making it Rs. 10 lakh Then we are making it a non-bailable offence and trying to have Special Courts for quickening the process of penal and legal implications. Of course, the National Drug Authority will be the enforcement agency and we will try to set it up as soon as it is passed in the Parliament and I am sure that after introduction, it will go to the respective Committee. It is going to be an autonomous professional body and we want it to be on the lines of the global bodies like the USFDA and EU. On the same lines, we are going to set up the National Drug Authority.

In fact, the hon. Members were asking what was the Government doing from 1975. There are Reports from various Committees like the Hathi Committee, Mani Committee and Mashelkar Committee. Finally, the UPA Government is going to do what has not been done in the last few years. We are going to do what has not been done in the last few years. We are moving on those lines. ...(*Interruptions*)

Coming to the issues raised by the hon. Members, Dr. Pandeya was saying that we are shrugging off our responsibility. We are definitely concerned about this problem. I had a lot of discussions with the authorities themselves. In fact, a lot of drug inspectors and drug controllers have been suspended at the State level because of their inaction. We are depending on the State Governments and the State enforcing authorities for the action. Prof. Malhotra mentioned about the samples. These samples were lifted by the State Governments. That is the information which I have to give to the entire House.

In this Session both the Bills will be introduced. ...(*Interruptions*) Dr. Pandeya was categorically saying that some of the chemists and druggists in the country are unlicenced. But according to law and according to the Act all of them must have licence. Not only the unit should have the licence but also the persons who are working there and those who are managing it. Without licence they cannot carry on their activities.

It is said that medicines are given without prescriptions. Drugs are made available over the counter. Since the number is huge – there are a lot of units in this country which have rural and urban base – we are not in a position to monitor each and every unit. But then we are trying to regulate them through the respective councils so that they can take action against them if anybody gives information about them.

Shrimati Sumitra Mahajan mentioned about unlicenced manufacturing. This is a clandestine operation. Dr. Pandeya was right in saying that most of these units who are doing this get the licence to majufacture a drug on the normal pattern. But during night or so, they manufacture these drugs clandestinely. This is very rampant and we are trying to take cognizance of it. If any hon. Member or anybody else gives information about this, we will take action immediately. I am not finding fault with the media and saying that it is exaggerated. I would also like to thank the media. Whenever there are some string operations, etc. immediately we send our officers. We need all necessary information from all parts of the country to take action against them.

There were some figures which were supposedly made by the Indian Medical Association. We approached the IMA to know whether they had given the statement. They had denied it. We asked the IMA whether they gave those figures. They said, "We have nothing to do with the statement." This is the status of it.

An hon. Member raised the issue about the labs and asked whether they are working properly. We are trying to see that they work properly. It is a continuous process. It is a World Bank aided project. We are spending nearly Rs. 350 crore on that. All the drug testing labs, both the Central Government and the State Governments are being modernized. Some of them have already been modernized. Modernisation is in regard to not only infrastructure but also in regard to man power. We are trying to train the man power in accordance with the global standards. We see to it that it takes place concurrently. ...(*Interruptions*)

MR. SPEAKER: Do not reply to him.

...(*Interruptions*)

DR. ANBUMANI RAMADOSS: Shri Basudev Acharia mentioned about WHO. He has asked whether WHO has stated that thirty per cent of the drugs in India are spurious. We asked the WHO about it. They have given a written reply to us saying that they have not issued any statement as such. ...(*Interruptions*) There is nothing to laugh in this.

This is a serious issue. We are not denying that this issue is not there in the country. We are trying to take all necessary steps to mitigate this problem. We are trying to improve the legal and penal punishment against anybody who is caught having these spurious drugs. Definitely, in the Amended Bill, which will be introduced shortly, there will be very stringent action taken against them. We are considering Mashelkar and Hathi Committee Reports. First, we are considering Mashelkar Committee Report. He has also recommended two parts. One is the enforcement part, and the second is the penal legal part again which we have incorporated.

Then a point was raised about the increase in testing facility. This is one of the good points which has been raised by the hon. Members. The Government has set up the required infrastructure, lab testing facilities and training of the manpower etc., and currently now 40,000 samples are being tested annually which is not enough. I agree with it. We need a minimum 100,000 samples to be tested every year. That is why, we are giving a lot of funds to the State Governments for requisite training of the personnel because they have the maximum manpower to test these facilities.

Sir, Prof. Vijay Kumar Malhotra has alleged that I have given a very irresponsible reply. But then this is a very elaborate reply and I would like to contradict him. He is a very senior Member and a very good friend of us. There are a lot of Committees in the Ministry of Health also. ...(*Interruptions*)

MR.SPEAKER: He is energising you.

DR. ANBUMANI RAMADOSS: He was also asking in Uttar Pradesh what was the action taken in this regard. In fact, in Uttar Pradesh, in Meerut, we have suspended the Drug Controller and the Drug Inspectors who are there. A lot of raids have been happening in that area. He was asking about the policy of the Government and also about the death penalty. In fact, I am continuing what my predecessor has recommended to the Government and the decision of the Government is that rather than death penalty, we will give a life imprisonment and will increase the fine. That is what we are trying to do. ...(*Interruptions*)

MR. SPEAKER: You cannot impose a penalty; the court has to impose a penalty.

DR. ANBUMANI RAMADOSS: Sir we are recommending.

MR. SPEAKER: Even if there is a provision for death, you cannot impose a penalty.

DR. ANBUMANI RAMADOSS: Sir we are recommending it in the Bill. ...(*Interruptions*)

MR. SPEAKER: We will have a proper discussion in my room with you.

DR. ANBUMANI RAMADOSS: Sir I would like to welcome Shri Anil Basu in my Chamber over a good cup of South Indian Coffee. ...(*Interruptions*)

SHRI ANIL BASU : Thank you very much.

MR. SPEAKER: Now you will keep quiet. But please do not give an impression that by disturbing the House, you will get Minister's invitation.

DR. ANBUMANI RAMADOSS: In fact, I have responded to Shri Tripathy's questions. I have responded about the IMA, WHO and other issues.

Sir, we have asked EU for their comments and reports. We have sent three reminders to the EU. They have not responded till date. I am not sitting on the Bill. We are definitely bringing the Bill before the House. We have introduced one part of the Bill in the last Session and during this Session, we will introduce both of them. I would like to request the hon. Members to pass both these Bills as soon as possible so that we could definitely increase the legal penal provisions and set up our Central Drug Monitoring Authority to monitor it. ...(*Interruptions*) We want to make the enforcement in a proper manner. ...(*Interruptions*)

Sir, with these few words, once again, I would like to assure the hon. Members and of course to the entire country that the Government has taken up this issue very seriously. It is a very serious issue. In fact, a number of studies have been done in this regard. I have asked the private agencies to do a lot of studies since there are a lot of clandestine operations. The Government also in the next four or five months is going to set up a very critical evaluation method. I will be bringing the facts and figures in the next Session as to what we are trying to do. It is going to happen throughout the country in a major way.

So, once again, I would like to assure through you, Sir to this House that we are taking this very seriously and if Members have any issues, they can bring it to my notice. ...(*Interruptions*)

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