



results are summarized in a letter prepared for the Ministry of Health (Annex 3) by the consultant while in the Bahamas. These findings indicate large scale contamination of the biological products with hepatitis B surface antigen (18 of 44 specimens tested). In addition, in 31 of the specimens which were tested, antibody to the LAV/HTLV-III virus was detected. CDC shared these findings with PAHO, which alerted health authorities in the Bahamas and, at the request of the Ministry of Health, the writer, accompanied by Dr. Walter Bond, Research Microbiologist from the Centers for Disease Control, consulted with the Ministry and visited the clinic.

Persons who were contacted during the visit are included in Annex 4.

Prior to departure to the Bahamas, the writer visited CDC to verify the latest information. The biological materials had been obtained directly from patients who were undergoing treatment by the clinic. In addition to the serological data, all materials were cultured for LAV/HTLV-III virus. At two weeks all cultures were negative so far, but an additional two weeks were required before they can be considered negative. Nevertheless, a negative culture does not exclude the presence of LAV/HTLV-III virus. For example, CDC has never been able to culture this virus directly from factor VIII concentrates used to treat hemophilia, but epidemiological data strongly implicate factor VIII preparations in the transmission of AIDS to hemophiliacs.

Epidemiological investigation has confirmed 1 case of hepatitis in a patient using biological preparations, 2 suspect cases and 1 probable case. Blood specimens from a patient who had been receiving biological material which was positive for AIDS antibody could not be tested due to technical problems (hemolysis). The writer then departed CDC for the Bahamas in the company of Dr. Walter Bond.

During the initial meeting with the Minister of Health and staff, the following issues and concerns were identified and discussed:

4.1 Potential for harm in the biological materials being prepared at the Immunology Researching Centre.

Comment:

Based on a careful review of previous investigations and reports (see Annexes 1 and 2 and Annex 5) we concluded that the potential for harm was considerable. As far as can be determined, the sterility of the product has never been documented by outside laboratories. Mixed microbial populations have been identified in these materials, whenever they have been tested. Based on incomplete descriptions of the production process, there is considerable potential for contamination in the preparation and packaging of the product. No quality control procedures have ever been documented. Furthermore the source materials for the preparation of the products are of unknown origin and potentially hazardous.

#### 4.2 The potential for harm to the Bahamas

Comment:

Several points were considered. Since the clinic employs Bahamians, there may be some danger to their health and through them to the health of the community, if, indeed, production procedures at the clinic are unsafe. Of considerable concern is the fact that if AIDS virus has contaminated the biological products, then given the hysteria which surrounds AIDS, there may be considerable adverse publicity which might be sufficiently distorted so as to affect the tourist industry in the Bahamas.

#### 4.3. The potential for harm done by the therapy itself.

Previous investigators have commented on this point. Since the clinic tends to select for patients with less severe disease, it is possible that they might benefit from and perhaps be cured by more conventional, scientifically accepted therapies. Little epidemiological information is available to document this issue.

#### 4.4. Concern among public health officials in the United States has reached the highest level within the Department of Health and Human Services. There is a real possibility that the clinic may become a source of friction between Bahamian and U.S. health authorities.

#### 4.5. Efficacy of the therapy

This issue has also been reviewed by previous investigators (see PAHO investigation, 1978, Annex 1, Position of the American Cancer Society, Annex 6, the Position of the National Cancer Institute, memo of June 6, 1985, Annex 7). Since immun augmentation therapy as defined by the Clinic has not been scientifically proven nor generally accepted by the scientific community, the consultants elected not to debate this issue nor to try to obtain data in support of it during the visit to the clinic. The Minister agreed.

In summary, in order to refine the possible risks suggested by the most recent data from the CDC, the consultants informed the Ministry that they would try to obtain new information in three areas: procedures for the preparation of the biological materials, fresh samples of the biological product and a listing of all patients seen in the past 12 months at the clinic. The latter would be for the purpose of issuing a warning to them that the materials that they are utilizing might be seriously contaminated.

The consultants were accompanied by Dr. Vernell Allen on their visit to the clinic. During the actual visit we were joined by Dr. Alfred Brathwaite as well. The visit to the clinic was essentially unproductive (see Dr. Bond's report). Of the three goals, only one

was possibly achieved when the clinic promised to forward the names and addresses of all patients seen at the clinic in the past 12 months directly to the Ministry of Health by the end of the week.

Some miscellaneous information was obtained, such as the fact that the clinic has treated AIDS patients. According to Dr. Burton, the last patient was treated in 1983, but this contradicts information obtained from Dr. Clement who led us to believe that an AIDS patient (a physician) was recently treated and Dr. Brathwaite who noted that the diagnosis of AIDS was mentioned in the laboratories of the Rand Hospital.

Following a general tour of the facility and conversations with Dr. Burton, the overall impression of this writer was one of dismay and concern for the lack of scientific knowledge displayed by the clinic staff, including its director, the unscientific atmosphere in the laboratories and the considerable potential for harm. Nothing which was seen or heard significantly altered the risks associated with the biological materials as documented by CDC's data. If anything, concern was heightened by observations and additional information. For example, the Rand Hospital was able to inform us that from January through June 1985, 13 Center patients had a total of 15 admissions and three of these died within 48 hours of admission. In addition, in the same time period, 19 Center patients (age range of 35 to 69) were dead on arrival at the hospital. Many of these cases were advanced cancer patients with bone metastases. Anemia was common, and five of the patients required a total of 13 pints of blood. Usually blood for transfusion for Center patients is obtained from relatives or friends, but occasionally this blood may replace stored blood which was used in emergency situations. This blood may then be used in Bahamian patients. ~~It was initially unproven~~  
At the team returned to Nassau

During the final meeting with the Minister of Health, the call consultants provided the following comments and recommendations on the issues and concerns which had been raised in the first meeting:

#### 4.6 Safety of the biological product and the potential for harm.

##### Comment:

During the visit to the center, no new information was obtained. Thus the risk associated with the biological products could not be refined. The consultants were not able to observe the process by which the biological materials were prepared. We were not able to obtain fresh samples, although, as stated in Dr. Bond's report, the clinic promised to forward some samples to the Ministry of Health the following week, after they had the chance to test them themselves first.

#### 4.7 Potential for harm to Bahamians.

Comment:

The consultants feel that there is considerable potential for adverse effects on the public health of the citizens of the Bahamas. Unsafe practices in the laboratories probably expose employees to the risks of hepatitis and perhaps AIDS. These employees could transfer these risks to their families and close contacts. Furthermore it may be possible that blood collected by the Rand Hospital from friends of gay patients treated for AIDS at the Clinic could be transfused into Bahamian patients at the hospital.

#### 4.8 International implications.

Comment:

Nothing which the consultants could see or observe altered our concern for the potential harm posed by the continued operation of this Clinic to the Bahamas and its tourist industry. Because of the real risk of adverse impact and the fact that concern had reached the highest level among U.S. public health officials, the writer telephoned CDC's Acting Director and requested that CDC postpone any immediate action to inform the U.S. public until the Ministry of Health of the Bahamas could select an appropriate course of action.

#### 4.9 Potential for harm to patients using the therapy.

Comment:

Because patients from the U.S. are using potentially contaminated materials, the consultants felt that they must be provided with a suitable warning. Upon receipt of the names and addresses of the patients seen at the Center in the last 12 months, the Minister of Health might wish to consider three possible options. The first option favored by the consultants would involve a letter sent directly from the Ministry of Health to the patients to appraise them of the risks associated with the materials and encourage them to dispose of the materials. The second option would be to provide the names and addresses to PAHO so that PAHO could notify the patients. A serious drawback to this action involves the fact that PAHO has responsibilities primarily for informing governments directly of health hazards but not necessarily citizens of particular countries. The third option would involve providing the names and addresses to a U.S. agency, such as the CDC, so that they in turn could advise their citizenry of this risk.

## 5. Overall recommendations.

After considerable deliberation the consultants reached the conclusion that only one course of action was available to the Ministry, specifically to ~~take appropriate action to close the Clinic.~~ Based on our review of all past and present available information and the experiences of visiting the clinic, we feel that no other action is reasonable. There are five reasons for this position:

- 5.1 ~~First and foremost, the clinic is producing an unsafe biological product with procedures and methods which appear to be unsafe for the staff involved. There are no indications of real interest in establishing scientifically accepted quality control measures.~~
- 5.2 The continued operation of this Clinic and the possible contamination of its product with the AIDS virus is potentially damaging to the Bahamas and represents a possible threat to the tourist industry.
- 5.3 The continued operation of this Clinic could prove to be a potentially embarrassing episode in relationships between U.S. and Bahamian health authorities.
- 5.4 The Clinic represents a threat to the safety of the staff and possibly to their families. The risk of acquiring hepatitis B virus and/or AIDS virus is present but could not be fully defined. Nevertheless both diseases are serious illnesses, and possible risks can not be ignored. The additional information that patients are treated in the Rand Hospital documents additional possible exposure of Bahamian laboratory workers and health care staff to LAV/HTLV-III virus and AIDS.
- 5.5 The Clinic is utilizing a controversial therapy and the weight of international scientific opinion is that this therapy is unproven. The continued operation of a Clinic using such therapy is embarrassing to the medical community in the Bahamas.

The consultants also endorsed the current efforts to update and modernize health legislation in the Bahamas and recommended that careful attention be paid to this process so that similar situations can be prevented in the future.

Annexes.