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REPORTS OF THE LOGISTICAL SPECIALISTS

**INFLUENZA IMMUNIZATION CAMPAIGN 1991-2
FOR CENTRAL AND EASTERN EUROPE**

Cooperative Agreement No. EUR-0016-A-00-1013-00

Submitted to:

**The Office of European Affairs
Bureau for Europe and the Near East
United States Agency for International Development
Washington, D.C.**

by

**The People-to-People Health Foundation, Inc.
(Project HOPE)
Millwood, Virginia 22646**

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LOGISTICAL SPECIALIST REPORT

BULGARIA

SUMMARY

The objectives of the Humanitarian Assistance Program for Bulgaria as outlined in the "Scope of Work" document dated September 23, 1991, were used as the basis for this report. I will also provide a description of the names, places, and findings while in Bulgaria.

The donation program was facilitated greatly by Dr. Ivan Kirov, Chief Expert of the Humanitarian Assistance Department for the Ministry of Health, as well as Dr. Stanislav Popova, Chief Expert of the Epidemiology Department of the Ministry of Health, and their staffs. D. Mario Mirchev, director of the Communicable Disease program and on Dr. Popova's staff, was assigned to assist me shortly after my arrival, replacing Dr. Nadezhda Vladimirova. Dr. Mirchev, who also accompanied me on the visits outside Sofia, was very attentive to my requests.

SCOPE OF WORK

1. Provide pharmacology technical advice and expertise to the Bulgarians.

This activity involved some clarification of trade names, package sizes, and indications for use versus known trade names in Bulgaria. However, from Dr. Kirov's office down to the personnel in the basic health care polyclinics, the Bulgarians seemed very knowledgeable of the donated drugs and vaccines.

One unfortunate incident was that two bottles of Lanoxin Tablets (1000's) were repackaged in 7 envelopes, labeled improperly as to Lanoxin 25 mg and part of them transferred to institutions. A letter from Dr. Kirov's office also contained this mistake. I had all labeling and letters corrected. On my visits to health care institutions inside and outside Sofia, I talked personally with three physicians and made them aware of the problem.

2. Meet with the Minister of Health, pharmacy local PVO's, and physician personnel concerning drug usage.

The drugs were distributed according to the plans in Appendix I. I was able to witness the receipt at Medipharma, the pick up from Medipharma by two of the seven hospitals, and usage at one of the sites. Donation forms signed by three of the seven hospitals are attached. The

remaining four are being faxed to me by Dr. Mirchev, and I will forward them to Paul Miller as soon as they arrive. The transfer forms were distributed with the medications and will be held at the hospitals if used.

In discussion with Dr. Kirov, as well as directors and pharmacists of hospitals at four of the sites, it was apparent that their familiarity of the drugs coupled with the PDR's accompanying the drugs, that translations and further clarification of proper drug usage and storage were unnecessary. I did, however, leave Dr. Kirov with a letter clarifying usage of certain drugs and vaccines. See Appendix II.

3. To work with Bulgarian influenza campaign coordinator on planning logistics for the influenza campaign.
 - a. The influenza campaign will begin in mid-November and end in mid-December with all records of immunized populations being returned to the MOH by January 1, 1992. The vaccinations will be reported in the age groups recommended by WHO, dosage given, dates of administration, and comments on reactions. The influenza vaccine will be targeted for children, and people at risk (one category of which they interpret as health care workers).

A letter was sent to each of the 28 HEIs, (Hygiene and Epidemiologic Inspectorates - i.e., County Health Departments), explaining the campaign and required documentation. I provided the information in Attachment VII as an aid in composing this letter. The distribution plan is attached, and the syringes, destruclick containers, and syringe discard boxes will be distributed to each of the 28 counties according to the same percentage as the vaccines. See Appendix IV.

Each county will send a car to Sofia with a cooler box containing ice packs. There will be a brief meeting in Sofia of the directors of these county health departments clarifying any aspect of the influenza program when their vaccines and supplies are picked up, week of November 4th.

- b. The Mumpsvox, while only a third of what was requested by Dr. Popova, will be given to the larger institutions in Sofia County. With Dr. Vladimirova's illness and Dr. Popova called to a WHO meeting in Graboro, she was unable to provide me with the plan. I asked that the immunization distribution plans for both influenza and Mumpsvox be sent to Dr. Apfel in Bratislava and that

the immunization records be provided on a follow-up visit to Bulgaria by Dr. Apfel next year.

- c. The MOH experts, Dr. Popova's staff consisting of Drs. Mirchev, Suchova, Vladimirova, Popova will conduct follow-up visits during the vaccination campaign for auditing and educational purposes.
4. Facilitate Customs clearance for all materials shipped from HOPE Center.

Both air and overland shipments arrived in Bulgaria.

- a. The vaccine shipment arrived on October 12, 1991 (Saturday night). On October 14 (Monday morning), I went with Dr. Nadezhda Vladimirova to the airport Customs office where we received the vaccine and accompanied it to the Epidemiological Center in Sofia that afternoon. We stored it in a walk-in refrigerator.
- b. The overland shipment arrived at 5:00 AM on October 16, 1991, and I went with Milena Grigorova, Dr. Kirov's assistant to clear the shipment. But only until I obtained a document verifying the shipment as a donation from AID and Project HOPE to the MOH would they clear it. Gerald Zarr used U.S. Embassy stationery, on which we composed the letter. See Appendix V.

NOTE: I would suggest in the future that for any donation, a statement be made on the Shipment Notification form indicating FROM WHOM and TO WHOM. The current information, i.e.: packing list, Shipment Notification form, and other documents do not explicitly tie this information together.

I witnessed the breaking of the seal and container with Ms. Grigorova, and verified the correct number of shipment containers.

- c. The second airway shipment containing syringes and diluent arrived at the Sofia Airport on October 16, 1991 in the evening. It was not cleared through customs until October 22, 1991. This was due to inadequate work by a bonding agent. The shipment was released only when Dr. Mirchev and myself pursued the matter. This agent has been relieved from duty.

The HOPE "Donation Acknowledgment Receipt" form for the entire donation was signed by the Minister of Health, Dr. Chernozemsky on October 17, 1991, in a special media

ceremony arranged by Dr. Kirov. See attachment. For the effect, U.S. Ambassador Kenneth Hill signed the donation as a witness.

Present at the ceremony were Dr. Chernozemsky, Ambassador Hill, Gerald Zarr, Thomas Moore and Dr. Kirov. For the event Dr. Kirov had arranged a display of the donated drugs, which was also video taped. I requested a copy of the video from the TV station, but because of a different electronic system between the U.S. and Europe, it will not work in the U.S. I am attempting to see if a conversion can be done and will send to HOPE if I am successful.

5. Identify appropriate refrigerated storage at various sites with assistance of local authorities.

As outlined in 4.a. above, the entire shipment of influenza and Mumps vaccine was adequately stored in the walk-in refrigerator at the Epidemiological Institute. However, 4700 doses of Mumps vaccine was exposed to elevated temperatures during shipment to Bulgaria or while in customs. (1700 doses exposed to 2.5 marks on the Heat Index Strip, 3000 doses to 1.5 marks on the heat strip). These vials have been separated. They will either be used within 30 days of arrival in Bulgaria or re-assayed for potency before use, according to Dr. Popova. It will remain there under lock and key until distribution takes place week of November 4th, 1991. A discussion of storage sites at each HEI follows.

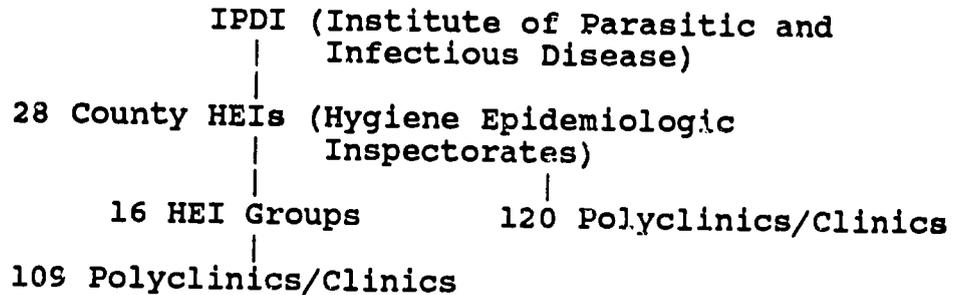
6. Assist with arranging local transport of the vaccines to refrigerated storage areas. (Cold chain must be maintained between 2 and 8 degrees Centigrade).

Transportation of the vaccine will be carried out in their normal manner, which involves a refrigerated truck for movement of large quantities within Sofia. Movement of vaccines to other centers is carried out as described in 3.a above, where each HEI sends a car to Sofia to pick up its own vaccines in thermal bags with ice packs inside.

I observed the cold chain not only in Sofia at the Epidemiologic Institute, but also at the HEIs in Sofia, Blagoevgrad, Plovdiv and several polyclinics in each of these HEIs. It was apparent that there are weaknesses in the cold chain. In a polyclinic in Blagoevgrad the thermometer was broken, and in a similar clinic in Plovdiv there was no thermometer at all. However, at the No. 11 Polyclinic in Sofia the temperature of the vaccines stored in the refrigerator there was at 4 degrees C.

These findings were supported by a report that I was inadvertently allowed to read of a cold chain study

conducted from January to June in Bulgaria by Dr. A. Battersby (U.K.) and sponsored by the WHO European Regional Office. Five counties took part in the study. The cold chain was identified as follows which remain intact today:



Dr. Battersby's report indicated that the chain was generally good, but pointed out several weaknesses, including the need for a refrigerator truck to the HEIs, more adequate coolers, and replacement of the older refrigerators when possible. In the interim he suggested the placement of 4 to 5 liters of salted water in the older refrigerators to hold temperatures better. In his report Dr. Battersby also provided brochures and addresses of examples of acceptable picnic chests (coolers).

7. Assist with arrangements for translation of literature which will be prepared for teams who are administering the immunizations and/or patients and/or their parents.

This activity was carried out as in 3.a above whereby a letter was sent from the MOH and a subsequent communication meeting in Sofia of the HEI directors with MOH personnel.

I also had discussions with personnel on my visit to several clinic sites. The physicians and nurses that I met at five different clinics in Sofia, Blagoevgrad and Plovdiv were very familiar with influenza and Mumps vaccine. Our discussion usually led to the advantages of the split virus over the live influenza vaccine they are accustomed to. In addition, a letter from the Ministry of Health will inform them of the plan and side effects of the vaccines.

8. Accompany immunization team to immunization sites on a random basis to assure appropriate use of vaccines.

Because of other vaccines having been given in October already and Dr. Popova's wish to wait 30 days before giving other immunizations, the influenza campaign and the Mumps vaccine campaign will be carried out after my visit. I have talked with health personnel at each of the clinics that I visited and feel secure in their understanding of the use of the donated vaccines.

9. Assist with record-keeping of individuals being immunized.

Since the campaign will be carried out after my visit, I will not be able to do this. However, I did work with Dr. Mario Mirchev of the Minister of Health in designing an immunization form for documentation of the donated vaccines.

10. Work with officials at distribution site to maintain security.

The medications were stored at Medipharma and the distribution carried out by them according to the attached plan to seven different hospitals.

The vaccines are locked in a walk-in refrigerator at the Institute of Parasitic and Infectious Diseases. The key is with Dr. Popova at the Ministry of Health until distribution. The syringes and diluent are locked up at the Central Lab for HIV Research in Sofia (due to lack of space elsewhere). Distribution will take place from these two centers.

SITE VISITS

1. Ministry of Health

- a. Epidemiology Department

Discussions of the Donation program were held with Dr. Stanislav Popova, Chief of the Department. She also accompanied me on visits to the Pediatric Institute and Institute for Infectious diseases. She thinks the major problems in Bulgaria are Hepatitis-B Infections (currently an epidemic in Plovdiv), Lyme Disease, and HIV Infections (there are 93 sero-positives in the country). WHO has been asked to assist with these problems.

Dr. Popova expressly asked me if we could provide Tuberculin syringe/needle packs. I told her that I would mention it in my report. She was away from the Ministry on an inspection in a county in the northwestern part of the country, and then away on a WHO sponsored conference on HIV in Graboro during my stay. From her staff Dr. Mario Mirchev, expert in communicable diseases, was my guide and assistant in carrying out my activities.

- b. Humanitarian Aid Service

Dr. Ivan Kirov, Chief Expert of the Department, met with me several times and discussed my needs. He made arrangements for the remainder of my stay before he left Bulgaria on October 22, 1991, for a ten day meeting in Italy.

In the last discussion with him, he asked for the status of the Oncohematology organization that AID/HOPE were considering at his request. He indicated that another program, the MSI in Arlington, Virginia, headed by Dr. Crystal, has worked out a plan for aid to Bulgaria in the area of oncology.

2. Sofia HEI (Hygiene and Epidemiological Inspectorate)

I met with Dr. Tanja Bahcrevanova, Epidemiologist, and Dr. Elena Nickolcheva, Epidemiology Director, in this HEI which is located on St. Vranja, N:20, Sofia. They demonstrated a telephone monitoring system for receiving reports of infectious diseases from the population of the 30 polyclinics and 5 clinics the Inspectorate is responsible for monitoring.

3. No. 11 Polyclinic under the Sofia HEI

Met with Dr. Lilly Aladjain, Chief Pediatrician, Dr. Alenka Velisarova, Medical Chief, and Dr. Penka Nardenova, Pediatrician at the Polyclinic. We discussed their vaccination schedules using BCG, Polio, DPT, Measles, Mumps, Rubella, Hepatitis A and B. We also discussed the donated vaccines and the planned influenza campaign. In this polyclinic, as is typically the case in Bulgaria, patients are seen until 12:00 noon; then the physicians and nurses make house calls visiting every home in their jurisdiction at least once a month. This polyclinic covers a population of 33,000 people, including about 5,800 children. There are six pediatricians, six nurses, 43 other specialty physicians and 17 dentists employed at the polyclinic.

I inspected a treatment room, and a thermometer check of the refrigerator indicated the contents were being held at 4 degrees C.

4. Institute of Infectious Diseases, Sofia.

Met with Professor Michael Radev, Director of Research and Dr. Rousey Vlaeff, Director of the Infectious Disease Hospital. The infectious diseases which predominate there are Hepatitis B, Prurulent Meningitis, Viral Encephalitis and Hemorrhagic Fever. We discussed the HOPE/AID donation, which I saw in use in the pharmacy. (A prescription for Rocef 1 Gm had been written for a patient with Lyme

Disease.) They have a policy to keep all prescriptions written for donated drugs in a separate file.

We also discussed the labeling problem with the Lanoxin 0.25 mg and corrected both the document and the actual medication container itself.

5. Institute of Pediatrics

Met with Dr. Anadoluska, Associate Professor of the Institute and also Chief of the Nephrology/Hemodialysis Clinic. We discussed efficacy of the split virus influenza vaccine. She will discuss with directors of all clinical specialties and properly inform them of the vaccine.

6. Blagoevgrad

a. HEI

Met with Dr. Dimitrov Mitzevsky, Communicable Disease Specialist, and Dr. Doumen Novoselsky, Acting Chief of the Communicable Disease Department of the HEI, who will be responsible for use of the vaccine. We discussed proper use of the vaccine and expected side reactions. I visited the immunization storage and saw proper refrigeration, as well as the thermos bags used for transporting vaccines from the HEI to the clinics.

b. Regional Hospital

Met with Dr. Peter Kamchev, Acting Director of the Hospital. We discussed this donation which he expressed deep gratitude for. He gave me a list of drugs they still badly need. (See Appendix VI.)

The Director is working with the "Pharmacists Without Borders" (French) and World Hospital (Belgian) organizations to purchase badly needed equipment and supplies at the best prices.

We reviewed the drugs which had already been picked up from Sofia. Half were not there. I noted which ones, and we called the Ministry of Health and Medipharma to discover what had happened. The remainder of the drugs were at Medipharma and were delivered on Friday, October 25, 1991.

c. Polyclinic

We visited the immunization clinic, and on inspection, I discovered that the thermometer in the refrigerator was broken. Dr. Novoselsky, embarrassed that a

Ministry of Health Expert would witness this, promised to remedy the situation.

7. Plovdiv

a. HEI

Met with the Director, Dr. Eugeni Dimitrov and saw a very clean, organized headquarters building. We discussed vaccines, and he indicated that he would follow the Ministry of Health recommendation to target Pediatric aged children.

In talking with him, he indicated that Bulgaria needs, among other things, disaster planning and has requested some material to rectify that need.

b. High Medical University

Met with Chief Pharmacist Jordan Milenkov and Dr. Ando Stezev, Medical Chief. Although they had not received the donated medication, we discussed the list, and I pointed out the Digoxin labeling problem. They were both very familiar with the drugs and were very appreciative of them, as well as the PDR.

Dr. Stezev indicated that they were in dire need of other drugs like Amikacin and Halothane. In the case of the latter drug, the Surgical Department has cancelled many types of surgeries for that reason.

c. Polyclinic No. 2

Accompanied by Dr. Fany Stoeva, Communicable Disease Specialist from the HEI, we met with Dr. Nadezhda Haitovc, Head of the Pediatric Unit and Tinka Kesovu, Chief Pediatric Nurse. We discussed the use of the split virus vaccine and its side effects, as well as the use of the destruclick and syringe disposable boxes. I inspected a refrigerator where vaccines are stored, and there was no thermometer. They explained that they used one thermometer between two refrigerators. I encouraged them to get another one.

LOGISTICAL SPECIALISTS REPORT

ROMANIA

Purpose: To ensure the complete and appropriate distribution of approximately 50,000 doses Influenza Vaccine, needles and syringes required for administration of the vaccine, monitor status of previously shipped antibiotics, and assist in the preparation for subsequent shipments of Hepatitis B vaccine and other medical supplies and equipment.

Relationships with all individuals in the Ministry of Health at Cantecuzina Institute, Colentina Hospital and other places were extremely pleasant. They were generous, helpful, and anxious to do everything required to accomplish the transfer of these and other materials useful in improving the health of the people of Romania. Drs. Nedelcu, Zolotusca, Popovici and Baldescu were especially hospitable.

The original plan submitted by Dr. Nedelcu was that the vaccine was to be distributed to institutes located in Bucharest and four additional areas of the country. It would be distributed from these five institutes to the 41 districts in which the target institutions are located. Sometime after my arrival, this scenario changed, and I was told there was no transportation to take the vaccine and syringes to the Institutes. Rather, it would be necessary for the Institutes to send cars to Bucharest to pick up the vaccine and distribute it to their assigned district sub-level epidemiologists. I pointed out that the volume of the equivalent number of syringes would preclude the use of small cars for such transportation. No response.

I was told originally there was insufficient refrigeration at the Institutes, which I found hard to believe, but accepted. Later I was told that refrigeration was no problem. This after I had scoured the city looking for household refrigerators we might purchase with AID counterpart funds. The "plan" was changed at least three times during my stay, and I began to suspect as early as 16-17 October that my efforts to insure distribution in accordance with HOPE's instructions were being stonewalled. These and other discrepancies were reported to Dr. Apfel during his visit, but we seemed powerless to protest too vigorously.

SYRINGES AND NEEDLES

Syringes and needles did not arrive until the day before my departure; they were scheduled for arrival on or about 14 October. Lufthansa made an arbitrary and unilateral decision to transfer from air freight to overland by truck at the Munich airport. Explained that smaller planes which service the

Bucharest airport have insufficient volume to accommodate such a large load.

Trucks were stopped at the Hungarian-Romanian border due to some attempts to smuggle arms and ammunition into Romania. All trucks were being stopped and search thoroughly. This was reported on Romanian television.

Constant calls to Lufthansa, threats, pleading, etc., could effect no change in the appearance of the syringes since the truck was already on the road. There seemed no point in transferring vaccine to regional Institutes of Hygiene and Public Health if there were no syringes with which to administer the vaccine.

Arrival of the shipment on Friday evening, 25 October, dictated, according to Dr. Nedelcu, that a truck and one or two assistants be "rented" for pick up at the airport and delivery of the syringes to Cantecuzina on Monday, 27 October. (The airport customs people required that they be notified 24 hours in advance of the anticipated arrival of personnel to pick up shipments.) The Ministry of Health "has no money" for such activities, and this will have to be arranged and paid for by the Bucharest Institute of H & PH.

INFLUENZA VACCINE

The influenza vaccine shipment arrived in Bucharest on the same flight with me Sunday, 13 October 91. Was transferred to Cantecuzina Institute the following day and placed in safe, refrigerated storage. Cold chain monitors indicated vaccine was not exposed to adverse temperatures between date of shipment and arrival. Temperature of storage area at the Institute registered 4 C.

Recommendation: Do not ship perishable biologicals and other drugs requiring refrigeration to arrive on week-ends. It is almost impossible to obtain transportation and retrieve shipment on Saturday and Sunday.

Printed Recommendations for Romanian Health Care Workers

Romanian health law specifies both the dose of influenza vaccine for children 6 months to 4 years of age (two doses of 0.1 ml. one month apart) and the interval between the most recent application of other vaccines, e.g. oral polio, BCG, etc. I expressed great concern about the dosage as it did not comply with CDC regulations or those recommended by Wyeth Laboratories in the package circular approved by the FDA. I convinced Dr. Nedelcu that these dosage guidelines should be followed closely. He revised the Romanian recommendations to be provided to the

districts and this was subsequently approved by the authorities at the Cantacuzino Institute. (See Romanian and English translations, Appendix B and Appendix C.)

Cantacuzino Institute Visit

At the Cantacuzino Institute I met with the Assistant Director, Dr. Constantin Ciufecu (Director Dr. Combiescu was out of town.), Dr. Adina Mogos, Dr. Sanda Biberi-Moroeanu, and Pharmacist Banica Ruxandra. All were extremely hospitable and, with the exception of Mrs. Ruxandra, we conversed easily in English. All expressed appreciation for HOPE's assistance.

Recommendations: Dr. Ciufecu pleads for the MSD Hepatitis B vaccine to be shipped in bulk for repackaging at the Institute.

Dr. Ciufecu feels that the expense of packaging on the American scene would pay for several thousand additional doses of vaccine. He can assure MSD that packaging by the Institute would meet all Romanian laws and standards while creating no hazards.

(COMMENT: I saw nothing in the Institute that would cause me to recommend this action.)

Samples of the Wyeth Influenza Vaccine had been received, tested, found to meet all Romanian standards, and approved for use in Romania. (See Appendix D - "Certificate of Control.") A "Certificate of Control" is also attached which attests to the quality of the Hepatitis B vaccine samples submitted previously. (See Appendix E.)

Dr. Ciufecu also assured me of the full cooperation of the Institute in complying with the planned influenza vaccine distribution program and necessary reporting to document its appropriate use.

Pharmacist Ruxandra conducted us to the cold storage area where we inventoried the vaccine shipment and found it to be correct. Ten cases with unbroken metal seals were present. We opened one case at random, retrieved the cold chain monitor and freeze watch indicators. All was in order. On a second visit with my interpreter I provided Mrs. Ruxandra with sample Transfer Forms and Acknowledgement of Receipt forms to be prepared each time vaccine was disbursed. She was told to hold the completed forms for the next visit of a HOPE representative or to mail them to Dr. Nedelcu at the Ministry of Health for later pick up by HOPE personnel.

On the follow-up visit with an interpreter, I re-emphasized the need for complete and accurate inventory control and reporting with Pharmacist Ruxandra. At that time, I also learned that Mrs.

Ruxandra is employed by the Ministry of Health rather than Cantacuzino Institute. As the person in control of the Influenza Vaccine, she is a "renter," and the relationships are not very warm.

Vaccine of Romanian Origin

Cantacuzino Institute is capable of producing 200,000 doses of Influenza Vaccine each year. It was hoped that the production run might increase to 300,000 doses for the 1991-92 season. Apparently, there is "no money" to support this increased effort. Suitable eggs from which to harvest the vaccine would cost approximately \$5.00 each.

On several occasions I expressed my concern about the plan to distribute the Romanian vaccine and the Wyeth product to the same districts. I feared that this would confuse the reporting. Dr. Nedelcu's response was, "not to worry." I was never able to obtain a plan which clearly outlined the manner in which these products would be distinguished except in their labeling.

Reusable Syringes and Needles

The original instructions drawn up by Dr. Nedelcu implied that reusable syringes could be used for the administration of the Wyeth vaccine. The document stated that syringes could be re-sterilized by boiling in a strong sodium hypochlorite (bleach) solution or by autoclaving. I strongly protested and asked that another edition be written which would make clear that only disposable syringes and needles should be used, that they should be used only once and that they be destroyed immediately after use. He willingly complied and included by suggestions. (See Appendix E.)

Publicity and Public Education

I was disturbed that no effort had been undertaken by the government to acknowledge the receipt of the vaccine or to provide some publicity concerning the arrival, distribution and importance of this substantial gift. This was discussed not only with those individuals at the Ministry of Health but with Dr. Havriliuc at the WHO office, Mr. Richard Hough at the AID office, and Dr. Apfel. All felt that it would have been appropriate for the government to undertake such activity. Dr. Nedelcu responded by saying that the public press, TV and radio media show no interest in cooperating with the Ministry on such programs. The Ministry has no press and documentation section to develop such news releases.

CEFMETAZOLE ("ZEFAZONE") INJECTION

Dr. Adrian Streinu-Cercel and Dr. Otilia Benea, Director and Assistant Director respectively at Colentina Infectious Disease Hospital were extremely gracious when I visited with them. A brief tour of portions of the very old building included a visit to the ward in which 35-40 young children with AIDS are housed and cared for.

I provided Dr. Streinu with a copy of the certificate from Upjohn extending the expiration date on the large supply of Zefazone which HOPE had shipped earlier. I was given an opportunity to see the balance of the antibiotic. Two rooms in the basement were jammed wall-to-wall and floor-to-ceiling with boxes of 1 Gm. and 2 Gm. vials. It was impossible to count or accurately inventory in that condition. I have confidence that Dr. Benea will properly account for its distribution. Copies of sample forms with which to record the disbursements were also provided with a request they be held for later retrieval. Some 6,000 vials have already been given to the adjacent Obstetrics and Gynecology pavilion and 1,000 Gm. have been administered to patients in the Infectious Disease wings.

Cefmetazole sensitivity discs were promised and supposedly shipped by Upjohn some weeks or months earlier. Dr. Benea, laboratory director, reported that they have never arrived. This situation has seriously hampered their ability to insure the appropriate use of this antibiotic. It must be used on an empirical rather than factual basis.

Recommendation: That Upjohn be requested to forward an additional supply of Cefmetazole ("Zefazone") sensitivity discs to Colentina Hospital as soon as possible.

SODIUM CHLORIDE INJECTION DILUENT FOR ZEFAZONE INJECTION

Dr. Streinu made an urgent plea that HOPE expedite the shipment of the promised Sodium Chloride Injection. There is no diluent available except for bags of commercial Sodium Chloride Injection for intravenous infusion. This is probably ideal, but it does not fit into their distribution system and they are also concerned that it may not be pyrogen free.

The military attache at the American Embassy told me that they have no word on an early Department of Defense flight to bring the saline and large shipment of clotrimazole ("Lotrimin") cream, ointment and solution. He also stated that Mr. Hough's office would be notified of the estimated arrival date of that shipment. A conference of all affected organizations will be convened approximately one (1) week prior to arrival. "If no one is there

to meet and take charge of the shipment, it will be available to the wolves."

I warned Dr. Streinu about the hazards of using large doses of sodium chloride injection with benzyl alcohol as a preservative in neonates. I also left them my personal copy of the American Hospital Formulary Service as a gift.

Recommendation: Arrange to have the 90,000 vials of Sodium Chloride Injection shipped as early as possible using some carrier other than the Defense Department.

The Colentina Hospital inventory of essential antibiotics is virtually depleted. They have no oral suspensions with which to treat young children and infants. This results in a total reliance on parenteral antibiotics when available - an unnecessarily expensive and traumatic method of treatment. They have no aminoglycosides such as gentamicin or tobramycin. The young pediatricians who accompanied me appealed for these essential, though relatively inexpensive, drugs.

Recommendation: Consider early shipment of essential oral antibiotics for oral suspension useful in treatment of pediatric infections; further, include a substantial supply of gentamicin or tobramycin and kanamycin for injection.

TRANSPORTATION AND DISTRIBUTION

I was thwarted at every turn as I attempted to discern how the vaccine and disposable syringes would be transported to those districts which lie several hundred miles from Bucharest. The trucks which HOPE had previously supplied to the Ministry were described as being in various states of disrepair. At any rate, they were non-functional and could not be used. Use of the small "Dacia" Romania cars was out of the question due to their small size. No insulated cold boxes were available.

Crown Agents

At Dr. Apfel's suggestion, I contacted Crown Agents, a British humanitarian group and, during three meetings, discussed at length their capacity to assist with the distribution and control of future shipments under HOPE's sponsorship. I also had an opportunity to visit the huge warehouse which they have leased on the outskirts of Bucharest.

I am firmly convinced that Crown Agents has the distribution of drugs, medical supplies, food and baby food under better control than any other agency currently working in Romania. They are dealing in millions of dollars worth of supplies coming from European Economic Community.

Their computerized inventory control and feed-back reports from the field are very efficient. Computers, fax and photo copy machines will be installed in the depots very soon to further streamline the inventory management. They possess a large fleet of trucks with and without refrigeration. The army has assigned a contingent of soldiers under the command of a young colonel who I met that has been of tremendous assistance as security, stevedores, and truck drivers. The relationship which has developed between Crown Agents and this military unit has been extremely symbiotic.

Their heated warehouse is clean, dry, very well organized, palletized, and free of insects and rodents as far as I could tell. No cold storage facilities exist at present, but they hope to have large capacity refrigerators installed shortly. There is adequate refrigeration in the depots.

Crown Agents is organized to deliver the needed supplies to 17 sub-level depots in strategic areas around the country. Some of these depots may be hospitals; others are private pharmacies. A total of 695 hospitals, creches, orphanages and other homes under management of the Ministries of Health, Labor and Education draw their supplies free of charge from the hospital sub-depots. Individuals and other agencies may draw from the private pharmacies, but are required to pay a small fee which is then returned to counterpart funds. This value system, they feel, is an essential part of the program. When persons receiving goods from the depots have to pay something, even a token amount, it is not considered useless. Thus, Romanians are participating in their own recovery rather than depending solely on handouts. (Dr. Havriliuc urged that HOPE develop a similar system so as to give some value to the materials we bring into the country. Otherwise, he feels that much of what we provide will be trashed.)

Crown Agents and their program really works. They know the right people, they know how to work the system, and, better still, know how to avoid the chaos of the existing system. When I pointed these facts out to Dr. Baldescu, he could not say that he had ever heard of Crown Agents. I note they are not included in the Ministry's Romanian Humanitarian Aid Directory.

In the event AID regulations prohibit the establishment of cooperative or consultative arrangements between HOPE and Crown Agents, Michael Fry, Crown Agents' senior logistics consultant, suggests that PATH (Program for Appropriate Technology in Health) located in Seattle might be useful in this regard. The address is:

P.A.T.H.
4 Nickerson Street
Seattle, WA 98109-1699
Tel: 206/285-3500

Recommendation: That HOPE investigate thoroughly the possibility of using the good offices of Crown Agents as managers of all subsequent shipment of humanitarian aid destined for Romania.

PLANNED HEPATITIS B VACCINE DONATION

On 22 October, Dr. Apfel and I spent considerable time discussing the late 1991, early 1992 Hepatitis B vaccination program for neonates with Drs. Nedelcu and Baldeşcu. Dr. Apfel will report more fully on this meeting. Dr. Apfel indicated that up to 500,000 doses may be forthcoming. Concerns about wastage and misappropriation by staff were raised. MOH must define and develop its strategy of immunization. Must define the dosage and schedule time frame as it relates to other immunization programs.

An educational conference utilizing some local and international experts and the Minister of Health at which up to 200 epidemiologists, obstetricians/gynecologists, pediatricians and nurses from around the country would be invited was discussed in detail. Dr. Apfel attempted to get a commitment for the government to pay travel expenses for those attending. Dr. Nedelcu agreed to develop a budget for submission to Dr. Apfel within a week. He also was to have made inquiries as to a suitable location. To my knowledge, he had done nothing by the time I left the country on 26 October.

My own investigation at the National Tourism Bureau identified what appeared to be an ideal location with a sufficiently large conference room at a ski resort in Sinaia. When I reported these details to Dr. Baldescu, he seemed very agreeable to the suggestion. Dr. Nedelcu shrugged them off and said nothing.

COMMENTS AND OBSERVATIONS

Failing Pharmaceutical Industry

I had an opportunity to spend some time with Mrs. Emilia Cheles, a pharmacist who works in a pharmaceutical manufacturing plant in Bucharest. She related that the facility is in serious difficulty due to years of neglect and the lack of replacement parts, raw materials, contemporary production methods and poor quality control. A large percentage of the total pharmaceutical needs of the country must be imported. The resulting drain of hard currency is difficult to support. She was unable to

identify any attempts currently underway to rebuild the pharmaceutical industry. None of my other contacts in the Ministry of Health could provide information indicating that any effort is underway to correct this serious deficiency.

It is axiomatic that nearly every medical decision results in a drug therapy selection. Surgery does not occur without drugs. Few radiological or laboratory examinations can be completed without drugs. The patient with cardiac, lung, GU, GI, OB or a host of other system failures must have drugs to survive.

Recommendation: Create a task force of pharmaceutical industry experts to review and make recommendations to rehabilitate the Romanian pharmaceutical industry as quickly as possible.

A New Minister of Health

Dr. Popovici, a young epidemiologist, and I were talking about the political situation which causes them so much distress. A new Minister of Health has just been appointed. He is an older man, a professor of pediatrics, whose son is active in the dominant political party. The epidemiology and preventive medicine group met with the Minister for the first time a few days after my arrival. (They did not even know his name.) They presented a review of their work which was backed up by graphs, tables and charts of their data prepared on the department's computer. He basically told them that what they are doing is of no value, that their fancy, computerized graphs and charts are useless. They tried to convince the new Minister that the country faces an escalating problem with AIDS.

His reply was that this is unimportant and not a problem. "In 10 years it will be a problem of sufficient magnitude to worry about; don't worry about it now. We've had cases of mushroom poisoning; that is something to worry about now." They were appalled by his insensitivity and shortsightedness.

It seems they need help in convincing the higher authorities of the credibility of their data and the long-run consequences of denying the problems they identify. There are over 250 epidemiologists in the country. I asked if there is an association representing these professionals and if they ever meet and develop consensus statements which might be used to influence health policy and political thought. Dr. Popovici replied that there is an association but that it is impotent. It met once last year and the meeting ended up in a "war." The older district epidemiologists show no interest in CDC methods the younger men have adopted and they decry the time wasted in data collection.

Credibility and Trustworthiness

During a rather candid discussion with Dr. Havriliuc, a native Romanian, he made the following statement in which I believe he was dead serious. Perhaps it deserves repeating for the benefit of others who might be assigned responsibilities in Romania: "Don't believe anything anyone tells you, including me."

He also urged that more attention be paid to conditions existing at the local district level rather than depending on the Ministry and hospital officials in Bucharest who will "continue to ask, ask, ask."

OTHER NEEDS

ELISA Reagent Kits

Cantacuzino and other Institutes with ELISA capacity are working effectively with the equipment. There has been adequate training of professional personnel, and the equipment is working well. Everyone is satisfied that all blood supplies are being screened for HIV and Hepatitis B. There is a problem with the existing supply of reagents.

Recommendation: Dr. Mogos desperately needs an additional supply of 500 Abbott reagent kits for the ELISA Hepatitis B antigen and 500 test kits for the ELISA anti-HBs. (See attached signed request.)

FDA Protocols

Recommendation: Dr. Biberi-Moroeanu requests an updated copy of that part of the Code of Federal Regulations dealing with the FDA and its regulatory functions and control of sera and vaccine production.

A Mouse

Recommendation: The epidemiology section at the Ministry of Health needs a mouse to support the data gathering and report generation they are conducting on the IBM PS/2 computer. If HOPE can supply this item, it should be shipped to Dr. Nedelcu as soon as feasible.

Absence of Purified Water at Colentina Hospital

Colentina Hospital has no source of distilled or purified water other than that which must be purchased. Two stills in the pharmacy are non-functioning. It is inconceivable to me that the hospital could provide adequate care without a reliable source of purified water. I could not discern how water and other fluids

are sterilized, but noted two very large "pressure cookers" standing idle in the halls and presume they were once used for this purpose. I received no indication that these distillation units need to be replaced, but I believe HOPE could provide a real service by arranging for one or more 10-20 gallon/hour high purity water stills with or without attached deionizing columns and carbon filtration units. This would require some additional review to determine if the existing steam plant and plumbing are capable of generating and carrying the necessary temperatures and pressures.

Failing Radiology Equipment

Dr. Streinu commented that the best X-ray unit at Colentina is now 14 years old and that the other unit is of 1942 vintage. He did not ask for assistance in obtaining newer equipment, but the need is obvious.

A PERMANENT PRESENCE FOR HOPE IN ROMANIA?

Dr. Apfel and I met with Dr. Rodica Maties, Director of International Cooperation, on 22 October to discuss the draft "Agreement on Technical Cooperation Between the Government of Romania and Project HOPE." The agreed upon draft was to have been submitted to the Minister of Health for his signature on 22 or 23 October. A number of minor changes were proposed and apparently agreed upon by Apfel and Maties. Dr. Apfel asked for a letter of intent from Maties indicating a positive approach to the conclusion of these negotiations and a signed agreement mutually satisfactory to both parties. Dr. Maties hoped to have these documents re-written and signed by the time I left Romania on 26 October. Apfel called and spoke with Maties in the interim, but nothing was given to me to return to Millwood. Did the Minister refuse? Did this new appointee not understand his own authority? Or did he fail to appreciate the strange bureaucratic structure within which he is now working?

CONCERNS INCREASED ABOUT INFLUENZA VACCINE DISTRIBUTION

My fears about the inability of the Ministry of Health to adequately control the utilization of the influenza vaccine were given added weight on 23 October. Drs. Nedelcu and Baldescu had a long session with representatives from Medecins Sans Frontieres (MSF). Apparently, the department was pressed to explain why 30,000 doses of Hepatitis B vaccine provided by MSF specifically for children in the east and south of the country had been distributed throughout the country where much of it was taken by staff and their families in the institutions they served. Due to its short expiration date, some urgency was required to complete

the three dose schedule. Delays in beginning the administration resulted in about 25% of the shipment being wasted.

CONCLUSION

I feel that I represented HOPE very well and made a number of useful contacts. Unfortunately, the delayed receipt of the disposable syringes prevented me from accomplishing the primary mission of ensuring the appropriate disposition of the influenza vaccine. I developed warm friendships and relations with people in the Ministry of Health and elsewhere. Everyone was cordial, friendly and helpful to the extent possible, considering the debilitated nature of the country and its economy. I believe we generally dealt from positions of mutual trust and respect. Confrontation never entered the picture, but their habit of evading my questions and providing conflicting answers was very frustrating.

I would be interested in knowing just what happens to be vaccine, now that we are out of the picture.

Thanks for giving me this marvelous opportunity. I enjoyed it in spite of the difficulties.

ATTACHMENT I

BULGARIA

APPENDIX I

DISTRIBUTION OF THE MEDICINES

Medicine name	Institute of Paediatrics	Hospital of Infec. Diseases	HMI Plovdiv	HMI Varna	HMI Pleven	HMI Stara Zagora	Regional Hospital Blagoevgr
Digoxin 5 mg amp. 2 ml	4 pk	3	2	2	2	2	2
Dopamine 80 mg amp. 5 ml	9 pk	10 pk	9	9	9	9	9
Physicians' desk Ref.	1 pk	0	1	1	1	1	1
Verapamil tabl. 80 mg	4 cs	8 cs	7 cs	5 cs +2BT	5 cs	5 cs	8 cs
Lanoxin tabl. ,25 mg	300	285	285	285	285	285	285
Fulvicin tabl. 125 mg	12 cs	10	10	10	10	10	10
Gentamycin sulfate, 20mg/2ml	1 cs	1 cs	1 cs	1 cs	1 cs	1 cs	1 cs
Gentamycin Garomycin 2 ml	3 cs	3 cs	3 cs	3 cs	3 cs	3 cs	3 cs
Amoxacillin susp. 250 mg/5 ml	825 BT	825 BT	825 BT	825	825	825	850
Celestone tabl. 0,6 mg	4 cs	4 cs	4 cs	4 cs	4 cs	4 cs	4 cs
Protamine sulfate 1% 5 ml	3 pk	6 pk	2 pk	2 pk	2 pk	2 pk	3 pk
Aminophillin amp. 250 mg/10 ml	85 pk	85	85	85	85	85	85
Heparin sodium 5 ml 10000 E/ml	74 pk	71	71	71	71	71	71
Boctrim susp. 480 ml	390 bot	385	385	385	385	385	385
Rocefine 1 mg	132 Bx	128 Bx	128 Bx	128 Bx	128 Bx	128 Bx	128 Bx
Siriuge W/Needle 1 cc, 25 G	16 cs	14 cs	14 cs	14 cs	14 cs	14 cs	14 cs
Siriuge W/Needle 3 cc 25 G	5 cs	5 cs	5 cs	5 cs	5 cs	5 cs	5 cs

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APPENDIX II

TO: DR. IVAN KIROV
CHIEF EXPERT, MINISTRY OF HEALTH

FROM: THOMAS MOORE
SOFIA - BULGARIA

DATE: OCTOBER, 18. 1991

SUBJECT: DONATION OF MEDICATION/VACCINES

We have discussed several things during my visit here in Sofia, but as a means of assuring certain details I issue this memorandum.

A. MEDICATIONS

1. The proper dose of Rocephin /Ceftriaxime/ per day is 1.0.Gm. This drug has been supplied to you in 1.0.Gm.Vials.

2. The Verapamil 80 mg. Tablets were issued to you from 2 different manufacturing companies.

3. Both adult strength and pediatric strength injectable Gentamycin /Garamycin/ were issued to you.

B. VACCINES

1. The diluent for the mumps VAX should be used to reconstitute /mix/ the vaccine to assure that it is not inactivated by water containing preservatives.

2. The destruclick / H 5685/ boxes should be used to break the needle off the syringe after immunization.

3. The boxes /H HRI 8881-675006/ should be used to discard contaminated syringes after immunization.

4. The 4,700 doses of mumps vaccine that were exposed slightly above 10°C, must be used within 30 days or after assay by the Epidemiological Institute at Dr. Stanislav Popova's discretion.

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APPENDIX III

SCOPE OF WORK
Thomas M. Moore, M.S.

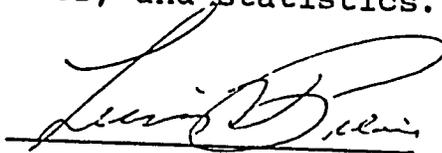
PROGRAM: Advance Team
Eastern Europe, Humanitarian Assistance

POSITION: Pharmacology Advisor
Bulgaria

DURATION: Depart U.S.--October 12, 1991
Return U.S.--October 26, 1991

1. Provide pharmacology technical advise and expertise to the Bulgarians.
2. Meet with the Minister of Health, pharmacy, local PVO's, and physician personnel concerning drug usage.
3. To work with Bulgarian influenza campaign coordinator on planning logistics for the influenza campaign.
4. Facilitate customs clearance for all materials shipped from HOPE Center.
5. Identify appropriate refrigerated storage at various sites with assistance of local authorities.
6. Assist with arranging local transport of the vaccine to refrigerated storage areas. (cold chain must be maintained between 2 and 8 degrees Centigrade)
7. Assist with arrangements for translation of literature which will be prepared for teams who are administering the immunization and/or patients and/or their parents.
8. Accompany immunization teams to immunization sites on a random basis to assure appropriate use of vaccines.
9. Assist with record keeping of individuals being immunized.
10. Work with officials at distribution site to maintain security.
11. Write a comprehensive report at the conclusion of your trip for submission to HOPE Center. This report should include all pertinent experiences, and statistics.

Prepared and Approved by:



Date: 9/23/91

APPENDIX IV

DISTRIBUTION OF THE INFLUENZA VACCINE IN BULGARIA, 1991

HEI / REGION	No of doses
1. Blagoevgrad	2500
2. Burgas	2700
3. Varna	3000
4. V. Turnovo	1500
5. Vidin	800
6. Vratza	1500
7. Gabrovo	800
8. Kurdzhaly	2000
9. Kustendil	1000
10. Lovech	900
11. Michailovgrad	1100
12. Fazardzic	2000
13. Pernic	800
14. Pleven	2000
15. Plovdiv	5000
16. Razgrad	1300
17. Rousse	1600
18. Silistra	1000
19. Sliven	1500
20. Smoljan	1500
21. Sofia (cap.)	6200
22. Sofia (county)	1300
23. St. Zagora	2000
24. Dobrich	1000
25. Turgovishte	1100
26. Hascovo	1700
27. Shoumen	1500
28. Jambol	700
Total	50000

APPENDIX II

To The Bulgarian Government
- Ministry of Health

10/16/91

This is to certify that the medical supplies and vaccines provided by Project Hope, and which arrived today are a program of humanitarian assistance financed by the United States Agency For International Development, the agency of the United States government that administers economic and humanitarian assistance worldwide.

The shipment arrived on truck number HH 1973 and container number ITLU 667257.

Would you please extend the usual customs free entry privileges to this humanitarian aid shipment financed by the United States Government.

Sincerely yours,

Gerald Zarr
Director of U.S. Agency for International
Development Office
Sofia, Bulgaria

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APPENDIX VI

DEAR GENTLEMEN, FRIENDS

THE CITY HOSPITAL OF BLAGOEVGRAD NEEDS OF YOUR
HELPS. WE NEEDS OF SOME MEDICINES AND CONSUMATIVES.

I ANTIBIOTICA CEFTAZIDIME,

A/ Cefalosporines - Ceftazidime, Cefnroxime, Cephalaxine,
Cefatxim, Ceftriaxone, HaMospok.

b/ Amivaciues

c/ Penicillines and semisintetic penicollies

d/ Tetracyclines

i/ Amnotericin - / Fungizou/

2. Sulfoamioles - Septriy, Cotrimoxazole.

3. Anticoggnlntia - Heparin, Sintrom, Calciparin.

Warfdrine

4. Corticosteroida - Celcosteron, Methylnprednisolon

Hydrocortison, Decaolron.

5. Caroliaca - Digitalin, Digoxin, Lanitop,

Cordaron, Rhitmonorm, Rhitmilen

Dopamin, Dobntrex

Isoket, /Isosorbitdinitrat/

Naniprus.

6. Antihistaminica - Tavegyl, Fenistil,

7. Analgetice - Fentanyl, Fentarociue

Dipidobhor, Petidine

8. Anticonvulsiva - Phenobarbital, Tegretol, Stazepin.

9. Benzodiazepines - Dormicum, Diazepam

Nalocson, Rivotril

10. Diuretica - Triampur, Spironolacton

II. Antidiarrgoica - Yntetrix - P, Imodium.

12. Vasodilatantia - Dusodril, Trental,

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13. Antiemetica - Cerucal, Reglan.
14. Atropine amp.
15. Novphillin
16. Aprotine - Trasylol
17. Beclometazone.
18. Chlorhexidine - Hibitan
19. Neuroleptica - Haloperidol
20. Insulin, Actrapid, NC
21. Sulfate Ferreux - Ferrogradumet.
22. Anesthetice - Lidocain, Mesocain, Bupivacain
23. Metronidazole - Flagul.
24. Methylethergometrin.
25. Bicarbonate de sodium.
26. Protamine sulfate, Pancronium Bromid.
27. Pyridostigmine Bromure - Kalymin, Mestinon.
28. Pentothal sodiane - Thyopentrol.
29. Narcotica, inhalat., Flopan, Halotan.

Code	Description	Unit	Price	Quantity	Total
	MATERIEL DE VENTILATION				
8951	CANULES DE GUEDEL NON DISPOSABLES, SET DE 5		610.50	10	6105
	SONDES ENDOTRACHEALES NON DISPOSABLES, 3 MM		2497.50	1	2498
	SONDES ENDOTRACHEALES NON DISPOSABLES, 4 MM		2497.50	1	2498
	SONDES ENDOTRACHEALES NON DISPOSABLES, 5 MM		2497.50	1	2498
	SONDES ENDOTRACHEALES NON DISPOSABLES, 6 MM		2497.50	2	4995
	SONDES ENDOTRACHEALES NON DISPOSABLES, 7 MM		2497.50	2	4995
	SONDES ENDOTRACHEALES NON DISPOSABLES, 8 MM		2497.50	4	9990
	SONDES ENDOTRACHEALES NON DISPOSABLES, 9 MM		2497.50	3	7493
	SONDES ENDOTRACHEALES NON DISPOSABLES, 10 MM		2497.50	2	4995
7263	SONDE A OXYGENE CH 10		777.00	10	7770

20'

ATTACHMENT VII

Precautions for wyeth influenza vaccine

1. Do not use for persons known to have anaphylactic hypersensitivity to EGGS.
2. Do not use for persons with acute febrile illness until fever is passed.
3. Soreness at site of vaccination for 1 to 2 days is reported to occur in 0- 30% of persons vaccinated.
4. Fever, malaise and myalgia may occur in persons who were not previously vaccinated. These reactions could occur within 6- 12 hours after vaccination and last for 1 to 2 days.
5. Allergic reactions such as hives, angioedema, asthma or anaphylaxis occur rarely and are believed to be related to egg allergy, although there is only a small quantity of egg protein in the vaccine.
6. Influenza vaccine should not be given within 3 days of vaccination with pertussis vaccine.



Founded in 1958

THE PROJECT HOPE HEALTH SCIENCES EDUCATION CENTER, MILLWOOD, VIRGINIA 22646 (703) 837-2100
FAX (703) 837-1813

DONATION ACKNOWLEDGMENT RECEIPT

The Ministry of Health of Bulgaria (country or state) certifies that the donation of Pharmaceuticals and Medical Supplies from Project HOPE has been received. The Ministry of Health further certifies that the donated materials will not be sold, but shall be distributed at no charge to the respective Hospitals, Dispensaries, Public Health facilities and other public agencies which serve the poor, the needy, or those suffering from medical conditions in which these medical supplies are appropriate.

The Ministry of Health herewith acknowledges the receipt of Pharmaceuticals and Medical Supplies. An accounting of where these products are being distributed will be given.

AWB # I96-0339-305I

BOL # I3I44, AWB # I96-0339-3I80

Shipment Identification
(BOL #, AWB #, Container #
or Other Appropriate number to
identify this shipment)

October 16, 1991 4:00 PM

Date and Time Received

Ivan Chernozemsky

Name of Authorized Receiving
Agent for the Ministry of
Health

October 17, 1991

Date

Minister of Health

Title of Receiving Agent

Seal/Stamp of Institution

Signature of Receiving Agent

[Handwritten Signature]

Witness



Founded in 1958

THE PROJECT HOPE HEALTH SCIENCES EDUCATION CENTER, MILLWOOD, VIRGINIA 22646 (703) 837-2100 FAX (703) 837-1817

DONATION ACKNOWLEDGEMENT RECEIPT
RECIPIENT INSTITUTION

This acknowledges receipt of the following pharmaceuticals and/or medical supplies. By signing, the recipient agrees that these items will not be sold nor be offered, nor made available to any party with intentions to sell or profit from the products. The products will be distributed at no charge to needy patients who are under the care of this institution.

The recipient institution further agrees to record the receipt of all products provided and the disposition or issuance within the institution. It agrees to provide written confirmation for review by the donor of all products received and issued upon the request of the donor.

* * * * *

Table with 2 columns: PRODUCT and QUANTITY. Includes items like Siringe W/Needle I cc, 25 G (14 cs), Dopamine 80 mg, amp, 2 ml (9 pk), Digoxin 5 mg amp; 2 ml (2 pk), etc.

Seal/stamp of Institution



Institution Name: Medical University

Address: Karl Marx Str. N I

City: PLEVEN

Date: 18. 10. 1991

Authorized Signature: Radka Valkova Mileva

Title: Director of pharmaceutical stock

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Founded in 1958

THE PROJECT HOPE HEALTH SCIENCES EDUCATION CENTER, MILLWOOD, VIRGINIA 22646 (703) 837-2100
FAX (703) 837-1813

DONATION ACKNOWLEDGEMENT RECEIPT RECIPIENT INSTITUTION

This acknowledges receipt of the following pharmaceuticals and/or medical supplies. By signing, the recipient agrees that these items will not be sold nor be offered, nor made available to any party with intentions to sell or profit from the products. The products will be distributed at no charge to needy patients who are under the care of this institution.

The recipient institution further agrees to record the receipt of all products provided and the disposition or issuance within the institution. It agrees to provide written confirmation for review by the donor of all products received and issued upon the request of the donor.

* * * * *

PRODUCT	QUANTITY
Syringe w/Needle 3 cc, 25 G	5 cs ✓
Digoxin 5 mg amp. 2 ml	4 pk ✓
Dopamine 80 mg amp. 5 ml	9 pk ✓
Physicians' desk Ref.	1 pk
Verapamil tabl. 80 mg	4 cs ✓
Laudax tabl. 25 mg	30 ✓
Fulvicin tabl. 125 mg	12 cs
Gentamycin sulfate, 20 mg/2 ml	1 cs ✓
Gentamycin Garamycin 2 ml	3 cs ✓
Amoxicillin susp. 250 mg/5 ml	825 bt ✓
Celastone tabl. 0,6 mg	4 cs ✓
Protamine sulfate 1% 5 ml	3 pk ✓
Aminophyllin amp. 250 mg/10 ml	90 pk ✓
Heparin Sodium 5 ml 10000 U/ml	74 pk ✓
Protien susp. 180 ml	390 bot ✓
Rofefine 1 mg	132 bx ✓
Syringe w/Needle 1 cc, 25 G	16 cs ✓

Seal/stamp of Institution

Institution Name: Institute of Pediatrics

Address: 11, Dimitar Nestorov Str.

City: Sofia

Date: 18.10.1991

Authorized Signature: Dimitar Stoinov

Title: Supplier



of Directors: Joseph E. Abels, Jr., J. Patrick Powell, Head of U. Bloom, PhD; G. D. W. Fisher, J. Campbell, Ph.D.; Elizabeth G. Cole, Theodore Cooper, M.D., Ph.D., and Day, Raymond E. Calender, M.D.; Henry Gen. D. Kelly, David L. Jones, M.D.; A. Tucker, M.D.; Robert L. Turner, M.D.; J. L. G. Lee, Paul L. Underberg, Jr., Robertson, Ph.D.; M. J. Adams, Robert A. Landreth, M.D.; Victor B. V. M.D.; David L. Wilson, Joseph D. Adams, College; Joseph D. Williams, Chairman; W. W. H. G. L. President; and other members of the Board: Henry Lee, Jr., M.D., Ph.D.; Douglas J. Rubin.



Founded in 1956

THE PROJECT HOPE HEALTH SCIENCES EDUCATION CENTER, MILLWOOD, VIRGINIA 22646 (703) 837-2100
FAX (703) 837-1813

DONATION ACKNOWLEDGEMENT RECEIPT RECIPIENT INSTITUTION

This acknowledges receipt of the following pharmaceuticals and/or medical supplies. By signing, the recipient agrees that these items will not be sold nor be offered, nor made available to any party with intentions to sell or profit from the products. The products will be distributed at no charge to needy patients who are under the care of this institution.

The recipient institution further agrees to record the receipt of all products provided and the disposition or issuance within the institution. It agrees to provide written confirmation for review by the donor of all products received and issued upon the request of the donor.

* * * * *

PRODUCT	QUANTITY
Digoxin 5 mg amp, 2 ml	3 pk
Diphenhydramine 10 mg amp, 5 ml	10 pk
Verapamil tabl. 80 mg	8 cs
Lidocaine tabl. 50 mg	285
Fulvicin tabl. 125 mg	10 cs
Gentamicin sulfate, 20 mg/2 ml	1 cs
Gentamicin amp, 2 ml	3 cs
Amoxicillin susp 250 mg/5 ml	855 Bx
Cholestyramine tabl. 0.6 mg	4 cs
Procaine sulfate 1% 5 ml	6 pk
Aminocillin amp 250 mg/10 ml	85 pk
Heparin sodium 5 ml 4000 U/ml	71 pk
Procton susp. 400 ml	385 bot
Roxycne 1 mg	128 Bx
Syringe W/needle 1 cc, 25 G	14 cs
Syringe W/needle 3 cc, 25 G	5 cs

Seal/stamp of Institution

Institution Name: Hospital of Infect. Diseases

Address: Dimitar Nestorov Blvd. 17

City: Sofia

Date: 18.10.1991

Authorized Signature: Rousey Vlaeff

Title: Main Physician



ATTACHMENT II

ROMANIA

APPENDIX A

ANNEX 1

List of sub-national coordinators involved in influenza vaccination with Wyeth vaccine - 1991-1992

- 1 . Institutul de Igiena si Sanatate Publica - BUCURESTI
Str. Dr. Leonte nr. 1 - 3 , Sector 5
- Dr. Anca Balan - epidemiologist
- 2 . Institutul de Sanatate Publica si Cercetari Medicale - IASI
Str. Dr. Victor Babes nr. 14 , cod 6600
- Dr. Ioan Buzdugan - chief epidemiologist
- 3 . Institutul de Sanatate Publica si Cercetari Medicale - CLUJ
Str. Pasteur nr. 6 , cod 3400
- Dr. Nicolae Ionescu - Director
- 4 . Institutul de Sanatate Publica si Cercetari Medicale - TIMISOARA
Str. Dr. Victor Babes nr. 16 - 18 , cod 1900
- Dr. Livia Plavosin - chief epidemiologist

APPENDIX B

MINISTERUL SANATATII
DIRECTIA MEDICINEI PREVENTIVE

VACCIN GRIPAL, TRIVALENT TIP A SI B, PURIFICAT, SUBUNITAR FORMULA 1991-1992, WYETH LABORATORIES INC., SUA.

DESCRIERE.

=====

Vaccinul gripal trivalent tip A si B, subunitar, este o solutie sterila pentru inoculare intramusculara. Vaccinul este preparat pe baza de gama inoculate cu virus gripal. Virusul cultivat este inactivat cu formaldehida, concentrat si purificat. Vaccinul contine numai antigenele gripale triple de in protectia specifica, cantitatea standardizata de hemaglutinina si antigenelor recomandate pentru sezonul 1991-1992 pe doza de 0,5 ml fiind urmatoarea:

- A/Taiwan/1/86(H1N1) = 15 micrograme HA
- A/Beijing/353/89(H3N2) = 15 micrograme HA
- B/Panama/45/90 = 15 micrograme HA

Vaccinul contine 1:10000 thiomersal ca prezervant.

In timpul prepararii vaccinului se utilizeaza gentamicina, dar in produsul final aceasta nu se detecteaza prin tehnicile curente de laborator.

PREZENTARE, CONDITIONARE, CONSERVARE.

=====

Vaccinul Gripal Trivalent Tip A si B, Purificat, Subunitar, Wyeth, este conditionat in flacoane de 5 ml, care contin 10 doze tip adult a 0,5 ml. Produsul se pastreaza la plus 2 - 8 grade Celsius. NU SE COMBILIAZA!

INDICATII SI UTILIZARE.

=====

Vaccinul Gripal Trivalent tip A si B, Purificat, Subunitar, Wyeth, este indicat pentru urmatoarele categorii de persoane:

1. Persoane in virsta de peste 60 ani.
2. Persoane (batrini si copii) rezidente in institutii tip: leagane, casele copii, unitati de handicapati, unitati de distrofici, camine de batrini, spitale de batrini, precum si salariatii acestor institutii.
3. Adulti si copii care sufera de boli cronice cardiovasculare si pulmonare (inclusiv astm), boli cronice metabolice (inclusiv diabet zaharat), disfunctii renale, hemoglobinopatii, imunosupresii (inclusiv induse medicamentos).
4. Gravide in special in primele trei luni de sarcina.
5. Personal medico-sanitar si auxiliar din unitati sanitare cu paturi si ambulatorii.
6. Grupuri de persoane care activeaza in servicii de importanta deosebita

CONTRAINDICATII

=====

- a) Persoane cu hipersensibilitate (alergie) la ou si carne de pasare;
- b) Persoane cu hipersensibilitate la gentamicina si alte aminoglicozide;
- c) Persoane cu antecedente de sindrom Guillain-Barre;
- d) Persoane cu boli febrile acute;

N.B. Infectia HIV manifesta sau asimptomatica NU este o contraindicatie intru vaccinarea antigripala cu vaccin gripal Wyeth.

APPENDIX C

MINISTRY OF HEALTH
DIRECTION OF PREVENTIVE MEDICINE

PLAN FOR VACCINATION WITH INFLUENZA VACCINE WYETH =====

1. INTRODUCTION

Ministry of Health have accepted humanitarian help from US Agency for International Development and Project Hope consisting of influenza vaccine Wyeth with antigenic component recommended by W.H.O. for influenza season 1991-1992, and also of disposable syringes and needles necessary for vaccine inoculation.

Utilisation of U.S. influenza Wyeth vaccine in Romania is approved on the basis of Control Certificate no. 424 from 15 October 1991 issued by Control State Center for Human Use Biological Products - MOH.

2. VACCINE UTILISATION

Influenza vaccine Wyeth is destined for specific protection in the following groups considered at risk:

- persons - children and elderly - institutionalised, and personnel working in these institutions including: orphanages, homes for preschool and schoolchildren, institutions for children with protein calories denutrition and other impairment, homes and hospitals for elderly etc.

- children, adults and elderly which need medical follow-up for chronic diseases;

- persons over 65 years of age;

- personnel working in medical settings at risk to transmit influenza or to be infected by patients.

Schedule of vaccination with influenza vaccine Wyeth depending of age group is as follow:

- children between 6 month and 35 month of age will receive two doses of 0.25 ml at 4 weeks apart;

- children between 3 years and 8 years will receive two doses of 0.5 ml at 4 weeks apart;

- persons of 9 years and over of age will receive a single dose of 0.5 ml.

3. VACCINE DISTRIBUTION

Influenza vaccine Wyeth and medical supplies for intramuscular inoculation will be distributed in the field in two stages:

- stage 1 will consists in distribution from central storage of Institute Cantacuzino to the four territorial Institutes of Hygiene up to 31 October 1991. In this stage the Institutes of Hygiene will take care with vaccine and medical suppliers taking over, transportation and storage of vaccine in refrigeration conditions.

N.B. In annex nr. 1 there are postal addresses and name of chief epidemiologist of the four territorial Institutes of Hygiene

- stage 2 will consists in distribution of vaccine from each territorial Institute of Hygiene to district Preventive Medicine Centers up to 15 November 1991. In this stage Preventive Medicine Centers will take care with vaccine and medical suppliers taking over, transportation, storage and distribution, in function of locally identified needs.

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Nr.424/15.X.1991

Către

MINISTERUL SANATATII
Direcția Medicinii Preventive

CERTIFICAT DE CONTROL

=====

Produsul: INFLUENZA VIRUS VACCINE

Lot: 4918181

Firma: WYETH-AYERST LABORATORIES

Sterilitate: 14 zile la 37°C și 20°C = satisfăcător

Inocuitate nespecifică: (șoareci și cobai) = satisfăcător

pH = 7,05

Neproteic: 32 μg/ml.

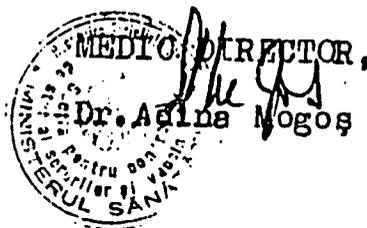
Proteină (Lowry) = 470 μg/ml.

HA (H₃A/Beijing/352/89) = 35,5 μg/ml.

HA (H₁A/Singapore/6/86) = 31,04 μg/ml.

HA (B/Panama/45/90) = 28 μg/ml. - Test făcut cu referința
B/Yamagata/16/88.

Ovalbumină ≤ 3 μg/ml.



APPENDIX E

MINISTERUL SANATATII
Centrul pentru Controlul de Stat
al Produselor Biologice de Uz Umen

Nr.425/15.X.1991

Către

MINISTERUL SANATATII
Direcția Medicinii Preventive

CERTIFICAT DE CONTROL
=====

Produsul: RECOMBIVAX HB

Firma: MERCK SHARP DOHME

Lot: 0782 T.

Sterilitate: 14 zile la 37°C și 20°C = satisfăcător

Inocuitate nespecifică: (șoareci și cobei) = satisfăcător





Founded in 1953

THE PROJECT HOPE HEALTH SCIENCES EDUCATION CENTER, MILLWOOD, VIRGINIA 22646 (703) 837-2100 FAX (703) 837-1813

DONATION ACKNOWLEDGEMENT RECEIPT
RECIPIENT INSTITUTION

This acknowledges receipt of the following pharmaceuticals and/or medical supplies. By signing, the recipient agrees that these items will not be sold nor be offered, nor made available to any party with intentions to sell or profit from the products. The products will be distributed at no charge to needy patients who are under the care of this institution.

The recipient institution further agrees to record the receipt of all products provided and the disposition or issuance within the institution. It agrees to provide written confirmation for review by the donor of all products received and issued upon the request of the donor.

* * * * *

PRODUCT	QUANTITY
ZEPHAZONE INJECTION, 2 Gm AND 1 Gm.	238.000 1000 vials

Seal/stamp of Institution



Institution Name: COLENTINA HOSPITAL
 Address: STR. DR. GROZAVICI NO. 1, SECTOR 2
 City: BUCHAREST, ROMANIA
 Date: OCTOBER 17, 1991
 Authorized Signature: [Signature]
 Title: [Blank]

Board of Directors: Joseph E. Mealy, Jr., J. Patrick Bartell, Herbert J. Bloom, D.D.S., Ph.D., Robert E. Campbell, Ph.D., Edward H. Cole, Theodore Cooper, M.D., Ph.D., J. Edward Day, Raymond E. Gabor, William E. Henry, Gen. P.X. Kelley, Irwin Lerner, Edwin A. Loring, Jr., Robert E. Luzzatto, Fred W. Lyone, Jr., Ph.D., Emil Mosbacher, Jr., Jerry E. Robertson, Ph.D., Ph.D., John B. Repton, Charles A. Sanders, M.D., William B. Walsh, M.D., Richard J. Whalen, Joseph D. Williams. Officers: Joseph D. Williams, Chairman; William B. Walsh, M.D., President; Joseph D. Williams, Executive Officer; William E. Henry, Treasurer; J. Edward Day, Secretary



Founded in 1958

THE PROJECT HOPE HEALTH SCIENCES EDUCATION CENTER, MILLWOOD, VIRGINIA 22646 (703) 837-2100 FAX (703) 837-1813

DONATION ACKNOWLEDGMENT RECEIPT

The Ministry of Health of ROMANIA (country or state) certifies that the donation of Pharmaceuticals and Medical Supplies from Project HOPE has been received. The Ministry of Health further certifies that the donated materials will not be sold, but shall be distributed at no charge to the respective Hospitals, Dispensaries, Public Health facilities and other public agencies which serve the poor, the needy, or those suffering from medical conditions in which these medical supplies are appropriate.

The Ministry of Health herewith acknowledges the receipt of Pharmaceuticals and Medical Supplies. An accounting of where these products are being distributed will be given.

AWB 257-2422-0431
Shipment Identification
(BOL #, AWB #, Container #
or Other Appropriate number to
identify this shipment)

13.10.1991 14.30 hr.
Date and Time Received

Dr. Beldescu Nicolae
Name of Authorized Receiving
Agent for the Ministry of
Health

24.10.1991
Date

Director of Dept. Prev. Medicine
Title of Receiving Agent

Seal/Stamp of Institution

Handwritten signature of Dr. Beldescu Nicolae

Signature of Receiving Agent