To Mark From Gil — Publicity

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To: Advisory Board on Medicine and Biology. [redacted]

Subject: MEDICAL POLICY.

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It is the desire of the Medical Advisor's Office of the Oak Ridge Directed Operations to present certain matters of medical policy to the Advisory Board on Biology and Medicine for their consideration. In view of the extremely important relationship of health protection and the medical program to practically all of the Commission activities, and in a larger sense to national welfare, it is imperative to obtain basic medical policy decisions as rapidly as possible. The degree of success which the Commission's program attains may well depend in a large measure on the adequacy and soundness of its medical, health-physics and biological programs.

Accordingly, the following questions and tentative solutions are submitted for your review and expression of opinion.

Dr. Albert H. Holland, Jr., Acting Medical Advisor of the Oak Ridge Directed Operations, will be available for subsequent meetings of your Board to provide further information if you so desire.

a. There are approximately twelve cooperating universities participating in the Oak Ridge Institute of Nuclear Studies, which is a group established under the laws of the State of Tennessee to conduct fundamental research using the facilities available at Clinton National Laboratories. Although these facilities are necessary for much of the biological research work, a great deal of other work can be performed at the individual universities. Many competent qualified scientists

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from these universities have applied through this office for funds to conduct various problems in biochemical, medical and biological research. Some of these suggested researches are extremely pertinent to the activities of the Commission, as for example, Dr. Alfred Chanutin at the University of Virginia Biochemical Laboratory wishes to establish a program for the electrophoretic study of plasma proteins following irradiation. If in his studies he can establish a constant pattern change which can be correlated with radiation exposure, we will then possess a new diagnostic method which can readily be used in the protection of our personnel throughout the atomic industry. This type of problem, while fundamental in nature, can also be considered as applied or "programatic" research, since it is intended to attempt to provide us with a definite answer to an extremely pertinent problem.

Accordingly, the question arises as to whether or not a regional Medical Advisor can initiate fundamental and/or "programatic" research at facilities within his area or with universities within his general geographic region? It is apparent that each Medical Advisor has a more intimate knowledge of the problems within his area; and therefore it seems desirable, subject to the approval of the Atomic Energy Commission Medical Director and the Advisory Board on Biology and Medicine, that he have the authority to negotiate with universities within his region for the express purpose of conducting both fundamental and "programatic" research.

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b. A second problem arises when one considers what responsibility the Atomic Energy Commission bears for the human administration of isotopes. This question can be subdivided into two phases: (1) When the materials are administered by private physicians and institutions outside the Project and (2) when given by physicians and researchers within the Project. This latter category includes contractors' personnel employing Atomic Energy Commission funds (indirectly) to perform tracer research, some of which is of no immediate therapeutic value to the patient. It therefore becomes desirable to establish acceptable medico-legal criteria for future human tracer research.

Careful consideration of this problem seems to indicate that once a recipient has been deemed "qualified" by the Isotopes Branch and their advisory committees to receive and use radioisotopes, the Commission bears little if any responsibility for human administration. Past medico-legal experience provides numerous instances of claims and suits againstmedical institutions for the use of experimental drugs. In practically every case the physician involved has taken the sole responsibility and therefore may or may not be guilty of malpractice, but the institution is exonerated. This analogy might well apply to our present problem.

The second part of the question is more difficult since much of our research is motivated by human application and human effects. If the expressed opinion of the Medical Board of Review, which convened last June, is accepted in establishing criteria

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for human administration, then obviously a great deal of our present human tracer studies must be discontinued. The pertinent facts of the case, pro and con, seem to be these: Pro -

(1) Tracer research is fundamental to toxicity studies.

(2) The adequacy of the health protection which we afford our present employees may in a large measure depend upon information obtained using tracer techniques.

(3) New and improved medical applications can only be developed through careful experimental and clinical trial.

(4) Tracer techniques are inherent in the radioisotope distribution program.

Note: no discussion of level of risk to human subjects — MG

Con -

(1) Moral, ethical and medico-legal objections to the administration of radioactive materials without the patient's knowledge or consent.

(2) There is perhaps a greater responsibility if a federal agency condones human guinea pig experimentation.

(3) Publication of such researches in some instances will compromise the best interests of the Atomic Energy Commission.

(4) Publication of experiments done by Atomic Energy Commission contractors' personnel may frequently be the source of litigation and be prejudicial to the proper functioning of the Atomic Energy Commission Insurance Branch.

c. The radioisotope distribution program is increasing in scope very rapidly. As a result certain questions arise for consideration to determine:

(1) What part the Atomic Energy Commission Medical Division will

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play in the isotope program?

(2) What responsibilities does the Atomic Energy Commission bear for the safe handling by the recipient for the more hazardous isotopes?

(3) What responsibilities does the Atomic Energy Commission bear for radioactive waste disposal?

(4) What part, if any, should the Atomic Energy Commission take with respect to cyclotron produced isotopes at the various universities throughout the country?

Are these funds by the AEC? —MG

Answers to the above questions cannot immediately be set forth. However, the following comments appear in order:

It is felt that the Atomic Energy Commission Medical Division should probably bear complete responsibility for all of the medical and health-physics phases of the Commission's activities. The medical and health aspects of the isotope program therefore is a subject of some concern to the Medical Director. The establishment of broad general policies of personnel protection, codes, and other related information may well fall within the scope of the Medical Division's activities.

With respect to safe handling of the more hazardous isotopes, as for example, Strontium 90, Calcium 45 and Carbon 14, many factors arise which increase the difficulty of solution. These are listed below:

We need to get a copy of this.

(1) Under the Atomic Energy Act does the Commission retain moral responsibility for the application of these substances?

(2) How can the Atomic Energy Commission properly enforce safe handling?

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(3) The U. S. Public Health Service has no legal authority within state boundaries and therefore can only act in an advisory capacity. Further, there does not appear to be a sufficient number of qualified men to initiate such a Public Health service

(4) State Public Health officers do have, in most instances, sufficient legal authority to enforce safe handling. However, few men are qualified at the present time to assume this responsibility.

(5) The Advisory Field Service of the Isotopes Branch provides "in the field" free consultation. A number of isotope recipients have availed themselves of this service. However, suggestions or recommendations requiring the expenditure of money for laboratory design in the interest of safe practice are not always received in a cordial manner.

Radioisotopes with a short half-life, such as Phosphorus, P^{32} and I^{131}, do not present a severe hazard in most cases. However, some substances may be of primary concern to an entire community if handled improperly. Some system of control is vital if extensive use of these substances is contemplated.

Intimately associated with the above problem is the question of radioactive waste disposal. As you no doubt are aware, many suggestions have been proposed by various people. Some of these are:

(1) Disposal at sea.

(2) Disposal by burial.

(3) Storage in vaults until decay has progressed to safe limits

(4) A system of garbage can collections and subsequent burial in federal burial grounds.

(5) Sealing the more hazardous contaminated wastes in suitable

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containers and dispatching them by interplanetary rockets out into space.

While some of these suggestions appear somewhat extreme and others appear quite reasonable, numerous problems arise concerning waste disposal. Ground burial is at present in use at some installations. However, ground water and soil contamination and subsequent selective absorption by various plants and animal organisms is a serious objection to this method of disposal. Burial at sea is not without some hazard when one considers such a program extending over a long number of years.

Numerous isotope purchasers receive material which is not suitable for dilution and disposal in city sewage systems. Therefore consideration must be given as to what responsibilities we bear with respect to:

(1) Radioactive waste disposal.

(2) Establishment of criteria for disposal.

(3) Desired methods of enforcement, if any.

With respect to the cyclotron produced isotopes at the various universities and research institutions throughout the United States, it might be desirable to have the same safety codes and personnel protection measures adopted. If cyclotron produced isotopes can be purchased, distributed and handled at will throughout the United States, the efforts of the Commission to maintain safe practices may be seriously handicapped. Obviously, this is a very delicate question for we do not wish in any way to encroach upon the scientific liberty of free institutions.

Again - aren't they AEC grantees/contractors? -MG

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d. Declassification of medical and biological documents has become a considerable task. All researchers are anxious to have their work appear in the journals as soon as possible. When critical process steps or materials are involved the problem is greatly simplified, since all must abide by security. However, there a large number of papers which do not violate security, but do cause considerable concern to the Atomic Energy Commission Insurance Branch and may well compromise the public prestige and best interests of the Commission.

Papers referring to levels of soil and water contamination surrounding Atomic Energy Commission installations, idle speculation on the future genetic effects of radiation and papers dealing with potential process hazards to employees are definitely prejudicial to the best interests of the government. Every such release is reflected in an increase in insurance claims, increased difficulty in labor relations and adverse public sentiment.

Following consultation with the Atomic Energy Commission Insurance Branch, the following declassification criteria appears desirable. If specific locations or activities of the Atomic Energy Commission and/or its contractors are closely associated with statements and information which would invite or tend to encourage claims against the Atomic Energy Commission or its contractors, such portions of articles to be published should be reworded or deleted. The effective establishment of this policy necessitates review by the Atomic Energy Commission Insurance Branch, as well as by the Medical Division, prior to declassification.

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In summary, it should be pointed out that this brief resume has not attempted to comprehensively present all of the problems which exist. It was deemed advisable, however, to set forth some of the major questions for your consideration. Even in the presentation of these major problems, no pretent is made for completeness. However, an effort was made to bring out the salient points in each instance. Primarily, the objective has been to call attention to those issues which appear to be fundamental to the establishment of a sound, progressive, coordinated medical and biological program for the Atomic Energy Commission.

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