



John C. Hiserodt, M.D., Ph. D., DAB No. 1466 (1994)

Department of Health and Human Services

Departmental Appeals Board

RESEARCH INTEGRITY ADJUDICATIONS PANEL

SUBJECT: John C. Hiserodt, M.D., Ph.D.

DATE: February 25, 1994

Docket No. A-93-117

Decision No. 1466

DECISION AS TO SCIENTIFIC MISCONDUCT; AND FINDINGS OF FACT, PROPOSED CONCLUSIONS OF LAW, AND RECOMMENDED DECISION FOR THE DEBARMENT OF JOHN C. HISERODT, M.D., Ph.D.

The Office of Research Integrity (ORI) of the Public Health Service (PHS), Department of Health and Human Services (DHHS), determined that John C. Hiserodt, M.D., Ph.D. (Respondent) had engaged in scientific misconduct. The conduct in question concerned applications for research funding which Respondent wrote and which were submitted to the PHS National Institutes of Health (NIH) in February and October 1989. ORI determined that Respondent had falsified data, fabricated figures and tables in these applications, and misrepresented experimental results in the applications. ORI proposed the following administrative actions be taken with respect to Respondent: (1) Respondent be prohibited from serving on PHS advisory committees, boards, or peer review groups for seven years; (2) Respondent's PHS- sponsored research be monitored for its accuracy by any awardee institution for seven years; and (3) the article, "The Expression and Functional Involvement of Laminin-like Molecules in Non-MHC Restricted Cytotoxicity by Human Leu-19+/CD3-Natural Killer Lymphocytes," which appeared in the *Journal of Immunology*, Vol. 141, 3318-23, 1988, be corrected to reflect that Figure 2 of this publication may not be relied upon.

Based on ORI's determination of scientific misconduct, the DHHS Deputy Assistant Secretary for Grants and Acquisition Management (Debarring Official) proposed to debar Respondent from eligibility for, or involvement as a principal in, non- procurement transactions (e.g., grants) of the federal government, and from contracting or subcontracting with any federal government agency. The term of the proposed debarment was five years. The Debarring Official informed

Respondent that his determination to debar Respondent will be made on the basis of a recommendation of the Research Integrity Adjudications Panel of the Departmental Appeals Board.

Respondent requested a hearing before this Panel to contest ORI's determination of scientific misconduct, ORI's proposed administrative actions, and the proposal to debar him. We conducted a de novo hearing at which both ORI and Respondent presented evidence. 1/ Both ORI and Respondent submitted posthearing briefs and reply briefs.

Thus, we have two distinct responsibilities in this appeal. First, we must decide whether Respondent committed scientific misconduct. If we find that Respondent has committed scientific misconduct, we must review the administrative actions proposed by ORI and decide whether they should be imposed. Our decision on the administrative actions is final. Second, we are to make findings of fact and propose conclusions of law in a recommended decision to the Debarring Official whether Respondent should be debarred from receiving federal funds for a period of years.

In performing these separate responsibilities, we will be relying on the same core findings of fact as to whether Respondent committed scientific misconduct.

SUMMARY OF DECISION

We conclude that ORI established by the preponderance of the evidence that Respondent committed scientific misconduct. We find that Respondent knowingly presented falsified data and fabricated experimental results to NIH in applications for funding for research which Respondent proposed to conduct and that Respondent fabricated results of experiments and falsified documents in an attempt to conceal his misconduct. We do not reach the question of whether Respondent committed scientific misconduct by failing to maintain primary data since our other factual findings so clearly support our conclusion that there was scientific misconduct under the applicable legal standards. Moreover, even if we were to find that ORI's other allegations concerning the retention of primary data were not substantiated, this would not mitigate against our conclusion that Respondent committed scientific misconduct.

Respondent engaged in the conduct which is at issue here prior to and after the effective date of regulations that define scientific misconduct. We find that Respondent's acts which occurred prior to the regulations' effective date are scientific misconduct under applicable and widely recognized professional standards which predated the regulations. We find further that Respondent's acts which occurred after the regulations' effective date are scientific misconduct under the regulations. Furthermore, all of the conduct by Respondent which we find to be scientific misconduct constitutes scientific misconduct under the professional standards which predated the regulations' effective date and under the regulations. We accordingly uphold the administrative actions proposed by ORI, subject to one minor modification.

We also make proposed conclusions of law determining that the alleged cause for debarment of Respondent have been proven. In particular, we

find that the preponderance of the evidence establishes that Respondent is not presently responsible to be a recipient of federal funding. We recommend to the Debarring Official that, in light of our findings and our proposed conclusions of law, a term of debarment of five years is appropriate.

In making our decision concerning the administrative actions and our findings of fact and proposed conclusions of law concerning Respondent's debarment, we specifically address the issue of Respondent's credibility. We find that Respondent is not a trustworthy individual and that this lack of honesty provides additional support for the term of debarment. Our recommendation of a five year debarment is in part based on our conclusion that Respondent's persistence in attempting to conceal his misconduct discredits his present responsibility to receive federal funds.

Below, we provide a discussion of the factual and legal basis for our decision as to misconduct and our proposed decision as to debarment. As part of this analysis, we discuss the law which applies to scientific misconduct and debarment. We address specifically, and reject, Respondent's contention that we lack authority to conclude that the conduct at issue in this case constitutes scientific misconduct, or to propose debarment.

Background

Respondent and the activities he directed at the Pittsburgh Cancer Institute of the University of Pittsburgh

In 1977, Respondent received a Ph.D. degree in the fields of immunology and biochemistry from the University of California, Irvine. In 1983, Respondent received a M.D. degree from the University of California, Los Angeles, School of Medicine. In 1986, while at the University of Michigan doing his residency training in pathology, Respondent was invited by Ronald B. Herberman, M.D., to join the Pittsburgh Cancer Institute (PCI) which was being formed at the University of Pittsburgh. Dr. Herberman was then and remains the Director of PCI.

Respondent accepted Dr. Herberman's offer and, beginning in 1986, was employed as an assistant professor in the Department of Pathology of the University of Pittsburgh and as an associate member of PCI. Respondent held these positions until he resigned them in January 1990.

Respondent's duties at PCI included heading a laboratory. The research which he pursued at this laboratory included research concerning natural killer (NK) cells. A NK cell is a lymphocyte or white blood cell that floats in the blood and acts as part of the body's immunological response to foreign substances. NK cells are unique because they have an innate ability to recognize and kill tumor cells. Respondent dedicated his research to discovering more about the mechanism by which a NK cell kills a tumor cell.

In 1987 NIH awarded a three-year research grant (RO1 CA43765-01) to the University of Pittsburgh to study the mechanism by which NK cells might kill cancer cells. Respondent was the principal investigator for this grant, and his laboratory at PCI was in part funded by it.

One of Respondent's principal research objectives was to discover the interaction between NK cells and tumor cells which leads to the lysis of tumor cells by NK cells. Lysis is a process whereby the integrity of the tumor cell is disrupted, so that the tumor cell leaks its internal contents and is no longer viable. Respondent's central theory was that there was a basement membrane protein known as or similar to laminin expressed on the surface of NK cells which was involved in NK cells' ability to recognize and kill tumor cells. Respondent contended that this laminin-like protein had a molecular weight of 48 kilodaltons; hence, he referred to it as "p48."

Respondent also theorized that tumor cells were capable of producing an antibody, another protein, which could bind itself to p48. The antibody would thus block the interaction between the NK cell and the tumor cell so that the NK cell would no longer be able to recognize and kill the tumor cell. Respondent called this antibody to p48 "anti-laminin."

Respondent's laboratory at PCI was staffed by laboratory technicians, graduate assistants, and post-doctoral researchers. The personnel who were associated with Respondent's laboratory who were involved significantly in the research projects led by Respondent into NK cells included the following individuals:

-- Michael W. Olszowy, Ph.D. Dr. Olszowy began working for Respondent as a laboratory technician in 1986. Beginning in 1986 or 1987, Dr. Olszowy was formally accepted as a Ph.D. candidate at the Department of Pathology of the University of Pittsburgh, with Respondent serving as Dr. Olszowy's thesis monitor. As a graduate student working in Respondent's laboratory, Dr. Olszowy conducted experiments in the area of NK cells which he designed and which were agreed to by Respondent. In 1987 and 1988, Dr. Olszowy and Respondent met almost on a daily basis to discuss the progress of experiments conducted by Dr. Olszowy. Dr. Olszowy received a Ph.D. degree from PCI and the University of Pittsburgh School of Medicine in 1992. Dr. Olszowy is currently a Post Doctoral Fellow at Washington University in St. Louis in the Department of Pathology.

-- Roderich Schwarz, M.D. Dr. Schwarz received his M.D. degree in 1984. In 1987, Dr. Schwarz began working in Respondent's laboratory at PCI on a post-doctoral research fellowship. Experiments performed by Dr. Schwarz in Respondent's laboratory included growing human infector cells (NK cells) and testing their cell killing activity. These experiments also included the effect of various antibodies on the cell killing activities of NK cells. Other of Dr. Schwarz's experiments for Respondent included studying the activity of NK cells by labeling them with radioactive substances and then measuring the amount of radiation they released over time as an expression of how many cells were killed by the NK cells. Dr. Schwarz also performed a total of four cell sorting experiments for Respondent, using a process known as flow cytometry. Dr. Schwarz is currently a resident in the Department of Surgery in the University of Pittsburgh.

-- William H. Chambers, Ph.D. Dr. Chambers came to the University of Pittsburgh as a post-doctoral researcher in 1986 and worked in Respondent's laboratory. Dr. Chambers is currently employed by PCI and

is an assistant professor in the Department of Pathology in the University of Pittsburgh Medical School.

The allegations of scientific misconduct in this case relate to two applications to NIH for research funding which Respondent wrote and which the University of Pittsburgh submitted to NIH in February and October 1989. The general objective of these applications was to receive funds for continuation of the research begun with the 1987 research grant.

On February 28, 1989, the University of Pittsburgh filed an application (February application) with NIH for research funding of \$961,904 (RO1 CA43764-04) entitled, "Role of Laminin/Laminin Receptors in NK Function." G. Ex. 1. Respondent wrote the February application and signed it as Principal Investigator/Program Director. The stated purpose of the February application was to perform studies on human cells similar to those which had been performed previously by Respondent on rat cells, to isolate and purify p48, to clone and sequence p48, to establish that p48 is a novel protein, and to discern its relationship to laminin. This application included a number of figures and tables.

NIH reviewed the application and, while finding the application to have merit, did not approve it for funding. One area of concern expressed by the NIH reviewers was the apparent cross-reactivity between rabbit anti-laminin and other substances besides p48. They expressed skepticism that the allegedly unique substance (rabbit anti-laminin) identified by Respondent could nevertheless react with several different proteins.

On October 31, 1989, the University of Pittsburgh filed an amended application (October application) with NIH (RO1 CA43765- 04A1) entitled, "Role of Laminin/Laminin Receptors in NK Function." G. Ex. 4. The application requested funding from NIH totaling \$1,024,112. Respondent wrote the October application and signed the application as Principal Investigator/Program Director. The October application was in many respects identical to the February application. The October application contained the same statements, figures, and tables as were contained in the February application purporting to prove the existence and function of p48. The October application also contained an additional figure (Figure 7) depicting the results of a nucleotide sequence, and text purporting to explain the cross-reactivity between anti-laminin and other substances. The additional discussion and experimental results in the October application were aimed specifically at responding to the concerns raised by NIH in its evaluation of the February application which resulted in its decision not to fund the proposed grant.

Attempts by researchers in Respondent's laboratory to identify p48 and the research techniques they used

Researchers in Respondent's laboratory attempted to identify p48 using a process known as immunoprecipitation of proteins. The purposes of immunoprecipitation include establishing the presence of proteins in cells or on the surface of cells and determining the molecular weights of proteins that have been identified. A protein's molecular weight is of critical importance in identifying that protein, inasmuch as each unique protein has a specific molecular weight which is different from

that of other proteins.

In performing immunoprecipitation, proteins which have been labeled with a radioactive substance are added to lanes in a gel. A gel consists of glass plates between which is contained a compound, acrylimide. Using a technique involving the use of an electrical current (electrophoresis), proteins that are added to a gel migrate different distances in the gel according to their molecular weights. Electrophoresis in a gel operates like a strainer which segregates proteins within the gel according to their molecular weights. The heavier the protein, the higher it will appear in the gel. In order to establish points of reference in a gel to determine the molecular weights of proteins that are precipitated, proteins of predetermined molecular weight are precipitated in designated lanes of the gel (marker lanes).

After radioactively-labeled proteins are precipitated in a gel, a photographic film is exposed to the gel to produce an autoradiogram, or photographic record of the proteins precipitated in the gel, which will include marker proteins in specified lanes, and proteins which have been precipitated as a consequence of immunoprecipitation. 2/ The radioactive substances, which include the immunoprecipitated proteins and the marker proteins, will then create images on the photographic film which correspond to their positions in the gel. The molecular weight of the immunoprecipitated proteins represented by the images produced in an autoradiogram can be determined by comparing them with the predetermined marker bands which are also present in the autoradiogram. The weight of a protein that appears between two marker bands in an autoradiogram can be determined by measuring its linear relationship to those bands. If the molecular weight of a protein immunoprecipitated in a gel is, for example, 48 kilodaltons, then the image of that protein produced by an autoradiogram of the gel should correspond to a point in the marker lane which is between the 43 and 68 kilodalton marker bands, and which is relatively close to the 43 kilodalton marker band.

The radioactive substances used in Respondent's laboratory to label proteins through immunoprecipitation included S-35 methionine and I-125 (radioactive iodine). S-35 methionine is methionine, an amino acid, which contains a radioactive sulfur molecule (S-35). The immunoprecipitation process using S-35 methionine is also known as metabolic labeling and will label all proteins located inside a cell. If an NK cell which has been exposed to S-35 methionine manufactures p48, the p48 manufactured by that cell will contain S-35 methionine.

A necessary step in immunoprecipitation of p48 involving S-35 methionine is to solubilize (break down) the cells being studied so that their proteins will be released into a solution. The proteins are then exposed to anti-laminin antibody so that p48 (assuming it exists) will bond to the antibody. Using a variety of techniques, the antibody (which now may be attached to p48) is removed from the solution. If material containing an antibody which has bonded to a protein that has been labeled with S-35 methionine is immunoprecipitated in a gel, then, presumably, an autoradiogram of that gel will produce an image of the labeled protein and will enable the researcher to determine that protein's molecular weight. If, in fact, a protein having a molecular

weight of 48 kilodaltons has been isolated using S-35 methionine labeling, then an image should appear on the autoradiogram corresponding to a molecular weight of 48 kilodaltons.

There is the possibility, however, that an experiment with S-35 methionine might produce inconclusive results. Because the process necessarily causes cells to rupture, there is no way to determine if any protein identified by S-35 methionine labeling comes from the surface of a cell or from inside it. It was important for Respondent to ascertain whether any protein he had identified as reacting to anti-laminin antibody was from the surface of a NK cell, inasmuch as he had theorized that p48 is present on NK cells' surfaces. One method to clarify the ambiguous results which might occur with S-35 methionine labeling is to use another labeling technique known as radio-iodination, which uses I-125 labeling.

Immunoprecipitation following I-125 labeling does not rupture the cell, thus enabling the researcher to determine the molecular weight of proteins found on the surface of the cell. I-125 labeling involves replacing tyrosine, an amino acid which is a component of proteins on the surface of cells, with radioactive iodine molecules. Proteins which have been labeled with I-125 are then immunoprecipitated and an autoradiogram is made to determine the molecular weights of these proteins. If a protein on the surface of NK cells having a molecular weight of 48 kilodaltons has been isolated using I-125 labeling, then an image should appear on the autoradiogram corresponding to a molecular weight of 48 kilodaltons.

Events leading up to the allegations that Respondent committed scientific misconduct 3/

Beginning as early as 1987, Dr. Olszowy became concerned that the experimental results which he and Respondent had interpreted as establishing the presence of p48 on NK cells might be artifacts. In science, an "artifact" is an experimental result which misleads a researcher into making an incorrect observation. Dr. Olszowy conducted numerous experiments in 1988 to resolve the issue of whether findings of p48 were based on artifactual data. The results of these experiments, which Dr. Olszowy communicated to Respondent, served only to strengthen Dr. Olszowy's conviction that findings of p48 were artifactual.

Dr. Olszowy first became concerned that the protein which he and Respondent had identified as p48 from experiments using S-35 methionine labeling might in fact be actin, a common protein present in cells. Actin has a molecular weight of 43 kilodaltons, and is therefore easily confused with other proteins having similar molecular weights.

Beginning in December 1988, Dr. Olszowy attempted to resolve his concern that what had been identified as p48 in experiments using S-35 labeling was in fact actin, by using I-125 labeling techniques. Actin is not present on the surface of cells and, therefore, experiments using I-125 labeling should rule out the presence of actin. However, the experiments Dr. Olszowy performed using I-125 labeling did not satisfy him that a unique protein having a molecular weight of 48 kilodaltons had been identified. Dr. Olszowy was unable to identify clearly a protein having a molecular weight of 48 kilodaltons, using I-125

labeling. Rather, his experiments produced evidence of a common protein, albumin, which is present in the fluid surrounding cells.

Dr. Olszowy began telling Respondent, at least one year prior to Respondent preparing and submitting the February application to NIH, that the protein identified as p48 might be based on artifactual data.

Dr. Olszowy and Respondent had several discussions concerning whether what had been previously identified as p48 was an artifact, with Respondent pointing out that experiments continued to show the blocking of lysis of tumor cells by anti-laminin. Respondent directed Dr. Olszowy to perform experiments to explain this apparent contradiction.

Prior to February 1989, Dr. Olszowy conducted experiments to resolve the contradiction identified by Respondent by injecting purified laminin manufactured from tumors in mice into rabbits in order to obtain anti-laminin antibodies. The laminin which was used in these experiments was 95-99% pure, leaving open the possibility that impurities in the laminin injected into the rabbits might produce antibodies to the impurities along with antibodies to the laminin. Dr. Olszowy hypothesized that the rabbits were producing antibodies to mouse immunoglobulin (IgG) along with antibodies to laminin. Dr. Olszowy concluded that antibodies to IgG were being manufactured along with anti-laminin antibodies, and, therefore, the anti-laminin that was being used to test the blocking of the ability of NK cells to destroy tumor cells was contaminated with antibodies to IgG. Dr. Olszowy further concluded that the blocking of the ability to destroy tumor cells in the experiments he had earlier performed was not due to the action of an antibody to p48, but rather was due to the blocking effect of an immune complex which included antibodies to IgG.

One reason that Dr. Olszowy repeatedly raised with Respondent the issue of p48 being explained by an artifact was that the possibility affected Dr. Olszowy's Ph.D. thesis. Dr. Olszowy's Ph.D. thesis was premised on the existence of p48. On several occasions, Dr. Olszowy asked Respondent to convene a meeting of his thesis committee so that the committee could be apprised of the results of Dr. Olszowy's research. Respondent did not agree to convene a meeting of the thesis committee, but told Dr. Olszowy that he should focus on doing other experiments on other subjects.

In October 1989, Dr. Olszowy asked Respondent how he could justify pursuing renewal of a research grant to study p48 when experimental results raised so strongly the possibility that p48 might be explained as artifactual. Tr. at 219. Respondent told Dr. Olszowy that if p48 turned out to be explained by an artifact, he would use any research money he obtained to study p48 for some other purpose. Tr. at 220. Respondent told Dr. Olszowy that this is basically what everyone did. Id.

Respondent prepared both the February and October applications without showing them to Dr. Olszowy. In neither the February nor October application did Respondent mention that p48 might be explained by an artifact, nor did Respondent mention any of Dr. Olszowy's experimental results which called into question whether p48 was a unique protein, as Respondent contended in the applications.

Dr. Olszowy discussed his concerns that p48 might be explained by an artifact with Dr. Chambers no later than 1988. Dr. Olszowy expressed concern to Dr. Chambers that Respondent's reluctance to convene a meeting of Dr. Olszowy's thesis committee jeopardized Dr. Olszowy's thesis, and ultimately, his progress towards obtaining a Ph.D. Dr. Olszowy and Dr. Chambers discussed how Dr. Olszowy could ethically reveal his concerns about p48 in a way which would apprise members of Dr. Olszowy's thesis committee of those concerns. Dr. Olszowy and Dr. Chambers agreed that it would be appropriate for Dr. Olszowy, after advising Respondent of his intentions, to raise these concerns at a meeting of the PCI Journal Club, a periodic gathering of investigators, graduate students, and post-doctoral fellows to discuss current scientific literature. Dr. Olszowy presented his findings concerning p48 to the Journal Club in November 1989. In attendance at the Journal Club was Dr. Carol Dahl, a faculty member on Dr. Olszowy's thesis committee.

Dr. Dahl and other faculty members who attended the Journal Club brought to Dr. Herberman's attention the findings that Dr. Olszowy had presented. Dr. Herberman was familiar with the contents of the October application and became concerned that Dr. Olszowy's findings appeared to contradict some of the central points of the October application. Dr. Herberman met with Dr. Olszowy on December 7, 1989, at which time Dr. Olszowy explained why he thought p48 might be explained by an artifact. Dr. Herberman then advised Dr. Olszowy that these findings appeared to conflict with the statements Respondent had made in the October application. Dr. Olszowy advised Dr. Herberman that he had never seen either the February or October applications.

Shortly after the December 7 meeting, Dr. Herberman provided Dr. Olszowy with a copy of the October application. On or about December 15, 1989, Dr. Herberman met again with Dr. Olszowy. Dr. Olszowy told Dr. Herberman that he recognized Figures 1 and 2 in the October application as being photographs of autoradiograms of experiments that Dr. Olszowy had performed. Dr. Olszowy then showed Dr. Herberman the actual autoradiograms on which Figures 1 and 2 were based. Dr. Olszowy told Dr. Herberman that the legends in Figures 1 and 2 in the October application did not report accurately either the methodology or the conclusions of his experiments. After this meeting Dr. Herberman compared the legend for Figure 1 of the October application against the autoradiogram produced by Dr. Olszowy for the experiment depicted in Figure 1, and concluded that the legend in the application misrepresented the molecular weight of the protein in Figure 1.

On December 20 or 21, 1989, Dr. Herberman met with Respondent. Also present at the meeting were: Dr. George Bernier, Dean of the University of Pittsburgh School of Medicine; Dr. Sheldon Adler, Associate Dean for Faculty Affairs of the University of Pittsburgh School of Medicine; and Dr. Thomas Gill, Chairman of the Department of Pathology at the University of Pittsburgh School of Medicine and Respondent's academic supervisor. Dr. Herberman told Respondent that Dr. Olszowy had raised questions about Figures 1 and 2 in the October application and asked Respondent to explain these figures. Dr. Bernier asked Respondent to provide either himself or Dr. Herberman with primary experimental data

to explain Figures 1 and 2.

Respondent told the other participants at the meeting that he believed that the October application described accurately the results which were depicted in Figures 1 and 2. When Dr. Herberman showed Respondent the autoradiograms that Dr. Olszowy had provided him for Figures 1 and 2, Respondent stated that he was not sure that the autoradiograms presented by Dr. Olszowy were the autoradiograms from which Figures 1 and 2 were derived. Respondent stated that he would have no problem in obtaining primary experimental data that would refute or explain Dr. Olszowy's contention that there were discrepancies between the legends for Figures 1 and 2 in the October application and the results depicted in the autoradiograms from which Figures 1 and 2 were derived. Respondent further stated that he intended to produce documentation to show that Figures 1 and 2 were derived from experimental results other than the autoradiograms which Dr. Olszowy had provided to Dr. Herberman.

On or about January 7, 1990, Respondent met with Dr. Herberman and provided him with a blue notebook, the cover of which was labeled "Hiserodt #3." G. Ex. 15. Respondent told Dr. Herberman that the Hiserodt #3 notebook contained experimental data which he had obtained from experiments which he had performed personally, which were different from those experiments performed by Dr. Olszowy. At that meeting Respondent told Dr. Herberman that he prepared the Hiserodt #3 notebook contemporaneously with the experiments he had performed. Respondent directed Dr. Herberman's attention to pages 33 and 34 of the Hiserodt #3 notebook and told him the entries on those pages represented the results of the experiment that was described in Figure 2 of the February and October applications. Respondent told Dr. Herberman that the photograph on page 34 of the Hiserodt #3 notebook was made from an autoradiogram which recorded the results of the experiment described in Figure 2 of the applications.

Also at the January 7 meeting, Respondent admitted to Dr. Herberman that he might have stated incorrectly the molecular weight of the protein in Figure 1 of the February and October applications. Respondent told Dr. Herberman that Dr. Olszowy had told Respondent at first that the molecular weight of the protein represented in Figure 1 was 48 kilodaltons; later Dr. Olszowy had told Respondent that the molecular weight of the protein was actually 73 kilodaltons. Respondent explained to Dr. Herberman that he had elected to accept Dr. Olszowy's first statement of the molecular weight of the protein.

On or about January 8, 1990, Dr. Herberman met with Drs. Bernier and Gill to discuss the January 7th meeting and the Hiserodt #3 notebook. At this meeting Dr. Bernier expressed skepticism about the veracity of the Hiserodt #3 notebook and about Respondent's representations concerning how he had prepared it. Drs. Herberman, Bernier, and Gill concluded that the University of Pittsburgh should withdraw the October application from NIH consideration, pending resolution of questions concerning how Respondent prepared the application and the Hiserodt #3 notebook. On January 9, 1990, the University of Pittsburgh wrote to NIH requesting that the October application be withdrawn from NIH consideration. G. Ex. 17-A. This request was signed by Respondent, Dr. Herberman, and two other officials of the University of Pittsburgh.

Drs. Herberman and Bernier again met with Respondent on January 18, 1990. At this meeting, Respondent at first reiterated to Drs. Herberman and Bernier that the Hiserodt #3 notebook recorded contemporaneously generated primary experimental data. Respondent asserted once more that the experiment which was the basis for Figure 2 was recorded in the notebook. Respondent also stated again that the autoradiogram which Dr. Olszowy had provided to Dr. Herberman, and which Dr. Olszowy contended was the autoradiogram from which the photograph in Figure 2 had been made, was not in fact the autoradiogram from which the photograph in Figure 2 had been made. Respondent told Drs. Herberman and Bernier that the autoradiogram provided to them by Dr. Olszowy bore a superficial resemblance to the autoradiogram from which the photograph in Figure 2 had been made.

Dr. Bernier then advised Respondent that he would have the ink in the Hiserodt #3 notebook dated, in order to determine whether the notebook contained contemporaneously recorded experimental data or was a fabrication. Respondent then admitted that he had prepared the Hiserodt #3 notebook within two or three weeks prior to the January 7 meeting. Respondent then further admitted that the figures in the applications did not describe accurately the results of experiments.

On or about January 23, 1990, Respondent signed minutes of the January 18 meeting, in which Respondent admitted that:

- Figure 1 in the October application consisted of an autoradiogram in which the lane markers had been deleted, and a listing of apparent molecular marker weights had been substituted;
- Figure 1 incorrectly designated the molecular weight of the protein depicted in that figure as 48 kilodaltons, when in fact the protein had an actual molecular weight of 73 kilodaltons;
- Respondent knew that there was a question about the actual molecular weight of the protein in Figure 1 prior to submitting the application, but elected to submit the application (and Figure 1) with an incorrect designation of the protein's molecular weight;
- no experiment corresponding to the depiction of Figure 2 in the October application had been performed on the date stated in Respondent's notebook;
- the experiment described in the legend to Figure 2 had not been performed;
- the experiment depicted in Figure 2 was an experiment involving rat lymphocytes, rather than subpopulations of human lymphocytes as stated in the description of Figure 2; and
- the Hiserodt #3 notebook was a fabrication that Respondent had prepared after Drs. Herberman and Bernier began to question the veracity of the October application.

G. Ex. 17.

On January 22, 1990, Dr. Bernier wrote to the Office of Scientific Integrity of the Department of Health and Human Services (the

predecessor of ORI) to inform it of allegations of misconduct by Respondent in connection with the October application. G. Ex. 19. This letter led to ORI's investigation and the allegations and proposals which form the basis of this case.

ORI issued a report of its investigative findings. G. Ex. 93. The conclusions contained in that report constitute ORI's determination of scientific misconduct and the basis for ORI's proposed administrative actions. They were also relied upon by the Deputy Assistant Secretary as the basis for the proposal to debar Respondent. The overall conclusion of the report is that Respondent deliberately falsified portions of the February and October applications. ORI based this conclusion on findings that:

-- Figure 1 in the February and October applications misrepresented the correct molecular weight determinations of the substance depicted in that figure.

-- Figure 2 in the February and October applications was represented as the results of an experiment using subpopulations of human lymphocytes when in fact, the experiment depicted in the figure involved rat lymphocytes.

-- A laboratory notebook which Respondent submitted to Dr. Herberman as proof of the correctness of Figures 1 and 2 was fabricated.

-- Other figures and tables in the February and October applications were falsified, fabricated, or misrepresented.

ORI also concluded that Respondent committed scientific misconduct by failing to maintain primary research data which supported certain figures and tables in the February and October applications, and by providing ORI with only summary information supporting these figures and tables, in response to ORI's request for supporting primary data.

Respondent's Arguments

Respondent advances both procedural and substantive defenses against ORI's charges of scientific misconduct. Respondent contends that ORI has no authority to investigate alleged misconduct involving any application that either did not receive funding from NIH or was not pending before NIH as of the date that allegations of misconduct were made to ORI or its predecessor agency. He argues that ORI has no authority to investigate Respondent's conduct or to make determinations that Respondent engaged in scientific misconduct, inasmuch as the University of Pittsburgh withdrew the October application before notifying ORI's predecessor of possible misconduct by Respondent. Respondent asserts, therefore, that the allegations of his misconduct involve only matters which are of concern to the University of Pittsburgh.

Using similar reasoning, Respondent contends that ORI lacks authority to investigate the allegations of scientific misconduct concerning the Hiserodt #3 notebook or to make determinations of misconduct concerning the notebook and Respondent's presentation of it to University of Pittsburgh officials. Respondent asserts that, inasmuch as he created

the Hiserodt #3 notebook several months after submission of the October application, in response to an inquiry from officials at the University of Pittsburgh, any questions about the notebook should be resolved by the University of Pittsburgh.

Respondent concludes his argument concerning authority to investigate and make determinations of misconduct by asserting that, inasmuch as ORI has no authority to investigate the allegations of his misconduct, this Panel has no authority to hear such allegations, to make findings of fact and conclusions of law as to misconduct, to impose administrative actions, or to make recommended conclusions concerning the proposal to debar him.

Respondent also denies that he committed scientific misconduct. Respondent asserts that figures and tables in the February and October applications, contrary to ORI's determinations, are true and correct. Respondent further avers that there were no standards in effect either at the University of Pittsburgh or within PHS, governing his obligation to maintain research data. Therefore, according to Respondent, his failure to provide ORI with data which satisfied ORI's demand for primary data to support certain tables and figures in the applications cannot be deemed to be misconduct. Respondent maintains, furthermore, that his laboratory notebooks contain the information necessary to support any questioned figures and tables.

Respondent asserts that, at bottom, the charges of scientific misconduct emanate from a conspiracy among his former colleagues at the University of Pittsburgh which is fueled by both personal and professional jealousy. Respondent contends that Dr. Olszowy was motivated to accuse him falsely of misconduct by jealousy over Respondent's personal relationship with Dr. Olszowy's former wife. Respondent alleges that the actions of Dr. Herberman and others at PCI and University of Pittsburgh Medical School were the product of their jealousy over his scientific discoveries in the field of NK cells.

Applicable Legal Standards

Scientific misconduct

The definition of scientific misconduct contained in the 1989 regulations states:

Misconduct or Misconduct in Science means fabrication, falsification, plagiarism or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data.

42 C.F.R. 50.102 (effective November 8, 1989, 45 Fed. Reg. 32,446 (August 8, 1989)). The regulation's definition of scientific misconduct plainly encompasses the deliberate making of material false or fabricated statements in proposing and reporting research in grant applications.

ORI's allegations of scientific misconduct by Respondent, however, address conduct which both predates and is subsequent to the adoption of

regulations defining scientific misconduct that became effective November 8, 1989. The principal allegations of misconduct occurring prior to November 8, 1989 -- that Respondent willfully falsified and fabricated experimental findings in applications for research funding -- involve allegations which, if proven, would establish violations of standards of conduct which predated the adoption of the 1989 regulations that define scientific misconduct. 4/ Indeed, Respondent has never argued that if ORI's allegations of falsifications and fabrications were proven true, the falsified and fabricated statements would not be considered to be scientific misconduct under the standards in the scientific community prior to the promulgation of the 1989 regulations.

The misconduct which Respondent is alleged to have committed after November 8, 1989 -- consisting of engaging in efforts to conceal his previous misconduct by fabricating a notebook -- would, if proven, be scientific misconduct under the 1989 regulation's definition of misconduct as including "fabrication." Thus, the misconduct which Respondent is alleged to have committed would be scientific misconduct under the standards in effect prior to November 8, 1989, or under the 1989 regulations.

Indeed, the standards of scientific conduct which are involved in this case have not changed with the adoption of the 1989 regulations. Thus, the willful falsification and fabrication of scientific data which Respondent is alleged to have engaged in would constitute scientific misconduct under either the standards predating the 1989 regulations or the 1989 regulations. Both prior and subsequent to the adoption of the 1989 regulations, applicants for research funds have had a duty to honestly and truthfully report the experimental results on which they premise their applications. Willful falsification of experimental results, or deliberate inclusion of materially misleading or inaccurate statements as to those experimental results in applications, was scientific misconduct prior to adoption of the 1989 regulations and continues to be scientific misconduct.

In cases involving allegations of misconduct that predate the effective date of the 1989 regulations, ORI's burden is to establish the standards of conduct that were applicable to similarly-situated researchers, and to prove further that the respondents in those cases violated such standards. Dr. Rameshwar K. Sharma, DAB No. 1431, at 1-2 (1993). In Sharma, we concluded that ORI established that those standards included, at a minimum, prohibitions against intentional, material falsification of research results in a grant application. Sharma at 2. The Sharma decision further concluded that ORI had not demonstrated that such standards included negligent inclusion of a false statement in a grant application. 5/ Id.

On the issue of standards prevailing prior to November 8, 1989, ORI presented the testimony of Helen Kim Bottomly, Ph.D. Dr. Bottomly is an expert in the field of cellular immunology and is knowledgeable in the standards commonly accepted in the scientific community for a principal investigator on an NIH grant. Dr. Bottomly's experience includes having served as a grant reviewer for NIH. Her testimony as to standards prevailing in the scientific community was neither challenged nor contradicted by Respondent. We find her testimony to be persuasive.

ORI proved through Dr. Bottomly's testimony that the prevailing standards of conduct for scientists in effect prior to November 8, 1989 included requirements that researchers honestly and truthfully report experimental results and make good faith efforts to verify the results of experiments reported by others and relied on in applications. Tr. at 615. Thus, we find here, as was found in Sharma, that prior to November 8, 1989, a person responsible for presenting an application for research funding had a duty to be honest and truthful about his or her research. The making of statements which are deliberately false or materially misleading about experimental results constitutes scientific misconduct under that standard. Negligent inclusion of a false statement, as opposed to dishonesty, has not been demonstrated by ORI to constitute scientific misconduct under the pre-1989 standards of conduct.

The hearing which we conducted in this case was a de novo hearing. Although the ORI report containing allegations of misconduct defines the issues which we decide here, it is not proof that Respondent committed scientific misconduct. ORI's burden of proof on all issues of scientific misconduct is to establish by a preponderance of the evidence that facts exist which meet the legal test for misconduct. Our decision as to whether Respondent engaged in scientific misconduct is based on the evidence offered by the parties and rests, ultimately, on our conclusions as to whether ORI proved scientific misconduct by a preponderance of the evidence. Likewise, ORI must prove the reasonableness of the proposed administrative actions under the circumstances of this case.

Debarment

Administrative debarment from grants and contracts is provided for by regulation. See 45 C.F.R. Part 76; 48 C.F.R. Subpart 9.4; and 48 C.F.R. Subpart 309.4. By means of an administrative debarment, individuals or entities are excluded from eligibility for grant and contract awards from the federal government for a specified period of time.

Administrative debarments are discretionary actions taken to protect the interests of the public and the government and are not punitive. *Gonzalez v. Freeman*, 334 F.2d 570 (D.C. Cir. 1964); 45 C.F.R. 76.115 and 48 C.F.R. 9.402(a) and (b). The regulations provide that the causes for debarment include:

Any other cause of so serious or compelling a nature that it affects the present responsibility

45 C.F.R. 76.305(d), 48 C.F.R. 9.406-2(c).

Federal policy requires the award of grants and contracts only to responsible parties. Debarment is not mandatory upon a determination that a cause for debarment exists. A determination to debar is made after consideration of "the seriousness of the . . . acts or omissions and any mitigating factors." 45 C.F.R. 76.300 and 48 C.F.R. 9.406-4(a). In any debarment action, the cause for debarment must be established by a preponderance of the evidence, with the burden falling on the agency proposing debarment. 45 C.F.R. 76.314(c)(1), (2), and 48 C.F.R. 9.406-3(d)(3).

The standard for debarment does not mention scientific misconduct

specifically as a cause for debarment. However, the "other cause" language of 45 C.F.R. 76.305(d) and 48 C.F.R. 9.406-2(c) would encompass scientific misconduct, where the misconduct is of so serious or compelling a nature that it affects the present responsibility of a person. Scientific misconduct of the types alleged in this case has been found to be an "other cause" justifying debarment in Dr. David C. Bridges, DAB No. 1232 (1991), and in Robert Edward McCaa, Ph.D., DAB No. 823 (1987). See also Dr. Paul F. Langlois, DAB No. 1409 (1993).

Regulations governing debarment provide that the period of debarment shall be commensurate with the seriousness of the cause. 45 C.F.R. 76.320(a), 48 C.F.R. 9.406-4(a). The regulations provide that generally, the debarment period should not exceed three years. However, a longer period of debarment will be justified in cases where circumstances warrant. 45 C.F.R. 76.320(a)(1), 48 C.F.R. 9.406-4(b).

This case was referred to us by the Debarring Official to make findings of fact and proposed conclusions of law. Regulations provide that, in cases of proposed debarment where additional proceedings (including an evidentiary hearing) are necessary, the Debarring Official may refer the matter to another official for findings of fact. 45 C.F.R. 76.314(b)(2), 48 C.F.R. 9.406-3(d)(2)(ii). The regulations provide further that the Debarring Official may reject any such findings, in whole or in part, only after specifically determining them to be arbitrary and capricious or clearly erroneous. *Id.* The findings of fact that we make below address both the issues of scientific misconduct and cause for debarment.

The Panel's Authority to Hear this Case, to Review Administrative Actions, to Make Findings of Fact and Proposed Conclusions of Law as to Debarment

Respondent asserts that this Panel is without authority to find that Respondent committed misconduct or engaged in conduct which justifies debarment. 6/ Respondent asserts that ORI or its predecessor have authority only to investigate misconduct involving an application actually pending within the Department of Health and Human Services at the time that the investigation is opened. He argues that because the October application was withdrawn before an investigation into Respondent's conduct was commenced, ORI is without "jurisdiction" to make findings of misconduct and we are without authority to review those findings and, presumably, to make recommended conclusions of law about Respondent's possible debarment.

Respondent did not articulate a basis, either in enabling legislation or in regulations, for his argument that ORI had no authority to investigate allegations of misconduct, and that we have no authority to adjudicate the issues. The gravamen of his argument is that, inasmuch as the October application was withdrawn prior to an investigation being commenced by ORI's predecessor, there was literally nothing pending before DHHS to investigate. Respondent argues further that it would be inequitable to Respondent to investigate and decide allegations that he engaged in misconduct, because to do so would penalize him for his efforts to correct errors that he had detected in the applications.

These arguments are close to those which the respondent made in Sharma. In Sharma, the respondent contended that the Public Health Act (Act), 42 U.S.C. 289b(b), authorized PHS to investigate allegations of misconduct only in cases where funding had been granted. The Presiding Panel Member there ruled that the authority to consider allegations of misconduct extends to applications for funds whether or not applications are funded. Dr. Rameshwar Sharma, DAB Docket No. A-93-50, Ruling on Respondent's Motion to Dismiss the Complaint (May 10, 1993) (Ruling).

The Ruling in Sharma found that the Act could not be read reasonably in so narrow a way as the respondent advocated. The language in the Act authorizing investigations into misconduct "in connection with projects for which funds have been made available" means that the alleged misconduct must only be connected with projects for which PHS funding has been made available. That would include proposals for funding that are not funded as well as those proposals that are funded. The Act neither states nor suggests that misconduct may be found only in cases where funding has been approved:

Surely, misrepresenting one's research accomplishments or capacities in an effort to obtain funding is connected with the research project being proposed. Furthermore, projects "for which funds have been made available" is broader than "funded projects." It can reasonably be interpreted to subsume projects proposed for funding under one of PHS's grant programs.

Ruling at 15.

We affirm the analysis contained in the Ruling. The authority to investigate scientific misconduct extends beyond applications for grants that are funded. The authority applies to misconduct made in the process of applying for grants, whether or not grants ultimately are funded.

Here, Respondent is contending that the applications at issue were not only unfunded, but were withdrawn prior to the commencement of an investigation by ORI's predecessor. We do not find this to be an impediment, either to the conduct of an investigation into possible misconduct, or the adjudication of determinations made by ORI. Withdrawal of an application does not strip DHHS of the authority to investigate misconduct that may have occurred in connection with the application process. 7/ The broad purpose of the Act plainly is to oblige DHHS to take action with respect to scientific misconduct which is committed in the process of applying for research funding. The event that triggers the authority to investigate and take action concerning misconduct is the filing of an application for research funds. The legitimate concern of DHHS in such cases, which is recognized implicitly in the Act, is to deal with attempts to deceive DHHS into approving funds.

The fact the applications in question were withdrawn prior to the commencement of this investigation does not affect DHHS's authority to impose debarment. The debarment regulations for procurement and non-procurement transactions respectively cover the debarment of a "contractor," defined in part as any individual who "reasonably may be

expected to submit offers for" government contracts and of persons "who have participated, are currently participating or may reasonably be expected to participate in transactions under Federal non-procurement programs." Thus, Respondent, who was a principal investigator under prior grants and who submitted these withdrawn applications seeking continued funding, is clearly covered by the debarment regulations as one who has had federal funding and who may reasonably be expected to seek federal grants or contracts in the future. 45 C.F.R. 76.110(a) and 48 C.F.R. 9.403. The issue in a debarment case is whether a party has engaged in conduct from which lack of present responsibility can be inferred. 45 C.F.R. 76.313 and 48 C.F.R. 9.406-1. In this case, what is at issue is whether Respondent attempted to deceive NIH into approving an application for research funds. The alleged deception is relevant to Respondent's present responsibility to handle federal funds because it relates directly to Respondent's honesty. The fact that in a given case an application might be withdrawn before a final funding decision may be made, while it may in some instances say something about a party's integrity, does not prevent the Debarring Official from taking action based on the representations made by the party who presented the application. Furthermore, Respondent signed the October application as the principal investigator, agreeing to accept responsibility for the scientific conduct of the project detailed in the application. G. Ex. 4, at 1.

Respondent also contends that ORI is without authority to investigate Respondent's presentation of the Hiserodt #3 notebook to University of Pittsburgh officials and that this Panel is without authority to hear allegations concerning the notebook, because he produced the notebook in the course of an internal investigation at the University of Pittsburgh. He argues that the notebook played no part in the University's submission of grant applications to NIH.

The premise of Respondent's argument is unsound. The notebook was an integral component of Respondent's attempt to convince NIH to fund a grant application. Although Respondent did not present the notebook to NIH, he prepared it in order to convince the University of Pittsburgh to offer continued support for the October application. To the extent that the notebook involves dishonesty by Respondent, it is part and parcel of the alleged attempt by Respondent to deceive NIH into funding a grant application through misconduct. The notebook and circumstances surrounding the notebook's creation and presentation are legitimate matters for ORI to investigate as an element of an alleged attempt to deceive NIH. Furthermore, the circumstances surrounding the notebook are relevant to the question of Respondent's possible debarment as they bear on the issue of whether Respondent is presently responsible to receive federal funds. We therefore have authority to consider the issues raised concerning the Hiserodt #3 notebook.

The grant applicant for the October application was the University of Pittsburgh. The October application was pending with NIH in December 1989, when Drs. Herberman and Bernier first met with Respondent to question him about allegations of false statements in the applications. These officials had the authority and responsibility on behalf of the University of Pittsburgh to ensure that applications filed by the

University were prepared honestly. Had these officials known at their first meeting with Respondent that the February and October applications were falsified, they doubtless would have acted immediately to inform NIH of that, and to withdraw from consideration the October application. In fact, they waited until early January 1990 to direct that the application be withdrawn. They waited until then because Respondent had assured them that he could produce primary experimental data to verify the experimental results described in the October application.

The Hiserodt #3 notebook which Respondent presented to Drs. Herberman and Bernier in January 1990 was represented by Respondent to constitute the primary experimental data that the two officials requested. These officials withdrew the application in January 1990, because they were not persuaded by Respondent's efforts. Had Respondent succeeded in convincing them that the October application was based on accurate experimental data, presumably the application would not have been withdrawn. Thus, the notebook was prepared by Respondent to at least influence indirectly NIH's consideration of the October application, and its preparation and presentation are a legitimate subject for ORI to investigate and for us to hear as an aspect of this case.

Discussion of Our Findings of Fact

ORI argued that the February and October applications contained numerous statements and figures which are false, which misrepresent the status of the research conducted in Respondent's laboratory, or for which Respondent has not produced primary supporting data. These statements include Figures 1 and 2 in the February and October applications, Figure 7 in the October application, Table 1 in the February and October applications, and Figure 4 in the February application, which is presented also as Figure 3 in the October application. ORI further alleged that Respondent fabricated the Hiserodt #3 notebook to conceal his falsification of Figures 1 and 2 in the October application (and in the February application as well, inasmuch as Figures 1 and 2 are essentially identical in the two applications).

We will discuss each of these figures and tables and the Hiserodt #3 notebook in turn. At the outset, we note that the preponderance of the evidence in this case establishes that Respondent falsified deliberately Figures 1 and 2 in the February and October applications, Figure 7 in the October application, Table 1 in the February and October applications, and Figure 4 in the February application, which is presented also as Figure 3 in the October application. The preponderance of the evidence establishes also that Respondent fabricated the Hiserodt #3 notebook in an effort to cover up his falsification of figures 1 and 2 in the October application (and in the February application as well).

Alleged statements for which Respondent has not produced primary supporting data include: Figure 5 in the February application, which is presented also as Figure 4 in the October application; Figure 7 in the February application, which is presented also as Figure 6 in the October application; and Table 2 in both the February and October applications. These statements are discussed later in this decision, beginning at page 50.

Figure 1 in the February and October applications

Figure 1 in the February and October applications is a photograph of an autoradiogram purporting to show the existence of a protein with a molecular weight of 48 kilodaltons. The identical photograph is in Figure 1 in both the February and October applications. The photograph shows five lanes in which molecules appear to have been immunoprecipitated. Alongside the left-hand margin of the photograph, Respondent added a legend showing the location of molecular weight markers, reading from the top down, of 200 kilodaltons, 97 kilodaltons, 68 kilodaltons, 44 kilodaltons, 27 kilodaltons, and 18 kilodaltons.

In both the February and October applications, Respondent represented in Figure 1 that immunoprecipitation of human A-LAK cells labeled with I-125 using anti-laminin antibodies produced evidence of a protein with a molecular weight of 48 kilodaltons. The photograph in Figure 1 contains images of proteins in lanes 2 and 4, which Respondent labeled "P 48." Respondent's intent in including Figure 1 in the applications was to convince NIH that he had experimental results which established the presence of p48 on human A-LAK cells by immunoprecipitation, using human A-LAK cells labeled with I-125 and anti-laminin (anti-p48) antibodies.

The captions to Figure 1 in both applications are identical except for the following: the caption in the February application states that lane 3 consists of "IgG Isotype control," whereas the caption in the October application states that lane 3 in the photograph consists of "IgG control"; and the caption in the February application states that lane 4 consists of "Anti-p48 MoAb (4.1.5)," whereas the caption in the October application states that lane 4 consists of "Anti-laminin (cross-reactive with kappa light chain)."

Dr. Olszowy testified credibly and without contradiction that the photograph in Figure 1 was made from an autoradiogram which he produced to record the results of an experiment that he had conducted in December 1988. Tr. at 226, 228, 244. Dr. Olszowy was able to identify the photograph in Figure 1 as coming from an autoradiogram that he developed from an experiment because of the presence of a pattern of spots on the photograph that matched the pattern of spots on the autoradiogram he developed. Tr. at 227- 28. He testified that exposure of photographic film to radiation to create an autoradiogram will result in incidental spotting on the developed negative. Tr. at 175. Thus, each autoradiogram produces its own unique pattern of extraneous dots or spots that can be viewed as the autoradiogram's "fingerprint." A researcher can identify an autoradiogram from its unique "fingerprint."

The autoradiogram identified by Dr. Olszowy as being the source for the photograph in Figure 1 actually depicted seven lanes rather than the five lanes depicted in the photograph in Figure 1. G. Ex. 98. The two lanes that were not represented in the photograph in Figure 1 were the two lanes on the extreme left and right side of the autoradiogram. These two outside lanes were the marker lanes that contained the proteins of predetermined molecular weight. The autoradiogram used to produce the photograph in Figure 1 had marker lanes marked with proteins with molecular weights of 200, 97, 68, 43, 24, and 14 kilodaltons. The

immunoprecipitation process kits used in Respondent's laboratory always produced these same standardized molecular weights in the marker lanes. Tr. at 172.

On this autoradiogram the I-125 labeling produced bands in the third and fifth lanes with a molecular weight of approximately 68-73 kilodaltons. Dr. Olszowy theorized that these bands denoted the presence of another artifact, the common protein albumin, rather than p48. Tr. at 226, 238-39.

But when Respondent used the photograph from this autoradiogram in Figure 1, Respondent did not include the whole photograph; rather, he deleted the outside marker lanes from the photograph, so that the bands in the third and fifth lanes in the autoradiogram now appeared in the second and fourth lanes of Figure 1. Instead of the marker lanes, Respondent typed a legend of molecular weights along the left side of the photograph. In doing so, Respondent moved the whole legend of molecular weights upwards, so that the bands appearing in the second and fourth lanes were depicted by Respondent as having a molecular weight of 48 kilodaltons rather than the actual molecular weight of 68-73 kilodaltons depicted on the autoradiogram. Thus the legend which Respondent included on the left side margin of the photograph in Figure 1 purporting to show molecular weight markers did not correspond with the actual molecular weight markers contained in the autoradiogram from which the photograph was made.

Respondent asserted that he cut off the marker lanes from the photograph because there was no need to include that information in the application. Tr. at 1137-39. Respondent testified that he "knew" that experiments had shown the existence of p48. Tr. at 1138-40, 1146. Respondent testified that in a rush to submit the February application he retrieved a photograph from his files and assumed that the protein depicted on that photograph showed the existence of p48. Tr. at 1135-36. Respondent explained that he made the starting point of the legend that appeared to the left of the photograph in Figure 1 the bands showing what he assumed was a protein at 48 kilodaltons and then labeled the other points on the legend, upward and downward, from there. Tr. at 1141, 1149.

We make the following findings in regard to Figure 1:

- o The legend showing molecular weights which Respondent included on the left side of the photograph in Figure 1 is false.
- o The molecular weight of the protein depicted in the photograph in Figure 1, which Respondent stated to be 48 kilodaltons, is actually 68-73 kilodaltons.
- o Respondent's statement in Figure 1 that the protein depicted in the photograph in Figure 1 has a molecular weight of 48 kilodaltons is false.
- o Respondent's representation in the caption to Figure 1 that it depicts experimental results establishing the presence of p48 in human A-LAK cells by immunoprecipitation, using A-LAK cells labeled with I-125 and anti-laminin (anti-p48)

antibodies, is false.

We further find that Respondent deliberately falsified Figure 1. We base this finding on the following:

o The highly self-serving nature of these false statements about Figure 1 makes it far more likely that they are deliberate rather than inadvertent. The false statements contained in Figure 1 are the heart of Respondent's contentions about the p48 protein. Respondent knew that he needed to satisfy NIH that he had identified p48 on the surface of NK cells in order to obtain funding of the applications.

o Respondent had a motive to falsely represent experimental data rather than report accurately the state of research in his laboratory. Respondent knew that NIH would not likely fund a grant if it was aware that the premise of the application was based on artifactual data. Respondent knew when he created Figure 1 that the meaning of the experimental data generated in his laboratory was in doubt. Respondent knew at the very least that any photograph of the autoradiogram that he used in the two applications might be argued by Dr. Olszowy to show that p48 did not exist. Yet, Respondent did not disclose in either of the applications that there was even the possibility of some conflicting data to his theory in his laboratory.

o Respondent has not explained persuasively his contention that he constructed Figure 1 based on an essentially unlabeled photograph and his memory of what it depicted. Respondent easily could have ascertained what the photograph he used for Figure 1 actually represented. Respondent knew that the original experimental data for experiments conducted in his laboratory, including the autoradiogram from which the photograph in Figure 1 was made, were maintained in an organized form by Dr. Olszowy and by other researchers. Respondent had access to this data at the time the applications were prepared, and, in fact, referred to it at times.

o The way which Respondent altered the photograph contained in Figure 1 is consistent with a deliberate falsification. In order to represent that the molecular weight of the protein depicted in the figure was 48 kilodaltons, Respondent had to delete marker bands from both sides of the photograph which, when read accurately, showed plainly that the protein depicted in the autoradiogram had a different molecular weight than is shown in the figure. The marker bands which Respondent deleted represented standardized molecular weights with which Respondent was familiar. The molecular weight markers which Respondent typed on the altered photograph do not correspond to the marker bands which Respondent deleted. Nor do these

molecular weight markers correspond to the standardized molecular marker bands utilized by Respondent's laboratory and PCI to calibrate autoradiograms.

o Respondent's contention that he misread the molecular weight of the protein depicted in Figure 1 is not plausible in light of the fact that Dr. Olszowy had specifically brought to his attention the fact that the molecular weight of the protein was 68-73 kilodaltons, rather than the 48 kilodaltons which Respondent represented the molecular weight of the protein to be.

o Respondent's contention that the misstatements in Figure 1 were the product of simple human error is belied by his failure to discover and correct his "error" in the February application in the several months between his submitting the February and October applications. In fact, Respondent not only repeated this "error" but also made highly specific revisions to his caption to Figure 1 in the October application which suggest that he had to evaluate the implications of Figure 1 before including it again in the October application.

Respondent's contention that his labeling of the protein in Figure 1 was an oversight is belied by the fact that he knew, from discussions with Dr. Olszowy, that there was at the very least a question about the molecular weight of the protein depicted in the photograph. In fact, Respondent admitted to Drs. Herberman and Bernier and, ultimately, signed a statement admitting that he had elected to disregard Dr. Olszowy's statement to him that the protein depicted in the photograph had a molecular weight of 68-73 kilodaltons.

We therefore find that the preponderance of the evidence establishes that Respondent deliberately misrepresented the molecular weight of the protein depicted in the photograph in Figure 1 as 48 kilodaltons in order to convince NIH that he had proof of p48 on the surface of NK cells.

Figure 2 in the February and October applications

Both the caption to Figure 2 and the photograph in Figure 2 are identical in the February and October applications. In both applications, Respondent represents in Figure 2 that the immunoprecipitation of purified human cells labeled with I-125 using anti-laminin antibody produced p48. Figure 2 contains a photograph of an autoradiogram which has experimental results that Respondent purports to explain in the caption to the photograph.

The photograph in Figure 2 has three lanes. On the right side of the photograph, Respondent wrote "P48" at a point corresponding to molecular weight bands in the second and third lanes. On the left side of the photograph, Respondent added a legend listing molecular weights of 200, 97, 68, 44, and 27 kilodaltons. The molecular weight bands in the second and third lanes are just above the legend's mark of 44

kilodaltons. Respondent's intent in submitting Figure 2 to NIH was to prove that he had established the presence of p48 on the surface of purified (sorted) human cells labeled with I-125 using anti-laminin antibody.

Dr. Olszowy testified that the photograph in Figure 2 was made from an autoradiogram which he made to record the results of an experiment he had conducted in June 1988. Tr. at 250. Dr. Olszowy testified that this autoradiogram had two separate gels on it and that the photograph in Figure 2 came from the right half of the bottom gel on the autoradiogram. Tr. at 252. Dr. Olszowy testified that he was able to identify the photograph in Figure 2 as coming from that part of the autoradiogram because the photograph, although cropped, shows a dark smear or blot that occurs at the bottom of the second lane that corresponds to a stain of excess radiation that appears at the bottom of the second lane in the lower right half of the autoradiogram. Tr. at 253.

Dr. Olszowy testified that the experiment depicted on the lower right half of the autoradiogram from which the photograph in Figure 2 was developed involved labeling rat cells with S-35 methionine. Tr. at 254, 256. Dr. Olszowy testified that on the autoradiogram beneath the experiment he wrote the words "35 S rat x-tract." Tr. at 251-52. Dr. Olszowy testified that it was his practice to put ink markings on autoradiograms as soon as he received the autoradiograms. Tr. at 256. Dr. Olszowy further testified that the original photograph made from this autoradiogram also had the words "35 S rat x-tract" underneath that portion of the gel that Respondent used in Figure 2. Tr. at 253-54.

In comparing the autoradiogram to Figure 2, Dr. Olszowy thus identified as untrue three statements in the caption to Figure 2: that purified or sorted cells were used in the experiment, that these cells were human cells, and that the experiment used the I-125 immunoprecipitation process. Tr. at 255-58.

Each of these misstatements is significant. First, purified or sorted cells are cells which have been run through a flow cytometer, producing 95-100% pure cells. The greater the purity of the cells, the less likely is the possibility of contaminants in the cells that would reduce the reliability of experiments made with these cells. Thus, results from an experiment using purified cells would be considered by a reviewer to be more accurate and reliable than an experiment using unsorted cells.

Second, the issue of whether human cells or rat cells were used in an experiment is important. Dr. Bottomly testified that the use of human cells rather than rat cells in an experiment was significant because the ultimate purpose of NK cell research is the killing of human tumors. Tr. at 634. Therefore an experiment involving human cells would be more likely to persuade a reviewer of the worthiness of the research than one employing rat cells.

Finally, the use of I-125 rather than S-35 methionine in an experiment trying to establish the existence of p48 on the surfaces of NK cells is extremely significant because I-125 labels only proteins found on the surfaces of cells. The S-35 methionine method, on the other hand, does

not discriminate between proteins which are contained in the cell's interior and proteins expressed on the cell's surface (because the cell's walls are destroyed). Thus, if the purpose of one's research is to establish the existence of a particular protein on the surface of a NK cell, evidence of that protein derived from an experiment using I-125 labeling would be more significant to a reviewer than would be evidence derived from an experiment using S-35 methionine labeling. Furthermore, use of I-125 labeling eliminates the possibility of the artifact actin being mislabeled as p48.

Respondent denied the existence of any false statements in Figure 2. Respondent asserted alternatively that if Figure 2 did contain errors, they were either unintentional or insignificant. Respondent contended that he created Figure 2 from a photograph dated June 28, 1988 that he retrieved from his files. Respondent testified that this photograph pictured an autoradiogram without any labeling whatsoever; there were no molecular weight markers or descriptive words under any lanes. Tr. at 1166. Respondent testified that he understood the photograph to represent several different experiments in which human NK cells, rat cells, and tumor cells were analyzed by immunoprecipitation with anti-laminin antibodies. Tr. at 1167. Respondent testified that he took this unmarked photograph which depicted both human and rat experiments, removed the part that he thought was the experiment with human cells, assumed that it was from an experiment using sorted cells with I-125, and used that part of the photograph in Figure 2. 8/

Respondent averred that the experiment depicted in Figure 2 was initiated based on discussions between Respondent and Dr. Schwarz. Tr. at 1167-68. He asserted that Dr. Schwarz performed the experiment depicted in Figure 2 in June 1988 using sorted human cells, and that Dr. Schwarz gave him the photograph he used to make Figure 2. Tr. at 1168. Respondent further maintained that as both experiments in the lower half of the photograph, one using human cells, the other rat cells, depicted the presence of p48, it was inconsequential that he might have mistakenly used that portion depicting an experiment with rat cells in Figure 2 and claimed it as an experiment using human cells. Tr. at 1170- 71.

It is apparent from the evidence that Dr. Olszowy's account of the relationship between Figure 2 and the experiment that Dr. Olszowy conducted is accurate. We conclude that Figure 2 was made from a photograph of an autoradiogram generated from an experiment conducted by Dr. Olszowy. Dr. Olszowy's testimony is corroborated by an original autoradiogram which is in evidence and which plainly is the autoradiogram from which the photograph in Figure 2 was made. G. Ex. 99. Furthermore, that autoradiogram bears the handwritten legend attested to by Dr. Olszowy. There is nothing in the record that supports Respondent's assertion that the experiment depicted in Figure 2 was performed by Dr. Schwarz.

We make the following findings in regard to Figure 2:

- o The experiment on which Respondent based Figure 2 did not involve human cells, as is stated by Respondent in the February and October applications, but involved rat cells.

- o Respondent's statement in Figure 2 that the experiment depicted in that figure involved human cells is false.
- o The experiment on which Respondent based Figure 2 did not utilize purified or sorted cells, as is stated by Respondent in the February and October applications, but utilized unsorted cells.
- o Respondent's statement in Figure 2 that the experiment depicted in the figure involved purified cells is false.
- o The experiment on which Respondent based Figure 2 did not involve labeling with I-125, as is stated by Respondent, but involved labeling with S-35 methionine.
- o Respondent's statement in Figure 2 that the experiment depicted in the figure involved labeling with I-125 is false.

We further find that Respondent deliberately falsified Figure 2. We base this finding on the following:

- o As with the statements in Figure 1, the highly self-serving nature of the false statements in Figure 2 makes it far more likely that they are deliberate rather than inadvertent. The false statements contained in Figure 2, along with the false statements contained in Figure 1, constitute the central "proof" in the February and October applications that Respondent had isolated p48 on the surface of human cells. Respondent knew that he needed to satisfy NIH that he had identified p48 on the surface of NK cells in order to obtain funding of the applications.
- o Also as with Figure 1, Respondent had a motive to fabricate experimental data rather than report accurately the state of research in his laboratory. Respondent knew that NIH would not likely fund a grant if it was aware that the premise of the application might be explained by an artifact.
- o While the presence of any one of three significant false statements in Figure 2 might be explained conceivably by inadvertent error, the presence of all three false statements is evidence of a deliberate falsification by Respondent. The cumulative effect of the three false statements was to persuade a reviewer that the experiment depicted in Figure 2 had more merit and significance than it actually did.
- o Respondent has not explained persuasively his contention that he constructed Figure 2 based on an unlabeled photograph and his memory of what it depicted. Respondent easily could have ascertained what the photograph he used for Figure 2 actually represented. Respondent knew that the original experimental data for experiments conducted in his laboratory, including the autoradiogram from which the photograph in Figure 2 was made, were maintained by his researchers. Respondent had access to this data at the time

the applications were prepared.

Respondent provided no plausible explanation for his asserted recollection that the experiment from which Figure 2 was ostensibly derived took place in June 1988.

Respondent's contention that Figure 2 was based on an experiment performed by Dr. Schwarz and on a photograph supplied to him by Dr. Schwarz of an experiment performed on June 28, 1988, is unsupported and is rebutted by the autoradiogram which is the basis for Figure 2.

o Respondent's assertion that it was insignificant whether the experiment showing the alleged presence of p48 used human cells or rat cells is contradicted by the expert testimony of Dr. Bottomly that the use of human cells adds weight to the value of an experiment to a reviewer.

o Had the false statement in Figure 2 been the product of inadvertence or simple human error, Respondent simply could have acknowledged that, instead of fabricating experimental results to cover up his misstatements. However, when Dr. Herberman raised questions about the accuracy of Figure 2, Respondent tried to cover up his false statements by fabricating experimental results and representing that the fabricated results constituted primary experimental data supporting Figure 2. See our discussion of the Hiserodt #3 notebook beginning at page 42.

We therefore find that the preponderance of the evidence establishes that Respondent deliberately falsified the results of the experiment depicted in Figure 2 of the February and October applications in order to deceive NIH into concluding that Respondent had established the presence of p48 on the surface of purified human cells using the I-125 process.

Figure 7 in the October application

The persons who reviewed the February application on behalf of NIH noted that, based on that application, polyclonal rabbit anti-laminin appeared to manifest unusual properties, including its ability to immunoprecipitate monoclonal kappa light chain of the IgG class antibody besides p48. In other words, anti-laminin appeared to react with several substances in addition to p48. The reviewers expressed skepticism that a specific antiserum (rabbit anti-laminin) could react with so many diverse molecules. Dr. Herberman discussed the NIH review of the February application with Respondent and suggested to Respondent that, in an amended application, he might allay the concerns expressed by the NIH reviewers by matching the DNA sequence of p48 with the DNA sequence of the kappa light chain of IgG. A high degree of homology (similar molecular sequences) between the DNA sequence of p48 (or anti-laminin) and that of the kappa light chain of IgG might explain the cross-reactivity between the molecules, and would resolve the skepticism about such cross-reactivity expressed by NIH reviewers.

In the October application Respondent added a figure (Figure 7) to those which he had included in the February application. In the caption to

Figure 7, Respondent describes the figure as representing the nucleotide sequence homology of the B2 subunit of laminin and a variable region sequence of kappa light chain. Respondent asserts that in areas of the figure marked with asterisks and delineated with boxes, there are sequence homologies of 60 to 70 percent. It is clear that Respondent's purpose in including Figure 7 in the October application was to provide an explanation for the cross-reactivity between anti-laminin and various molecules and thus to allay the concerns expressed by the NIH reviewers in their review of the February application.

Dr. Olszowy, at Respondent's direction, did the computer sequence comparison that produced Figure 7. Dr. Olszowy testified that the comparison showed that the portion of laminin B2 which Respondent reproduced as Figure 7 is in a portion of DNA which is never translated into protein. Tr. at 273. As for providing an explanation for the cross-reactivity between anti-laminin and other molecules, Dr. Olszowy termed the result of the comparison, "a complete washout." Id. Dr. Olszowy explained that if the comparison is from an untranslated sequence of DNA, it is nonsense to assume that the comparison is in any way an indication that laminin B2 and the kappa light chain of IgG have similar protein sequences. Tr. at 276-77. Dr. Olszowy testified that he told Respondent that the sequence depicted in Figure 7 was from an untranslated portion of DNA. Tr. at 277.

Respondent testified that he put Figure 7 in the October application "almost as an afterthought." Tr. at 1195. Respondent explained that he supplied Figure 7 to NIH as a potential explanation for the cross-reaction between p48 and the kappa light chain of IgG. Id. Respondent testified that he used the word "speculative" in the application to describe Figure 7 because he had no information that the portion of the sequence could not be translated in the NK cell. Tr. at 1196.

Respondent, however, did not tell NIH that the homologies depicted in Figure 7 were from portions of DNA that are untranslated -- that is to say, do not play a meaningful role in the reproduction of proteins -- and that, therefore, Figure 7 does not provide a significant explanation of the cross reactivities between the anti-laminin antibody and other substances. Figure 7 is thus misleading, and suggests a finding which the underlying research did not in fact establish.

There is nothing in the text of the October application that advises a reader that Figure 7 represents untranslated portions of DNA molecules. Respondent discusses Figure 7 at page 24 of the text of the October application. After describing Figure 7, Respondent states:

Although speculative, these data suggest that the NK-associated 48 kDa protein may be related to classical B cell antigen recognition receptors and may, therefore, represent a novel recognition receptor expressed on NK cells. These speculations remain valid if the p48 protein is indeed, translated from B2 chain messenger RNA or a highly related mRNA.

G. Ex. 4, at 4. The use of the word "speculative" does not signal that Figure 7 is derived from untranslated portions of DNA. Rather, it suggests that the similarities depicted in Figure 7 are a possible,

albeit speculative, explanation for the cross-reactivity between the antibody and other substances. A reviewer reading this language might infer reasonably that Respondent was representing that the homologies depicted in Figure 7 are from the translated portion of DNA, inasmuch as there would be no possible explanation for cross-reactivity in homologies contained in the untranslated portion.

We make the following findings in regard to Figure 7:

- o The homologies depicted by Respondent are from untranslated portions of DNA.

- o Homologies in untranslated portions of DNA of different molecules do not explain possible cross-reactivity of those molecules, because the untranslated portions of DNA are not responsible for the manufacture of proteins.

- o Respondent did not state, either in the legend to Figure 7 or elsewhere in the October application, that the homologies depicted in Figure 7 were from untranslated portions of DNA.

- o A reviewer would not be able to determine from reading Figure 7 that the homologies depicted in that figure are from untranslated portions of DNA.

- o Respondent's inclusion of the term "speculative" in the portion of the text of the October application which describes the DNA sequence homologies between anti-laminin and other molecules does not suggest to the reader that the homologies depicted in Figure 7 are from untranslated portions of DNA.

- o Figure 7 in the October application is misleading because it suggests to a reviewer that the homologies depicted in the figure explain the cross-reactivity between anti-laminin and various molecules, when in fact, the homologies depicted in the figure do not explain such cross-reactivity.

We further find that Respondent deliberately failed to include in Figure 7 the relevant information that the homologies depicted therein are from untranslated portions of DNA. We base this finding on the following:

- o It was very much in Respondent's self-interest to provide an incomplete and misleading description of Figure 7 in the October application. Respondent knew that he had to explain the cross-reactivity of anti-laminin and other molecules in order to obtain grant funding from NIH because of the concerns expressed by the reviewers of the February application. Had Respondent told NIH that the sequences he depicted in Figure 7 were from untranslated portions of DNA, he would have made it clear that he was not offering meaningful evidence to respond to the concerns expressed by NIH.

- o Respondent knew that the homologies that he depicted in Figure 7 were from untranslated portions of DNA. Dr. Olszowy did the research which produced the computer-generated DNA sequence on which Figure 7 was based, and told Respondent

that the similarities which had been discovered were from the untranslated portions of the molecule.

o Respondent knew that homologies between untranslated portions of DNA would not explain the cross- reactivity between anti-laminin and other molecules, including IgG.

o Respondent has not offered a persuasive explanation for his failure to apprise NIH that the DNA sequence depicted in Figure 7 is from the untranslated portions of the molecule. Respondent's assertion that he included Figure 7 in the October application as an afterthought, suggesting that he attached little significance to the figure and that it was not intended to mislead anyone, is not credible. In fact, we find that Respondent offered Figure 7 as critical evidence intended to persuade NIH to fund the application.

We therefore find that the preponderance of the evidence establishes that Respondent included Figure 7 in the October application in order to mislead deliberately NIH reviewers into concluding that DNA sequence homologies accounted for the cross- reactivity between anti-laminin and other molecules.

Table 1 in the February and October applications

In both the February and October applications, Respondent included a Table 1, which was a representation of laminin (p48) on various human lymphoid subsets. The caption to Table 1 is identical in the February and October applications. In the caption to Table 1, Respondent represented that the laminin expression on the sorted cells depicted in the table was determined by a process known as three-color flow cytometry "using Texas Red labeled anti-laminin." Flow cytometry is a method for sorting and separating cells.

Dr. Schwarz performed the cell sorting experiments employing flow cytometry for Respondent's laboratory. Dr. Schwarz testified that, upon examining the data in Table 1, he did not know the source of that data. Tr. at 559. Dr. Schwarz testified that he performed only one experiment using three-color flow cytometry with Texas Red labeling and that experiment was a failure. Tr. at 558-59. Dr. Schwarz testified that three-color flow cytometry is a more accurate and sophisticated mechanism for cell sorting than is two-color flow cytometry. Tr. at 578. Dr. Schwarz explained that two-color flow cytometry is less precise than three-color flow cytometry and will not produce as reliable results as are produced by three-color flow cytometry. Tr. at 593-94. Thus, by asserting that three-color flow cytometry had been utilized in the experiment that produced the data represented in Table 1, Respondent claimed greater accuracy and precision for the experimental results depicted in Table 1 than was justified.

Respondent testified that he did not perform the experiment which produced the data used in Table 1, but that he received that information from Dr. Schwarz. Tr. at 1175. Respondent contended that he stated in the application that the results were determined by three-color cytometry using Texas Red labeled anti- laminin because he erroneously interpreted how Dr. Schwarz performed the experiment which produced the

data used in Table 1. Tr. at 1175-76. Respondent explained that he had asked Dr. Schwarz to do a three-color analysis of the anti-laminin antibody Respondent had personally prepared. Tr. at 1176. When he received the results from Dr. Schwarz, Respondent testified that he erroneously assumed that Dr. Schwarz had used three-color cytometry, when Dr. Schwarz had actually employed a two-color process. Id. Respondent contended that the only mistake he made in Table 1 was describing it as using three-color flow cytometry when it actually used two-color flow cytometry and that the results depicted in Table 1, while representing a modified two-color flow cytometry experiment, would be close to the results received from a three-color flow cytometry experiment. Tr. at 1177-78. Respondent stated that he had no reason to question the numbers in Table 1 because those results were similar to numbers obtained from other experiments using two-color flow cytometry. Tr. at 1178-79.

We make the following findings in regard to Table 1:

- o Respondent's assertion that Dr. Schwarz performed the cell-sorting experiments from which Respondent derived Table 1 is false. Dr. Schwarz's uncontradicted testimony is that he did not know the source of the data produced in Table 1 and that he never performed successfully a sorting experiment involving three-color flow cytometry.
- o During the period between January 1987 and the spring of 1989, Dr. Schwarz attempted to perform only one experiment for Respondent involving three-color flow cytometry, and that experiment was a failure.
- o The data in Table 1 could not have been derived from the three-color flow cytometry experiment performed by Dr. Schwarz.
- o Respondent's representation in Table 1 of the February and October applications that cells were sorted by three-color analysis using Texas Red labeled anti-laminin is false. There is no evidence to show that Respondent or others working with him ever performed successfully such experiments.

We further find that Respondent deliberately falsified Table 1. We base this finding on the following:

- o It was in Respondent's self-interest to represent in Table 1 that cells had been sorted using three-color flow cytometry, because three-color flow cytometry is a more accurate and precise method of cell sorting than is two-color flow cytometry.
- o Respondent's contention that Table 1 represents an actual modified two-color flow cytometry experiment is unsubstantiated. Respondent produced no evidence to prove that he or others working with him had actually performed even a modified two-color flow cytometry experiment. Dr. Schwarz did not perform either a two-color or a three-color cell sorting experiment which produced data corresponding to

that which is represented in Table 1.

o There is no evidence that Dr. Schwarz or anyone else told Respondent anything that would cause Respondent to believe reasonably that sorting experiments had been carried out successfully using three-color flow cytometry. Respondent's assertion that he erroneously concluded that Dr. Schwarz had performed three-color flow cytometry, when in fact Dr. Schwarz had performed two-color cytometry, is not credible in light of Dr. Schwarz's credible testimony that he never told Respondent that he had successfully sorted cells using three-color flow cytometry. Furthermore, in view of the difference between three- and two- color flow cytometry, Respondent's contention that he interpreted erroneously the results of Dr. Schwarz's experiments is not plausible. Respondent is an experienced scientist who knows the difference between three- and two-color flow cytometry.

We therefore find that the preponderance of the evidence establishes that Respondent deliberately stated falsely in the February and October applications that experiments described in Table 1 had been performed with cells sorted by three-color analysis using Texas Red labeled anti-laminin.

Figure 4 in the February application and Figure 3 in the October application

Figure 4 in the February application is identical to Figure 3 in the October application. 9/ The figures depict two graphs which demonstrate the inhibition to killing of target cells caused by the presence of the antibody to p48. In the captions to the figures, Respondent stated the figure depicted experimental results showing anti-laminin inhibition of target cell killing by IL-2 activated Leu 19+/CD3- NK cells and Leu 19+/CD3+ T cells. Respondent stated further that the experiment used sorted cells of more than 97% purity which were tested for killing against three different target cells in the presence or absence of anti-laminin antibodies.

Respondent contended that Dr. Schwarz performed the experiments which supported these two graphs. Tr. at 1180.

Dr. Schwarz denied performing these experiments. He testified that whenever he performed a cell sorting experiment, he kept records of the experiment in his laboratory notebook. Tr. at 556. Dr. Schwarz testified that, while he performed three cell sorting experiments for Respondent of the type depicted in the figures, he did not draw the graphs depicted in those figures. Tr. at 557. Dr. Schwarz testified that the results of the sorting experiments he performed were not depicted in the graphs, and his laboratory notebook did not contain any of the data depicted in the graphs. Id.

Respondent offered no evidence to prove that he, Dr. Schwarz, or someone other than Dr. Schwarz performed these experiments. The graphs which Respondent offered as Figure 4 in the February application and Figure 3 in the October application were therefore offered by Respondent without any substantive proof that they were based on actual experiments.

We make the following findings in regard to Figure 4 in the February application and Figure 3 in the October application:

- o Respondent's assertion that Dr. Schwarz performed the cell sorting experiments from which Respondent derived the data depicted in Figure 4 in the February application and Figure 3 in the October application is false.

- o Dr. Schwarz performed a total of three cell sorting experiments for Respondent of the type described in the figures.

- o None of the experiments which Dr. Schwarz performed for Respondent yielded results which match the data depicted in the figures.

- o Respondent's representations in Figure 4 in the February application and Figure 3 of the October application that experiments had been performed by or for him using sorted cells and yielding the results depicted in the figures are false.

We further find that Respondent deliberately falsified Figure 4 in the February application and Figure 3 in the October application. We base this finding on the following:

- o It was in Respondent's self-interest to represent that the experiments in the figures, showing that the purported anti-laminin blocked the killing effect of NK cells, had been performed as depicted.

- o Respondent's contention that the experimental data which is the basis for the graphs depicted in the figures were supplied to him by Dr. Schwarz is refuted by Dr. Schwarz's testimony that he never performed the experiments depicted in the figures.

- o Respondent has not produced any records or other documents which support his contention that he relied upon data supplied to him by Dr. Schwarz.

We therefore find that the preponderance of the evidence establishes that Respondent deliberately stated falsely in Figure 4 of the February application and Figure 3 of the October application that experiments using sorted cells had been performed by or for him yielding the results depicted in the figures.

The Hiserodt #3 notebook

ORI determined that Respondent fabricated the Hiserodt #3 notebook deliberately in an attempt to deceive Drs. Herberman and Bernier into believing that figures in the October application were accurate and truthful. Three individuals had first-hand knowledge of the circumstances surrounding the Hiserodt #3 notebook: Dr. Bernier, Dr. Herberman, and Respondent. Each testified about the notebook at the hearing.

Dr. Herberman testified that, at the first meeting with Respondent on December 20, 1989 to discuss the October application, he and Dr. Bernier

asked Respondent for primary data concerning Figures 1 and 2. Tr. at 951. Dr. Herberman testified that Respondent responded that there would be no problem in providing the primary data for Figures 1 and 2. Tr. at 956.

Dr. Herberman testified further that on January 7, 1990 Respondent came to Dr. Herberman's office and gave him the Hiserodt #3 notebook. According to Dr. Herberman, Respondent explained to him that the notebook contained primary experimental data for experiments that he had performed himself over the previous one and a half years. Id. Dr. Herberman testified that Respondent stated that, while Dr. Olszowy performed the majority of experiments in the laboratory, Respondent himself carried out several experiments and recorded these in his own laboratory notebook. Id. Dr. Herberman averred that Respondent then opened the notebook to pages 33 and 34 and stated that the pages contained the primary data for the experiment described in Figure 2 of the October application. Tr. at 956-58. Dr. Herberman further testified that Respondent told him that he had made the entries in the notebook contemporaneously with his receipt of experimental results. Tr. at 957.

Dr. Herberman recounted that at his January 8, 1990 meeting with Dr. Bernier he showed Dr. Bernier the notebook and that Dr. Bernier expressed doubts about the notebook being a laboratory notebook that had been used for a year and a half because of the notebook's pristine condition. Tr. at 965. Dr. Herberman then testified about events at the January 18 meeting. Dr. Herberman testified that when Dr. Bernier asked Respondent whether the notebook was a contemporaneously-generated primary notebook or a notebook that had been just recently prepared, Respondent replied that it was a contemporaneously-generated primary notebook. Tr. at 969. Dr. Herberman testified that when Dr. Bernier then raised the possibility of having the Federal Bureau of Investigation date the ink in the notebook, Respondent broke down and admitted that he had prepared the notebook during the two or three weeks prior to the January 7 meeting with Dr. Herberman. Tr. at 969-70.

In his testimony, Dr. Bernier confirmed that at the December 20, 1989 meeting he asked Respondent if he had primary data for Figures 1 and 2, and that Respondent had answered that he did. Tr. at 435. Dr. Bernier testified that in early January 1990, Dr. Herberman showed him the notebook that Respondent had presented to Dr. Herberman, and that Dr. Herberman stated that Respondent had told him that the entries in the notebook were made at the time the experiments were performed. Tr. at 437, 464. Dr. Bernier testified that, upon examining the notebook, he thought the notebook was in too pristine a condition to have been a laboratory notebook assembled over a period of years. Tr. at 437. Dr. Bernier testified that at the January 18, 1990 meeting, in response to his questions, Respondent indicated that the information in the notebook was entered at the time the experiments were performed. Tr. at 440. Dr. Bernier testified that when he suggested that the entries in the notebook could be dated by some type of ink analysis, Respondent suddenly became very remorseful and admitted that the figures in the grant application were incorrect and that he had constructed the notebook over the Christmas 1989 vacation. Tr. at 440-41.

At the hearing Respondent testified that after leaving Dr. Herberman's office on December 20, 1989, he returned to his laboratory. Respondent testified that he looked for the autoradiograms and photographs for Figures 1 and 2 in the applications, but that he could not find them. Respondent testified that, in his desire to prove to Dr. Herberman that his laboratory had detected p48 in a number of experiments, he went to his files on the evening of December 20 and assembled data which supported the concepts that laminin-like molecules were expressed on NK cells and that the blocking function that had been seen was not an artifact. Tr. at 1113. Respondent testified that he took the only notebook he could find and put the data from his files into the notebook, recalling to the best of his knowledge when those experiments were done and what they showed. Id. Respondent testified that he worked until 10:00 or 11:00 the night of December 20 completing the notebook from beginning to end. Tr. at 1114-15. Respondent testified that the notebook represented that p48, and not any artifact, had been seen in a number of experiments. Tr. at 1116.

Respondent averred that he attempted to deliver the notebook to Dr. Herberman at his office the next day, but that Dr. Herberman was not there. Tr. at 1117-18. Respondent then went on his planned Christmas trip to California. Respondent testified that when he returned, he made an appointment to see Dr. Herberman in his office on January 7, 1990. Tr. at 1119. He recalled that he brought the notebook along with a binder and loose paper and gave them to Dr. Herberman. Id. Respondent asserted that Dr. Herberman never asked him if the notebook was his original primary data notebook. Tr. at 1120. Respondent testified that he told Dr. Herberman that he could not find the primary data for Figures 1 and 2, but that he brought other experiments supporting the presence of p48 in human and rat cells. Id.

According to Respondent, at the January 18, 1990 meeting with Drs. Herberman and Bernier, Dr. Bernier asked Respondent if the experiments in the notebook were his experiments. Tr. at 1125. Respondent admitted replying that they were. Id. However, he contended that he meant by this statement that the experimental results were present in his files, and not that he himself had personally performed the experiments. Id. Respondent then asserted that Drs. Herberman and Bernier asked him if a particular experiment indicated in the notebook as being performed in December 1988 had been performed, with Dr. Herberman stating that he had checked the records of the flow cytometer which indicated that no such experiment had been performed at that time. Tr. at 1126. Respondent testified that he could not understand that because he knew that particular experiment had been done at least twice by Dr. Schwarz. Tr. at 1126-27.

Respondent testified that the January 18 meeting ended with him telling Drs. Herberman and Bernier that he was sorry for the mistakes he had made in the notebook and in the grant application. Tr. at 1127.

On January 23, 1990, Respondent signed minutes of the January 18 meeting, which included the admission that the Hiserodt #3 notebook was a fabrication prepared after an investigation of the applications had begun. G. Ex. 17.

The appearance and contents of the Hiserodt #3 notebook support strongly an inference that Respondent deliberately created the notebook to deceive Drs. Herberman and Bernier into believing it was a contemporaneous recording of experiments performed by Respondent. The notebook's contents do not support Respondent's contention that the notebook constituted a summary of experimental results addressing the issue of whether p48 could be explained by an artifact. The very title of the notebook, "Hiserodt #3," suggests that Respondent intended Drs. Herberman and Bernier to regard the notebook as the third in a series of his laboratory notebooks. The entries in the notebook are not summary statements at all; rather, they look like contemporaneous observations of experimental results. The appearance of a contemporaneously generated record is reinforced by the fact that the notebook reports experimental results in a chronological sequence. Thus, the notebook's structure would appear to have no purpose other than to convince Drs. Herberman and Bernier that the results were recorded contemporaneously. Furthermore, the notebook contains many experimental results that are irrelevant to the issue of p48. The inclusion of irrelevant data suggests that Respondent was trying to convince Drs. Herberman and Bernier that the results proving the existence of p48 were generated in the course of other laboratory activities and were recorded contemporaneously. Finally, the use of different color inks at various points in the notebook plainly appears intended to make a casual reader think that results were recorded at different times.

We conclude that, on balance, Dr. Herberman's and Dr. Bernier's accounts of Respondent's statements concerning the Hiserodt #3 notebook are credible. Respondent's version is not. Respondent's version is belied by his written admission that he fabricated the notebook. It is belied by the appearance and contents of the notebook. Finally, it is belied by the changing and inconsistent accounts that Respondent has given of the circumstances under which he created the notebook. See our discussion of Respondent's credibility, beginning at page 47.

We make the following findings in regard to the Hiserodt #3 notebook:

- o Respondent told Dr. Herberman when he presented him with the Hiserodt #3 notebook at the January 8 meeting that the notebook contained contemporaneously-generated primary data, including the experiment on which Figure 2 in the February and October applications is based.
- o Respondent told Drs. Herberman and Bernier at the January 18 meeting that the Hiserodt #3 notebook contained contemporaneously-generated primary data.
- o The format and content of the Hiserodt #3 notebook were designed by Respondent to suggest that the notebook is a record of experimental results generated contemporaneously with the outcome of experiments performed by Respondent.

The Hiserodt #3 notebook does not contain contemporaneously-generated experimental results from experiments performed by Respondent.

- o Respondent admitted that the Hiserodt #3 notebook is a

fabrication he created after officials at the University of Pittsburgh began to inquire about the veracity of the October application.

We also conclude that Respondent fabricated the laboratory notebook which he presented to Dr. Herberman in January 1990 as a deliberate cover up of false statements in the February and October applications, based on the following:

- o The only purpose Respondent could have had in presenting the notebook to Dr. Herberman was to satisfy the request of Drs. Herberman and Bernier for contemporaneously-generated experimental data to substantiate Figures 1 and 2 in the February and October applications. Had Respondent told Dr. Herberman that the notebook contained reconstructed data, as he now asserts, he would have in effect admitted that he was unable to substantiate Figures 1 and 2 in the applications.
- o The format and contents of the notebook were designed by Respondent to deceive Drs. Herberman and Bernier into believing that it was a contemporaneous record of experimental results.
- o Respondent told Dr. Herberman when he presented him with the notebook in early January 1990 that it contained contemporaneously-generated primary experimental data which substantiated elements of the February and October applications, when Respondent knew that the notebook was, at best, a reconstruction of experiments. Indeed, when Respondent presented the notebook to Dr. Herberman, he directed Dr. Herberman's attention to specific pages in the notebook and contended that they contained the primary experimental data supporting Figure 2 in the February and October applications.
- o At the January 18, 1990 meeting, Respondent again contended at first that the notebook contained contemporaneously-generated primary data supporting the February and October applications when he knew that this contention was untrue.
- o At the January 18, 1990 meeting, after Dr. Bernier mentioned the possibility of having the F.B.I. date the ink in the notebook, Respondent then admitted that the notebook did not contain contemporaneously-generated primary data. Subsequently, Respondent signed a statement in which he acknowledged that the laboratory notebook was a fabrication which he prepared after PCI and University of Pittsburgh officials had raised questions concerning the veracity of the February and October applications.

We therefore find that the preponderance of the evidence establishes that Respondent fabricated the Hiserodt #3 notebook in order to deceive others into believing that he had primary experimental data to support the statements he made in the February and October applications concerning Figures 1 and 2, to cover up the false and misleading

statements in those applications, and to persuade officials at PCI to continue to support the applications.

Respondent's credibility

We make findings about Respondent's credibility because they affect our conclusion as to his intent in writing the February and October applications. We also make such findings because our conclusion as to Respondent's credibility bears directly on our findings concerning his present responsibility to deal with federal monies, and our debarment recommendation. The regulations pertaining to debarment provide that the causes for debarment include "any other cause" that affects "the present responsibility" of an individual. 45 C.F.R. 76.305(d); 48 C.F.R. 9.406-2(c). Certainly, the credibility and general honesty of a person is key to the present responsibility of that person to receive federal grant funds. Whether Respondent can be trusted with future federal grant funds depends on Respondent's ability to comport himself with complete truthfulness.

We have discussed the deliberate falsehoods Respondent made in the figures and tables of the February and October applications to make his research appear more favorable for grant purposes. We have found Respondent's explanations for the misrepresentations in the applications not to be credible. We have found that Respondent deliberately falsified experimental results and omitted available information that might indicate his thesis about the existence of p48 was incorrect. Respondent augmented the falsehoods in the February application with additional falsehoods in the October application. Thus, when the February application, with its falsified figures and tables, did not receive funding because of concerns expressed by NIH reviewers, Respondent concocted another figure, Figure 7, to address those concerns. When Respondent was confronted about the falsified figures in the applications by Drs. Herberman and Bernier, Respondent attempted to cover up the falsehoods with a fabricated notebook.

We find that Respondent's dishonest behavior was not limited to an isolated incident; rather, he engaged in an unremitting pattern of behavior evidencing indifference to the truth. What emerges from this pattern of falsehoods and deceptions is the conclusion that, at least in his dealings with NIH and the University of Pittsburgh, Respondent has acted in a manifestly dishonest way.

Furthermore, Respondent's pattern of dishonesty did not end when the October application was withdrawn and the University of Pittsburgh reported Respondent's misconduct to ORI's predecessor. Throughout ORI's investigation of Respondent and the proceedings before this Panel, Respondent has demonstrated that he is still not a trustworthy individual.

We find that Respondent continues to be less than truthful, in light of his conflicting and inconsistent testimony concerning his discussions with Drs. Herberman and Bernier and his preparation of the Hiserodt #3 notebook, as well as the fact that his testimony is contradicted in key respects by the credible testimony of other witnesses and by exhibits in evidence. Examples include the following:

o When interviewed by ORI on November 14, 1990, Respondent stated that he prepared the Hiserodt #3 notebook on January 5, 1990, after returning from his vacation in California.

G. Ex. 84, at 133. At a deposition taken on April 24, 1992, in a civil lawsuit brought by Respondent against the University of Pittsburgh, Respondent again testified that he prepared the notebook on January 5, 1990, after his return from California. G. Ex. 85, at 159.

o However, in his testimony at the hearing for this case on September 3, 1993, Respondent testified that he prepared the Hiserodt #3 notebook on the evening of December 20, 1989, before he left for his vacation in California. Tr. at 1113-15.

o When interviewed by ORI on November 14, 1990, Respondent stated that he was aware at the December 20 meeting with Drs. Herberman and Bernier that they had the autoradiograms and laboratory notebooks created by Dr. Olszowy. G. Ex. 84, at 76.

o However, in his testimony at the hearing for this case on September 3, 1993, Respondent testified that he went back to his laboratory after the December 20 meeting and searched for Dr. Olszowy's autoradiograms and notes but was unable to find them. Tr. at 1112, 1117.

o When interviewed by ORI on November 14, 1990, Respondent stated that he had the autoradiogram in his office for Figure 2 of the February and October application. G. Ex. 84, at 150-51. At the deposition in the civil lawsuit which Respondent gave on April 24, 1992, Respondent testified that on December 20, 1989, after the December 20 meeting with Drs. Herberman and Bernier, he went back to his office and found the photographs he had used to construct Figures 1 and 2 in the February and October applications. G. Ex. 85, at 148.

o However, in his testimony at the hearing for this case on September 3, 1993, Respondent testified that, on December 20, 1989, after the December 20 meeting, he went back to his office and searched his files, but was unable to find the photographs he had used to construct Figures 1 and 2 of the February and October applications. Tr. at 1112.

o In his testimony at the hearing for this case on September 3, 1993, Respondent testified that he did not represent to Dr. Herberman or to Dr. Bernier that the Hiserodt #3 notebook contained contemporaneously- generated primary experimental data. Tr. at 1120. This testimony is contradicted by the credible testimony of Drs. Herberman and Bernier. It is also contradicted by the Hiserodt #3 notebook which was made by Respondent to look like contemporaneously- generated primary experimental data through such artifices as the use of different colored inks and the inclusion of extraneous data. It is further

contradicted by Respondent's admission that the Hiserodt #3 notebook is a fabrication. G. Ex. 17.

o Respondent's testimony that Dr. Schwarz did the cell sorting experiments which are the basis for Table 1 in the February and October applications and for Figure 4 in the February application and Figure 3 in the October application is contradicted by the credible testimony of Dr. Schwarz that he did not perform the experiments.

Additionally, in the course of the hearing Dr. Olszowy testified that, after his discovery that the existence of p48 could be explained by an artifact, when he asked Respondent how Respondent could continue to pursue grant funds for a project that was no longer viable, Respondent replied that he would use the grant funds for something else because that is what everybody else does. Tr. at 219-20. It is difficult to imagine Respondent uttering a more self-damaging indictment of himself. Despite having ample opportunity to cross-examine Dr. Olszowy, Respondent never questioned Dr. Olszowy about this statement. During his own testimony, Respondent never even denied making the statement attributed to him by Dr. Olszowy.

Respondent has attempted to attribute the allegations of his dishonesty to conspiracy against him by former colleagues and University of Pittsburgh officials. Respondent offered no evidence that would suggest to a reasonable fact finder that he is the victim of a conspiracy; to the contrary, the credible testimony of the other witnesses in this case refutes Respondent's contention. For example, we find no support for Respondent's assertion that Dr. Olszowy's statements and testimony were fueled by personal animus resulting from a brief relationship between Respondent and Dr. Olszowy's former wife, which took place well after Dr. Olszowy's divorce.

Our Conclusions as to Scientific Misconduct

Applying our above analysis and the legal standards to the facts we have found, we conclude that:

o The deliberate changing of data and results to support Respondent's reported conclusions and including such false and deceptive statements in the February and October applications violate a prevailing and recognized standard in the scientific community that researchers report their findings honestly.

o The deliberate changing of data and results to support Respondent's reported conclusions and including such false and deceptive statements in the February and October applications is falsification within the definition of scientific misconduct contained in 42 C.F.R. 50.102.

o The deliberate making up of data, as evidenced by the Hiserodt #3 notebook, to support statements made by Respondent in the applications is "fabrication" and falls within the definition of scientific misconduct contained in 42 C.F.R. 50.102.

We conclude, moreover, that it is unnecessary for us to make findings that Respondent failed to provide adequate primary data to ORI, or to maintain such data, for Figure 5 in the February application, which is presented also as Figure 4 in the October application, Figure 7 in the February application, which is presented also as Figure 6 in the October application, and Table 2 in both the February and October applications. We reach this conclusion for two reasons. First, given our findings that Respondent falsified deliberately experimental results and fabricated the only purported primary data he presented in order to obtain grant funding, it is unnecessary to separately consider Respondent's failure to maintain data. The willful falsification of experimental results and fabrication of data which we find Respondent to have committed is so egregious in this case that there is no need for us to look beyond that in order to find misconduct of a very high order of magnitude.

Second, ORI's proof as to the issue of Respondent's failure to maintain primary data concerning Figure 7 in the February application, which is presented also as Figure 6 in the October application, and Table 2 in both the February and October applications, is not nearly so persuasive as its proof as to Respondent's willful falsification of certain other experimental results. Indeed, ORI did not offer independent expert testimony as to the meaning of "primary data" and as to the standards prevailing in the scientific community for maintenance of primary data.

Discussion of 1) Our Recommendations and Proposed Conclusions of Law Concerning Debarment, and 2) Administrative Actions

The misconduct engaged in by Respondent is egregious. Respondent deliberately falsified critical sections of two applications for NIH research funding and attempted to cover up his actions by fabricating a notebook. Respondent has continued to deny engaging in misconduct notwithstanding overwhelming and essentially un rebutted evidence to the contrary. Respondent has not presented us with evidence of any circumstances which would justify or explain his misconduct.

Our responsibilities in this case include recommending whether Respondent should be debarred and, if so, recommending a term of debarment. It also includes deciding on the propriety of administrative actions proposed by ORI. For the reasons discussed below, we recommend that Respondent be debarred and that a term of debarment of five years be imposed. For the reasons discussed below, we also uphold the proposed administrative actions determined by ORI, subject to ORI's modification of its position regarding the correction of an article which appeared in Journal of Immunology.

Debarment

The cause for debarment here is "any other cause of so serious or compelling a nature that it affects the present responsibility" of Respondent. 45 C.F.R. 76.305(d) and 48 C.F.R. 9.406-2(c). A preponderance of the evidence in this case establishes that Respondent is not presently responsible to serve as a recipient of federal funds. Thus, we have concluded that a cause for debarment has been established. The existence of a cause for debarment, however, does not mandate that a

debarment be imposed. The regulations provide that a determination to debar is made after consideration of the "seriousness of the . . . acts or omissions and any mitigating factors." 45 C.F.R. 76.300 and 48 C.F.R. 9.406(1)(a). The record here contains evidence of no mitigating factors supporting a decision not to debar. Moreover, considering the seriousness of Respondent's violations of certain fundamental standards of conduct, we find no reason to refrain from debarment.

Respondent violated fundamental standards of conduct. In light of the high degree of trust inherent in research grants of the type Respondent sought, under which performance cannot be readily verified or qualitatively monitored, there is no lesser sanction that would adequately protect the public interest. The government has an obligation to award its limited federal research monies only to those it determines will use those funds responsibly.

ORI proposed that Respondent be debarred for five years, and we so recommend that a term of debarment of five years be imposed. This is a case where circumstances warrant a term of debarment longer than the three-year term which is the benchmark debarment period provided for by regulations. 45 C.F.R. 76.320. The longer term is, in our opinion, merited by the egregious circumstances of this case and by Respondent's failure to offer any mitigating circumstances for his misconduct.

The conduct engaged in by Respondent establishes that he is not presently responsible to act as a recipient of federal funds. Grant awards for scientific research depend "heavily upon the trust which the government places in the principal investigator to direct and oversee the research conducted with the support of grant funds." McCaa at 58; Bridges at 88; Langlois at 11. Respondent flagrantly breached that trust by attempting to deceive NIH into funding grant applications premised on falsified experimental data. Respondent further demonstrated his lack of responsibility by attempting to cover up his deception, and in so doing, to further deceive NIH.

We base our recommendation that a five-year term of debarment be imposed on both the egregious nature of Respondent's misconduct and Respondent's failure to offer any mitigating evidence to justify imposition of a shorter term of debarment than five years. Respondent engaged in a pattern of false statements and deception extending over a period of several years. He deliberately falsified not one, but two applications for research funding. When he was unsuccessful in his first attempt to deceive NIH into approving funding for his research, he engaged in additional falsehoods and deceptions intended to deceive NIH further. He concealed from NIH and from officials at the University of Pittsburgh the fact that the premise of his research and of the grant applications had been called into serious doubt. He attempted to cover up his falsehoods and deceptions when they were on the verge of being discovered.

The misconduct engaged in by Respondent involves the central premise of the research for which he sought NIH funds. Had Respondent succeeded in deceiving NIH, he would have obtained dishonestly more than \$1,000,000 of public funds and deprived honest scientists of scarce research

dollars.

Respondent has offered no justification for his misconduct. He continues to deny engaging in dishonesty, despite overwhelming evidence to the contrary. He has offered less than honest explanations for his actions and his motivations. He has provided no convincing explanation for his attempt to deceive NIH or University of Pittsburgh officials. Perhaps most important, Respondent has not demonstrated any awareness of his ethical responsibility as a scientist. There is nothing in the record of this case to show that Respondent can be trusted to serve as a recipient of public funds, either now, or in the foreseeable future. For all of these reasons, we conclude that circumstances warrant a debarment of more than three years, and we recommend a five-year term.

Respondent contends that it would be inequitable to debar him now. Respondent asserts that he was stigmatized by ORI and its predecessor's investigation into his misconduct. During the pendency of the investigation, according to Respondent, he was unable to obtain either academic or private employment in his chosen field. Therefore, according to Respondent, debarment at this time would constitute an additional and unreasonable punishment for his conduct.

Respondent misperceives the reasons for debarment. Debarment is not a punishment. It is a remedy which is designed to protect federally funded programs from individuals who have shown by their conduct that they are not trustworthy to deal with program funds. We recommend debarment here because Respondent has established by his dishonesty that he is untrustworthy and that he is likely to continue to be untrustworthy. We recommend debarment not to punish Respondent, but to protect program funds. Therefore, any impediments to Respondent's past employment that may have resulted from the investigation conducted by ORI and its predecessor are irrelevant to our recommendation.

We make the following proposed conclusions of law regarding our recommendation that Respondent be debarred.

Respondent's dishonest and deceptive conduct with respect to the February and October applications, his attempts to cover up that dishonest and deceptive conduct from University of Pittsburgh officials, and his continuing lack of honesty with respect to his misconduct, establish that he is not presently responsible to participate in transactions under federal non-procurement programs. 45 C.F.R. 76.110(a) and 76.305(d); 48 C.F.R. 9.406-1(a).

The egregious nature of Respondent's dishonesty, his pattern of dishonest conduct, and his continuing denial of dishonesty along with the absence of any mitigating circumstances in this case, are circumstances warranting that Respondent be debarred for more than three years. 45 C.F.R. 76.320(a)(1).

The circumstances of this case warrant that Respondent be debarred for a term of five years. 45 C.F.R. 76.320(a)(1).

Administrative actions

ORI proposed three administrative actions be taken with respect to Respondent: (1) Respondent be prohibited from serving on PHS advisory committees, boards, or peer review groups for seven years; (2) Respondent's PHS-sponsored research be monitored for its accuracy by the awardee institution for seven years; and (3) an article which appeared in the Journal of Immunology be corrected.

Respondent needs to demonstrate that he has become a truthful individual, committed to the integrity of his scientific research. Currently, he has not shown, for the myriad of reasons discussed above, that he is fit to offer advice on scientific matters or to evaluate the work of other scientists. Requiring that Respondent be prohibited from serving on PHS advisory committees, boards, or peer review groups for a period of seven years is reasonable under the circumstances of this case.

Similarly, he has not shown that he can perform research without supervision. Requiring that an institution employing Respondent monitor him for the accuracy of any PHS-sponsored research for a period of seven years is also reasonable under the circumstances of this case. 10/

ORI also proposed that corrections be made to the article, "The Expression and Functional Involvement of Laminin-like Molecules in Non-MHC Restricted Cytotoxicity by Human Leu-19+/CD3- Natural Killer Lymphocytes," which appeared in Journal of Immunology, Vol. 141, 3318-23, 1988. Figure 2 in that article is a reproduction of Figure 4 in the February application and Figure 3 in the October application, which we have found to have been falsified deliberately by Respondent. ORI proposed that the article be corrected to reflect that Figure 2 may not be relied upon.

In response to our inquiry seeking the authority for such an action, ORI acknowledged that it does not have the authority to compel a non-PHS scientific journal to accept proposed corrections or retractions to a previously-published article. ORI explained that scientific journals generally require that the author of a published article agree to a correction or a retraction before it will be published. ORI argued, however, that as a condition for receipt of future federal funding, Respondent can be compelled to request that the Journal of Immunology article be corrected, because the article involves the reporting of research developed with PHS funds. Respondent has not disputed this contention. We conclude that it is appropriate to order that, as a condition for receiving federal funds in the future (independent from any debarment that may be imposed), Respondent be required to request that the Journal of Immunology article be corrected so as to advise readers that Figure 2 in the article may not be relied upon.

Conclusion

For the reasons discussed above, we conclude that ORI proved by the preponderance of the evidence that Respondent committed scientific misconduct. We conclude that the proposed administrative actions are justified (with one minor modification). We further recommend to the Debarring Official that Respondent be debarred for a period of five years.

Donald
F. Garrett

M.
Terry Johnson

Steven
T. Kessel Presiding Panel Member

1. The hearing was held in Pittsburgh, Pennsylvania at the request of the parties. Only the Presiding Panel Member of the Panel was present at the hearing, but the other Panel members were provided the transcript of the hearing and all the exhibits admitted at the hearing. Although given the opportunity, neither party requested that a scientist be a member of the Panel.

At the hearing Respondent was represented by counsel as he was throughout all proceedings in this matter before this Panel. While ORI called 10 witnesses, Respondent called no witnesses other than himself at the hearing to refute the allegations of scientific misconduct.

Exhibits offered by ORI which were received into evidence are referred to in this decision as "G. Ex. (number), (page)." Exhibits offered by Respondent which were received into evidence are referred to in this decision as "R. Ex. (number), (page)." References to the transcript of the hearing are made as "Tr. at (page)."

2. All of the autoradiograms which are in evidence in this case had standardized marker bands generated by a kit which is manufactured for the purpose of producing standard marker bands. These standardized marker bands were 200 kilodaltons, 97 kilodaltons, 68 kilodaltons, 43 kilodaltons, 24 kilodaltons, and 14 kilodaltons.

3. The background information in this section was derived from the testimony given at the hearing held in this appeal. To the extent there was a controversy over any particular event described in this section, we have evaluated the testimony of Respondent and that of Drs. Olszowy, Herberman, Bernier, and Schwarz and have included the version of events that we found credible. We discuss the reasons for our findings on the credibility of these individuals below.

4. Respondent has not contended that the prevailing standards in effect prior to November 1989 imposed a less stringent obligation of honesty and truthfulness on applicants for funding than is imposed by the regulations. Respondent has argued only that, under the standards contained in the 1989 regulations, he cannot be found to have committed scientific misconduct because all the questioned statements are not false. See Brief on Behalf of John C. Hiserodt, M.D., Ph.D.

5. In actions relating to activities that occurred before the adoption of the 1989 regulations, we have never imposed our own definition of scientific misconduct. Rather, we have required ORI to demonstrate the prevailing definition within the scientific community at the time in question for a similarly situated scientist, including the level of intent required. Thus, we did not in Sharma hold that negligence in

making erroneous statements was not scientific misconduct. We held in *Sharma* that ORI, after full opportunity to do so, failed to demonstrate based on evidence from the scientific community that negligence in making erroneous statements of the type that occurred in that case was scientific misconduct. We also recognized that the definition of scientific misconduct adopted by PHS in 1989 acted as a limit on the scope of any proceedings and that the definition excluded "honest error" or any conduct which does not "seriously deviate" from accepted practices.

6. In 1992, the Research Integrity Adjudications Panel, under the direction of the Departmental Appeals Board in the Office of the Secretary of the Department of Health and Human Services, was given responsibility for hearing appeals from the findings of scientific misconduct made by ORI. See 57 Fed. Reg. 53,125 (November 6, 1992). This Panel's authority to hear this matter is based on ORI's having found (whether correctly or not) that scientific misconduct occurred and Respondent's having appealed that finding. *Id.*; "Guidelines: Hearings Before the Research Integrity Adjudications Panel" (September 30, 1992).

7. The October application was withdrawn by PCI in January 1990. Respondent's contention that he telephoned NIH in late December 1989 to withdraw the October application is without substantiation and contradicted by the credible testimony of Dr. Herberman. *Tr.* at 966. In fact, PCI had begun to investigate allegations of misconduct by Respondent before it withdrew the October application. Therefore, we do not accept Respondent's assertion that he withdrew the October application in order to correct "errors" in that application.

8. At the hearing Respondent proffered two exhibits that were rejected by the Presiding Panel Member. One, R. Ex. 7, was a photograph of an autoradiogram showing two gels, with the right-hand portion of the lower gel cut out. Respondent maintained that this was the photograph from which he cut out the segment used in Figure 2. The other exhibit, R. Ex. 11, was, according to Respondent, the original page depicting Figure 2 from the applications; on this page, Respondent asserted, was the section of the photograph he cut out from R. Ex. 7.

Respondent produced these exhibits for the first time on the last day of the hearing held in this case. The Presiding Panel Member denied admission of these exhibits because of Respondent's failure, in direct contravention of repeated instructions by the Presiding Panel Member, to submit copies of proposed exhibits to ORI in a timely fashion. Respondent offered no explanation for his untimely presentation of the exhibits. The Presiding Panel Member ruled that ORI would be prejudiced by the introduction of the exhibits at such a late time in the proceedings.

9. This figure is also reported as Figure 2 in an article co-authored by Respondent and Dr. Schwarz entitled, "The Expression and Functional Involvement of Laminin-like Molecules in Non-MHC Restricted Cytotoxicity by Human Leu-19+/CD3- Natural Killer Lymphocytes," in the *Journal of Immunology*, Vol. 141, 3318-23, 1988.

10. Obviously, if the Debarring Official determines to debar

Respondent, no federal funds will be available to Respondent for the period of debarment. This administrative action is meaningful only for time not encompassed by any debarment

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