Statement by Dr. Joshua Lederberg

February 19, 1976

Having worked within the framework of the NIH Grants/Peer Review System for most of my scientific career, I felt that it was a particular privilege and obligation to comment on the efficiency and fairness of this system at the occasion of the present hearings. My first encounter with this system began over 25 years ago;during the 12 years that I worked at the University of Wisconsin; and throughout the course of my subsequent work at Stanford. Especially during the middle period I served on many NIH study sections and have also served on the National Advisory Mental Health Council for the NIMH. I have also related to a variety of other government agencies and can therefore make some comparative estimates of the way that different variants of the system and other ways of administering research in fact operate.

At the outset I should summarize that although my own personal experiences with Peer Review have sometimes been quite frustrating, at others very smooth, it is difficult to imagine any alternative system that could function nearly as well in practice in meeting the national goal of strengthening the productivity of important health research in this country and supporting the careers of dedicated research scientists. This is certainly not to pretend that this is a perfect arrangement;but to assert that it stands rather high in the scale of practical human affairs in achieving its asserted goals. If the Congress and the people wish to put a higher priority on other objectives - for example,by hypothesis,equal access to federal support for research as a matter of equal personal right(rather than in terms of scientific quality or its utility for the public good) then the Peer Review System may not be the most effective instrument. However, if there is to be a significant diversion of goals,then this issue should be addressed directly and institutions established whose avowed

redirection of purpose is clearly stated. There is nothing to prevent the allocation of specific components of the overall budget, within the framework of the existing grants system, in such measure as may be politically determined to be most appropriate for other purposes. The most obvious of these would be the diversion of resources to weaker institutions or less able scientists with the hope that these funds might by themselves upgrade those capabilities. Needless to say, one should not embark upon such new and expensive programs without a very careful consideration about the likelihood that they will achieve the objectives of the intended investment.

The existing system of Peer Review and its counterpart in the overall framework of the scientific enterprise is based essentially on the concept of motivated mobility. It is indeed true that the so-called prestigious institutions receive more than a demographic proportion of support for scientific work. Yet it is precisely the same institutions that are the target for the careers of many younger scientists, who aspire to work in the company of excellence, and in a context that experience has shown to be so highly productive. These institutions are deeply self-conscious that their most treasured resource is the positions on the faculty; and they spend an enormous effort in seeking out the most qualified candidates. This is not to decry the attractions that other more distributed institutions may have for many very competent people, and here we have the network of open publication and the avid pursuit of evidence of new discovery as one of the fundamental structures on which scientific progress is based. Given these competitive, open, pluralistic institutions it is really not likely, nor is there any significant evidence, that true talent remains long hidden from view or that it persistently fails to find recognition from the existing review system.

If these arguments for maintaining the essential structure of Peer Review are for the moment granted, we must then face the sincere concerns of many who may feel that the review process should be less secret, that it perhaps might involve wider circles of critics than at present, that investigators should have greater opportunity to learn the reasons why their proposals may not have been accepted and have a better opportunity to rebut criticisms that have been made. In particular, it has been suggested that the entire proceedings of scientific review be made open and public, and that more elements of constitutional due process should be attached to a program that involves a commitment of tax dollars to a public purpose.

I am deeply sympathetic with these concerns; and in various situations have attempted myself to bring about some of the reforms that have in fact tended to alleviate some of them. We do have a dilemma with respect to the practical possibility of obtaining critical and candid reviews if these are done in public. The process is very similar to what is involved in many personnel actions which are the one area of public administration which has been widely deemed to be the most qualified for some exception to complete public ventilation of every claim and counter-claim. It is not only the reviewers who stand at risk from a public proceeding - there are also grave potential embarrassments to the applicants and there is really considerable question as to whether justice would be better served by a complete removal of the cloak of confidence.* However, as an experimental pragmatist, I could hardly argue against attempting a trial, within a well defined and limited context of such an approach, and would certainly recommend this before there were any sudden upheavals in the overall system.

These concerns have, of course, evolved in a setting of more and more rapidly growing confrontation and with the assertion of the right to due process as a basic guideline in every human interaction. Before yielding to

*any more than one would advocate that trial juries deliberate in public

the temptation to avow such an approach as the essence of liberty, we should keep in mind the costs to the operation of any social system if each transaction could be valid only if the parties appeared in court and had the right of counsel. We would find that it would take six years rather than six months to complete a review of any given proposal if we had to give credit to all of the arguments that litigious contestants might wish to offer. This is hardly a speculation since we know that already the gravest impediment to the allocation of criminal justice is the inordinate delay and the clogging of our judicial pipelines that apply even under existing legislation.

We should then be seeking effective reforms that attempt to meet these sometimes conflicting objectives, in a way that results in a practical degree of fairness and of efficiency and of concern for the variety of interests involved. I believe that the key to this objective was already foreseen by the Congress in the form of its legislation for the establishment of the various institutes of the NIH. With each such institute the Congress has almost always had to prevail against a reluctant Executive in insisting that the legal power to award grants be vested in an Advisory Health Council rather than in the appointee of the President directly. These Councils have occasionally, but only occasionally, been allowed to operate in the fashion implied by the enabling legislation. They were intended to represent public interest and a wide variety of interests of the participants in the research enterprise to help be sure that the overall purposes of the research budget of the NIH were met by the overall program of supported grants. The study sections, by law, are in fact agents of these Advisory Councils, report to them and it is the Councils' legal approval that is binding as a necessary condition in the grants process. Throughout several administrations the Executive has been reluctant to provide the highest and most representative

quality of appointments to many of these councils - with some notable exceptions - and the directors of some institutes but not others have made the most appropriate use of them. Obviously, such a council with a heavy representation of lay-membership can hardly be expected to redo the work of the professional peer groups, the study sections, in the detailed examination of the substance of thousands of applications. These councils do however have the potential to be sure that the review process is conducted fairly, to provide avenues of appeal and redress, and to be sure in other ways that the public interest is best served by the entire operation. It is at this level, in my opinion, that concerns about the equity of distribution of grants by geography, or by any other criterion that has been suggested, could most appropriately be validated: by encouraging the appointment of an appropriately representative group of members to these councils. As council membership must, by law, rotate fairly quickly, there is little opportunity for the development of the kinds of cliques and cabals that are claimed to impede the fair operation of the peer review process. I do not think this is entirely a hypothesis since my reflections on these procedures stem from my term with the National Advisory Mental Health Council, at a time when it was perhaps at the peak of its competence and influence to fulfill its legislative and social mandate. It was subsequently subjected to considerable interference, expressed mainly in the form of inordinate delays in the appointment of new members and in the use of the crassest political criteria in the attempted choice of new nominations. Since these matters have been brought to light, I believe there has been considerable alleviation of this problem but it has surprised me that so little has been said about the role of the advisory councils as the tempering influence to make the Peer Review System work well and fairly, and in a way that appears to be fair.

As to the rights of applicants to understand more clearly the reasons for the fate of their applications, it first of all has to be said that the vast majority of disappointed applicants these days have had their work approved on a scientific basis;but had failed to find funding because of inadequate budgets,and administrative decisions about the cutoff points for this funding. This disparity between the reservoir of frustrated talent and the resources that are being made available for the pursuit of research should not be laid to the door of the Peer Review System. Nevertheless, there are a number of reforms that I have strongly advocated in the past,and have been gratified to see adopted in considerable measure in recent years. These have to do mainly with taking more time and trouble to indicate to applicants more detail about the difficulties that may have occasioned low priority scores,or rejection,or deferral of their applications. I believe that many institutes have in practice worked out a fair accommodation between the needs for practical operation of the review system and the right of information on the part of the applicants. The structure of the system should not be molded by a very small minority of the most litigious and often scientifically unproductive workers. There are a number of administrative details that should be worked on but which doubtless will require the investment of more not less money to make the system work well. It is especially irksome that it takes so long - often the best part of a year - between the time that an application must be submitted and the time that one gets any significant information about its outcome. There is usually not enough opportunity for some dialogue, for the working out of compromises, for the removal of particular difficulties;and a process that in principle could be done within a few months can sometimes be stretched out for several years or beyond the life-time of the idea and of the zest to pursue it on the part of the investigator. This process has not been helped by the

rapidly increasing accumulation of regulatory encumbrances that have sought to enforce highly desirable social objectives - for example the protection of rights of human subjects - in ways whose administration seems calculated simply to add to delays in the processing of applications. A number of certificates of compliance must be attached to applications, even before they are submitted rather than during the many months during which they are under consideration;and if these could be conditions of the award of a grant rather than of the acceptance of an application, many months would already be saved. These encumbrances aggravate the problems of communication that investigators face,and which they may attribute to the essential core of peer review quite inappropriately.

I have just one other concern about the detailed operation of the Peer Review System and that is for reasons of administrative simplicity its judgments end up being transformed into a single number, the priority rating, that is supposed to represent the consensus of the study section. I believe that this is far too crude a measure of a sometimes diverse set of views that reflect different dimensions of approval,or of concern; and that this number does not give enough latitude in the further negotiation of the grant between the NIH and the investigator,to correspond to the true range of opinions of the reviewers about the project. For this reason alone, I believe that an intense, empirically oriented study of the peer review process would be most desirable, not with the aim of wrecking it, but with the aim of making some new technical innovations in the way in which reviews are conducted ,and the results of reviewers' deliberations are scaled.

I also believe that there has been a growing tendency, under budgetary stringencies, to increase the cost and judicial burdens of the review process by demanding re-examination of research projects on an increasingly shorter term. It used to be unusual but imaginable that an ongoing research project

could look forward to as much as 7 years of support. Now a growing number of projects are only funded for 3 years and sometimes less; which is hardly time to recuperate from the rigors of applying for one grant before having to begin to renew the process. Of course, there are many circumstances where it is vitally important to track the progress of a particular piece of work in some detail. But these exceptional circumstances really should not be confused with the bread and butter type of support - for the fundamental operation of our institutions of higher learning and research - which are not likely to change very much in the fundamental quality of their work in so short a time. Some of the faults of the Peer Review System can certainly be laid to the sheer volume of material that has to be processed by a group of dedicated but overworked and essentially unpaid volunteers who serve on the review committees. More meticulous procedures for dealing with the process could become more practically available if it were not invoked so frequently.

A number of other administrative reforms might be recommended to allesome of the difficulties of dealing with the inevitable disappointments of some applicants, and their understandable tendency to question the fairness of the system -- although I believe that the central ingredient is better and brisker interchange of information between the investigators and the NIH itself. (Site visits, which have been restricted for budgetary reasons, are among such devices.) Since the competitive rivalry among scientists, which is a central part of the system for innovative discovery, can of course breed occasional personal antagonisms, applicants may feel that they have been abused by the presence of a specific individual on the review committee. We might experiment with a procedure that allowed an applicant to request that some single individual member of a review panel be excused from deliberations on his own case, leaving the burden to the other members of that group. Likewise applicants should be encouraged to designate the names of referees who are familiar with their work, and should be consulted at least by mail as potential advocates to submit further information into the review process.

These and many other procedural variations should be within the latitude of an innovative and concerned Advisory Council to try, towards the continued

perfection of the peer review system.

The integrity of that system is important first of all, of course, as a matter of responsible government administration. The public should also note that the scientific community has developed its own devices for the rapid and effective advancement of knowledge, which operate somewhat differently from the adversary system with due process that describes more formal government procedures. Scientists are expected to tell the truth, not just to present the best case for their own side, and to look for technicalities and dilatory tactics with which to win a case. For a community of mortal humans, that system has worked very well: the best evidence perhaps is that isolated infractions -- like the rare scientists who have lied in print -- make headlines. For it to continue working it must of course get social reinforcement : recognition of the basic values of approaching scientific truth through the open publication of results, and their availability to reexamination of every detail by others.. And there must of course be serious sanctions -- as there are perhaps more in science than in any other field of human activity -- against lying. The social losses from a disturbance of that system, and its replacment by a quasi-judicial-legalistic-adversaryone could be so large as to undercut both the material and the philosophical advances on which our modern culture is founded.