

**Grants peer review : opinions on the NIH grants peer review system ; public hearings and letters, survey of 1975-76 review groups : summary, phase II of the report to the Director, NIH / by the NIH Grants Peer Review Study Team**

NIH Peer Grants Review Study Team (U.S.)

[Bethesda, Md.] : [Dept. of Health, Education, and Welfare, Public Health Service], National Institutes of Health, 1978, i.e. 1979

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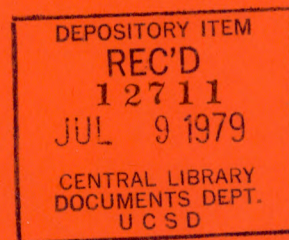
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## OPINIONS ON THE NIH GRANTS PEER REVIEW SYSTEM

- Public Hearings and Letters
- Survey of 1975-76 Review Groups



**Summary**  
**Phase II of the Report to the Director, NIH**  
**by the**  
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**December 1978**

**Prepared under contract**  
**Cooper-Williams Associates**



## FOREWORD

This report (Phase II) supplements the three-volume Phase I report on the NIH research grants review system presented to the Director of the National Institutes of Health in December 1976 by the NIH Grants Peer Review Study Team. Volume I, Grants Peer Review, Report to the Director, NIH, Phase I, constituted the major document, presented the Study Team's specific recommendations, and included discussions of the bases for the recommendations.

Following a careful review of the report, Dr. Donald S. Fredrickson, Director of the National Institutes of Health, announced in February 1978 that he had approved 33 of the 69 recommendations in toto and another 9 with minor modifications. Five of the suggested changes could be implemented without action by the Director. Actions on 19 of the recommendations were deferred pending additional study, and only 3 of the recommendations were rejected. Since then, the NIH staff has worked toward implementing the approved recommendations and toward reviewing those that were deferred.

The broad charge given to the Study Team when it was established on April 28, 1975, included the statement that it would be expected "to make appropriate contact with members of the scientific community and current and former members of the Advisory Groups, in order to examine perspectives, criticisms, suggestions for alternatives or improvements to the peer review system." From its inception, the Study Team recognized the importance of obtaining such comments and suggestions from a wide range of biomedical researchers and interested lay persons before the report and any recommendations were developed. In order to do this, three public hearings were held, letters of comment were solicited, and members of the 1975-76 NIH review groups were surveyed. The facts, opinions, and suggestions which were obtained from these sources were given considerable weight by the Study Team in formulating its recommendations.

So that the NIH would be able to benefit fully from these comments on the peer review system and the suggestions for its improvement, the Study Team decided to have a detailed analysis prepared, even though it could not be completed before the Study Team made its December 1976 report to the Director. This Phase II report contains such an analysis.

Part I describes the activities of the NIH Grants Peer Review Study Team and supplies detailed information on the characteristics of the three groups from which the Study Team sought comments--the members of the 1975-76 NIH grant review groups, the witnesses at the public hearings, and those interested persons who wrote in response to the Study Team's request for comments. It also provides statistical information on the opinions of these three groups about the NIH review system and their evaluation of the system's strong and weak points.

Part II deals with the substance of the comments on the NIH grants review system made by the 93 witnesses and 1,400 correspondents. It deals also with answers to the questionnaire distributed to the 1975-76 review group members and the comments volunteered by one-half of the 1,274 members who responded. The 11 chapters in Part II relate to the major subjects discussed by the witnesses and correspondents and include excerpts from relevant comments.

We believe this Phase II report not only provides a response to the original charge to the Study Team to obtain the opinions of the scientific community, but also strengthens the Study Team's recommendations made in the Phase I report. We hope that any future studies of the NIH peer review system will take further cognizance of the thoughtful comments and perceptive suggestions made by members of the scientific community, which are given in detail in this report.

The project was performed by Cooper-Williams Associates, Sumner, Md. This organization devised the classification system, designed the indexing methodology, planned the statistical tables, and monitored all of the work performed.

The computerization of the contents of the letters and the survey, the indexing, and the production of the computer tables were performed by Information Management Services, Inc. under the direction of Robert Burton, assisted by Jerome Felix and David Roney.

The report was planned and written by Pearl Cooper Williams and David Carnahan Williams of Cooper-Williams Associates.

Special acknowledgement is due Dr. Mathilde Solowey, who has exercised general oversight over the preparation of this Phase II report after serving as Executive Secretary of the NIH Grants Peer Review Study Team. Without her continued interest and dedication, the Phase II report would not have been possible.

The NIH Grants Peer Review Study Team, thus having completely responded to its charge, has discharged its obligations and respectfully presents this final submission (Phase II) of its report to the Director, NIH.



Ruth L. Kirschstein, M.D.  
Chairperson, NIH Grants Peer  
Review Study Team

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## CHAPTER 1. SUMMARY

This report is one of several resulting from an intensive examination of the NIH Grants Peer Review System initiated in April 1975. The examination was carried out by the Grants Peer Review Study Team (made up of NIH staff), which submitted its report and recommendations to the Director of NIH in January 1977. After comments had been solicited from all Institutes, the Director announced his decisions on the recommendations on February 8, 1978.

The charge given to the Grants Peer Review Study Team in April 1975 was broad—to conduct a detailed and comprehensive study of the NIH peer review system that would focus on the philosophy and procedures of peer review, the system's applicability to NIH awarding systems and programs, the attributes and problems of alternatives, and the role and character of peer review in the decision-making process at NIH.

From its inception, the Study Team recognized that its appraisal of the peer review system would be strengthened by obtaining the opinions of concerned individuals who were not NIH staff members. Substantial efforts were made to obtain opinions concerning the current NIH peer review system and suggestions for its improvement from a broad range of biomedical researchers and other interested persons in time for their comments to be considered before the Study Team developed its recommendations. Three approaches were used:

1. Active solicitation of letters of comment.
2. One-day public hearings in each of three cities.
3. A survey of all members of the 1975-76 NIH grant review groups.

Notices of the hearings were published in the Federal Register. A letter signed by the Chairperson of the Study Team was mailed to 30,000 individuals in the biomedical research community and related public interest groups. As a result of these and other measures to communicate with all interested persons, 78 witnesses testified at the three hearings (in Chicago, San Francisco, and Bethesda), 15 additional persons supplied written testimony, and 1,400 letters were received. The facts and opinions brought out by the 93 persons participating in the hearings and set forth in the 1,400 letters were given considerable weight by the Study Team in formulating its recommendations to the Director of NIH. So that the NIH could benefit fully from the comments contained in the hearings and letters, it was decided to have a detailed analysis prepared. This analysis, conducted by non-NIH consultants, is presented in this report.

The third approach used by the Study Team to obtain information for its deliberations was to conduct a survey of all the members of the 1975-76 grant review groups in order to obtain informed judgments from that part of the scientific community which was actively participating in the

NIH peer review system. Questionnaires were distributed to the 1,354 members of 12 National Advisory Councils, 51 Divisions of Research Grants (DRG) Study Sections and 24 Institute Initial Review Groups (IRGs). A total of 1,274 responses (94 percent) was received. Because an analysis of the survey findings--both of the statistics and the comments--is available in the various reports that have been completed, the present report concentrates on the analysis of comments made in the letters and during the public hearings. Whenever pertinent, however, findings from the survey of the 1975-76 review group members are cited.

### Characteristics of Persons Stating Opinions

To permit a meaningful evaluation of the opinions expressed, relevant data concerning the individuals who made the comments--their qualifications, positions, institutional connections, and experience with the NIH grants system--was analyzed. This was considered particularly necessary in regard to the witnesses and correspondents, as they were individuals who had volunteered their opinions and had not been selected to represent either biomedical scientists, the scientific community, or the interested public.

The characteristics of the witnesses were found to differ from those of the correspondents in almost every aspect for which information was obtained. Witnesses more often represented formal organizations and included a higher proportion of women and of individuals who had never applied for an NIH research grant. Of those who had applied, a smaller proportion of the witnesses than of the correspondents had had their grants funded. Also, a smaller percentage of witnesses than of correspondents were faculty members or had served on NIH review groups.

The largest single group of correspondents (almost two-thirds) were faculty members, with over one-half identifying themselves as professor and almost one-fourth as Department Head or Chairman. The second largest group (about one-sixth) held administrative positions, such as President, Dean, Assistant Dean, or Department Director of a hospital or research institute. The exact position of a sizeable number (again one-sixth) could not be identified from their letters, but a substantial proportion of these followed their signatures with the MD or PhD designations. Of the 93 witnesses (in person or by written submission), approximately one-fourth were faculty members and another one-fourth were officials of an organization. One-tenth held administrative posts. Exact positions were not identified for almost one-third. Eight percent of the correspondents and 16 percent of the witnesses were women.

Over four-fifths of the 1,400 correspondents were employed at, or affiliated with, institutions of higher education. Research institutes, laboratories, and hospitals that were not owned by educational institutions employed another one-tenth. Only small percentages wrote as representatives of professional societies, State agencies, public interest groups, or other organizations. Somewhat over one-half of the 93 witnesses came from institutions of higher education and almost one-quarter represented professional societies.

A large majority of both correspondents and witnesses had applied for NIH grants at least once between FY 1967 and FY 1976--87 percent of the 1,400 correspondents and 73 percent of the 93 witnesses. Sixty percent of both groups had applied more than once. Over three-quarters of the correspondents and almost two-thirds of the witnesses had had one or more grant applications approved and funded in the ten years FY 1967 through FY 1976. Only 67 correspondents and 5 witnesses had experienced nothing but disapproval from the review system.

Over two-thirds of the correspondents and three-fourths of the witnesses had not been regularly appointed members of any NIH review group during the ten years FY 1967 through FY 1976.

### Opinions Concerning the NIH Peer Review System

The current NIH system for the review of research grant applications was strongly endorsed by an overwhelming majority of each of the three groups canvassed. Approximately 96 percent of the 1975-76 NIH review group members rated the NIH system as "excellent" or "good." Over 83 percent of the 1,400 correspondents and 73 percent of the 93 witnesses approved of the system.

Those individuals who had had the most experience with the system were the most favorably inclined. Members of the 1975-76 NIH grant review groups were more favorable to the system than the 1,493 correspondents and witnesses. Those correspondents who were familiar with the system were generally more favorable than those who were not.

Unlike the survey of 1975-76 grant review members, which was conducted by a structured questionnaire requesting ratings from "excellent" to "very poor," the attitudes of the correspondents and witnesses could only be ascertained through a careful study of the letters and hearing transcripts. Five categories were used:

1. Favorable, explicitly stated.
2. Favorable, implied by the contents of the letter or testimony.
3. Unfavorable, favored the concept of peer review, but disapproved of NIH procedures or policies.
4. Unfavorable, opposed the concept of peer review.
5. Not indicated.

Almost three-quarters of the 1,493 correspondents and witnesses explicitly stated that they favored the NIH review system (category 1), while the contents of the letters and testimony of another 10 percent implied a favorable attitude (category 2). One-eighth of the correspondents and witnesses accepted the concept of peer review, but commented unfavorably on one or more aspects of NIH policies and procedures (category 3). Less than two percent of the total opposed the concept of peer review (category 4).

A larger proportion of the witnesses than of the correspondents disapproved of NIH policies or procedures in conducting peer reviews. This difference in attitudes is understandable when the different composition of the two groups is taken into account. A higher proportion of witnesses than of correspondents were in those groups which had had little direct experience, either as review group members or as grant applicants, with the review system.

Men and women correspondents held almost identical opinions concerning the NIH grant review system. Although the 15 women who testified at the hearings were more critical than the male witnesses, this comparison must be viewed with caution because of the small number involved.

The large number of persons whose letters or testimony represented only their own opinions were more favorable in their attitudes than the small number representing informal ad hoc groups--generally composed of several members of a department or staff at a given institution. Those who represented formal organizations were as favorable (85 percent) as those expressing individual opinions (83 percent).

Approximately 85 percent of the large group of correspondents and witnesses who were faculty members had favorable attitudes towards the peer review system, with full professors and department heads being even more favorable than associate or assistant professors. Correspondents and witnesses affiliated with schools of arts and sciences, schools of medicine, and university hospitals were more favorable in their opinions of the NIH system than those affiliated with other health professional schools (such as dentistry or veterinary medicine) or with university research laboratories. Among correspondents and witnesses who were not primarily affiliated with academic institutions, those representing professional societies were the most favorably inclined (almost 85 percent).

Those correspondents and witnesses who had applied one or more times for research grants during FY 1967 to FY 1976 were more favorably inclined (84 percent) to the review system than those who had not (75 percent). Those whose only experience had been to have their application or applications approved and funded were, as might be expected, highly favorable (93 percent). Even among the 72 correspondents and witnesses whose only experience had been disapproval, two-thirds basically favored the NIH system.

It would seem that the correspondents and witnesses who had been exposed to only a single type of NIH action regarding grant applications were more apt to have their opinions concerning the NIH review system affected by that experience than were those exposed to multiple types of NIH actions. However, the individual mix or the multiple actions experienced apparently did have some effect on attitudes, particularly if one of those actions was a disapproval.

Ninety-two percent of the 467 correspondents and witnesses who had

been regularly appointed members of an NIH review group during the ten years 1967-1976 were favorable to the system, compared with 78 percent of the 1,026 individuals who had not been members.

### Strong Points, Weak Points, and Suggested Changes

Many commentators, both those who were favorably disposed to the review system and those who were not, pointed out specific strengths and weaknesses or suggested changes in certain aspects of the system. A wide range of topics was discussed. While many remarks were addressed to the specific subjects listed in the NIH Grants Peer Review Study Team's announcement of the public hearings, many dealt with other subjects of concern.

A total of over 12,000 comments were made by the 1,493 correspondents and witnesses. Of the total comments, almost one-half mentioned a weak point or suggested a change in the NIH system. Some 30 percent of the over 12,000 comments cited a strong point, while 23 percent consisted of neutral remarks that mentioned a subject, but did not indicate whether the commentator considered it an asset or a defect. (Comments that simply suggested changes were generally classified as weak points on the basis that such a suggestion implied a need for improvement.)

Forty-two percent of the 1,493 individual commentators cited both strong and weak points in the system. However, over one-fourth of the correspondents and witnesses confined themselves to pointing out only strong points and roughly the same proportion mentioned only the system's weak points.

Over two-thirds of all 1,493 correspondents and witnesses mentioned at least one strong point in the current NIH review system, with the proportion of witnesses roughly the same as for the correspondents. Seventy-eight percent of those whose basic opinion of the NIH system was favorable mentioned a strong point, whereas only 22 percent of those whose basic opinion was unfavorable did so. Commentators who had had recent experience with the NIH review system, either as grant applicants or as review group members, were more apt to mention the system's strong points than those without such experience.

A wide variety of strong points were mentioned in letters and testimony. Of these, 12 were cited by at least 100 commentators. The strong point stressed by the largest number (35 percent of all correspondents and witnesses) was the value of review by scientific peers, with approval based on the quality of the proposal. A close second, mentioned by 30 percent, was the general excellence of the NIH review system.

The remaining ten leading specific strong points were cited by substantially fewer individuals. They were: The effectiveness of the NIH system in maintaining a strong, high-quality national biomedical science base (15 percent); the performance, fairness, and lack of bias shown by review group members (13 percent); the importance of the confidential



treatment of an applicant's proposal (10 percent); the excellence of the reviews performed by Initial Review Groups, including specific IRG procedures (10 percent); the value of group discussions and procedures (9 percent); the preferability of the NIH review system to other systems used in the United States and abroad (9 percent); opposition to any change in the current system (8 percent); the general fairness of the system (7 percent); the extent to which the system meets the best standards of public accountability for the expenditure of public funds (7 percent); and the absence of cronyism and conflicts of interest (7 percent).

The survey by questionnaire of the 1975-76 review group members indicated that seven aspects of the NIH review system were approved by at least 90 percent of the members. These were: (1) the reviews performed by Initial Review Groups, particularly for traditional research project grant applications; (2) the fairness and lack of bias in the system among review group members and NIH staff; (3) the lack of bias against minorities, young investigators, and women; (4) the high caliber of the scientific and technical members of the review groups; (5) the qualifications and performance of NIH staff; (6) the performance of review group members, as shown by their discussion of applications and their behavior during the review process; and (7) the value and high quality of site visits.

A great variety of weak points in the peer review system, as well as a multiplicity of suggestions for improvement, were mentioned by correspondents and witnesses. Ten aspects of the system were cited as weak points by at least 100 correspondents and witnesses. The weak point stressed by the largest number (28 percent) dealt with the specific review procedures used by the Initial Review Groups. The largest number of these critics were concerned with the evaluation criteria used by the Initial Review Groups, while others pointed out difficulties with the performance of site visits or the procedures for the development and normalization of priority scores.

The specific weak point commented on by the second largest number of witnesses and correspondents (25 percent) was the selection of review group members. Substantially fewer correspondents and witnesses cited what were perceived as the eight other leading weak points: Lack of ability to present rebuttals and appeals, including specific criticism of current procedures and the need to establish a formalized appeals procedure (14 percent); the balance of NIH research support, particularly between targeted and basic research and between small and large grants (14 percent); representation of appropriate experts on Initial Review Groups (12 percent); problems arising as a result of factors outside of NIH, such as the irregularity of Federal funding and political pressures (10 percent); support for innovative research (9 percent); charges of elitism and cronyism (9 percent); communications and feedback from NIH (9 percent); and the workload of review group members (7 percent).

Comparisons between the replies by the 1975-76 review group members to specific survey questions (to all of which a majority had responded favorably) and the comments volunteered on any subject by the correspondents and witnesses are difficult. However, it is clear that some as-

pects of the system caused concern in both groups: certain procedures of the Initial Review Groups; the selection of review group members; cronyism; and the workload of review group members.

Among the NIH review group members surveyed, the least support was given to two NIH restrictions governing applicant notification. The lowest favorable rating (56 percent of the members responding "excellent" or "good") was given the requirement, then in effect, which prohibited informing the applicant of the priority score assigned by the Initial Review Group and the third lowest favorable score (69 percent) was given the requirement which delayed informing the applicant of the overall IRG recommendation until completion of the final review by the National Advisory Council. Another aspect given a relatively low favorable rating (67 percent) was the adequacy of the review for program relevance, which is the primary responsibility of the National Advisory Councils.

Of the total of just over 12,000 comments made by the 1,493 witnesses and correspondents, approximately one-fourth were suggestions for changes or improvements in the peer review system. Only about 50 suggestions, however, involved changing the entire system.

Well over one-half of all correspondents and witnesses (839 individuals) made at least one suggestion for changing the system. Those whose opinions of the review system were basically unfavorable were more apt to suggest changes. Almost 78 percent of the disapprovers made at least one suggestion for change, compared with 53 percent of those who approved of the current system. Members of the 1975-76 review groups surveyed expressed a general lack of enthusiasm for changing the current system--at least with regard to 19 of the 20 suggested changes listed in the questionnaire filled out by them.

A high proportion of correspondents and witnesses citing weak points made at least one suggestion for a change. On the whole, the percentage of persons making suggestions may be considered a guide to those areas about which the correspondents and witnesses felt strongly and to which they had also given sufficient thought to develop recommendations. The specific weak points for which at least one-third of the individuals noting such points made suggestions were: Lack of a system for rebuttals and appeals (62 percent); selection of members (59 percent); specific IRG review procedures (55 percent); NIH communication and feedback (53 percent); workload of review group members (39 percent); and representation of appropriate experts on Initial Review Groups (34 percent).

### The NIH Grants Peer Review System: An Overview

Over 450 hearing witnesses and correspondents paid tribute to the overall excellence of the peer review system, although many added suggestions with regard to how it could be improved in one way or another. Some paraphrased Churchill's well-known observation about democracy, saying that the peer review system had its shortcomings, but was superior to any other such system in existence.

A very considerable number of commentators noted that, like any system administered by human beings, peer review could not be expected to achieve absolute perfection. No system, it was said, could function independently of personalities and be free of occasional abuse.

Some hearing witnesses and correspondents maintained that the results of the system offer compelling evidence to its soundness, one even citing evidence that these results had improved over the course of time. A number noted that the system, over the years, has been impressively free of scandal. Even some scientists who had experienced personal disappointments with the system paid tribute to its fairness.

A number of hearing witnesses and correspondents compared the peer review system with the systems used to award grants in other Federal agencies. A dozen Federal agencies were cited, the National Science Foundation most often—undoubtedly because it was the agency, apart from NIH itself, with which biomedical researchers have had most experience. It was clear that these commentators considered the NIH system superior to mail or in-house reviews. Two correspondents observed that the recognized superiority of the NIH system had prompted other US grant-awarding agencies to evolve towards it.

A number of correspondents, drawing from their experience, compared the NIH system favorably with those used in other nations. Great Britain was cited eight times, Canada three, and the USSR, France, Germany, Italy, and Switzerland twice each. Single citations were The Netherlands, Australia, Sweden, Norway, Finland, India, Japan, and Bulgaria.

A number of hearing witnesses and correspondents expressed a strong preference for the review procedures used with respect to NIH research grant awards as compared with those used for contracts. Some suggested that the full dual peer review procedure be applied to contracts and one wrote that, unless this be done, contract funding should be abolished altogether. In the view of these commentators, current procedures for awarding contracts resulted in less public accountability, a poorer cost-benefit ratio, and a lower quality of research, yielding little knowledge of importance.

Almost 130 correspondents and hearing witnesses voiced vigorous opposition to changing the current peer review system in any substantial manner. Some noted that it had evolved gradually over the past 25 years, and cautioned that any changes should be made with great care, perhaps with prudent experimentation.

The Study Team had invited hearing witnesses and correspondents to comment on "the effectiveness of the (peer review) system in serving and responding to societal needs and expectations for biomedical research on disease-related problems." Of the 70 who did so, the majority (over 40) considered it effective for this purpose. Thirty did not, or gave qualified answers. A number noted that societal expectations tended to be excessive and ill-founded. Some maintained that the primary responsibility for taking account of societal needs lay, in fact, outside the peer re-

viewer's jurisdiction. Others recognized the dilemma posed in seeking to match investigator-initiated research with societal needs, and suggested a variety of solutions, including the establishment of national goals and objectives for research.

Hearing witnesses and correspondents were also invited to comment on the effectiveness of the peer review system in "assisting in the maintenance of a strong, high-quality national biomedical science base." Over 200 said that it was indeed effective, although some expressed doubts, the most common being that the system tended to focus on short-range projects with assured results and not to give enough support to really innovative, but longer-range, ideas.

Hearing witnesses and correspondents were invited to comment on "the extent to which the (peer review) system assists in meeting the best standards of public accountability for expenditure of public funds." Over 100 found, in effect, that the system did meet these "best standards," many of them interpreting the question to mean whether the US taxpayer was receiving full value for his tax dollars. A small number expressed doubts, including some who focussed more closely on the precise phrase, "public accountability." Two correspondents suggested that review groups be informed of the outcome of the research projects they had funded. Interpreting "accountability" as meaning "financial responsibility," one correspondent pointed out that Study Section members could not act as project supervisors, noting that this was a task, if it were to be done, for full-time employees of NIH. Focussing on the word "public," several correspondents proposed open Congressional hearings and/or a Congressional committee devoted to NIH.

A number of correspondents (but very few witnesses) expressed almost evenly-divided views on the cost-effectiveness of the system. The majority praised it as very cost-effective, enlisting the services of a large number of highly-talented experts at relatively little cost to the government. The minority who questioned the cost-effectiveness of the system tended to include in their assessment the value of the reviewers' time and the time put in by investigators in preparing their grant applications. A number volunteered a wide variety of suggestions for cutting costs, ranging from reducing the complexity of grant applications to more effective sharing of facilities.

#### The Value of Scientist and Lay Involvement in the Review Process

The value of review by scientific peers, with approval based upon quality, was endorsed by approximately 500 hearing witnesses and correspondents. Among the handful who expressed reservations, some stressed that it was important not only to have Initial Review Groups composed of scientists, but to have the appropriate scientists on them. A number stressed the value of participation of non-government scientists in the review process. In addition to bringing to the review process a much wider range of talents and knowledge than could be available from the NIH staff itself, these outside reviewers were held to be less constrained by NIH administrative policies and less vulnerable to political pressures. It was held that only scientists actively involved in research could keep

up to date with developments in their fields. Moreover, it was claimed that outside participation constituted a safeguard against the development of a narrow "party line" in particular fields and forestalled the rise to power of "research arbiters" controlling an undue proportion of the available funds.

A number of hearing witnesses and correspondents (over 50 in all) expressed concern about the possibility or actuality of the plagiarism of ideas resulting from the peer review process. Some maintained that the mere risk of such plagiarism had led to a reluctance on the part of investigators to put forward their full and explicit research programs. Thirty-five of the 50-odd commentators cited above warned of the possibility of plagiarism, conscious or unconscious, without alleging that it had actually taken place. Six expressed, in general terms, suspicion that plagiarism had in fact occurred. Six charged, again in general terms, that there had indeed been plagiarism. Seven cited specific instances of what they regarded as clear plagiarism, at their expense.

A number of witnesses and correspondents singled out the dual aspect of the peer review system for commendation, although some confessed ignorance of the role of the National Advisory Councils. A few correspondents expressed skepticism as to whether the dual review system had actually been effective. The very few witnesses and correspondents who commented on citizen and public (lay) involvement in the review process saw it as good.

#### Presence or Absence of Bias in the System

A number of hearing witnesses and correspondents (over 100) commented in general terms on the fairness and absence of bias in the system. Asked to rate the system in this regard, 95 percent of the 1975-76 NIH review group members surveyed found it "excellent" or "good."

Some hearing witnesses, some correspondents, and a handful of the 1975-76 grant review group members, in comments added to their survey questionnaires, discussed pro and con the effect of "elitism" in the awarding of NIH grants--that is, the relationship of the prestige of the applicant and/or the prestige of the institution to which he or she was attached to the making of an award. Of the hearing witnesses and correspondents who commented on individual prestige as a factor, three-fifths thought that a scientist of national repute had a better chance than a relatively unknown investigator with a proposal of equal merit. Three-fifths saw an applicant from an elite institution as having an advantage. Some correspondents dealt indirectly with the issue, citing geography (particularly California and the Northeast) as a factor. No specific questions on elitism were put to the 1975-76 review group members in the survey questionnaire which they filled out. However, almost fifty added comments on this issue, of whom two-thirds felt that the reputation of a prominent investigator was a significant factor in the reviews, nine seeing a similar effect from the prestige of the applicant's institution. Still others, however, said that past achievements were not, in fact, decisive unless they were matched by present performance.

Of well over 100 witnesses and correspondents who commented on the possible impact of cronyism, three-fifths considered it a real factor, although a few added it was rare. Questioned whether there was a bias due to cronyism, 9 percent of the 1975-76 review group members surveyed found it "significant" or "very significant," 19 percent "moderate," and 72 percent "insignificant" or non-existent. In a related area, a few correspondents felt that peer review group members had an undue advantage in obtaining grants, and a few others claimed that there was an advantage accruing to applicants who at an earlier stage in their careers had held NIH posts.

A considerable number of commentators dealt with the possibility of conflicts of interest in the review process. Of the 1975-76 review group members surveyed by questionnaire, 19 percent considered procedures in this regard only "fair," "poor" or "very poor." Over 200 witnesses and correspondents discussed this subject, with almost half of them expressing concern of varying degrees about conflicts of interest.

The most common concern had to do with applicants being judged by competitors in an identical field of research. Others felt that, in an era of increased competition for funds, Study Section members might be less sympathetic to grant applications of "outsiders," preferring to safeguard available funds for their own projects. Some suspected that the review groups amounted to mutual assistance societies, in which one person's favorite project was approved in return for similar consideration for another's. A few felt that review group members with a vested interest in particular theories might be hostile to projects which could challenge those theories. However, the peer review system also had staunch defenders against conflict of interest charges among the correspondents and witnesses.

There was very little complaint that the peer review system is biased against women and blacks. Only a few hearing witnesses and correspondents touched on the subject. Among the 1975-76 review group members surveyed, only 1 percent found significant bias against blacks. Only 2 percent saw bias against women as significant.

### "Opening Up" the Review System

Hearing witnesses and correspondents were invited to comment on the impact of the Freedom of Information Act, the Federal Advisory Committee Act, and the Privacy Act on the peer review system. For the most part, they dealt with these Acts as a single package (with special emphasis on the Freedom of Information Act). Well over 100 hearing witnesses and correspondents discussed the subject. A quarter of these either welcomed the new legislation or considered that it would have no serious effect on the peer review process. Another, somewhat smaller, number felt that the new legislation was, with safeguards of various kinds, tolerable. Over a half of the commentators deplored it.

Some correspondents feared that, in view of the new legislation, applicants would refrain from putting forward their full research plans be-

cause of fear of plagiarism. Several called for the exposure of persons seeking copies of research proposals, in order to deter possible plagiarism.

A majority of those commenting on making individual reviewers' critiques available to principal investigators and identifying the reviewers themselves favored the former but opposed the latter. Of almost 200 hearing witnesses and correspondents discussing these issues, only a small number opposed making the critiques available, while the majority in favor of maintaining reviewers' anonymity was almost four to one.

Peer review group members for 1975-76, in filling out their survey questionnaires, registered their views on the same two subjects. Some 53 percent said that the effect of making reviewers' critiques available to principal investigators would be "favorable" or "very favorable," as opposed to 41 percent who thought it would be "unfavorable" or "very unfavorable" (6 percent foresaw "no effect"). An overwhelming 93 percent rated the consequences of identifying the reviewers as "unfavorable" or "very unfavorable."

Hearing witnesses and correspondents favoring the availability of reviewers' critiques saw in them a substantial scientific resource which was not being fully utilized. They indicated that the suggestions and criticisms of scientists on the review committee could provide valuable guidance to applicants in the conduct of their experiments, the design of future research, and the preparation of further applications.

A rather small minority of commentators favored releasing the names of reviewers to investigators, but most warned that the consequences would verge on disastrous. They further maintained that most scientists would be reluctant to serve on review groups without the assurance of anonymity for the reviewers.

Of the relatively few hearing witnesses and correspondents who commented on the subject, all favored sending summary statements routinely to applicants, and the majority favored including priority scores with them. No question on the routine distribution of summary statements was included in the survey of 1975-76 peer review group members. Asked about the policy then in effect of withholding priority scores, 56 percent rated it "excellent" or "good."

The majority of the biomedical research community was clearly opposed to open meetings of the peer review groups. For example, fully 85 percent of the 1975-76 review group members surveyed held that opening the sessions would have an "unfavorable" or "very unfavorable" effect.

The majority of witnesses and correspondents who commented on opening the review sessions to the public opposed such a step, warning that freedom of expression would be inhibited and that young scientists, in particular, might find it difficult to express negative opinions about the proposals of older and more eminent researchers. Among the small minority who favored opening the review sessions to the public, greater openness and less

secrecy was a common theme. These individuals recognized that this meant opening the sessions to the applicants themselves. They tended to see positive advantages in this, although they recommended a variety of precautions, ranging from a secret ballot to asking the applicant to leave the room and/or closing the session at an appropriate point in the proceedings.

### Selection and Composition of Review Groups

Most of those who commented on current procedures for selecting review group members seemed generally satisfied with them, although almost one-third of the 1,400 correspondents had specific criticisms or suggestions concerning these procedures. The witnesses at the public hearings were somewhat less favorably inclined, with 51 offering criticisms or suggestions for changes in the selection procedures. This seemed, in good part, due to the recognition of these procedures as a key element, perhaps the key element, in the whole peer review system. Of the members of the 1975-76 review groups surveyed, 74 percent considered the procedures "excellent" or "good," as compared with 26 percent who termed them "fair," "poor," or "very poor."

The selection process itself did not seem to be very well understood. A number of correspondents professed ignorance concerning it. There seemed to be a rather widespread feeling that the present process resulted in "inbreeding." The peer review group members were often seen as predominantly white, male, of mature years, and identified with large and prestigious institutions in the Northeast, California, and the Upper Midwest. A very common complaint was that the review groups were "self-perpetuating"--that retiring members select their own successors. Some correspondents even deployed their analytical talents to detect long-lasting "dynasties," as retiring members allegedly selected their colleagues or students and so on ad infinitum.

Some correspondents expressed the feeling that non-members of review groups were deprived of valuable advantages by exclusion from what one correspondent termed the "House of Peers." In the minds of some, great professional benefits would result from contacts and discussions in the review groups with outstanding researchers in their own and related fields. Others saw more down-to-earth advantages. They were convinced that, if their institutions were represented on review groups, such representatives would acquire invaluable know-how in the preparation of grants applications ("grantsmanship," as some put it) from which they, and their colleagues at their institutions, would greatly benefit.

By far the most commonly advocated method of opening up review group membership to more scientists was the reduction of the term of service for members. Over a hundred hearing witnesses and correspondents recommended this, most suggesting two or three years rather than the prevailing four, a few even proposing one-year terms.

A considerable number of commentators wanted to widen the pool of po-



tential review group members. A number called for opportunities for scientists to nominate persons or to volunteer themselves for service in review groups. Another common suggestion was that national scientific societies be encouraged to submit recommendations. A wide variety of other sources were suggested in order to obtain names to be added to a list of eligibles.

The question of the method of selection of review group members also attracted the attention of correspondents and hearing witnesses. Selection by the executive secretaries was both supported and criticized. A number of commentators proposed that members be elected by one process or another, while others inclined toward a procedure randomized in whole or in part. It would be difficult to reconcile either one of these approaches with the need, expressed by a substantial number of commentators, for "balance" in the review groups.

Few hearing witnesses or correspondents dealt specifically with the selection of Advisory Council members. No question on this subject was included in the survey of 1975-76 members of review groups. However, it is of interest to note that members of the Councils were substantially more critical of the review group selection process than were members of Initial Review Groups. Compared with the 76 percent of Initial Review Group members who considered selection procedures "excellent" or "good," only 61 percent of Council members were of this opinion. Praise for the Councils was not lacking, however.

A very common complaint, registered by almost 100 hearing witnesses and correspondents, was the absence from Study Sections or the insufficient representation on them of specialists thoroughly informed in the applicant's area of work. A number of commentators suggested that this problem might be met by the solicitation of outside consultants. A small number of hearing witnesses and correspondents suggested that investigators submitting grant applications participate in the selection or rejection of reviewers for their applications.

A number of witnesses and correspondents discussed the impact of affirmative action on the selection process. Generally, they supported the effort to obtain wider representation in the review panels, but insisted that this should not be at the expense of scientific qualifications. Some members of minority groups were particularly emphatic on this point.

#### Adequacy of the NIH Grants Peer Review Process

Almost 200 hearing witnesses and correspondents took occasion to pay tribute to the fairness and lack of bias of review group members, and almost as many testified to their high caliber and the conscientious performance of their duties.

About 100 hearing witnesses and correspondents noted excessive workloads for peer review groups as a problem, a majority of them expressing concern that it was affecting review quality. The 1975-76 members surveyed were not asked specifically whether their workloads were excessive, but 93

percent did say that they opposed any increase. Some hearing witnesses and correspondents complained that one result of heavy workloads was that the verdict of the primary reviewers was too often accepted with little or no discussion.

Almost 200 correspondents and hearing witnesses commented on the role of the Advisory Councils. Over three-fifths were generally favorable; the others were more or less critical, focussing on the performance of the Advisory Councils themselves. In the survey of 1975-76 review group members, 86 percent of Council members rated review procedures in general "excellent" or "good," 10 percent, "fair," and 4 percent, "poor" or "very poor." It seems reasonable to infer that these assessments were largely based upon their own observations of the Councils at work.

Well over 100 hearing witnesses and correspondents took occasion to comment favorably on the value of group discussions and procedures as a vital element of the peer review system, with a very few expressing reservations. Several commented on the value of peer pressure in assuring the highest standards of performance by individual scientists in the review groups. One noted, as an incidental benefit, that group responsibility for difficult decisions helped to make them more defensible if they were criticized.

Almost 300 witnesses and correspondents discussed the adequacy of initial reviews, with one-quarter finding them generally excellent. Three-quarters noted what they considered to be inadequacies; however, only a minority of these voiced drastic criticisms, with most singling out one or another aspect in which they thought the system could be improved. A very common complaint was that the applications deserved more careful reading than they often received. Several correspondents made proposals for evaluating the performance of Initial Review Groups. Several others proposed measures to improve the performance of individual reviewers, or to penalize inadequate reviewers.

A number of commentators discussed specific review procedures such as: Evaluation criteria; priority scores and normalization; site visits; appropriateness of requested budget; period of support; and review of program project and center grants.

Among the correspondents and witnesses who commented on evaluation criteria the question most discussed was whether applications should be judged on the basis of what the applicant proposed to do or on the basis of his or her record of prior achievement. Many commentators expressed doubt about the validity of predictions concerning future research, some saying that what is known isn't science, and others saying that applicants, on occasion, had set forth as plans for future investigations work which they had already partly or substantially completed. Many other commentators felt that greater or even exclusive emphasis should be placed on an applicant's track record. In sharp contrast, a rather larger number of commentators felt that the identity of the applicant should be concealed from the reviewers, at least initially.

A smaller number of commentators cited as appropriate criteria the scientific merit of the proposal, the originality of the central idea, relevance, the procedures proposed, publications, and citations. Correspondents both supported and opposed applications by researchers who proposed to work outside their accustomed fields.

The overwhelming majority of persons commenting on the use of priority scores approved the practice, although a few said they did so for lack of any better alternative to offer. Of the 1975-76 review group members surveyed, 82 percent termed the priority rating system "excellent" or "good," as compared with 18 percent who considered it "fair" or "poor." Among the hearing witnesses and correspondents who commented on the system, three-quarters were favorable.

Suggestions for modification of the priority score system were numerous. The most common one was to use approval with a low priority (generally 5.0) as a substitute for disapproval. Some commentators dealt with the impact of a single "blackball" rating on an applicant's chances. Some others suggested that the highest and lowest priority scores be eliminated, as is done in judging some athletic events.

Of the few correspondents who dealt with the current normalization procedures for priority scores, some were critical. Some, in fact, proposed a comprehensive review study of the existing priority score and normalization system.

Among the small number of hearing witnesses and correspondents who discussed the use of site visits, two-thirds found them valuable for the review process. Some indicated dissatisfaction with the composition of the site visit teams.

Asked to assess the peer review system with regard to the review of the appropriateness of the requested budget, 78 percent of the 1975-76 review group members responded by rating it "excellent" or "good." Only a handful of correspondents discussed the question. Several complained of a trend toward automatic budget-cutting by some Study Sections, with the result that requests tended to be inflated to take account of this.

With regard to the adequacy of the review of the period of support provided for investigators, 83 percent of the 1975-76 review group members surveyed considered it "excellent" or "good." However, a small number of hearing witnesses and correspondents objected vehemently to what they saw as a trend toward recommending shorter grant periods, which they regarded as showing a "stop and go" attitude towards research. Specifically, several complained of what they saw as a growing tendency toward three-year rather than five-year grants.

The adequacy of the initial review of program project and center grant applications was rated "excellent" or "good" by 78 percent of the 1975-76 review group members surveyed. In contrast, the dozen hearing witnesses and correspondents who commented on this issue were generally critical, saying that these reviews were less well done than those for regular re-

search grants. Some felt that one result of such umbrella applications was that projects might be funded which, if applied for by individual investigators, would fail to make the grade.

### Support for Innovative Research and New Investigators

Whether or not the NIH Peer Review System tends to discourage innovative research was one of the issues attracting the most comment. Of almost 170 hearing witnesses and correspondents who dealt with this question, almost 90 percent deemed the system unreceptive to new ideas. Two of the questions put to members of the 1975-76 review groups focussed on this issue. Queried as to whether there was a bias in the system against new ideas, 84 percent said that they had observed either none or insignificant amounts of such bias. The second question concerned bias favoring new ideas; here only 51 percent saw a "significant" or "very significant" bias, as compared with 18 percent who saw the bias as "moderate" and 31 percent "insignificant" or non-existent.

A number of correspondents felt that the system is becoming less, rather than more, responsive to new ideas, and blamed this trend on a growing shortage of funds relative to requests. This, they said, has made the review groups less willing to take risks, particularly in view of the increased stress on accountability and the possibility of Congressional or public criticism. Other correspondents felt that a tendency toward prudence is inherent in any committee system. Still others blamed this unresponsiveness on the background and makeup of the NIH groups themselves; their alleged high degree of continuity and in-breeding, led them, it was charged, to become over-committed to fashionable lines of research and indifferent or even hostile to alternative approaches.

Particular kinds of applications encountered difficulties, some correspondents said. Most often cited in this connection was the inter-disciplinary proposal, which tended to fall between two or more review groups, to its disadvantage--a problem which some applicants sought to overcome by presenting a basically inter-disciplinary proposal so that it fitted neatly into the agenda of a single, hopefully friendly, review group.

Some of those who claimed to detect resistance to new ideas in the NIH review system also foresaw serious consequences both for the state of biomedical research in the United States and for the careers of young investigators. There were, however, defenders of the system who saw it as open to innovation. A number of hearing witnesses and correspondents proposed detailed plans to encourage innovative research.

Members of the 1975-76 NIH review groups answered two questions with specific reference to young investigators. Queried about a possible bias in the review system against youth, 91 percent termed it "insignificant" or non-existent. As to bias for youth, 11 percent found it "significant" or "very significant." On the other hand, well over 100 hearing witnesses and correspondents felt that, to a greater or lesser degree, the system operated to the disadvantage of young or inexperienced investigators, as

compared with one-half that number who felt it dealt fairly with them.

Among those who felt that there was bias against young or beginning investigators, there were advocates of a variety of remedies. Perhaps the simplest was to provide more adequate information for the beginning applicant. Several correspondents suggested that a register of advisers (possibly former peer reviewers) be established to provide counsel to new applicants. Finally a number of correspondents put forward detailed plans for channelling more funds to young or beginning investigators.

### Rebuttals and Appeals

Well over 100 hearing witnesses and correspondents criticized the lack of adequate provisions for rebuttals and appeals in the peer review system. This was widely resented among biomedical researchers, both because of the loss of time and momentum in professional careers and, often, because of the difficulty of holding a research team together in the hope of better luck with the next round of applications.

It was clear that a large number of researchers blamed their lack of success on misunderstandings of their proposals by review groups, or even bias against them. Therefore, there was a very substantial demand for full and timely opportunity for principal investigators to rebut criticisms of their proposals; this was voiced by almost 150 hearing witnesses and correspondents. Seventy went further, and called for some kind of formalized appeals mechanism. A number proposed the appointment of an ombudsman. The specific need for an effective appeal against the initial assignment of an application to a Study Section and Institute was pressed by some commentators.

Other suggestions in the area of rebuttals and appeals were put forward by a few hearing witnesses and/or correspondents. Some advocated an opportunity for applicants to appear in person before review groups to clarify misunderstandings and rebut criticisms. A few pointed to the lack in review groups of an advocate for the applicant, and suggested that one or more persons be appointed to fulfill this function. Some others suggested various arrangements by which obscure points might be clarified by the applicants, either in person or by telephone. A number of correspondents pressed for the right of rebuttal, in time for it to be considered by the relevant Council.

A number of proposals were put forward by hearing witnesses and correspondents for a more or less formalized appeal system, such as the right to appeal to a different Study Section or ad hoc committee, to an arbitrator, to an appeals board, to a three-member review committee for each Institute, etc.

### The Role of the NIH Administration in the Peer Review Process

A. number of correspondents and hearing witnesses focussed on the need

for better channels of communication related to the NIH review system. It should be noted, however, that some commentators went out of their way to highlight the contributions the peer review process itself has made to the improvement of communications within the biomedical research community.

Over 50 correspondents and witnesses voiced the need for wider dissemination within the biomedical research community of information on the peer review system itself. The need for a clearer grasp of priorities and goals in research was stressed by almost thirty commentators. A few correspondents felt that Study Sections were inadequately informed about the possible overlap between proposals made by applicants and investigations being pursued under other funding. Looking outside the scientific community, a few correspondents emphasized the importance of better communication with the Congress.

Questioned on the qualifications and performance of the NIH staff, over 90 percent of the 1975-76 review group members termed them "excellent" or "good," with the approval rate for executive secretaries reaching 94 percent. Almost 90 hearing witnesses and correspondents commented on the NIH staff, with over two-thirds praising it and the rest critical to varying degrees. Of those who were critical, some correspondents thought they detected a decline in the quality of the staff. A number of 1975-76 review group members, in comments added to their survey questionnaires, complained that staff interference in the review process takes place on occasion. Some correspondents complained of what they regarded as an excess of bureaucracy at NIH.

Almost 50 hearing witnesses and correspondents found fault with the NIH requirements for grant proposals and applications. By far the most common complaint was that they require too much time which might better be spent on teaching and research. A number made suggestions to simplify them.

The proper assignment of grant applications to Study Sections and Institutes was clearly a matter of great concern to the biomedical research community. Over 100 hearing witnesses and correspondents offered comments or criticisms on this subject. While the subject was not included in the survey of 1975-76 review group members, over 20 persons volunteered comments on it, all in terms critical of NIH procedures as they understood them.

The most frequent suggestion for remedying this situation was that the applicant himself should be able to suggest to which Study Section and Institute his proposal be assigned, usually with NIH reserving the ultimate decision. A number of correspondents suggested that a Study Section, if it found a given proposal to be outside its scope, should be able to recommend its referral to a more appropriate Study Section.

A small number of correspondents complained vigorously about what they saw as the crippling effect of the disapproval of an application on the prospects for future applications from the same investigator.

Among the suggestions for improvement in the peer review system sub-

mitted for comment to the 1975-76 review group members was that of initiating a special study on how to shorten the time between the submission of an application and its funding or denial of funding. This proposal was rated "excellent" or "good" by 77 percent of those responding; of the 20 suggestions put before the members, this was by far the most strongly supported. Almost 70 hearing witnesses and correspondents complained that the peer review process takes too long, among the consequences cited being the waning of initial enthusiasm on the part of investigators and the obsolescence of research plans. Some correspondents cited particular problems caused by the time lag for beginning investigators and renewal applicants. Some commentators urged that applicants be given earlier notice of possible denials.

### Balancing NIH Research Support

The balance in the NIH grants program between targeted and basic research projects was vigorously discussed by a number of correspondents and hearing witnesses. Almost 50 said that there should be more basic research, some of them complaining of what they saw as a trend against basic research in recent years. On the other hand, 20 commentators called for more applied, and particularly more clinical, research projects. Twenty commentators objected to "directed" research, while two correspondents favored it. Several correspondents saw a need for the education of the public on the importance of basic research.

The issue of small vs. large grants stirred considerable discussion among hearing witnesses and correspondents. Most who commented (almost 70) expressed a strong preference for more small grants to more individual investigators. A number sharply criticized large (program project and center) grants, although these grants also had their defenders. Some commentators maintained that individual investigators were more creative. Others claimed that a given allocation of funds was more cost-effective if divided among a number of investigators than if dedicated to a few large projects.

Over 30 correspondents vigorously attacked what they regarded as a trend towards large grants at the expense of small grants. Some charged that large grants stifled creativity; that they involved more scientists than any principal investigator could effectively administer; and that in fact the people who headed them tended to be research impresarios or skilled practitioners of grantsmanship rather than creative investigators. On the other hand, some criticized small grants as leading to insecurity and a lack of continuity. Finally, some commentators urged the importance of achieving a sound balance between large and small grants and proposed means of achieving it.

A limited number of hearing witnesses and correspondents complained of inadequate consideration under the NIH review system for particular medical specialties and scientific disciplines. A small number complained that particular types of institutions tended to be passed over in the award of research grants. These included small institutions generally,

community hospitals, developing institutions, land grant colleges, smaller medical schools, two-year colleges, and minority schools.

### Problems Arising from Factors Outside NIH

A number of hearing witnesses and correspondents were concerned about political pressures on scientific research generally and on the NIH review system in particular. Thirty found this interference related to the setting, by political forces, of priorities and funding unrelated to scientific considerations and opportunities. Other correspondents, while not citing any past political interference, feared that it might materialize in the future. Some correspondents urged an effort to educate political leaders on the nature and requirements of scientific research.

A number of hearing witnesses and correspondents discussed the growing number of approved but not funded applications, which they blamed on shortfalls in Federal funding. Some foresaw a serious impact on the peer review system. Particularly stressed were the psychological and practical effects on investigators who found themselves in this category.

### Recommendations and Decisions

On December 29, 1976, the NIH Grants Peer Review Study Team submitted its report and 69 recommendations to the Director of NIH. The recommendations were based upon a careful study of relevant issues made by the Study Team, plus information obtained from the scientific community and the interested public through public hearings, letters of comment, and the survey of 1975-76 review group members.

The Director of NIH then appointed a small working group of senior staff members and program heads to examine each recommendation in the light of its legal and operational implications and to communicate with each Bureau, Institute, and Division in order to solicit their comments.

On February 8, 1978, the Director of NIH announced that he had approved 33 of the 69 recommendations. An additional 9 were approved with minor modifications. The NIH Deputy Director was given the responsibility to carry out the approved recommendations and to arrange for further studies of 19 of the proposals, pending additional examination and discussion. Three of the Study Team's recommendations were rejected and 5 required no action by the Director.

\* U. S. GOVERNMENT PRINTING OFFICE : 1979 281-217/3132



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