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DEPARTMENT OF THE ARMY
U.S. ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND
FORT DETRICK, FREDERICK, MD. 21702-5012

REPLY TO
ATTENTION OF

SGRD-ZC (70) 18 October 1990

MEMORANDUM FOR RECORD

SUBJECT: Third Tri-Service Task Force (Project Badger) Meeting ~~(S)~~

1. (U) The third meeting of Project Badger Executive Committee was held at Headquarters, U.S. Army Medical Research and Development Command (USAMRDC), 0900-1200, 18 October 1990. Present were:

Tri-Service Executive Committee

COL Harry G. Dangerfield, (USAMRDC, Chairman)
CDR Fred Paleologo, (USN/NMRDC)
LT COL Sharon Falkenheimer, (HQ, USAF/SGHR)
Dr. Anna Johnson-Winegar, (SGRD-PLA, USAMRDC)

Task Force Technical Advisors

COL Garland M. McCarty, (CDR, USAMRDC)
COL George Lewis, (DASG-RDZ, Pentagon)
COL Bill Bancroft, (SGRD-PLA, USAMRDC)
LTC George Sisson/Mr. Jay Winchester, (SGRD-JA, USAMRDC)
LTC Kelly McKee, (SGRD-UIM, USAMMDA)
MAJ Mike Balady, (SGRD-UMB, USAMMDA)
MAJ Bob Eng, (DASG-HCLL, OTSG)
MAJ Larry Lightner, (DASG-RDZ, Pentagon)
Mrs. Jean Smith, (SGRD-ACQ, USAMRDC)
Dr. Walt Brandt, (SGRD-UMB, USAMMDA)

2. ~~(S)~~ COL Dangerfield opened the meeting with a request that COL Lewis give a precis of activities of the Joint Staff regarding Project Badger. COL Lewis reported that the Joint Staff was working with four key operative words: Accelerate, Stockpile, Monitor and Delay. He said that General Powell had a firm grasp on the situation and was interested in the status of negotiations with the FDA on the IND for B and in the timetable for accelerated production of both A and B. General Powell wants an update on these at the end of October. COL Lewis said that he would probably need updated information to feed to the J-4 staff by the middle of next week. The numbers on availability of both vaccines and predicted production dates (enclosure 1) from Michigan as of 1630, 17 October 1990, were obtained by Dr. Johnson-Winegar for the Joint Staff and will be locked tomorrow. COL Lewis will give this data to COL McCarty and Dr. Collis.

Classified by: Multiple Sources
Declassify on: OADR

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3. (U) COL Dangerfield prefaced the meeting by setting two parameters: the Task Force will be looking at Best Case and Worst Cast scenarios and focusing on numbers of doses, not people.

4. ~~(S)~~ Anthrax Vaccine:

a. (S) CDR Paleologo and LTC McKee stated that there was no good information available concerning endemic disease (A) in [redacted] According to officials in these countries, the disease is not endemic. Efforts to obtain serologic prevalence data are in progress. It was agreed not to worry about the potential for reaction to immunization in indigenous populations having natural immunity and that this is a problem to be addressed by policy makers.

5 U.S.C. 552 (b)(1)

b. (U) Dr. Brandt reported that his survey of potential veterinary producers of A revealed that the vaccine is not produced in fermenters, but is grown on agar. This eliminates those companies from producing a licensed product for human use.

c. (U) Dr. Johnson-Winegar reported on the status of the Market Investigation being done by Sherikon. A total of approximately 150 firms will have been surveyed telephonically. From this survey, likely potential producers for A will be determined based on three criteria:

(1) Whether or not they have functional fermenters;

(2) If they can produce vaccines under GMP/GLP conditions;

(3) If they can produce vaccines under at least BL-2 biocontainment conditions.

She estimates that approximately 15 companies will meet these criteria.

d. (U) Dr. Johnson-Winegar discussed the plan to have a meeting of prospective participants and pointed out that immunization was required for anyone entering the Michigan Production Facility. Further, they are interested in working with the Task Force, but not in entertaining a large group of people. She reminded the group that, although the Army holds the patent on the production process, Michigan holds the license. Therefore, companies working with Michigan would need to use the Michigan Technical Data Package (TDP). The FDA's position on

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licensing products produced elsewhere is that they will not commit themselves without seeing the data. Leverage may be needed in the future if this becomes a problem. The Executive Committee decided to cancel the planned meeting in Michigan.

e. (U) The strategy for working with industry is as follows:

(1) Dr. Johnson-Winegar will draft a Statement of Work and RFP. With Michigan's agreement, the TDP would be added as an appendix to the RFP. A draft should be completed by 25 October.

(2) The most likely companies identified in the survey will be selected. COL McCarty, Commander, USAMRDC, will call the CEO of each directly, outline the requirements, investment incentives, etc., and determine if the company is seriously interested.

(3) Each interested company would be sent an RFP and would be asked to identify a technical point of contact. This would be followed by visits to interested companies from USAMRDC and Michigan technical experts to assess production capability and related details. It is anticipated that interested companies would include in their cost estimates the price for replacement of equipment and/or lost business during production of A.

f. ~~(S)~~ MAJ Balady reported on his discussion with Porton. Their preproposal is at enclosure 2. COL Lewis commented that CONUS production is preferable to OCONUS; however, OCONUS production, particularly in participating countries would be acceptable.

g. (U) COL Bancroft reported that, at least for production of A, Pine Bluff is not a viable candidate. This facility was discussed in more detail later in the meeting.

h. ~~(S)~~ An additional source was identified by Dr. Johnson-Winegar. 5 U.S.C. 552 (b)(1) [redacted] This facility is Government Owned-Contractor Operated. The risks of production of A, normally produced in [redacted] 5 U.S.C. 552 (b)(1) [redacted] to be high; however, successful fermentation would produce a large number of doses in a relatively short time. Mrs. Smith will contact the Contracting Officer for NCI and

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Dr. Johnson-Winegar will obtain more information from the facility manager. Both will be completed by next week's meeting. Additionally, there may be a treaty issue involved in producing such large quantities of A. This would be addressed later if necessary.

i. ~~(S)~~ A summary of short term actions for A is:

(1) Continue to pursue commercial sources to augment Michigan.

(2) Determine viability of NCI facility.

5. ~~(S)~~ Botulism Toxoid:

a. (U) COL Dangerfield commented that the antisera treatment potential needs to be pursued. Attendees were reminded that any product will be produced requires an IND and will not be licensed.

b. (U) Production of BF utilizes fermentation; this product will be supplied through a contract with Porton. There is a potential that BC could be obtained from a veterinary producer. MAJ Balady will identify potential producers through CDC.

c. ~~(S)~~ Discussion focused on the carboy method of producing B. Possible places for such production are 5 U.S.C. 552 (b)(1) because of the presence of inoculated people and secure Government facilities, and the 5 U.S.C. 552 (b)(1) already under a task order contract to USAMRDC. Limiting factors in this type of production are incubator availability/space and carboy 5 U.S.C. 552 (availability. COL Bancroft will investigate these concerns. MAJ Balady and Dr. Roy (USAMMDA) will examine 5 U.S.C. 552 (b)(1) and Dr. Brandt and Dr. Johnson-Winegar will contact 5 U.S.C. 55 If necessary, a structure (e.g., 5 U.S.C. 552 (b)(1) could be put up in a short time to house this type of production facility.

6. (U) Mrs. Smith provided the Task Force with a search of former and current USAMRDC contracts for A and B research (enclosure 3).

7. (U) COL McCarty reminded the Committee that the figures, timeliness/reporting dates we must meet were given to him by Dr. Collis (enclosure 4). COL McCarty also presented Task Force information on numbers of U.S. military personnel which have a bearing on developing a long term plan (enclosure 4) for A production.

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8. (U) The next meeting of the Project Badger Executive Committee will be 25 October 1990, 0900, at HQ, USAMRDC, Commander's Conference Room.

4 Encls

HARRY G. DANGERFIELD
Colonel, MC
Chairman