

Letter from J. E. Moore, M. D., to Dr. A. N. Richards

October 6, 1942

I have recently received a letter of enquiry from Dr. Charles M. Carpenter of the University of Rochester School of Medicine who believes that he may be able to work out a human experiment on the chemical prophylaxis of gonorrhoea. He has asked me to supply him with a statement that in my opinion such human experimentation is desirable. I have in turn replied enquiring from him as to whether he wishes a statement from me on an entirely personal basis or in one of my official capacities - as Chairman of the Subcommittee on Venereal Diseases, National Research Council, or as Special Consultant, U. S. Public Health Service. In either of the latter cases I have pointed out to Dr. Carpenter that I could not make such a statement without the approval of higher authority.

May I ask you to supply me with the attitude of the Committee on Medical Research toward human experimentation in general, and toward the particular problem of human experiment in the chemical prophylaxis of gonorrhoea.

Reply of A. N. Richards, Chairman, to Dr. J. E. Moore

October 9, 1942

In your letter of October 6th you ask that I advise you of the attitude of the Committee on Medical Research toward human experimentation in general, and toward the particular problem of human experiment on the chemical prophylaxis of gonorrhoea.

The Committee on Medical Research will hold its next meeting on October 29th. I shall present your question to them at that time. In the meantime I have confidence that the Committee will support me in the statement that human experimentation is not only desirable, but necessary in the study of many of the problems of war medicine which confront us. When any risks are involved, volunteers only should be utilized as subjects, and these only after the risks have been fully explained and after signed statements have been obtained which shall prove that the volunteer offered his services with full knowledge and that claims for damages will be waived. An accurate record should be kept of the terms in which the risks involved were described.

In answer to the second part of your question which concerns this specific case, the Committee on Medical Research must rely on the judgment of the Responsible Investigator, supplemented by the judgment of the committee in whose field the investigation is proceeding.

(Revision of Dr. Richards' letter of October 9, 1942)
Reply of A. N. Richards, Chairman, To Dr. J. E. Moore

October 31, 1942

In your letter to me of October 6 you raised the question of the attitude of the Committee on Medical Research toward human experimentation in general and toward the particular problem of human experiment in the chemical prophylaxis of gonorrhoea. I gave you a tentative reply under date of October 9 and brought the matter before the CMR at its meeting on October 29.

The statement in the second paragraph of my letter of the ninth referring to the general attitude was upheld.

"Human experimentation is not only desirable, but necessary in the study of many of the problems of war medicine which confronts us. When any risks are involved, volunteers only should be utilized as subjects, and these only after the risks have been fully explained and after signed statements have been obtained which shall prove that the volunteer offered his services with full knowledge and that claims for damages will be waived. An accurate record should be kept of the terms in which the risks involved were described."

I was instructed to recall the third paragraph of that letter and to offer in its place something to the following effect:

Whenever human experiments are planned as part of work called for in an OSRD contract recommended by CMR, the Committee on Medical Research should know in detail what they are. Further, it must be understood that legal responsibility for possible damages rests with the individual in charge of the experiments and the Institution for which he is agent. Arrangements can be made whereby both he and the Institution can be protected by insurance.

Hoping that the above statements provide adequate answer to your questions,
I am

Reply of J. E. Moore, M. D., to Dr. A. N. Richards

November 2, 1942

Thank you for your letter of October 31 outlining the attitude of the Committee on Medical Research toward human experimentation. I have forwarded a copy of your letter to Doctors C. M. Carpenter of Rochester, New York, and to Alfred Cohn of New York City, both of whom are interested in the possibility of human experimentation in gonorrhoea, though neither have as yet an OSRD contract for this purpose.

Letter from John A. Rogers, Colonel, Medical Corps, to Dr. Lewis H. Weed
December 4, 1942

It is understood a proposal has been made that the National Research Council undertake an investigation in search of an effective prophylaxis and improved treatment for gonorrheal infections, using selected human volunteers.

It is unnecessary to reaffirm the interest of this office in any scientific research the object of which is to reduce the incidence of this social disease, particularly in an armed force. Any progress in this field will have a direct bearing on the conservation of manpower engaged in war work of any character and it is hoped it will be possible for the Council to undertake such an investigation.

Letter from Ross To McIntire, Rear Admiral (MC), to Dr. Lewis H. Weed
December 5, 1942

The incidence of gonorrhea in the armed forces and the lost manpower resulting therefrom constitutes a problem of major military importance. New and improved methods for the prevention of gonorrhea are urgently desirable. Unfortunately, adequate experimental studies cannot be carried out in animals, since no known animal species is susceptible to local infection with the gonococcus. Laboratory studies other than in experimental animals do not provide definitive information capable of translation to man. The crucial experiment in the development of new prophylactic agents against gonorrhea lies in the experimental inoculation of human volunteers.

It is hoped that such experimental studies in human beings may be undertaken under the auspices of the National Research Council.

Letter from Thomas Parran, Surgeon General, to Dr. Lewis H. Weed
November 19, 1942

I have been informed that Doctor Charles M. Carpenter of the Strong Memorial Hospital of Rochester, New York, is interested in studies of the epidemiology and prophylaxis of gonorrhea and that the plan involves the utilization of human subjects for experimental inoculation by laboratory methods. No laboratory animals are available for this work inasmuch as such animals cannot be successfully inoculated with the gonococcus.

Because of the great prevalence of gonorrhea and its importance in the production of noneffective man-days both in the armed forces and civilian population, I believe that the human inoculation experiments proposed by Doctor Carpenter are justifiable if the human subjects are selected on a voluntary basis. The work should contribute some worthwhile new findings in the epidemiology and prevention of gonorrhea.

E. Dyer, Director, National Institute of Health to Dr. A. N. Richards
January 18, 1943

I have carefully studied the proposals (473, 474 and 475) for chemotherapeutic studies on human volunteers on the prophylaxis of gonorrhea submitted by Doctors Miller, Carpenter, and Cohn. The outline of methods to be employed seems adequate to insure a definite answer and to safeguard the volunteers. It is my opinion that the importance of the subject and the chances of success are such as to warrant the use of human volunteers, especially in view of the fact that the answer can be obtained in no other way. I favor the proposals.

Letter from Ernest L. Stebbins, M. D., Commissioner of Health, New York City to
Dr. A. N. Richards
January 19, 1943

Gonorrhea is a disease of major importance to the armed forces of our nation due to the loss of man-power it occasions. There is very little accurate information available as to effective means of prevention. There is some evidence that the methods of chemical prophylaxis at present employed are unsatisfactory. The development of effective prophylaxis of gonorrhea is, therefore of great importance in national defense. This view is shared by the Surgeon Generals of the United States Army, United States Navy, and the United States Public Health Service.

We are hoping that some of the experiments for using human volunteers, now being planned by the National Research Council, can be carried out in New York City. In order to correlate the medical and legal aspects of the problem, I am calling a meeting of those interested in the subject, to be held in my office at 125 Worth Street on Friday, January 22, 1943, at 10:30 A.M.

I should very much like to have you attend this meeting or designate a representative of the Committee on Medical Research to be present.

Letter from O. H. Perry Pepper, Chairman, Committee on Medicine to Commander Cushing
January 16, 1943

I herewith transmit the triplicates of three identical proposals for contract in research for a study of chemical and chemotherapeutic prophylaxis of gonorrhea in human volunteers. Each of these proposals was received by the Committee on Medicine from the Subcommittee on Venereal Diseases with a rating of "A". The Committee on Medicine has also rated these proposals "A" and I have so marked the rating slips.

This letter is added merely for the purpose of drawing attention to the opinions expressed in the attached letters to me from members of the Committee on Medicine. I would like these letters forwarded to the Committee on Medical Research with the proposals, with especial attention being drawn to the opinion expressed by Dr. Paul

Letter from James E. Paullin to Dr. O. H. Perry Pepper

January 13, 1943

I wish to acknowledge receipt of your communications of January 8 in which there is inclosed from the Subcommittee on Venereal Diseases a project from the Gonococcus Research Unit, Department of Health, City of New York concerning the chemical and chemotherapeutic prophylaxis of gonorrhoea induced in human volunteers. The project as I see it as submitted by Dr. Cohn is a very worthwhile thing to do and I think from the standpoint of furnishing medical information in controlling gonorrhoeal infection it would be most worthwhile. For this reason I would vote A on this project.

On the other hand I must take this opportunity of reminding the Committee on Medicine that if such a proposal is recommended and if such is accepted, that sooner or later information concerning this method of experimentation is going to become known to the public and sooner or later someone of these individuals who has offered himself for the purpose of this experimental research is going to fall in the hands of a very unscrupulous lawyer and this in turn may serve not only to embarrass the National Research Council but may tend to destroy a great deal of its usefulness and make it an object of severe criticism.

I have read with a great deal of interest the legal forms which you have drawn up and which are to be signed by the men who submit to the experimental inoculation. On the other hand he can always say he did not understand fully what was being done. Therefore, for the good of the Council and the protection of the Committee on Medicine, unless we can be absolutely assured that there will be no kick back, I vote to reject the project.

I am also in receipt of your proposal from Dr. C. Phillip Miller, University of Chicago, concerning the same project. My comments concerning this are identically the same.

Letter from Roger I. Lee, M. D., to Dr. O. H. Perry Pepper

January 11, 1943

I am glad to vote "A" on the proposal of Dr. Cohn and I am glad to accept the Vote "A" on the two other identical proposals.

As I tried to indicate in the discussion, the only thing that really bothers me is, if, by any curious chance, these experiments were to be carried out only in one state which had a bad repute, whether justified or not, in the handling of its prisoners. That objection is obviated by beginning with the State of New York and by the inclusion of three states in the program. I believe, however, that the situation ought to be watched in order to prevent such a contingency as I have outlined.

Letter from Arthur L. Bloomfield to Dr. O. H. Perry Pepper

January 11, 1943

I have read the outline of Dr. Cohn's project with great care and it seems to me that it would be extremely desirable to carry out this research. I should like to approve it with a rating of "A", and am also willing to do the same for the two associated projects.

The only point about which there could be any question is what one might call the public relations side, but I assume that has been carefully considered and that the conclusion has been reached that there would be no criticism from that standpoint.

Resolution of Subcommittee on Venereal Diseases

December 1, 1942

"THAT HUMAN EXPERIMENTATION IN THE PROPHYLAXIS OF GONORRHEA IS DESIRABLE IN PRISON INMATES THROUGH THE COOPERATION OF STATE AUTHORITIES. THE CHAIRMAN, SUBCOMMITTEE ON VENEREAL DISEASES, SHALL BE AUTHORIZED (if this recommendation is approved by NRC, CMR, and OSRD) TO APPROACH THE RESPONSIBLE AUTHORITIES IN SELECTED STATES WITH A VIEW TO THE CARRYING OUT OF SUCH EXPERIMENTATION BY RESPONSIBLE PHYSICIANS ACTING UNDER OSRD CONTRACTS. THE DETAILS OF SUCH EXPERIMENTATION AND ITS RISKS SHOULD BE DRAWN UP BY A CONFERENCE, THE PERSONNEL OF WHICH SHALL BE SELECTED BY THE CHAIRMAN SUBCOMMITTEE ON VENEREAL DISEASES. THE PROPOSALS OF DR. CHARLES M. CARPENTER, ROCHESTER, NEW YORK, AND DR. ALFRED M. COHN, NEW YORK CITY, INFORMALLY SUBMITTED TO THE SUBCOMMITTEE ON VENEREAL DISEASES ON DECEMBER 1, 1942, SHALL BE APPROVED IN PRINCIPLE, SUBJECT TO QUALIFICATIONS ARRIVED AT BY THE CONFERENCE AUTHORIZED ABOVE."

Reply from Dr. A. N. Richards to Dr. J. E. Moore

December 12, 1942

I understand from your letter of December 11 that the proposals of Dr. Charles M. Carpenter and Dr. Alfred M. Cohn for experimentation on human subjects in the prophylaxis of gonorrhea, while approved in principle by the Subcommittee on Venereal Disease and the Committee on Medicine, await further discussion by the Conference which you propose before being submitted to the Committee on Medical Research.

I believe it would be appropriate for you to call a meeting of the proposed conference group immediately so that the final definition of the proposals may be before the Committee on Medical Research as soon as possible.

If the prosecution of the investigations is dependent upon contracts with OSRD it would not seem wise to approach the State authorities until contracts are assured.

The wording of the recommendation is such as to lead me to remark that OSRD will not execute a contract with an individual physician, but only with the institution (University or Hospital) of which he is a member. It would be well to see to it that the responsible institutional authority who endorses the application for contract is made fully aware of the content of the proposal.

When the proposals are submitted to the Committee on Medical Research, I suggest that copies of the letters referred to in the first paragraph of your letter be attached for inclusion in our files.

behalf Commissioner Stebbins and an informal opinion has been obtained from the New York City, from whom a verbal and informal opinion has been obtained that legal objection to such experimentation in New York City or State may be made. The State Penal Code includes a definition of "maiming" which seems, in the opinion of the Corporation Counsel to preclude the carrying out of the study in New York. This section of the Penal law of New York State follows:

MCKINNEY'S PENAL LAW - Book 39

SECTION 1400 MAIMING DEFINED: punishment

A person who wilfully, with intent to commit felony, or to injure, disfigure, or disable, inflicts upon the person of another an injury which:

1. Seriously disfigures his person by any mutilation thereof; or,
2. Destroys or disables any member or organ of his body; or,
3. Seriously diminishes his physical vigor by the injury of any member or organ,

Is guilty of maiming, and is punishable by imprisonment for a term not exceeding fifteen years.

The infliction of the injury is presumptive evidence of the intent.

1. PRIOR LAW - COMMON LAW RULE

"Mayhem at common law is defined by Blackstone as the violently depriving another of the use of such of his members as may render him less able in fighting either to defend himself or to annoy his adversary. (4 Black.204.) It was recognized as a felony at a very early period of the common law, and the offender was punished by the loss of the same member of which he had deprived the party maimed; membrum pro membro. It was treated as an offense against the State, for the reason assigned by Lord Coke (1 Inst. 127): "for the members of every subject are under the safeguard and protection of the law, to the end a man may serve his king and country when occasion shall be offered." The special injuries which constituted mayhem are stated by Hawkins as follows: 'And therefore the cutting off or disabling or weakening a man's hand or finger, a striking out his eye or foretooth, or castrating him, are said to be maims; but the cutting off his ear or nose are not esteemed maims, because they do not weaken, but only disfigure him.' (1 Hawkins' Pleas of the Crown, 107)"

SECTION 1401 WHAT INJURY MAY CONSTITUTE MAIMING

To constitute maiming, it is immaterial by what means or instrument, or in what manner, the injury was inflicted.

SECTION 1402 MAIMING ONE'S SELF TO ESCAPE PERFORMANCE OF A DUTY

A person who, with design to disable himself from performing a legal duty, existing or anticipated, inflicts upon himself an injury, whereby he is so disabled, is guilty of a felony.

SECTION 1403 MAIMING ONE'S SELF TO OBTAIN ALMS

A person who inflicts upon himself an injury, such as if inflicted upon another would constitute maiming, with intent to avail himself of such injury, in order to excite sympathy, or to obtain alms, or any charitable relief, is guilty of a felony.

SECTION 1404 SUBSEQUENT RECOVERY ON INJURED PERSON, WHEN A DEFENSE

Where it appears, upon a trial for maiming another person, that the person injured has, before the time of trial, so far recovered from the wound, that he is no longer by it disfigured in personal appearance, or disabled in any member or organ of his body, or affected in physical vigor, no conviction for maiming can be had; but the defendant may be convicted of assault in any degree.