

December 17, 1968

Honorable Norman F. Lent
Chm., Joint Committee on Health
State Capitol
Albany, New York

Dear Senator Lent,

I am writing to request serious consideration to the potential hazards in the proposed amendment to the public health law in relation to human research (S. 4015A, A.5586A). I have read the proposed amendments and find them too restrictive in their text with regard to the continuation of research; and too vague in the definitions of 'research'.

Since 1952 I have been engaged in research in mental illnesses, with specific emphasis on treatments using biological methods. First at Hillside Hospital in New York (1952-1962), then as the director of the Missouri Institute of Psychiatry (1962-1966) and now at the New York Medical College where I am Director of the Division of Psychopharmacology and Drug Addiction, I have found that none of the techniques which are needed in the study of man can be carried out in animals. Mental illnesses seem peculiarly human frailties, and their study, while recommended in animals by others, are totally unsuccessful. Progress in treating the mentally ill seems to come only from studies in patients, as with convulsive therapy, the many new drugs, and recently, in the treatment of opiate addiction.

At present, our emphasis is in the biological treatment of opiate addicts. The peculiar nature of the illness, and the methods which are now useful (methadone maintenance, cyclazocine and naloxone antagonism) have been developed in patient studies.

The proposed law suggests that all studies will have to be cleared by a committee, half of whom will be laymen. Considering the difficulties with methadone maintenance with Federal authorities, and initially with state authorities, I am sure that such a committee will prevent any research which at the time may be considered hazardous, thereby preventing progress.

Let me cite a specific example. In our studies of methadone in the treatment of addicts, we have measured the effects of methadone on brain function and find that the changes are so like some that we have found useful in the treatment of severe schizophrenic patients, that we proposed a study of methadone in the therapy resistant psychotic

patients at our institution. The proposal was carefully reviewed by our College committees and approved. On referral to the Commissioner of Hospitals, however, the proposal was disapproved since methadone is considered an addicting drug. It is strange that laymen are willing to allow the severe mentally ill, for whom all hope has been abandoned after all other methods have been tried, to forgo a potential therapeutic benefit, out of fear.

All research must be daring to be successful. All human research can be monitored by our peers, and the present committees have shown themselves to be useful. Since their introduction during the past few years at the urging of the Federal granting agencies, it seems premature to establish another mechanism before this one is fully established.

Specific objections to the legislation are as follows.

The Commission will consist of laymen in the majority. Modern techniques are too complex to be reviewed by the laity except when one expects responses based on prejudice and emotion. Research cannot be judged by emotion and should be judged by reason-- wherever possible/

The Commission will sit far away from the site of the research. It seems that there will be only one full time member, and it is inconceivable that the site of the research, the qualifications of the investigator, and the quality of the protective devices can be monitored except in the locale where the study is done. If a committee of visitors is established, then the device will be overly cumbersome and expensive.

The conflict between research, as poorly defined, and treatment as medical practice, is not resolved by the legislation. If I treat a patient with a new treatment will this be exempt if I am paid for it as part of medical practice; but not exempt if done for no fee as part of a research program?

The problem of consent has been adequately discussed in the Federal legislation of a few years ago. There are special problems in dealing with the mentally ill, and the proposed state legislation does not define the safeguards which experience has shown to be useful and necessary.

There are other problems which are not clarified in the bill. It is regretted that the legislature finds it necessary to propose state legislation in an arena where existing legislation, if adequately administered, would be most adequate to protect our fellow citizens and ourselves. American research has been in the forefront in all fields except in the care of the mentally ill. Most of the modern advances in their treatment have come from Europe. In part this resulted from our overinvestment in psychotherapy; and in part, from the restrictions placed on research in our institutions for the acute mentally ill. The addition of this burden, as exemplified in the proposed legislation, will handicap American research even further-- for such legislation is unlikely to remain restricted to our state, since we have been a bellweather state.

In writing this letter, I am acting on my own behalf as Director of the Division of Psychopharmacology and Drug Addiction of the Department of Psychiatry; and as the Executive Director of the International Association for Psychiatric Research, Inc. The IAPR was established in 1967 to provide a mechanism whereby collaborative research could be undertaken in other localities where the restrictions were less stringent. Because of limitations in committee actions at the Federal level, we have undertaken some important research in treatment of mentally ill in Istanbul, thereby confirming studies originally reported from France. We have also begun a study of marijuana in Greece since the restrictions imposed on the study and supply of this important agent in the United States have been so great that we have had to go through multiple committees and 18 months delay before undertaking such studies in New York.

Your consideration of these comments is appreciated. The proposed legislation will, in our opinion, do more harm to our citizens and ourselves than any potential good that may be imagined. Your committee's disapproval is requested.

Sincerely yours,

Max Fink, M.D.
Professor of Psychiatry