

July 5, 1985

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525 Twenty-Third Street, NW
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Dear Dr. St. John:

This letter is to summarize findings in my capacity as Consultant to the Pan American Health Organization on the 2 July 1985 site visit to the Immunology Researching Centre, Ltd., Freeport, Grand Isle, Bahamas. The purpose of my visit was to evaluate functioning of the Centre's laboratory areas and determine if the standard operating procedures were compatible with microbiologically safe injectable serum reagents used in Immunoaugmentative Therapy (IAT). The site visit team was composed of Dr. V.T. Allen, Chief Medical Officer, Bahamas Ministry of Health, Dr. Alfred Braithwaite, Chief of Pathology, Rand Memorial Hospital, Freeport, and ourselves, and we were attended at various intervals on the visit by Mr. Grainger, General Manager of the Centre, Dr. Robert Clement, Medical Director of the Centre, Mr. Maynard, Legal Counsel for the Centre, Dr. Lawrence Burton, Director of the Centre, and to a lesser extent by 6 laboratory workers. During the visit, approximately 2 1/2 hours were spent in conference or patient treatment areas and approximately 30 minutes in laboratory areas. Dr. Burton met with us only in the main conference room of the Centre.

I was ~~unable~~ to conduct a meaningful evaluation of the laboratory facilities for the following reasons. In direct questioning of Dr. Clement, the site visit team was told that no written standard operating procedure would be provided since no such document existed. Further, the team was informed that there were no individual written protocols (quality control or otherwise), no records were available for inspection, and that there would be no direct observation of the IAT serum reagent preparation steps from start to finish. Dr. Clement also denied the team access to randomly selected fresh specimens of serum reagent, but he did conduct a very brief (20 minute) walking tour of the laboratory prep area and the portion of the main laboratory where a segment of the diagnostic procedures were being performed by lab workers. The tour was terminated when Dr. Clement was informed that Dr. Burton was available for conference. A directed tour of the reagent preparation area was not conducted, and very little, if any pertinent information on laboratory procedures was provided by Dr. Clement.

The following items were the most notable during the prep area and diagnostic lab tour:

1. In the prep area, two small table top autoclaves with no facility for temperature, pressure or time recording were observed. Dr. Clement opened one unit, and it was observed to be cool and fully loaded with uncovered 500 ml beakers approximately 2/3 full of fluid. Dr. Clement said that he should not have opened the unit, since the fluids were

sterile buffers used to prepare laboratory reagents. He did not know how long the load had been processed, since only the person responsible for that step would have that knowledge.

2. A tabletop dry air oven, also without recording devices was noted in the prep area and was located adjacent to a door explained to be "the animal room." Dr. Clement indicated that he did not know what was processed in the oven and was unable to locate a key to the animal room. The odor around the door left little doubt that animals (presumably mice) were housed behind the locked door.
3. A coffee maker and coffee cups were located on a counter top near the animal room.
4. There was no visible evidence that microbiologic media, reagents, or specimens were prepared or disposed of in the prep area.
5. In the diagnostic laboratory, workers were observed making spectrophotometric determinations on the contents of approximately 20 test tubes. It was explained that the tubes contained patient serum with added "buffers" and that the tubes had been heated in boiling water "just to 55°C" to precipitate certain components. One worker filled the spectrophotometer cuvette from a serum tube, wiped the optical surfaces of the cuvette with a tissue, inserted the cuvette into the machine and then made unexplained adjustments to the wavelength control. When the "proper" reading was obtained, a number (not visible on any control or readout) was called out and then repeated and recorded by a second worker. When asked what was being read on the spectrophotometer, a worker not involved in the readings replied that the "immune levels" of the patients were being determined. The worker at the spectrophotometer then poured the fluid back into the serum tube and passed the tube across the machine to a third worker who inserted a tuberculin syringe (no needle) into the tube, mixed the contents by moving the plunger up and down, and then using the syringe transferred 0.1 - 0.2 ml of the contents to a metal centrifuge tube. The syringe was then placed tip down in the serum tube and the tube/syringe unit was placed beside the centrifuge tube in a rack. (The syringes are apparently washed and re-used "for something . . . maybe injecting mice" according to another lab worker). Meanwhile, the worker at the spectrophotometer removed residual fluid from the cuvette by inverting and tapping the edge on a tissue on the counter top. The cuvette was then filled from the next serum tube, the optical surfaces were wiped with the same tissue used to wipe the cuvette the first time, and a "reading" was again determined and recorded. Tissues were not changed during the observed processing and the workers did not wear gloves. The tour was terminated at this point to meet with Dr. Burton in the conference area.

The conference with Dr. Burton was relatively unproductive in terms of obtaining further information regarding production details of IAT serum fractions. His responses to direct questions and his spontaneous conversation evidenced conceptions of general scientific knowledge and good manufacturing practice that are contrary to contemporary standards. A listing of the more significant portions of this conference are as follows:

1. Discussing preparation of the IAT serum fractions, the sources of the starting materials were unclear but could be either patient-derived and/or from outdated units of blood. In any event, the overall process involves pooling of blood or blood products or tissues of unknown origin. Dr. Burton described a process where forty 250 ml bottles of "fractions" were combined to make 10 liters which was then dialyzed to reduce the volume to 1/10 the original. According to Dr. Burton, this concentrated material was filtered twice through a "micropore" filter since he "never could figure out how to sterilize a protein fraction other than that." He went on to state that if there was "anything" in his fractions, then there was a fault in the "micropore" filters and maybe they should filter the fractions 3 times instead of twice. When asked if the site visit team could observe the preparation and dispensing of the fractions, Dr. Burton replied that if we wanted to see how it was made, "you can go to Washington, pay 3 dollars, and get a copy of my patent."
2. Dr. Burton stated that he did not acknowledge the association of HTLV-III/LAV virus or its antibody with AIDS and that until Koch's Postulates are fulfilled with his material (i.e., animals are "made sick") that he does not believe that his materials can be implicated in disease transmission. He continued by informing us that one of the causes of "so-called AIDS" is exposure to aged extract of kelp (agar), since agar stored in the refrigerator for 72 hours will cause tumors in mice while fresh agar will not. Agar is supposed to be a current or past component of "K-Y Jelly."
3. Dr. Burton also stated that he did not acknowledge the association of HBsAg in a product with potential for HBV infection, since he does "not trust tests that have a cutoff point." He continued by saying that until "hepatitis virus is cultured in the laboratory or in animals" (he claimed to have done this many times using mice), that he will not believe that his product is dangerous. He indicated that his methods are the "old-fashioned methods . . . but they work."
4. After a discussion where Dr. Burton was told that a solution could be heated to kill HBV but that HBsAg in the solution may retain its immunologic reactivity, he exclaimed that his materials were "vindicated" since they had been autoclaved, a factor not previously described to the team (prior conversations had indicated that "sterilization" was accomplished by filtration).

5. When asked if he would allow immediate taking of random specimens from his serum fraction lots for sterility testing and also HBsAg and anti-HTLV-III/LAV testing, Dr. Burton refused. When asked if he would submit the specimens immediately and directly to the Minister of Health via Dr. Allen, the refusal was the same. Dr. Burton explained that the specimens were "not available today" and besides, he wanted to "filter them 2 or 3 more times" and test them himself to be certain "they are OK" before they were released. He said he would give specimens (his choice) to the Minister of Health "next week."
6. Discussing testing, Dr. Burton commented that although he disagreed with HBsAg and anti-HTLV-III/LAV test methods, he would add these capabilities to his laboratory. He added, however, that he would use one of his "sophisticated spectrophotometers" to modify the "Squibb" test in order to avoid inaccuracies of tests with cutoff points.
7. Dr. Burton stated that sterility tests on the serum fractions are done by injecting (amount unspecified) samples of a fraction (number, source and lot unspecified) into a number of white mice (8 or 16) and observing (time unspecified) to see if they "get sick."

Prior to the site visit team departure, a very brief walk-through of the facility was conducted once again but with Mr. Grainger in attendance. Although unoccupied, the fraction preparation area evidenced nothing other than open bench areas with a variety of equipment (centrifuges, spectrophotometers, etc.). Equipment one would expect in an area slated for aseptic filling operations (laminar flow clean benches in controlled, limited access areas, pass-through autoclaves, etc.) were not seen. Frozen patient treatment material (serum fractions) in plastic flip-top vials directly next to open tubes of blood were seen on a counter top in the fraction preparation area.

From direct observations during the very brief laboratory tour and also from the information gained in conversation with Drs. Clement and Burton, ~~it is my~~ **conclusion** that the parenteral therapeutic agents produced at the Immunology Researching Centre, Ltd. ~~may have a high risk of being contaminated by~~ **microorganisms either from source materials or from extraneous sources during processing or packaging.** The IAT serum fractions may therefore, present a health hazard to the patients injected with the material. Further, the poor

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aseptic practices demonstrated in the Centre's diagnostic area during the tour suggest that the laboratory workers may also be at increased risk of acquiring a variety of bloodborne diseases.

If I may be of further help in this situation, please contact me at any time.

Sincerely yours,



Walter W. Bond
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cc: D.R. Hopkins, M.D., Acting Director, CDC