OFFICE OF THE DIRECTOR OF DEFENSE RESEARCH AND ENGINEERING
Washington, D.C. 20301

2 March 1967

MEMORANDUM FOR (See Distribution)

SUBJECT: Minutes of the 65th Joint Medical Research Conference

The following attended the Conference in Room 1E801(5), the Pentagon, at 0900 hours on January 19, 1967.

Dr. Edward L. Alpen, NRDL, D/N San Francisco
M/Gen T. C. Bedwell, MC ODASD(H&M)
L/Col Hamilton H. Blackshear, MC Hq USAF(AFRSTA)
L/Col Jerome G. Bricker, Hq OAR, USAF
Major Thomas E. Davis, MC, USAMRDC, OTSG, DA
L/Col Jack Fitzpatrick, MC, USAMRDC, OTSG, DA
Col Frederick J. Frese, Jr, MC Hq AFETR, Cape Kennedy (Visitor)
Major William R. Godden, Medical Division, Hq DASA
L/Cdr Robert E. Grunawalt, Medical Division, Hq DASA
Dr. Frank W. Hartman, OSG, Hq USAF
Col R. R. Hessberg, MC, Hq USAF (AFRSTA)
Col Donald L. Howie, MC, USAMRDC, OTSG, DA
Capt James R. Kingston, MC ONR, DN
Dr. Carl Lamanna, ARO, OCRD, DA
Col Marshall E. McCabe, MC, Prof. Division, OTSG, DA
Dr. G. M. McDonnel, The Center for Health Sciences, UCLA, Chairman
Col Henry S. Parker, MC, ODASD(H&M)
Capt Joe P. Pollard, MC, BuMed, D/N
Capt Carl E. Pruett, MC, DCNO(Dev), D/N
Col Robert K. Quinnell MC, AFMSR, USAF
Colonel Richard R. Taylor, MC, ODDR&E, OSD
B/Gen Colin F. Vorder Bruegge, MC, USAMRDC, OTSG, DA
Col Harold W. Whitcher, RAMC, British Army Medical Liaison Officer

The Chairman called the meeting to order. The minutes of the 64th JMRC were amended at the request of Commander Moss, NMRI, as follows: p. 3, para (b), line 3 - substitute "balanced salt solutions" for "colloids."

Copies of Project Themis were distributed and the present status discussed by Colonel Taylor.

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(FOUO) MEDICAL ASPECTS OF DASA SPONSORED RESEARCH

General Vorder Bruegge introduced the subject because of the impact of decreasing DASA funding for nuclear weapons effects medical research in FY-68. It is apparent that longer range planning is needed due to the inter-relationship between DASA and departmental RDT&E programs. The Departments have a responsibility to maintain in-house competence in this area. Lt. Commander Grunawalt noted that the medical research program has the lowest priority in DASA. In FY-66 the program was $5.919M, FY-67 $5.47M, and FY-68 planned $4.73M. Efforts are being made to maintain adequate funding of the Armed Forces Radiobiology Research Institute, Bethesda. Departmental requests are considered next. History of recent departmental project funding is as follows:

	(Thousands)		
	FY-66	FY-67	FY-68 (Tentative)
Army	$452	$236	$ 30
Navy	979	615	398
Air Force	546	841	495

These cuts will have greatest impact at the Naval Radiological Defense Laboratory, Walter Reed Army Institute of Research, and the USAF School of Aerospace Medicine. There was agreement that Departmental RDT&E programs could not support terminated projects because they would conflict with the assigned DASA mission and other priority needs.

Impact:

a. Army - General Vorder Bruegge said the major problem will be to interest and retain medical officers in a career in nuclear medicine in the presence of little research opportunity. An alternative may be to conduct research and training at AFRRI, but the Institute is not of sufficient size to conduct the single DOD program. In addition its funding is inadequate.

Besides the possibility of future use of nuclear weapons, it was noted that nuclear power is coming into being for other purposes--e.g. ships, and field power sources. The possibility of accidents cannot be dismissed. The Armed Forces military services require a capability for adequate methods of threatment of radiation sickness.

b. Navy - Dr. Alpen stated that there has been a one-third reduction of the budget of NRDL for FY-68. DASA sponsored neutron, low dose and incapacitation studies are being abolished. A freeze has been placed on personnel replacements at NRDL and the scientific staff will be reduced by 12 investigators by June 30, 1967. The new $2.0M animal facility

(FY-66 program) which has just been completed will not be opened. The major question at this time is whether this is a temporary or permanent situation. Dr. Alpen believes that there is no point in an inadequate program. Lt. Colonel Fitzpatrick noted that the Department of Defense will sorely miss this capability if nuclear weapons are ever used.

c. Air Force - Colonel Hessburg stated that Air Force conducts little basic radiobiology research. Most effort is for test support of weapons. As long as tests continue the Air Force has little problem.

d. DASA - New physical facilities are becoming available at AFRRI from the MILCON construction program, however, due to FY-68 fund cuts, manpower and procurement of capital equipment has been frozen.

Dr. McDonnel is to discuss this problem with Dr. Foster prior to the next meeting.

(FOUO) WOUND SURVEY IN VIETNAM

The Army Medical Service is preparing to participate with other elements of DA in a wound ballistic study in Vietnam. These studies are oriented to the development of better weapon systems, and helmets, boots and body armor. There has been a shift in the causes of wounds and in protection requirements. There are implications on the structure of the Army and the types of weapons needed.

Colonel J. Hansen stated that the preliminary ground work will be accomplished by a team of 1 representative from AMC, 1 from ARO and 1 from USAMRDC which will be evaluating ballistics, morbidity, mortality and effectiveness of U.S. and foreign weapons. AMedS primarily will be providing medical support but it is expected thatthere will be information of immediate medical value. The team will be based at the Biophysics Laboratory, Edgewood, arriving 15 April for training and become operational in Vietnam 15 August. Headquarters will be in Saigon with two operating teams with active combat units: (1) with airborne, (2) non-airborne. The Army Materiel Command will have overall responsibility in Vietnam. All information will be returned to Edgewood for analysis and dissemination. AMC has primary funding responsibility.

IMMERSION FOOT STUDY

Department of Navy representative, Captain Anderson has not returned from Vietnam. Presentation delayed until the next JMRC.

CLINICAL INVESTIGATION OF NEW DRUGS

Dr. Hartman reviewed the DOD/HEW memorandum of understanding of 1963 regarding the use of investigational drugs. There are now new considerations which should be considered because of FDA regulations concerning (1) the quality of informed consent and (2) HEW consideration of drugs and vaccines as synonomous.

The problem was recently highlighted by the unwillingness of Dr. Mogabgab (Contract to USAMRDC) to conduct common cold vaccine studies at Kessler AFB following the FDA ruling on informed consent. The Air Force Surgeon General believes that the Armed Forces Epidemiological Board should consider this problem. The AFEB President, Dr. G. Dammin has expressed willingness to have such a session.

The report from Senator Seymour R. Thaler, New York State Legislature (NYT 1/11/67) regarding the Willowbrook hepatitis studies in children was also noted. Information from Dr. F. Quimby (Library of Congress) suggests U.S. Congressional interest.

In addition, the FDA has just halted use of B-proprionate lactate sterilized plasma, which is reported to have been used in 3,000 cases without delerterious effects.

Colonel Howie stated that the Army has had no significant difficulty working with the FDA. The Army is currently studying on a limited basis with FDA cognizance and support: (1) live adeno-4 vaccine, (2) antimalarial drugs, and (3) adenine additive to whole blood. Specific authorization has been obtained for double blind studies, consent has been obtained on vaccine vs placebo studies, and good protocols produced.

Limited approval has been given by FDA for use of new antimalarial drugs immediately required in Vietnam and for adenine additive to whole blood. FDA wants to be assured that Army knows what they are doing and what they need. The Army-FDA relationships are good despite a very great increase in work. There have been no unreasonable disapprovals of Army proposals from FDA since the DOD/HEW agreement in 1963. Proposed clinical investigations involving investigational drugs and vaccines are considered by an OTSG Clinical Investigation Board and a copy sent to FDA. All USAMRDC contracts include pertinent clauses requiring informed consent as specified in AR 40-7 and AR 70-25.

Colonel Hessburg and Captain Pollard stated that there was no Air Force or Navy problem. The consensus was to reaffirm the need to establish close and continuing communication with FDA.

Dr. Hartman stated that the Interdepartmental Committee on blood had met three weeks ago. The Army program on adenine was well advanced and had an adequate number of cases, but the Division on Biological Standards (DBS) has refused to add adenine to the standards unless there is an adequate research basis. Parallel Air Force studies are also progressing satisfactorily. Thus adenine additive will add at least two weeks to the shelf life of whole blood and is ready for limited trial in the transfusion program. The Interdepartmental Committee, the DASD(H&M), and the NRC have reported favorably. Cases must be followed carefully. Colonel Shields, MC AMRL, Fort Knox, is prepared to institute the study.

Colonel Howie stated that the DBS is reluctant to give other than limited military approval. Studies are needed of the effect of adenine on plasma fractions and on stockpile plastic bag effects. Studies will be underway in Vietnam within a month, including the logistical chain from CONUS, in Vietnam storage, and use in combat casualties. Colonel J. Hansen noted that 7200-9200 units of whole blood per month were being delivered to Vietnam from Japan and CONUS. These are arriving at the user level in 12 - 14 days after being drawn, leaving a present use period of about two weeks. Adenine additive offers the hope that the shelf-life period may be extended to at least four weeks.

In view of these discussions it was the consensus of the conference that there was no requirement for revision of the 1963 DOD/HEW agreement on clinical investigation of new drugs at this time.

The 66th meeting, scheduled for February 16, was cancelled due to a Congressional Subcommittee meeting. The next meeting is scheduled for March 9 at 0900 in Room 2A312 of the Pentagon.

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Ofc Asst Director (Chemical Technology)

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