UNITED STATES GENERAL ACCOUNTING OFFICE
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HUMAN RESOURCES DIVISION

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The Honorable Frederick W. Richmond
Chairman, Subcommittee on
Domestic Marketing, Consumer
Relations, and Nutrition
Committee on Agriculture
House of Representatives

Dear Mr. Chairman:

Subject: Nutrition Research Peer Review at the National Institutes of Health (HRD-81-95)

As previously arranged, we are providing you with the information we obtained at the request of the former Chairman of the Subcommittee on Nutrition, Senate Committee on Agriculture, Nutrition, and Forestry, dealing with nutrition-related research at the National Institutes of Health (NIH). The Chairman raised a number of questions principally aimed at determining whether NIH's peer review system

--provided adequate peer review of (1) applied research proposals and (2) research proposals using innovative approaches,

--used qualified individuals to review nutrition-related proposals,

--funded nutrition-related grant proposals less frequently than other grant proposals,

--funded researchers with prior NIH support more readily than previously unsupported researchers, and

--favored researchers from institutions with substantial prior support from NIH.

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The information we obtained is included in enclosure I. Enclosures II, III, and IV are excerpts from NIH guidelines for referring research grant applications to NIH's Nutrition Study Section, Human Embryology Study Section, and Pathology B Study Section, respectively.

Briefly, we found that all grant proposals submitted to NIH were peer reviewed in a similar manner whether the proposals were for basic or applied research, or considered innovative or non-innovative research approaches. (See enc. I, p. 3.) The curricula vitae of individuals serving in the peer review system for nutrition research grant proposals indicated that they were qualified to review such proposals.

Data on the type of research funded, prior NIH research support, and total funding level of institutions employing NIH grant recipients show that differences exist in the percentage of grants awarded researchers in various categories. These data, however, do not lead us to conclude that there has been a bias toward any category of researcher or institution.

We trust that the information in the enclosures will be helpful to your Subcommittee. As agreed with your office, we will not release this report to other interested parties for 30 days unless you have approved its release or make its contents public.

Sincerely yours,

Gregory J. Ahart
Director

Enclosures - 4

ENCLOSURE I

NUTRITION RESEARCH PEER REVIEW AT NIH

At the request of the former Chairman, Subcommittee on Nutrition, Senate Committee on Agriculture, Nutrition, and Forestry, we obtained information on selected aspects of the process used by NIH to review, approve, and fund nutrition-related research grant applications. 1/ Specifically, we addressed the following questions:

--Does the system provide for adequate peer review of (1) applied research proposals and (2) research proposals using innovative approaches?

--Are qualified individuals used to review nutrition-related proposals?

--Are nutrition-related grant proposals funded less frequently than other grant proposals?

--Are researchers with prior NIH support funded more readily than previously unsupported researchers?

--Are researchers from institutions with substantial prior NIH support funded more readily than researchers from institutions which receive little NIH support?

--Are NIH estimates of expenditures for nutrition-related research reasonable?

--Does the situation involving Dr. Leon Vann (see p. 12) indicate a breakdown in the peer review system at NIH?

SCOPE AND METHODOLOGY

We made our review during 1980 at NIH headquarters in Bethesda, Maryland. We reviewed the activities of NIH's Division of Research Grants (DRG) because it operates a substantial part of the peer review system at NIH. We also reviewed 5 of the 11 NIH institutes. 2/ We chose them because they represent a cross section of large and small institutes and collectively accounted for over 75 percent of the amount NIH reported as expenditures for nutrition research in

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1/These applications contain proposals to perform research as described on page 11.

2/The National Cancer Institute (NCI); the National Heart, Lung, and Blood Institute; the National Institute on Aging; the National Institute of Arthritis, Metabolism, Diabetes, Digestive and Kidney Diseases; and the National Institute of Child Health and Human Development (NICHD).

To respond to the Chairman's specific questions, we

--analyzed DRG's policies and procedures for assuring that research grant applications are reviewed by qualified peers;

--compared the approval and award rates between nutrition grant applications and all research project grant applications submitted to (1) five selected institutes, (2) all NIH institutes, and (3) peer review groups which assessed the scientific merit of the applications; 1/

--reviewed reports by the NIH Grants Peer Review Study Team on NIH's peer review system;

--used our medical adviser to examine the qualifications of members of three study sections which reviewed 28 percent of the disapproved nutrition-related grant applications.

--examined the circumstances surrounding the disapproval of the nutrition grant applications submitted to NIH by Dr. Leon Vann;

--compared the approval and funding rates for nutrition grant applications submitted to NCI from researchers according to their levels of prior NIH support and the amount of NIH research funds received by their employer institutions; and

--asked principal investigators of randomly selected research projects to corroborate NIH's estimate of the amount being spent for nutrition research from their projects' budgets.

The information obtained on each of the questions addressed in our review was discussed with NIH officials whose comments have been included where appropriate.

1/We limited our tests to project grants because in fiscal years 1978 and 1979 they comprised 79 percent of all new research grants awarded. Also, these grants are available to all researchers whereas other grants, such as center grants or animal resource grants, are generally limited to those representing institutions which have the special facilities needed to qualify for such grants.

ENCLOSURE I

DOES THE SYSTEM PROVIDE FOR ADEQUATE PEER REVIEW OF (1) APPLIED RESEARCH PROPOSALS AND (2) RESEARCH PROPOSALS USING INNOVATIVE APPROACHES?

All research grant applications sent to NIH go through a two-stage peer review process without the proposed research being categorized as basic or applied. No data or studies are available on the success applied research grant applications have in the peer review system. Also, no designation is given to applications containing an innovative research approach. An NIH study was done regarding whether the peer review system was biased against innovative research proposals.

First stage of peer review

Scientists in DRG read research grant applications submitted to NIH and assign them to the institute responsible for supporting research in that scientific area. Simultaneously, they usually assign each application to 1 of 86 study sections, or initial review groups. Each study section has an executive secretary who (1) reviews all applications assigned to the study section to assure that they are properly assigned, (2) forwards applications to study section members for review, and (3) asks two or three members to be primary reviewers and present each application at the next study section meeting. Most study sections have 12 to 20 members who are authorities in their scientific fields.

Sometimes none of the 86 established study sections have sufficient expertise to review a research grant application. In these instances, DRG officials take one of the following actions:

--Where an application falls within the general purview of an established study section, that study section's membership is supplemented by experts in fields not adequately represented by the regular members. These experts participate as regular members in deciding on the scientific merit of applications they review. Also, experts who are not study section members may be asked to submit critiques on the grant application.

--In a few instances, DRG will convene a special study section. Only about 3 percent of the research project grant applications that went through the peer review process in fiscal years 1978 and 1979 were reviewed by special study sections.

A study section can recommend that an application be either funded or disapproved. If an application is recommended for funding, a numerical priority score is assigned on the basis of its scientific merit relative to the "state of the art" of a particular

ENCLOSURE I

research area. The priority score is used to rank an application for funding. A study section can recommend disapproval of an application for several reasons, one of the most important being lack of scientific merit.

After reviewing an application, the study section sends it to the appropriate institute's staff. If the staff disagrees with the study section's recommendation on an application, it makes an alternative recommendation to the institute's advisory council.

Second stage of peer review

Each institute has an advisory council, which must approve grant applications before they can be funded. These councils are the second stage of the dual review process and consist of about 12 to 18 members who are leaders in medical science, education, and public affairs.

While these advisory councils may review the scientific merit of a grant application, their primary responsibility is to evaluate whether the application relates to the mission and needs of the respective institutes. When advisory councils disagree with study section recommendations, the applications usually are referred back to the study sections for reconsideration. If they agree with the study section's recommendations, all approved applications are eligible for funding. However, not all approved applications are funded.

An advisory council may identify a grant application as warranting a higher or lower priority score than that given by the study section when the application has particularly high or low program relevance. In this case, the application is moved up or down in funding order depending on its program relevance designation. During fiscal years 1978 and 1979, 182 applications--about 1 percent of all approved grant applications submitted to the institutes reviewed--were identified as having a high or low program relevance. Eight of the 182 were nutrition grant applications and were moved up in funding order.

Peer review approval of applied and innovative research

Because NIH does not identify whether applications are for basic or applied research, information on the funding of applied research was not readily available. However, a grants peer review study team appointed by the Director of NIH addressed the question of whether the peer review system was biased against innovative research proposals.

The team sent questionnaires to 1,354 members of NIH's study sections and national advisory councils during 1975 and 1976. Members were asked to indicate the extent of significant biases, if any, they observed in the review of applications both against and for innovative ideas. The following table shows how peer review members responded to this question.

	Number of respondents observing bias	
Degree of bias	Against innovative ideas	For innovative ideas
Very significant	12	275
Significant	36	334
Moderate	143	215
Insignificant	310	155
None	691	215
Total responses	1,192	1,194

The team also sent letters to 30,000 people (whose names were on the mailing list for the NIH Guide for Grants and Contracts) requesting suggestions and comments on the NIH peer review system. Of the 1,493 people responding 1/ either in writing or during public hearings, 167 commented on the system's treatment of innovative research. About 89 percent (or 148 of the 167 individuals) believed that the system was biased against innovative research proposals; about 11 percent (or 19 individuals) believed the system encouraged innovative proposals.

The study team's reports to the Director of NIH did not state whether the team thought there was bias against innovative research in NIH's peer review system. However, the team recommended in December 1976 that the Director consider the feasibility of developing an experiment involving limited support for certain speculative, high-risk, innovative research proposals. As of December 1980, the Director had not implemented this recommendation because he believed it would be extremely difficult to define innovative research.

ARE PEERS QUALIFIED TO REVIEW NUTRITION-RELATED PROPOSALS?

The effectiveness of the peer review system at NIH depends largely on the assurance that each research grant application will

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1/According to data in the grants peer review study, about 85 percent of the respondents had applied for an NIH research grant at least once between fiscal years 1967 and 1976. About 69 percent of the respondents had never served on an NIH study section or advisory council.

be assigned to a study section whose members are qualified to evaluate the application's scientific merit. NIH guidelines 1/ describe the subjects that each study section is qualified to review. They state that members selected for study sections must have demonstrated competence as researchers in the basic scientific or clinical discipline or research speciality needed for the study section.

During hearings in October 1979 before the Subcommittee on Nutrition, Senate Committee on Agriculture, Nutrition, and Forestry, the Subcommittee Chairman and witnesses criticized the NIH peer review system's ability to handle nutrition grant applications. The criticisms concerned the lack of peers to review such applications. Some witnesses believed that most reviewers in the system were experts in basic research, while most of the nutrition research grant applications concern applied or problem-oriented research and require review by those with clinical experience.

To determine if nutrition grant applications were being assigned to properly qualified study sections, we

--examined the qualifications of members of three study sections which, during fiscal year 1979, reviewed over 38 percent of all nutrition grant applications reviewed by the five institutes we reviewed;

--examined the NIH guidelines indicating the kinds of applications that the three study sections review; and

--reviewed applications which the study sections recommended not be funded.

We believe the members of the three study groups were qualified to review such proposals.

Nutrition Study Section

NIH guidelines state that the Nutrition Study Section reviews grant applications dealing with applied and experimental nutrition research in humans and animals, as well as related problems involving microorganisms and plants (see enc. II). Nutrition Study Section membership represents the fields of pediatrics, internal medicine, and biochemistry. The membership has expertise in the field of nutrition, both in research and in clinical practice.

We randomly selected 5 of the 31 research project grant applications assigned to NICHD in fiscal year 1979, which the Nutrition

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1/These guidelines are contained in the Referral Handbook of Initial Review Groups, and excerpts are in enclosures II, III, and IV.

Study Section reviewed and recommended against funding. From the curricula vitae of the study section members, we believe that the expertise existing within the study section was generally sufficient to enable appropriate reviews of these applications. We noted, however, that four of the applications dealt with obstetrics, but none of the study section members were obstetricians.

We discussed this with the executive secretary for the Nutrition Study Section, who said that obtaining an obstetrician's views on these four applications would have improved the balance of expertise of the groups. However, he also pointed out that, in one of the four instances, the applicant had requested a review by the Nutrition Study Section after his previous application had been disapproved by the Human Embryology and Development Study Section, which has obstetricians as members. He stated that, in the three other instances, either regular members or special reviewers, while not obstetricians, were knowledgeable in the proposed research areas. Except for applications to NICHD, relatively few applications assigned to the Nutrition Study Section involve the area of obstetrics.

Human Embryology and Development Study Section

NIH guidelines state that the Human Embryology and Development Study Section reviews applications dealing with mammalian embryology and human development (see enc. III). The study section membership includes individuals with backgrounds in pediatrics, obstetrics, biochemistry, nutrition, internal medicine, research design and practice, clinical experience, human growth and development, pharmacology, endocrinology, and genetics.

We randomly selected 5 of the 23 nutrition-related research project applications assigned to NICHD in fiscal year 1979, which the Human Embryology and Development Study Section had recommended against funding. We believe, from a review of the curricula vitae of the study section membership that the expertise within the study section was sufficient to enable appropriate reviews of these applications.

Pathology B Study Section

NIH guidelines state that the Pathology B Study Section reviews applications primarily concerned with spontaneous and experimental lesions associated with metabolic and cellular disease, particularly cancer (see enc. IV). This study section is composed almost entirely of pathologists with clinical and research experience.

We randomly selected 5 of the 20 nutrition-related research project grant applications to NCI in fiscal year 1979, which the Pathology B Study Section had recommended against funding. We believe, from a review of the curricula vitae of the study section membership, that the expertise within the study section was generally sufficient to appropriately review these applications. However, one of the applications involved an epidemiological study, and none of the study section members were epidemiologists. The executive secretary of the study section acknowledged that input from an epidemiologist could have been useful to the review of this application.

None of the regular study section members are nutritionists. However, a special reviewer with expertise in nutrition was present when the study section reviewed the five nutrition-grant applications we selected. In commenting on the need for a nutritionist as a regular study section member, the executive secretary for the study section said too few nutrition-related applications are received to necessitate adding a nutritionist as a regular study group member.

ARE NUTRITION-RELATED GRANT PROPOSALS FUNDED LESS FREQUENTLY THAN OTHER GRANT PROPOSALS?

During an October 1979 hearing before the Subcommittee on Nutrition, Senate Committee on Agriculture, Nutrition, and Forestry, the discussion often centered on the need for nutrition research funded by NIH and what might be causing the low NIH funding rate for nutrition research. To determine whether nutrition grant applications were being funded at a lower rate than other applications, we obtained data from five institutes on the disposition of research grant applications during fiscal year 1979. Our analysis of the data showed that the nutrition grant applications were approved and funded at rates lower than the average rates for all research applications.

During fiscal year 1979, a total of 8,374 research project grant applications were reviewed by the five NIH institutes included in our review. Of these, over 74 percent (or 6,234) were approved as eligible for funding and 35 percent (or 2,936) were funded. The 8,374 applications included 699 nutrition grant applications, of which 65 percent (or 455) were approved as eligible for funding and 29 percent (or 203) were funded. As the comparison shows, nutrition grant applications had a 9-percent lower approval rate than all grant applications and a 6-percent lower funding rate than all grant applications.

ENCLOSURE I

Because the recommendations of the study sections are a major factor in determining whether a grant application is approved and funded, we analyzed the disposition of applications submitted to the six study sections that reviewed 423 of the 699 nutrition grant applications. One of the six study sections--the Nutrition Study Section--reviewed only nutrition grant applications. This study section recommended approval of 57 percent of the 191 applications it reviewed, and 26 percent of the applications were funded.

The remaining five study sections approved 60 percent of the nutrition grant applications and 66 percent of all applications they reviewed for five institutes. Twenty-three percent of the reviewed nutrition applications and 32 percent of all applications were funded. Collectively and individually, the five study sections approved nutrition research applications at a less frequent rate than they did for all grant applications.

We found that nutrition grant applications reviewed by all other study sections were approved and funded at rates higher than those for the six study sections previously discussed. NIH officials told us that one possible explanation is that the current status and the opportunities for research in nutrition are more favorable in some study sections' areas than they are in other study sections' areas.

ARE RESEARCHERS WITH PRIOR NIH SUPPORT FUNDED MORE READILY THAN PREVIOUSLY UNSUPPORTED RESEARCHERS?

NCI provided data on 166 nutrition research grant applications received during calendar year 1979. We divided these applications into three groups: those from reseachers with (1) no prior funding from NIH, (2) 1 to 4 years of prior funding from NIH, and (3) over 4 years of funding from NIH. The following table shows the results of our analysis.

Years of research support from NIH	Grant applications reviewed	Reviewed applications approved for funding	Reviewed applications funded
Not previously funded	56	28	10
Funded from 1 to 4 years	52	34	11
Funded for over 4 years	58	29	15
Total	166	91	36

The table shows that the previously unfunded researchers had 18 percent (10 of 56) of their applications funded, while the researchers with prior support got 23 percent (26 of 110) of their applications funded. An NIH official responsible for extramural research commented that these data showed new researchers in nutrition were doing reasonably well under the peer review system.

ARE RESEARCHERS FROM INSTITUTIONS WITH SUBSTANTIAL PRIOR NIH SUPPORT FUNDED MORE READILY THAN RESEARCHERS FROM INSTITUTIONS WHICH RECEIVE LITTLE NIH SUPPORT?

The table below shows the total NIH grant awards for fiscal year 1978 which were made to the institutions where the researchers who submitted the 166 selected nutrition grant applications work. We established six funding levels to obtain an indication of whether researchers from institutions heavily supported by NIH had better success in getting their research applications funded than those researchers from institutions with less NIH support.

Fiscal year 1978 NIH support to institutions employing researchers	Grant applications reviewed	Reviewed applications approved for funding	Reviewed applications funded
(millions)			
Under $5	82	39	14
$5 to $9.9	28	14	8
$10 to $14.9	15	10	5
$15 to $19.9	6	2	1
$20 to $24.9	14	10	3
$25 and over	21	16	5
Total	166	91	36

The table shows that 82 of 166 (49 percent) of the nutrition grant applications submitted to NCI in calendar year 1979 came from researchers at institutions receiving less than $5 million in NIH grant support during fiscal year 1978. These researchers submitted 43 percent (39 of 91) of all applications approved and 39 percent (14 of 36) of all applications funded. Researchers from institutions which received at least $5 million in support from NIH during fiscal year 1978 submitted 51 percent of the applications. They had 57 percent of all approved applications and 61 percent of all the funded applications. There is no trend, however, to indicate that approval and funding rates consistently increase as the amount of NIH support to the institution of the researcher increases.

ENCLOSURE I

ARE NIH ESTIMATES OF NUTRITION-RELATED RESEARCH EXPENDITURES REASONABLE?

NIH has reported to the Congress that its support for nutrition research in fiscal year 1979 was about $133.9 million. Because nutrition research usually represents only part of a research grant, NIH can only estimate its expenditures for nutrition research. To test the reasonableness of the reported fiscal year 1979 estimate, we randomly selected 30 projects from a list of 1,557 nutrition research projects funded by NIH in fiscal year 1979. We asked each principal investigator to corroborate NIH's estimate of the amount spent for nutrition research, based on the following definition prepared by the NIH Nutrition Coordinating Committee. 1/

> "The term nutrition research includes studies designed to assess the consequences of food or nutrient intake and utilization in the intact organism, including man, and the metabolic and behavioral mechanisms involved. These studies encompass investigation of nutrient variables at the cellular or subcellular level. This definition also includes:
>
> --Research designed to elucidate the metabolic role or function of nutrients in both animal models and man.
>
> --All studies concerned with genetic-nutrient-environmental interactions where a nutrient is a variable.
>
> --Dietary studies expected to produce significant changes in health status, including the maintenance of health and the treatment of disease in man. Such studies might include clinical trials, epidemiological studies, metabolic studies, surveillance, and nutritional status monitoring studies."

Principal investigators for 23 of the 30 selected projects accepted NIH's estimate of project costs for nutrition research. Principal investigators for six of the projects believed NIH's estimate was too high, while the principal investigator for one project believed NIH's estimate was too low. The following table compares NIH's estimates with estimates by principal investigators.

1/This Committee consists of representatives from 11 NIH institutes and NIH divisions which support nutrition research. It also includes representatives from other organizations within the Department of Health and Human Services and the Office of Science and Technology Policy.

ENCLOSURE I

	Total project expenditures	Estimated expenditures for nutrition	
		Per NIH	Per principal investigator
Principal investigators in agreement with NIH estimates (23 projects)	$ 3,267,050	$ 1,717,606	$ 1,717,606
NIH estimate considered to be too high (6 projects)	1,030,191	222,106	62,419
NIH estimate considered to be too low (1 project)	107,543	53,772	80,657
Total for sample	4,404,784	1,993,484	1,860,682
Total for all nutrition-related projects funded in fiscal year 1979	$325,293,138	$133,851,890	a/$124,968,915

a/Estimate based on projects selected. Allowing for a possible sampling error of about 6 percent, this total could range from $116,686,174 to $133,251,657. A 95-percent confidence level was used in making our computations.

DOES THE SITUATION INVOLVING DR. LEON VANN INDICATE A BREAKDOWN IN THE PEER REVIEW SYSTEM AT NIH?

Dr. Leon Vann has had two nutrition grant applications disapproved for funding by NIH. He has corresponded extensively with various NIH officials about this situation, claiming that the research proposals in his applications were not reviewed by qualified individuals. NIH officials have suggested repeatedly that Dr. Vann submit a revised proposal, but he has not done so.

In 1974, Dr. Vann submitted a nutrition research grant application to NIH which was peer reviewed by a study section and not recommended for funding. In 1977, Dr. Vann followed up on this action by talking to NIH officials about the rejection of his application. Acting on the suggestion of NIH officials, Dr. Vann submitted a new application with an expanded proposal in November 1977 which was also disapproved by a study section. Since that time, Dr. Vann has written numerous letters to NIH officials in which he has argued that (1) his proposal was not thoroughly reviewed by the study section, (2) peer reviewers may not have been qualified to critique his proposal, and (3) some criticisms of his proposal were not supported by references to other scientific sources.

In responding to Dr. Vann's letters, NIH officials, on several occasions, invited Dr. Vann to submit a revised proposal which could include new information to overcome the criticisms of the study section. Dr. Vann, however, continued to correspond with NIH officials and insisted that the peer reviewers' criticisms were in error.

The Director of NCI wrote to Dr. Vann in February 1979 suggesting that he (1) submit a new proposal and (2) provide NIH with the names of three individuals who Dr. Vann believed would give his proposal a quality review. The letter stated that attempts would be made to include at least one of these individuals on the study section. Dr. Vann continued to insist that the review of his 1977 proposal was faulty, and he wanted NIH to respond to his challenges regarding the peer reviewers' criticisms.

An NIH official contacted Dr. Vann in April 1979, and advised him that three members of the study section which rejected his second application would be sent a package of all relevant materials regarding Dr. Vann's case. These individuals were to review the information and provide comments. This action resulted in another letter being sent to Dr. Vann which elaborated on the original criticisms of Dr. Vann's 1977 proposal. Dr. Vann continued to complain in writing to NIH officials about the review given to his proposal.

Dr. Vann has stated to NIH and us that his intent in seeking answers to his questions is not to use the resulting information for submitting a revised proposal. Instead, Dr. Vann is seeking an admission that the review of his 1977 proposal was in error. NIH has continued to reply to Dr. Vann's letters, and it has informed him that a special study section comprised of selected scientific peers would be convened to review a revised proposal if Dr. Vann were to submit one.

According to the Deputy Director, Division of Research Grants at NIH, the usual practice of submitting a revised proposal to the same study section that reviewed the original proposal was followed in this case (i.e., the same study section reviewed Dr. Vann's 1974 and 1977 applications). This is done so that the peer reviewers can assess whether their initial criticisms have been overcome. In addition to the usual peer review given to Dr. Vann's revised proposal, NIH took an additional step by asking three members of the study section to reevaluate the proposal. Dr. Vann was notified by a May 31, 1979, letter that the reviewers found his proposal to have weaknesses in aspects of experimental pathology and biochemistry.

Examination of the curricula vitae of study section members who reviewed Dr. Vann's application indicated that they were well qualified to review the application. In fact, one member is considered a world renowned figure in the field of Dr. Vann's proposed research, and papers written by this individual were cited in Dr. Vann's application.

NIH officials believe that there is a difference of scientific opinion between the peer reviewers and Dr. Vann regarding his proposed research. They do not view Dr. Vann's situation as a weakness or a breakdown in the peer review system.

ENCLOSURE II

EXCERPTS FROM NIH GUIDELINES FOR REFERRING RESEARCH GRANT APPLICATIONS TO THE NUTRITION STUDY SECTION

GENERAL:

The Nutrition Study Section reviews proposals in the areas of applied and experimental nutrition of humans and animals, as well as related problems involving microorganisms and plants.

SPECIFIC:

1. The requirements of normal living organisms for the specific major nutrients, vitamins and trace elements, and factors that affect these requirements.

2. Nutritional practices in nonspecific disease or special states of being such as in obesity, malnutrition, pregnancy, childhood and the aged.

3. Alteration of biochemical and physiologic lesions by dietary practice. (As in diabetes, atherosclerosis, digestive diseases, anemia, inborn errors of metabolism, etc.).

4. The effects of nutrition or specific nutrients on resistance to disease and other stresses.

5. Biochemical and physiological effects of malnutrition.

6. Methods of evaluating the nutritive status of man.

7. Application of techniques for measuring body composition in above areas.

8. Nutritive value of raw and processed foods and factors which affect the nutritive value of these products.

OVERLAP:

The emphasis of the above is on experimental designs involving nutritional variables, in in vivo situations, and overall effects. In contrast, when sharp focus is on detailed intermediary metabolism of the major nutrients, on specific function of organs of the gastrointestinal tract, or on the elements of blood, overlap

often exists with MET, 1/ GMA, 2/ and HEM, 3/ respectively. Specific areas 2 and 3 are often involved.

1/Metabolism Study Section.

2/General Medicine A Study Section.

3/Hematology Study Section.

ENCLOSURE III

EXCERPTS FROM NIH GUIDELINES FOR REFERRING RESEARCH GRANT APPLICATIONS TO THE HUMAN EMBRYOLOGY AND DEVELOPMENT STUDY SECTION

GENERAL:

This study section reviews applications dealing with mammalian embryology and human development. Of special interest are research projects which emphasize etiology and prevention of infant mortality, morbidity, and congenital anomalies.

SPECIFIC:

1. Physiology and Reproduction: Later stages of mammalian embryogenesis, beginning with implantation; pregnancy and parturition; placentation; placental transfer of gases, nutrients, antibodies, pharmacological agents, and teratogens; fetal membranes, amniotic fluid.

2. Fetus and Embryo: Uterine environment of mammalian embryo, organogensis, maturation of enzyme systems, fetal physiology; amniocentesis, prenatal diagnoses, experimentation on extrauterine viable human fetuses.

3. Parturition: Initiation of labor, uterine contraction, events associated with birth process, abortion.

4. Neonatal Period: Initiation of respiration, resuscitation, anoxia, thermoregulation, physical examination of newborn, problems of prematurity, bilirubinemia (erythroblastosis), respiratory distress syndrome, infant mortality, pediatric hematology, exchange transfusions.

5. Anomalies (Teratology): Congenital anomalies and etiology. Factors during pregnancy and during delivery responsible for birth anomalies, animal experiments designed to produce development abnomalies.

6. Experimental Embryology: Animal experiments aimed at elucidation of mechanism of mammalian development.

ENCLOSURE III

OVERLAP:

GEN 1/--prenatal diagnosis.

HEM 2/--pediatric hematology.

In each case, only applications in which clinical management of pregnancy or of the infant as an important factor, should be assigned to HED. 3/

1/Genetics Study Section.

2/Hematology Study Section.

3/Human Embryology and Development Study Section.

EXCERPTS FROM NIH GUIDELINES FOR REFERRING RESEARCH GRANT APPLICATIONS TO THE PATHOLOGY B STUDY SECTION

GENERAL:

This study section reviews applications primarily concerned with projects dealing with spontaneous and experimental lesions associated with metabolic and cellular disease, particularly cancer. While the major emphasis is on morphologic changes, the nature of the lesions requires the extensive application of standard biochemical, immunochemical and biophysical techniques in their explorations.

SPECIFIC:

1. Oncological pathology: Etiology of cancer; hormonal and viral carcinogensis, pathogensis of cancer - invasion, regression, metastasis, vascularization of tumors, metabolism of tumor cells; tumor transplantation; tumor diagnosis, exfoliative cytology, cytogenetics, tissue culture studies on tumors, serologic studies on tumors and cytogenetics of tumors.

2. Metabolic pathology: Nutritional deficiency and storage diseases; carbohydrate metabolism in diabetes - experimental induction of diabetes, islet cell enzyme changes in experimental diabetes; thyroxin and triiolothyronine effects, estrogen effects, thyroiditis, adrenal decortication and regeneration, adrenal hormone effects. Intestinal lipodystrophy, ulcerative colitis, hemosiderosis, hemochromatosis and hepatic disease. Effects of acute amino acid deficiency, protein metabolism in hepatic disease; cirrhosis and hepatoma.

3. Cellular pathology: Metabolic changes in normal and tumor cells, mitochondria and microsomes, DNA/RNA changes, citric acid cycle, application of radioautographic technic, ultrastructural changes in cells and studies of pathology of cellular changes *in vitro* through use of cell and organ culture systems. Cell hybridization technics.

4. Radiation pathology: Radiation injury, in which the basis of the proposal is the study of the lesions and not a study of radiation *per se*.

5. Immunopathology: Immune alterations, tumor immunology, immunodeficiency diseases, antibody formation, immune responses, autoimmune mechanisms and lymphocyte function, when the emphasis is on the lesion rather than the immunological aspects of the proposal.