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CONTINUING ETHICS AND MANAGEMENT CONCERNS AT NIH AND THE PUBLIC HEALTH SERVICE COMMISSIONED CORPS

HEARING

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

OF THE

COMMITTEE ON ENERGY AND COMMERCE
HOUSE OF REPRESENTATIVES

ONE HUNDRED NINTH CONGRESS

SECOND SESSION

SEPTEMBER 13, 2006

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CONTINUING ETHICS AND MANAGEMENT CONCERNS AT NIH AND THE PUBLIC HEALTH SERVICE COMMISSIONED CORPS

WEDNESDAY, SEPTEMBER 13, 2006

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
Washington, DC.

The subcommittee met, pursuant to notice, at 1:03 p.m., in Room 2123 of the Rayburn House Office Building, Hon. Ed Whitfield (Chairman) presiding.

Members present: Representatives Whitfield, Burgess, Blackburn, Barton (ex officio), Stupak, and Dingell (ex officio).

Staff present: Mark Paoletta, Chief Counsel for Oversight and Investigations; Alan Slobodin, Deputy Chief Counsel for Oversight and Investigations; Mike Abraham, Legislative Clerk; Ryan Ambrose, Legislative Clerk; Matthew Johnson, Legislative Clerk; Christa Carpenter, Counsel; David Nelson, Minority Investigator/Economist; and Jonathan Brater, Minority Staff Assistant.

MR. WHITFIELD. I call the hearing to order this afternoon, and today's subject is continuing ethics and management concerns at NIH and the Public Health Service Commissioned Corps.

This hearing builds on our previous oversight hearings in 2004 on NIH ethics and hearings in 2006 on NIH's handling of human tissue samples. In the last 2 years, NIH has been faced with unprecedented ethics concerns. Based largely on information provided by the committee, NIH conducted its own investigations and found 52 individuals in violation of ethics rules. The full results of these investigations have been submitted to the committee and now we consider whether NIH and the Corps have vigorously enforced the rules.

Two of the most serious cases involve Dr. Trey Sunderland of the National Institute of Mental Health and Dr. Thomas Walsh of the National Cancer Institute, both of whom happen to be officers in the Corps. In both of these cases, we are troubled about whether NIH and the Corps has acted appropriately. In the case of Dr. Sunderland, we had questions about why NIMH continued to deal with Dr. Sunderland in a business-as-usual way while he was under investigation and his

retirement from NIH was on hold. In 2005, it was determined that Dr. Sunderland had engaged in undisclosed, unreported, and unapproved consulting for activities in which he was paid over $700,000 and that some of his consulting conflicted with his government job. In November 2005, Dr. Thomas Insel, the Director of the National Institute of Mental Health, proposed to the Corps that Dr. Sunderland be considered for termination but except for not receiving a $12,000 bonus. Dr. Sunderland has continued to enjoy privileges that belong to the dedicated NIH scientists and Corps officers who faithfully followed the rules.

Did NIMH take steps to prevent Dr. Sunderland from representing them and going on taxpayer-funded trips? No. In one case, Dr. Sunderland took a taxpayer-funded trip costing over $3,000 to a scientific association meeting in Hawaii in December 2005 only a few weeks after Dr. Insel had proposed that Dr. Sunderland be terminated from the Corps. Was Dr. Sunderland as a Commissioned Corps officer deployed to help on Hurricane Katrina or Rita relief? No, but NIMH did clear him to go to Geneva, Switzerland, in September for a couple of days at taxpayer expense. Were steps taken even after Dr. Sunderland took the Fifth Amendment at the June subcommittee hearing? No. Was he denied the ability to engage in paid activities outside his employment? No. Did they even take away his title of Branch Chief even after Dr. Sunderland's branch was in effect closed? No. After integrity questions were raised, did NIMH take steps to restrict Dr. Sunderland's access to confidential data? No.

Dr. Insel told us at the June 14 hearing that his hands were tied to take any action on Dr. Sunderland because Dr. Sunderland was a Commissioned Corps officer, but after the committee staff raised questions about why NIMH continued to approve trips and activities for Dr. Sunderland, Dr. Insel did in August 2006 finally restrict Dr. Sunderland from traveling to represent NIMH.

Dr. Walsh also presents another serious case. Over a 5-year period, Dr. Walsh engaged in unreported and unapproved consulting with 25 companies taking more than $100,000 in payments. The NIH ethics panel determined in the one activity it has reviewed involving Dr. Walsh that there were conflict-of-interest violations. Although the Corps received a proposal for Dr. Walsh's termination at the beginning of this year, the Corps chose not to act on the Walsh matter. Given the paramount interest in protecting the integrity of the Corps and NIH, we must ask the question, why didn't the Corps act on the Walsh case? Instead of being proactive, it appears that the Corps and the NIH seemed passive really on this issue, taking the minimum steps to enforce the rules that are the foundation of maintaining public trust. We know that

public trust is vitally important, and in our previous hearings on this subject, that has been emphasized.

We recognize that NIH has taken needed steps to improve the ethics program, but more action is needed. The NIH system is one of multiple silos of information holding financial records, outside activity forms, recusals and waivers, leave records, technology transfer agreements, and human subject protection records. However, these silos are not yet connected to each other to provide an informed review.

Through these hearings, we expect the Corps and NIH to improve their systems to prevent these violations, detect them better when they occur, and to act decisively and appropriately. We look forward to the testimony of all the witnesses today, and I will certainly be introducing you all after Mr. Stupak and other members have made their opening statements. At this time I recognize the Ranking Minority Member, Mr. Stupak, for his opening statement.

[The prepared statement of Hon. Ed Whitfield follows:]

PREPARED STATEMENT OF THE HON. ED WHITFIELD, CHAIRMAN, SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

Today the Subcommittee examines continuing ethics and management concerns at the National Institutes of Health (NIH) and the Public Health Service Commissioned Corps. This hearing builds on our previous oversight hearings in 2004 on NIH ethics and hearings in 2006 on NIH's handling of human tissue samples.

In the last two years, NIH has been faced with an unprecedented ethics mess. Based largely on information provided by the Committee, the NIH conducted its own investigations and found 52 individuals in violation of ethics rules. The full results of these investigations have been submitted to the Committee and now we consider whether NIH and the Corps have vigorously enforced the rules.

Two of the most serious cases involve Dr. Trey Sunderland of the National Institute of Mental Health (NIMH) and Dr. Thomas Walsh of the National Cancer Institute (NCI), both of whom happen to be officers in the Corps. In both of these cases we are troubled about whether the NIH and the Corps acted appropriately.

In the case of Dr. Sunderland, we have questions about why NIMH continued to deal with Dr. Sunderland in a "business as usual" way while he was under investigation and his retirement from NIH was on hold. In 2005 NIH had determined that Dr. Sunderland had engaged in undisclosed, unreported, and unapproved consulting for activities in which he was paid over $700,000, and that some of consulting conflicted with his government job. In November 2005, Dr. Thomas Insel, the Director of the National Institute of Mental Health, proposed to the Corps that Dr. Sunderland be considered for termination.

But except for not getting a $12,000 bonus, Dr. Sunderland has continued to enjoy privileges that belong to the dedicated NIH scientists and Corps officers who faithfully followed the rules. Did NIMH take steps to prevent Dr. Sunderland from representing the NIMH and going on taxpayer-funded trips? No. In one case, Dr. Sunderland took a taxpayer-funded trip costing over $3000 to a scientific association meeting in Hawaii in December 2005, only a few weeks after Dr. Insel had proposed Dr. Sunderland's termination to the Corps. Was Dr. Sunderland as a commissioned corps officer deployed to help on Hurricane Katrina or Rita relief? No, but NIMH did clear him to go to

Geneva, Switzerland in September for a couple of days at taxpayer expense. Did NIMH take such steps even after Dr. Sunderland took the Fifth Amendment at the June Subcommittee hearing? No. Did NIMH deny Dr. Sunderland the ability to engage in paid outside activities? No. Did NIMH even take away Dr. Sunderland's title of branch chief even after Dr. Sunderland's Branch was in effect closed? No. After integrity questions were raised, did NIMH take steps to restrict Dr. Sunderland's access to confidential data? No.

Dr. Insel told us at the June 14th hearing that his hands were tied to take any action on Dr. Sunderland because Dr. Sunderland was a Commissioned Corps officer. But after the Committee staff raised questions about why NIMH continued to approve trips and activities for Dr. Sunderland, Dr. Insel in August 2006 finally restricted Dr. Sunderland from traveling to represent NIMH and from no longer getting approval for certain outside activities, and reassigned him to the extramural branch.

Dr. Walsh presents another serious case. Over a five-year period, Dr. Walsh engaged in unreported and unapproved consulting with 25 companies, taking more than $100,000 in payments. The NIH Ethics Panel determined in the one activity it has reviewed involving Dr. Walsh that there were conflict of interest violations. Although the Corps received a proposal for Dr. Walsh's termination at the beginning of this year, the Corps chose not to act on the Walsh matter. Given the paramount interest in protecting the integrity of the Corps and the NIH, why didn't the Corps act on the Walsh case?

Instead of being proactive, both the Corps and the NIH seem passive, taking the minimal steps to enforce the rules that are the foundation of maintaining public trust. I do recognize that NIH has taken needed steps to improve its ethics program, but more action is needed. The NIH system is one of multiple silos of information holding financial reports, outside activity forms, recusals and waivers, leave records, technology transfer agreements, and human subject protection records, but these silos are not yet connected to each other to provide an informed review. Through these hearings, we aim to get the Corps and the NIH to improve their systems to prevent violations, detect them better when they occur, and to act decisively and appropriately.

I thank the witnesses and look forward to their testimony. I thank the Minority side for its work in this investigation. I now recognize my friend, the Ranking Member of the Subcommittee, Bart Stupak, for his opening statement.

MR. STUPAK. Thank you, Mr. Chairman.

This hearing is a result of a 4-year investigation by the Oversight and Investigations Subcommittee. Four years after this subcommittee pointed out conflict-of-interest problems at the National Institute of Health, this agency still does not have any safeguards to prevent the types of abuse as we previously discovered. The National Institute of Health spends $29 billion of taxpayers' money on biomedical research. It operates with wide latitude to focus our resources on most promising lines of research and yet the National Institute of Health cannot rid itself of conflict of interest.

Today three institutions will be singled out for their failure to prevent conflicts of interest. First and foremost is the Office of Inspector General, an office that has not been called to appear before us today, and I do not know why not. They should be here. Three years ago this subcommittee identified over 100 National Institutes of Health

employees that had not reported income from drug and biotech companies. At that point the Office of Inspector General should have been the first agency to investigate files, interview the possible violators and their supervisors, peers and subordinates. The Inspector General should have immediately and aggressively obtained all pertinent information in the possession of the drug companies regarding the alleged payments. Instead, the Office of Inspector General did nothing. Simply put, the Office of Inspector General failed to fulfill its statutory responsibility. Instead, the office delegated whatever investigations might be done to the NIH itself.

Then we have the Public Health Service Corps represented today by Assistant Secretary for Health since there is no Surgeon General at this time. The Public Health Service, also referred to as Commissioned Corps, is organized along paramilitary lines and enlistment is open to certain professionals at the National Institutes of Health and in the Department of Health and Human Services. The Public Health Service Corps is an organization that accepts no responsibility for the performance of its employees at the NIH including the ethical behavior of its officers, but is charged with administering all discipline in excess of 14 days, suspension. Last fall the National Institutes of Health informed the Public Health Service that two of its employees would be terminated if they were civilians and they had not been employed correctly by the NIH but yet to date the Commissioned Corps has taken no action. This arrangement leaves the National Institutes of Health in a compromised position, having limited ability to discipline its researchers. Furthermore, it is unclear what, if any, advantage the National Institutes of Health gains from having employees that have joined the Public Health Service and are technically assigned or detailed to their jobs by the Public Health Service. The overriding rationale is that the medical doctors and other doctors of the Public Health Service are on duty 24/7 and may be assigned anywhere anytime to handle public health crisis. In fact, a number of the Commissioned Corps medical doctors were assigned to assist with the public health disasters in the wake of Hurricanes Katrina and Rita. Curiously, though, Dr. Trey Sunderland, who had lost his lab and was awaiting disciplinary action, was not sent to the Gulf Coast. Instead, Dr. Sunderland, a public service officer who asserted his Fifth Amendment rights rather than explain his conduct to this subcommittee, was permitted to attend a conference in Switzerland while New Orleans was underwater. I expect our witnesses today to explain this curious pampering of Dr. Sunderland in this instance.

Finally, like in previous hearings, the National Institutes of Health and particularly the National Institute of Mental Health have much explaining to do. Specifically, I and others want to understand if the

work that Dr. Sunderland performed for the last 2 decades at the taxpayers' expense was as a matter of science worth the millions of dollars that taxpayers invested or an opportunity for personal financial gain and professional boasting. Dr. Sunderland's studies included Alzheimer's patients and their families from which blood and spinal fluid samples were taken over time with the goal of trying to identify biomarkers that would predict the early onset of this terrible disease. We know, for example, that Pfizer and other drug companies consider these samples and related patient histories invaluable and paid Dr. Sunderland for turning over these public samples. We know that senior officials at the National Institutes of Health bent over backwards to allow Dr. Sunderland to continue this research in New York despite their knowledge of serious ethical and possible criminal charges pending against Dr. Sunderland. This subcommittee suspects that Dr. Sunderland assumed this New York research while on the National Institutes of Health payroll without formal authorization. Is this another example of ethical lapse and failure to assert accountability over Dr. Sunderland?

What I cannot understand is why the National Institutes of Health, what is their plan to do with Dr. Sunderland's very expensive and possible value Alzheimer's study. We are told that the National Institute of Mental Health will not continue to fund it, and both the Institute on Aging and the Institute on Neurological Disorders and Stroke have no interest in pursuing this research. Why is that? If this research was important enough to spend millions of dollars a year for over a decade and if no one has developed biomarkers that predict the onset of Alzheimer's, and if there seems to be a consensus that early detection is critical in understanding and delaying the progression of this disease, then why is the National Institutes of Health going to abandon these patients and the hope for a cure? Does this mean any time a National Institutes of Health researcher is caught with his or her hand in the cookie jar that research in their field is terminated? Why wasn't the study reassigned 2 years ago when it was discovered that Dr. Sunderland was ethically compromised? What is the National Institutes of Health's responsibility to study early onset of Alzheimer's? Why has Dr. Sunderland not been removed from the National Institutes of Health projects despite the allegations? The National Institutes of Health, the Public Health Service, and the Inspector General have much to explain.

I hope for some honest accountability today. If the National Institutes of Health cannot discipline Dr. Sunderland and if the Public Health Service is tardy in taking action and the Office of Inspector General failed to investigate, then the question must be asked, is anyone accountable? Who has the responsibility to hold individuals accountable,

or is the NIH simply broken down, cannot fulfill its mission for the American people in a responsible, ethical, and professional manner.

With that, Mr. Chairman, I yield back.

MR. WHITFIELD. Thank you, Mr. Stupak. At this time, Mrs. Blackburn, you are recognized for 5 minutes.

MRS. BLACKBURN. Thank you, Mr. Chairman. In the interest of time and knowing that we are going to have a vote, I will submit my statement, and just to welcome our witnesses. We hope that we will have the opportunity to have a dialog with you and to get some information. This is a tremendous concern to us. What has been perceived as arrogance by some of our agencies and avoidance of dealing with ethical and management issues is of concern to us and we hear about it from our constituents. So we look forward to a frank discussion. Thank you.

MR. WHITFIELD. Thank you, Mrs. Blackburn. I am going to ask unanimous consent to introduce the binder, our document binder, into the record. Without objection, so ordered.

[The information follows:]

Ex.	Description	[illegible]
	EXHIBIT	
1	Letter from the Committee to the NIH re: Hearing and Questions	8/31/2006
2	Letter from Zerhouni to the Committee Responding to Questions	7/8/2005
3	Results of NIH Review of 103 Individuals	9/12/2006
4	Spreadsheet of Sunderland's Outside Activities	2005-2006
5	Spreadsheet of Sunderland's Approved Travel	2005-2006
6	Summary of OMA Report on Sunderland's Outside Activiy Discrepancies	
7	OMA Interview with Dr. Sunderland	8/19/2004
8	Letter from Ethics Director Holli Jaffe to Colleen Barros re: Sunderland	4/1/2005
9	Letter from Insel to Captain Canton of the Corps re: Sunderland	11/21/2005
10	OMA Referral of Sunderland Investigation to Inspector General	9/24/2004
11	Letter from Gottesman to Division of Compiance, Reporting Findings and Actions	6/13/2006
12	Summary of Informaton in Response to Question #8 of June 20th Committee Letter	
13	Letter from Sunderland to Study Patients Informing of Intent to Resign from NIH	12/21/2004
14	LA Times Article	7/16/2006
15	Newsday.com Article re: Inability of Sunderland to Resign	3/22/2005
16	Sunderland Bio from Creativity Foundation Website	
17	The New Standard' Article Referring to North Shore's Recruitment of Sunderland	Q4 2005
18	NIMH/North Shore Psychopharmacology Workshop Itinterary	4/25/2006
19	2004 North Shore Annual Report mentioning Sunderland's Proposed Position	2005
20	NIH File on Sunderland Trip to Hawaii in December '05	
21	NIH File on Sunderland Trip to Geneva in September '05	
22	Letter from Congressman Moran to NIH re: Alzheimer's Study and Insel Response	7/5/2005
23	E-Mail from Casey Hemard to Slobodin re: Current Status of Biocard Study	9/6/2006
24	E-Mail Correspondence and Information re: CSF Leftover from Lithium Study	2005
25	NIH E-Mail Response to Slobodin Questions re: Karen Putnam	2/21/2006
26	Documents and Forms re: the transfer of 5 Freezers from NIH to North Shore	6/7/2005
27	Sample Transaction Activity Reports of Sunderland Shipping CSF	
28	Transportation Service Orders for Shipments to Litwin-Zucker	Oct. 2005
29	Letter from Commissioned Corps to Sunderland re: Non-Approval of Medical Pay	5/4/2006
30	MRB/ISP Validation Record	12/29/2005
31	E-Mails re: Sunderland's Contract Bonus	12/30/2005
32	E-Mail from Fitzsimmons to Sunderland re: North Shore	2/10/2006
33	E-Mail correspondence between Insel and Gottesman re: Sunderland's Departure	2/9/2006

34	E-Mail from Insel to Kington re: Sunderland Responsibilities	3/31/2005
35	Fitzsimmons & Gottesman E-mail Discussion	1/20/2005
36	Letter from Kington re: General Review of Scientists' Outside Activities	1/19/2005
37	E-Mail from Insel to Fitzsimmons re: Current Situation with Patients at North Shore	2/5/2006
38	Letter from Insel to Sunderland re: Workplace Restrictions	8/3/2006
39	HHS E-Mail Response to Slobodin Commissioned Corps Questions	9/11/2006
40	GAO Report re: The Need for the Public Health Service's Commissioned Corps	May-96
41	Letter from Committee to NIH re: Dr. Walsh	7/28/2006
42	List of payments from Pfizer to Walsh	
43	Letter to Captain Canton from NCI with Investigative File on Walsh	12/2/2005
44	OMA Review of Dr. Walsh Activities	Mar-05
45	Letter from NIH Ethics office to Colleen Barros re: Walsh Activities with Merck	6/1/2005
46	Letter from OMA to Human Resources re: Review of Walsh	9/9/2005
47	Walsh Invoice to Pfizer for Mock Advisory Meetings	11/12/2001
48	Letter and Attachments from Walsh Attorneys to NIH OMA	10/4/2004
49	LA Times Article re: Walsh Misconduct	9/10/2006
50	Fitzsimmons Report to Committee in Response to Questions	9/12/2006
51	NCI List of Walsh Gifts	1993-2001
52	E-Mails between Fitzsimmons and Diepold re: Jan 1 Departure	11/23/2004

[redacted]

Tab 1

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August 31, 2006

The Honorable Elias Zerhouni, M.D.
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

Dear Dr. Zerhouni:

The Subcommittee on Oversight and Investigations intends to hold a hearing on September 12, 2006, about continuing ethics and management concerns at the National Institutes of Health (NIH) and Public Health Service (PHS) Commissioned Corps.

In preparing for this hearing, the Subcommittee will need a detailed update on NIH's internal review of Agency employees involved in consulting activities with nongovernmental organizations. The NIH previously provided an update on July 8, 2005. The Subcommittee has reason to believe that the NIH has completed all of its investigative work in this internal review and has taken administrative actions in all cases where NIH determined violations had occurred. The Subcommittee needs more detailed information to get a clearer sense of how NIH management responds to individuals who willfully break NIH rules and regulations.

To assist our preparation for the upcoming hearing, some non-public information and records are needed. Pursuant to Rules X and XI of the U:S. House of Representatives, please provide the following by Thursday, September 7, 2006:

1. A list with the following information from the NIH internal review of consulting activities (including self-reported or media-reported cases that were in addition to the cases generated from information provided by the Committee): the number of NIH scientists reviewed; the number of individual cases that resulted in a determination of violation; the number of individual cases referred to the PHS Commissioned Corps; and

the number of individual cases referred to the Office of Inspector General, Department of Health and Human Services (OIG).

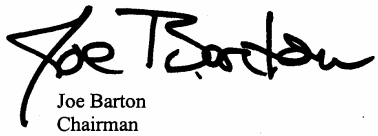
2. For the individual cases that resulted in a determination of violation(s), a list of the following: the name of the individual and position (including whether the individual was a member of the PHS Commissioned Corps); a description of the nature of the violation(s) determined (including but not limited to compensation amounts and number of activities); whether the individual case was referred to the PHS Commissioned Corps and the date of referral; whether the individual case was referred to the OIG and the date of referral; and disciplinary action taken and date of such action.

3. For each of the individual cases referred to the OIG that are now closed investigations, records of the OIG report provided to NIH as a basis for administrative action

Please note that, for the purpose of responding to these requests, the terms "records" and "relating" should be interpreted in accordance with the attachment to this letter.

If you have any questions, please contact Alan Slobodin of the Majority Committee staff at (202) 225-2927 or David Nelson of the Minority Committee staff at (202) 226-3400.

Sincerely,



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Attachment

ATTACHMENT

1. The term "records" is to be construed in the broadest sense and shall mean any written or graphic material, however produced or reproduced, of any kind or description, consisting of the original and any non-identical copy (whether different from the original because of notes made on or attached to such copy or otherwise) and drafts and both sides thereof, whether printed or recorded electronically or magnetically or stored in any type of data bank, including, but not limited to, the following: correspondence, memoranda, records, summaries of personal conversations or interviews, minutes or records of meetings or conferences, opinions or reports of consultants, projections, statistical statements, drafts, contracts, agreements, purchase orders, invoices, confirmations, telegraphs, telexes, agendas, books, notes, pamphlets, periodicals, reports, studies, evaluations, opinions, logs, diaries, desk calendars, appointment books, tape recordings, video recordings, e-mails, voice mails, computer tapes, or other computer stored matter, magnetic tapes, microfilm, microfiche, punch cards, all other records kept by electronic, photographic, or mechanical means, charts, photographs, notebooks, drawings, plans, inter-office communications, intra-office and intra-departmental communications, transcripts, checks and canceled checks, bank statements, ledgers, books, records or statements of accounts, and papers and things similar to any of the foregoing, however denominated.

2. The terms "relating," "relate," or "regarding" as to any given subject means anything that constitutes, contains, embodies, identifies, deals with, or is in any manner whatsoever pertinent to that subject, including but not limited to records concerning the preparation of other records.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892
www.nih.gov

JUL 08 2005

The Honorable Joe Barton
Chairman, Committee on Energy
and Commerce
House of Representatives
Washington, D.C. 20515-6115

Dear Mr. Chairman:

On March 10, 2005, the Chairman and Ranking Member of the Committee requested an update on NIH's internal review of Agency employees involved in consulting activities with nongovernmental organizations and a full explanation of the factors leading to my conclusion that there was a need for stricter ethics rules at NIH.

As I testified before the Committee, I believe collaborations and other scientific interactions between NIH personnel and nongovernmental researchers–for that matter, exchanges between all scientists–are a prerequisite for the advancement of biomedical research and the expeditious translation of discoveries to treatments. In the modern world of scientific inquiry, with fields of discovery converging amid increasing requirements for multidisciplinary research, such interactions are more important than ever before.

Yet, the need for scientific exchange does not supersede the legal and moral responsibility of NIH employees to engage with their private-sector colleagues in a manner that does not result in real or apparent financial conflicts of interest. Besides the direct harm such conflicts could pose for patients, or the inequities they could create among firms and their investors, they could undermine the public trust in biomedical research and NIH. At their worst, these conflicts, whether potential or actual, could reduce the Nation's commitment to research priorities and slow the substantial progress we have made to reduce suffering and death from disease and injury.

As the Director of NIH, I am responsible for seeking a balance between the need for collaboration and our ability to maintain public trust in the performance of our mission. After I first began to learn of the problems associated with the NIH ethics program in mid 2003, I came to believe that the loosening of ethics rules governing NIH employees in 1995, coupled with increasing complexity of the industry, had created unfortunate vulnerabilities about such issues as consulting with industry or the receipt of honoraria for lectures.

I also recognized deficiencies in the NIH ethics program. In particular, I was concerned that applications for outside activities, such as consulting with industry, had not been subjected to independent peer review by scientists who would understand the implications of providing scientific services to private companies and determine whether overlap existed between official and outside activities. Therefore, in November 2003, I announced the formation of the NIH Ethics Advisory Committee (NEAC) to review such applications.

Over time my opinion evolved on the need for restrictions on employees consulting with organizations where the potential for conflicts of interest exist, in particular the pharmaceutical and biotechnology industries that could be affected by decisions made by NIH scientists and managers. This evolution occurred as I examined information provided during hearings of the Oversight and Investigations Subcommittee, cases reviewed internally by NIH, and the deliberations of the Blue Ribbon Panel I appointed to review NIH ethics policies and procedures.

As I considered the evidence, I sought answers to the following critical questions:

1) Are the regulations governing the ethical conduct of NIH employees sufficient in terms of preventing even the appearance of conflicts of interest while ensuring public trust in NIH's ability to remain free of bias as the Agency pursues and supports biomedical research?

2) Have NIH employees violated existing regulations or conducted themselves in a manner–even in cases where the conduct is allowable–that would result in a diminishment of public trust in the Agency?

3) Is the NIH ethics program adequately processing and overseeing the outside activities and financial holdings of NIH employees?

In the case of question 1, I have concluded that the rules in existence since 1995 are not, in fact, sufficient to prevent possible conflicts of interest or even the appearance of conflicts of interest or maintain the public's trust in NIH as an unbiased supporter of biomedical research. Consulting with outside companies, promoting products, accepting equity ownership in conjunction with ongoing consulting arrangements, and consulting with organizations involved in research similar to inquiries being conducted by NIH scientists themselves were all among the activities or investments permissible under the previous rules if an employee recused himself or herself appropriately and adhered to other requirements. In addition, we have seen that additional internal oversight and review by scientists of specific consultations is needed for these activities.

In regard to question 2, we discovered cases of employees who consulted with research entities without seeking required approval, consulted in areas that appeared to conflict with their official duties, or consulted in situations where the main benefit was the ability of the employer to invoke the name of NIH as an affiliation.

As for question 3, we found that the decentralized ethics processing system at NIH lacked adequate peer review, applied policies and regulations inconsistently across the NIH, and lacked the authority or ability to sufficiently question the information being provided by NIH employees. As an illustration of our response, I asked NEAC, a committee made up of NIH scientists, to independently review the cases that had already been approved under the old rules for employees who wished to continue the activities.

The long and varied review of the Agency's ethics program has been one of my top management priorities because the NIH leadership understands that, regardless of the number of scientific opportunities and advances, a requirement for the success of NIH is the unwavering trust of the patients and public whom we serve. Our process of review was detailed and deliberative. Individual cases had to be vetted carefully due to the complexity of the arrangements as well as the requirement that all employees be afforded due process, including adherence to privacy and personnel rules.

In mid-2004, I concluded that the body of evidence revealed a vulnerable ethics management system at NIH, characterized by insufficient oversight and inconsistent application of rules. The rules themselves, I decided, simply did not provide adequate protection against potential conflicts of interest and allowed activities that the Congress, the scientific community, and the general public found inappropriate. These included cases of individuals performing consulting services that, in my view, conflicted with their official duties or were used to promote the use of certain products.

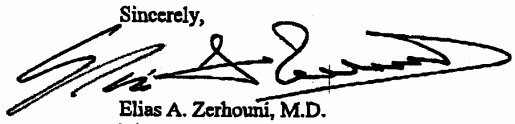
Most importantly, I determined that these cases, while not representative of the significant majority of NIH employees who abide by the rules, were the symptoms of systemic weaknesses in the regulations and processes used to manage the NIH ethics program. Having reached these conclusions, I believed that the only prudent response was to completely halt consulting between NIH employees and the pharmaceutical and biotechnology industries through changes in the rules and to overhaul the ethics program at NIH.

In response to my request, the Department and the Office of Government Ethics worked with me to make changes and agreed that the regulatory changes should be interim final regulations, to be followed by an evaluation of comments and consideration of changes to ensure that the regulations will adequately and effectively address the problems identified.

Answers to your specific questions about the NIH internal review of individual cases involving allegations of ethics breaches or inappropriate conduct are contained in the attachment. We have expended considerable time and resources to review all of these activities completely, fairly, and accurately. While the review is still ongoing I am pleased to respond to your specific questions about the status, methodology, and results of our review to date. Because the entire review is not complete, I request that all the information provided in the enclosure be treated as confidential.

I want to reiterate my appreciation of the Committee's work in this area. Many of the issues of concern were identified by the Committee's inquiry and subsequent hearings. You have my pledge that I will continue to work with the Committee on this matter as we move forward by correcting deficiencies and ensuring public trust.

Sincerely,



Elias A. Zerhouni, M.D.
Director

Enclosure

cc:
The Honorable Ed Whitfield
Chairman, Subcommittee on Oversight
and Investigations
Committee on Energy and Commerce
House of Representatives

The Honorable Bart Stupak
Ranking Member, Subcommittee on
Oversight and Investigations
Committee on Energy and Commerce
House of Representatives

Responses to Committee Questions
July 7, 2005

1-2. Number of NIH Scientists under Review and Basis for Each Review

A total of 103 individuals are under review.

The House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, identified a total of 81 individuals who allegedly had unapproved outside consulting activities.

In addition to those individuals, we are reviewing the outside activities of seven individuals reported in the December 2003 and December 2004 *Los Angeles Times* articles, and the activities of 2 individuals cited by the Subcommittee in its hearings in May and June 2004.

Finally, we are also reviewing the pharmaceutical and biotechnology consulting activities that were reported by 29 NIH employees in response to my June 28, 2004, request that all NIH employees report outside activities that had not been previously approved or reported on financial disclosure reports.

It is important to note that there is an overlap among these three categories (e.g. some individuals identified by the Subcommittee were also included among the employees who reported activities in response to the June 28,2004 request).

3. Nature of the Source Documentation or Information Involved

We understand that the list provided by the Subcommittee was prepared from a comparison of data provided by NIH and data provided by pharmaceutical and biotechnology companies in response to the Subcommittee's request for information.

At the request of NIH, the Subcommittee provided responses and supporting documentation it had received from the pharmaceutical and biotechnology companies to assist NIH in reviewing the specific activities cited by the Subcommittee Also, NIH contacted the pharmaceutical and biotechnology companies directly and obtained additional information and documentation related to the activities the companies had identified as being performed by NIH employees.

NIH also obtained source documents and information from the NIH Ethics Office (NEO) files, information individual employees had retained related to their outside consulting and official duty activities, and information from the files of Deputy Ethics Counselors (DECs) in the NIH Institutes and Centers.

4. Number of Interviews Conducted

Seventy-six of the 81 individuals identified by the Subcommittee were interviewed in person or contacted by phone, mail, or e-mail. The five individuals not interviewed or contacted included those no longer at NIH that we were unable to locate or those we determined it was not necessary to contact because available documents allowed us to resolve the allegation(s) involving them.

All other individuals being reviewed have been interviewed.

5. Methodology of the Review

- For the 81 individuals on the list provided by the Subcommittee, the NIH Office of Management Assessment (OMA):

  a. Obtained a copy of the institute's file for each individual, including all requests for approval for outside activities for the 1999-2004 period, financial disclosure reports, leave records, information relating to approved official duty activities, listings of all current major projects and papers published since January 1, 2003, and copies of Cooperative Research and Development Agreements where the individual served as the Principal Investigator;
  b. Interviewed each individual (except as noted in Question #4 above) and provided a summary of the interview to the individual for comment;
  c. Consulted with the DEC for each individual's institute as well as the NIH Office of Human Resources and the NEO, where appropriate;
  d. Worked with the pharmaceutical or biotechnology company that reported the activity to the Subcommittee to obtain additional information to clarify or corroborate information received from the Subcommittee or the individual;
  e. Prepared a draft report that was given to the individual for comment; and
  f Incorporated comments, as appropriate, into a final report for each individual.

- For the remaining individuals not on the Subcommittee list, NIH conducted a similar analysis; although we did

not have supporting documentation of the nature that had been provided by the pharmaceutical and biotechnology companies for the Subcommittee list of 81 individuals. The NIH reviewers collected all available information on the activities self-reported by the individuals, the newspaper articles, and the activities identified in the congressional hearings, and performed their analyses based on that information.

- Cases in which documentation of prior approval is not found are referred to the NEO. The NEO is coordinating an analysis by a committee of senior scientists to determine whether there was a conflict between the activity and the individuals' official duties at NIH.

6. Restrictions on the Review

There were no restrictions on the review. The reviewers were able to contact anyone in the agency to obtain and clarify information and they had access to all documents within the agency. The reviewers also contacted pharmaceutical and biotechnology companies and other outside sources for the same purpose. Their work was conducted using the Government Auditing Standards established by the Government Accountability Office as guidance.

7. Number of Individual Cases Reviewed [That] Have Been Completed

The fact finding portion of the review has been completed for all 81 cases on the Subcommittee's list. The fact finding portion of the review was comprised of a determination of whether the employee received prior approval; took the requisite leave, if necessary; and disclosed the outside position and any income received from the activity on his or her financial disclosure report, if the individuals were filers. For those cases where prior approval was not obtained, the review also included the conflict of interest analysis described in the response to Question #5.

8. How Many Individual Cases Have Not Been Completed?

In the cases involving individuals other than those on the Subcommittee list, determinations of whether the employee received prior approval, took the requisite leave, and disclosed the outside position and any income received on his or her financial disclosure, if the individual was a filer, have been made and the reports are being completed. Once the reports are completed, the cases will be forwarded to the NIH Office of Human Resources (HR) and NEO, as appropriate.

9. **How Many Individual Cases Have Been "Cleared" and on What Basis Were Those Cases "Cleared"?**

Thirty-seven individuals on the Subcommittee list were determined to have had prior approval for the activity (either an outside or official duty activity); the activity was properly reported on their annual financial disclosure report, if the individuals were filers; and they were on approved leave for the activity, if necessary.

The cases identified that were not on the Subcommittee list are still under review, as described in the response to Question #8

How Many Individual Cases Resulted in a Determination of Inappropriate or Questionable Conduct that was not a Violation?

We did not make such a determination. The primary purpose of the reviews is to determine whether documentation was available showing that prior approval was obtained for the activity, whether the activity was reported on the individual's financial disclosure reports, if the individuals were filers, whether the individual was on approved leave when participating in the activity, if necessary, and, where prior approval was not documented, whether the activity conflicted with the employee's official duties. If the documentation was not found, individuals were cited as violating regulations or agency policy. An identified conflict with official duties also constitutes a violation.

How Many Individual Cases Resulted in a Determination of a Violation?

NIH determined that thirty-six individuals on the Subcommittee list violated policies or regulations and were referred for administrative action. In addition, eight reviews found violations of policies or regulations by individuals who are no longer NIH employees, and are not subject to administrative action by NIH.

The cases identified that were not on the Subcommittee list are still under review, as described in the response to Question #8.

12. **Description of Any Violations Determined by the Review**

The OMA found three types of violations which resulted in recommendations for administrative action. The violations are:

1. Documentation was not available to show that prior approval had been obtained for the activity;
2. The activity was not reported on the individual's financial disclosure report (if the individual was a filer); and
3. The individual was not on approved leave when participating in an outside activity, if necessary.

In cases where documentation was not available showing that an individual obtained prior approval for an outside activity, the NEO is coordinating an analysis by a committee of senior scientists to determine whether there was a conflict between the activity and the individual's official duties at NIH.

13. How Many Individual Cases Resulted in Disciplinary Actions and a Description of Those Actions?

As stated in #11 above, 36 individuals from the Subcommittee list violated policies or regulations and were recommended for administrative action. The NIH Office of Human Resources is assessing the findings and conclusions to ensure consistency in the disciplinary actions that will be taken by management officials. NIH will move ahead with specific actions when that consistency assessment is completed.

14. How Many Individual Cases Were Referred to the Office of Inspector General, DHHS, to Investigate Allegations of Criminal Violations and the Dates of those Referrals?

Nine individuals were referred to the HHS Office of Inspector General for investigation. The referrals were made on August 10, 2004, August 12, 2004, September 24, 2004, November 2, 2004 (2), January 25, 2005, and February 23, 2005 (3).

15. What Factors Led You to Believe There Was a Need for Stricter Ethics Rules at NIH?

I have closely followed emerging conflict of interest issues and the progress of NIH reviews of potential conflicts of interest involving NIH scientists. As it became clear that problems were being identified, I decided it was necessary to move aggressively to protect the integrity of the science conducted at NIH and to maintain public confidence in the nation's premier medical research institution.

[redacted]

Tab 3

RESULTS OF NIH REVIEW OF 103 INDIVIDUALS

			Individual	Date Left NIH	Institute	NIH Ethics Panel Finding Decision	NIH Ethics Panel Finding Date	10 OIG Referrals	OIG Action Date	Recommended for Disciplinary Action
Congressional List of 81	44 With Violations	1	Abernethy, Darrell R.		AG	No overlap	5/27/05			√
		2	Berger, Ann		CC	No overlap	5/27/05			√
		3	Brewer, Bryan[1,2]	3/8/05	HL	N/A[5]		11/2/04 1/13/06	3/30/05 N/A	√
		4	Charney, Dennis	7/1/04	MH	N/A[5]				
		5	Chase, Thomas	1/31/05	NS	N/A[5]				
		6	Cheson, Bruce	6/28/02	CA	N/A[5]				
		7	Chrousos, George[5]		HD	N/A[5]				√
		8	Cidlowski, John[1]		ES	Overlap	5/23/05			√
		9	Clore, Marius		DK	N/A[5]				√
		10	Delaglio, Frank[1]	4/28/06	DK	No overlap	10/6/05			√
		11	Diamond, Betty	6/30/02	AR	N/A[5]				
		12	Fojo, Antonio[1]		CA	N/A[5]		2/23/05	4/7/05	√
		13	Goldspiel, Barry		CC	No overlap	5/2/05			√
		14	Gonzalez, Frank		CA	N/A[5]				√
		15	Grieg, Nigel		AG	No overlap	5/27/05			√
		16	Gottman, Frank	NNMC	CA	N/A[5]				
		17	Hallenbeck, John		NS	N/A[5]		2/23/05	3/8/05	√
		18	Hunter, Lawrence	4/26/00	CA	N/A[5]				
		19	Jensen, Robert		DK	No overlap	5/31/05			√
		20	Klein, Harvey[2]		CC	No overlap	4/27/05			√
		21	Kupferberg, Harvey	6/17/00	NS	N/A[5]				
		22	Liang, T. Jake		DK	No overlap	5/31/05			√
		23	Manji, Husseini		MH	No overlap	4/27/05	11/2/04	4/7/05	√
		24	Martin, Roland	4/30/05	NS	N/A[5]				
		25	Masur, Henry		CC	No overlap	5/10/05 6/8/05			√
		26	McFarland, Henry		NS	No overlap	6/10/05			√
		27	McKay, Ronald D.		NS	No overlap	5/27/05			√
		28	Meltzer, Paul		HG	N/A[5]				√
		29	Murphy, Diane		NS	No overlap	5/23/05			√
		30	Nyaka, Abraham	10/2/05	ES	N/A[5]		2/23/05	4/30/06	√
		31	O'Grady, Naomi		CC	No overlap	5/27/05			√
		32	Post, Robert[1]	11/30/05	MH	Overlap	5/31/05 10/14/05			√
		33	Putnam, Karen	7/22/05	MH	Overlap	5/10/05			√
		34	Roden, Maureen	Spec. Vol.	CA	N/A[5]				√
		35	Rogawski, Mike		NS	No overlap	5/31/05			√
		36	Sibley, David		NS	No overlap	5/31/05			√
		37	Simons, Stoney		DK	N/A[5]				√
		38	Strober, Warren		AI	N/A[5]				√
		39	Sunderland, Trey[1, 2, 4]		MH	Overlap	4/1/05 10/12/05	9/24/04 2/6/06 6/2/06	N/A N/A	√
		40	Walsh, Thomas[1, 4]		CA	Overlap	6/1/05	1/25/05	4/22/05	√
		41	Warach, Steven[1]		NS	Overlap	10/11/05			√
		42	Weinberger, Daniel		MH	No overlap	6/23/05			√
		43	Wysocki, Annette	7/8/02	DC	N/A[5]				
		44	Zarate, Carlos		MH	Overlap	5/5/05			√
	37 Without Violations	45	Bukh, Jens		AI	N/A[5]				
		46	Collins, Francis		NOT NIH	N/A[5]				
		47	Collins, Peter L.		AI	N/A[5]				
		48	Cooper, Philip J.	8/8/00	AI	N/A[5]				
		49	Dybul, Mark		AI	N/A[5]				
		50	Ferris, Frederick		EY	N/A[5]				
		51	Fleisher, Thomas		CC	N/A[5]				
		52	Fomace, Albert Jr.	2/1/05	CA	N/A[5]				
		53	Frank, Joseph		CC	N/A[5]				
		54	Gottesman, Michael		OD	N/A[5]				
		55	Hodge, James		CA	N/A[5]				
		56	Hyman, Steven	12/9/01	MH	N/A[5]				
		57	Kirk, Allan		DK	N/A[5]				
		58	Klaiman, Mark	10/6/95	CC	N/A[5]				
		59	Knopp, Michael	11/18/01	CC	N/A[5]				
		60	Levy, Daniel[1]		HL	N/A[5]				
		61	Longo, Dan		AG	N/A[5]				
		62	Ly, Diana		DK	N/A[5]				
		63	Marler, John		NS	N/A[5]				
		64	Marques, Adriana		AI	N/A[5]				
		65	Max, Mitchell		DC	N/A[5]				
		66	Metcalfe, Dean		AI	N/A[5]				
		67	Moskovitz, Jackob	1/20/04	HL	N/A[5]				

Prepared by the Office of Management Assessment-
Revised 06-12-06-

RESULTS OF NIH REVIEW OF 103 INDIVIDUALS

			Individual	Date Left NIH	Institute	NIH Ethics Panel Finding Decision	NIH Ethics Panel Finding Date	10 OIG Referrals	OIG Action Date	Recommended for Disciplinary Action
		68	Murphy, Phillip M.[1]		AI	N/A[5]				
		69	Nabel, Gary		AI	N/A[5]				
		70	Nelson, Larry		HD	N/A[5]				
		71	Pihlstrom, Bruce		DC	N/A[5]				
		72	Pritchard, John[1]		ES	N/A[5]				
		73	Salem, Norman		AA	N/A[5]				
		74	Schlom, Jeffrey		CA	N/A[5]				
		75	Siraganian, Reuben		DC	N/A[5]				
		76	Tatarannl, Antonio	12/31/04	DK	N/A[5]				
		77	Taylor, Simeon	7/1/00	DK	N/A[5]				
		78	Troendle, James		HD	N/A[5]				
		79	Wood, Lauren		CA	N/A[5]				
		80	Young, Neal		HL	N/A[5]				
		81	Zamoyska, Rose		NOT NIH	N/A[5]				
18 Self-Reports for Pharma/Biotech Companies	8 With Violations	82	Chines, Peter		HG	No overlap	10/3/05			√
		83	Dutra, Amalia		HG	No overlap	10/3/05			√
		84	Gahl, Bill		HG	No overlap	10/12/05			√
		85	Giedd, Jay		MH	No overlap	10/3/05			√
		86	Harris, Curtis		CA	N/A[5]				√
		87	LeRoith, Derek	9/3/05	DK	N/A[5]				√
		88	Park, Myung Hee		DC	No overlap	10/3/05			√
		89	Schwartzberg, Pam		HG	N/A[5]				√
		90	Catzone, Toni		AA	N/A[5]				
		91	Chesney, Margaret		AT	N/A[5]				
		92	Erdos, Michael		HG	N/A[5]				
		93	Khan, Javed		CA	N/A[5]				
		94	Liotta, Lance[2,3]	8/1/05	CA	N/A[5]		8/12/04	6/2/05	
		95	Ma, Ge		DC	N/A[5]				
		96	Pawlosky, Robert		AA	N/A[5]				
		97	Rubin, Jeff		CA	N/A[5]				
		98	Shears, Stephen		ES	N/A[5]				
		99	Turner, Maria		CA	N/A[5]				
Other	3 L.A. Times	100	Gallin, John		CC	N/A[5]		2/10/04	6/17/04	
		101	Germain, Ronald		AI	N/A[5]				
		102	Katz, Stephen		AR	N/A[5]				√
		103	Moshell, Alan[3]	4/30/06	AR	N/A[5]		8/10/04	4/30/06	
									Total	44

[1] 11 individuals (Brewer, Cidlowski, Delaglio, Fojo, P. Murphy, Post, Sunderland, Walsh, Warach, Levy, and Pritchard) who were also part of the 29 self-reports.
[2] 4 individuals (Brewer, Klein, Sunderland, and Liotta) who were also part of the 7 who were mentioned in the media.
[3] 2 individuals (Liotta and Moshell) who were part of the June 2004 Congressional hearing.
[4] 2 individuals (Sunderland and Walsh) referred to the PHS Commissioned Corps.
[5] Panel was only asked review outside activities without prior approval.
Individuals who are no longer at NIH.
Individuals who were misidentified as NIH employees in the Congressional List.

Prepared by the Office of Management Assessment-
Revised 09-12-06-

RESULTS OF 103 INDIVIDUAL REVIEWS BY NIH HUMAN CAPITAL GROUP

		Individual	Position	Date Left NIH	IC	Number Reported	Number of Events	Events w/ Problems	Compensation Received	Infraction	Appt Type	Action	Date
44 With Violations	1	Abernethy, Darrell R.	Medical Officer		AG	1	1	1	400	Failure to adhere to procedures before engaging on outside activities		Letter of Caution	12/22/05
	2	Berger, Ann	Staff Clinician		CC	1	1	1	700	Failure to adhere to procedures before engaging on outside activities		Oral Admonishment	12/20/05
	3	Brewer, Bryan[1, 2]		3/8/05	HL	21	21	1	17,250			N/A Resigned / Retired	
	4	Chamey, Dennis		7/1/04	MH								
	5	Chase, Thomas		1/31/05	NS								
	6	Creson, Bruce		6/28/02	CA								
	7	Chrousos, George[5]	Medical Officer (Research)		HD	3	3	1	2,750			No Additional Action Warranted	
	8	Cidlowski, John[1]	Senior Investigator		ES	11	11	10	20,371	Failure to adhere to procedures before engaging on outside activities		7-day ADA[8] Suspension	12/8/05
	9	Clore, Marius	Senior Investigator		DK	1	1	1	1,500	Failure to adhere to procedures before engaging on outside activities		Oral Admonishment	12/19/05
	10	Delaglio, Frank[1]	Staff Scientist	4/28/06	DK	8	10	10	40,047	Failure to adhere to procedures before engaging on outside activities		10-day ADA[8] Suspension	2/7/06
	11	Diamond, Betty		6/30/02	AR								
	12	Foio, Antonio[1]	Lead Clinical Investigator		CA	2	2	1	0	Failure to adhere to procedures before engaging on outside activities	CC	Letter of Caution	12/20/05
	13	Goldspiel, Barry	Pharmacist		CC	6	6	1	6,635	Failure to adhere to procedures before engaging on outside activities		Letter of Caution	12/20/05
	14	Gonzalez, Frank	Research Chemist		CA	2	2	1	11,000	Failure to adhere to procedures before engaging on outside activities		Letter of Caution	12/8/05
	15	Greig, Nigel	Senior Investigator		AG	1	6	1	-	Failure to adhere to procedures before engaging on outside activities		Letter of Caution	12/22/05
	16	Grollman, Frank	NNMC	?	CA								
	17	Hallenbeck, John	Chief Stroke Branch		NS	1	1	0	608	Failure to adhere to procedures before engaging on outside activities		Oral Admonishment	12/20/05
	18	Richter, Lawrence		4/26/00	CA								
	19	Jensen, Robert	Senior Investigator		DK	2	2	2	4,000	Failure to adhere to procedures before engaging on outside activities		Letter of Caution	11/22/05
	20	Klein, Harvey[2]	Senior Investigator		CC	2	2	1	5,000	Failure to adhere to procedures before engaging on outside activities		Letter of Caution	12/20/05
	21	Kupferberg, Harvey		6/17/00	NS								
	22	Liang, T. Jake	Senior Investigator		DK	1	1	1	500	Failure to adhere to procedures before engaging on outside activities		Letter of Caution	11/22/05
	23	Manji, Husseini	Senior Investigator		MH	1	8	7	29,000	Not adhering to NIH requirements for obtaining prior approval before engaging in outside activities and for failing to report payments rec'd from outside activities		10-day ADA[8] Suspension	12/20/05
	24	Martin, Roland		4/30/05	NS	1	3	3	21,023				
	25	Masur, Henry	Supv Medical Officer (Intramural)		CC	5	5	4	8,500	Failure to adhere to procedures before engaging on outside activities		Letter of Caution	12/20/05
	26	McFarland, Henry	Clinical Director		NS	3	5	2	46,938	Failure to adhere to procedures before engaging on outside activities		Oral Admonishment	12/20/05
	27	McKay, Ronald D.	Chief, Laboratory of Molecular Biology		NS	1	1	1	1,111	Failure to adhere to procedures before engaging on outside activities		Letter of Caution	12/20/05
	28	Meltzer, Paul	Senior Investigator		HG	1	1	1	10,000	Failure to adhere to procedures before engaging on outside activities		Letter of Caution	11/23/05

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Revised 9/12/06

RESULTS OF 103 INDIVIDUAL REVIEWS BY NIH HUMAN CAPITAL GROUP

Congressional List of 81

	Individual	Position	Date Left NIH	IC	Number Reported	Number of Events	Events w/ Problem	Compensation Received	Infraction	Appt Type	Action	Date
29	Murphy, Diane	Health Scientist Administrator		NS	1	2	1	5,750	Failure to adhere to procedures before engaging on outside activities		Letter of Caution	1/3/06
30	Nyska, Abraham		10/2/05	ES	1	1	0	500			N/A Retired	
31	O'Grady, Naomi	Staff Clinician		CC	1	1	1	850	Failure to adhere to procedures before engaging on outside activities		Letter of Caution	12/20/05
32	Post, Robert[1]		11/30/05	MH	19	19	19	51,141			N/A Resigned	
33	Putnam, Karen		7/22/05	MH	1	6	6	63,000			N/A Resigned	
34	Roden, Maureen	Special Volunteer	?	CA	1	1	1	26,100		Spec. Vol.	N/A Non-employee	
35	Rogawski, Mike	Medical Officer		NS	1	1	1	1,062	Failure to adhere to procedures before engaging on outside activities		Letter of Caution	12/27/05
36	Sibley, David	Senior Investigator		NS	1	1	1	1,538	Failure to adhere to procedures before engaging on outside activities		Letter of Caution	12/27/05
37	Simons, Stoney	Research Chemist		DK	1	1	1	500	Failure to adhere to procedures before engaging on outside activities		Oral Admonishment	12/19/05
38	Strober, Warren	Medical Officer (Intramural)		AI	1	1	1	2,476	Failure to adhere to procedures before engaging on outside activities		Letter of Caution	11/22/05
39	Sunderland, Trey[1, 2, 4]	Branch Chief		MH	15	64	64	710,880	Not adhering to NIH requirements for obtaining prior approval before engaging in outside activities, failing to report payments rec'd from outside activities and not appropriately requesting leave on a day he performed an outside activity.	CC	Proposed Removal Referred to CC for Action	Pending
40	Walsh, Thomas[1, 4]	Lead Clinical Investigator		CA	25	38	38	99,970	Not adhering to NIH requirements for obtaining prior approval before engaging in outside activities, failing to report payments rec'd from outside activities and not appropriately requesting leave on a day he performed an outside activity.	CC	Proposed Removal Referred to CC for Action	Pending
41	Werach, Steven[1]	Senior Investigator		NS	12	13	13	57,330	Not adhering to NIH requirements for obtaining prior approval before engaging in outside activities, failing to report payments rec'd from outside activities and not appropriately requesting leave on a day he performed an outside activity		7-day ADA[6] Suspension	2/27/06
42	Weinberger, Daniel	Branch Chief		MH	3	5	3	11,750	Failure to adhere to procedures before engaging on outside activities	CC	Letter of Reproval	1/30/06
43	Wysocki, Annette		7/6/02	DC								
44	Zarate, Carlos	Staff Clinician		MH	4	4	3	10,120	Not adhering to NIH requirements for obtaining prior approval before engaging in outside activities and for failing to report payments rec'd from outside activities		7-day ADA[6] Suspension	12/19/05

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RESULTS OF 103 INDIVIDUAL REVIEWS BY NIH HUMAN CAPITAL GROUP

		Individual	Position	Date Left NIH	IC	Number Reported	Number of Events	Events w/ Problem	Compensation Received	Infraction	Appt Type	Action	Date
37 Without Violations	45	Bukh, Jens			AI								
	46	Collins, Francis	Not NIH Employee										
	47	Collins, Peter L.			AI								
	48	Cooper, Philip J.		8/8/00	AI								
	49	Dybul, Mark			AI								
	50	Ferris, Frederick			EY								
	51	Fleisher, Thomas			CC								
	52	Fornace, Albert Jr.		2/1/05	CA								
	53	Frank, Joseph			CC								
	54	Gottesman, Michael			OD								
	55	Hodge, James			CA								
	56	Hyman, Steven		12/9/01	MH								
	57	Kirk, Allan			DK								
	58	Klaiman, Mark		10/6/95	CC								
	59	Knopp, Michael		11/18/01	CC								
	60	Levy, Daniel[1]			HL								
	61	Longo, Dan			AG								
	62	Ly, Diana			DK								
	63	Marler, John			NS								
	64	Marques, Adriana			AI								
	65	Max, Mitchell			DC								
	66	Metcalfe, Dean			AI								
	67	Moskovitz, Jackob		1/20/04	HL								
	68	Murphy, Phillip M.[1]			AI								
	69	Nabel, Gary			AI								
	70	Nelson, Larry			HD								
	71	Pihlstrom, Bruce			DC								
	72	Pritchard, John[1]			ES								
	73	Salem, Norman			AA								
	74	Schiom, Jeffrey			CA								
	75	Siraganian, Reuben			DC								
	76	Tatarainl, Antonio		12/31/04	DK								
	77	Taylor, Simeon		7/1/00	DK								
	78	Troendle, James			HD								
	79	Wood, Lauren			CA								
	80	Young, Neal			HL								
	81	Zamoyska, Rose	Not NIH Employee										
ma/Biotech Companies	82	Chines, Peter	Computer Scientist		HG	1	1	1	4,000	Failure to adhere to procedures before engaging on outside activities		Letter of Caution	11/23/05
	83	Dutra, Amalia	Staff Scientist		HG	1	2	2	47,905	Failure to adhere to procedures before engaging on outside activities		Letter of Caution	11/29/05
	84	Gahl, Bill	Clinical Director		HG	1	3	2	3,000	Failure to adhere to procedures before engaging on outside activities		Oral Admonishment	12/8/05
	85	Giedd, Jay	Investigator (Tenure Track)		MH	1+	237	237	474,730	Violation of NIH Ethics requirements, failure to request prior approval of outside activities on HHS form 520, failure to disclose the nature and income of outside activities on OGE form 450.		45-day Suspension	2/14/06
	86	Harris, Curtis	Senior Investigator		CA	2	2	1	12,000	Failure to adhere to procedures before engaging on outside activities		Letter of Caution	12/8/05
	87	LeRoith, Derek		9/3/06	DK	1	1	1	5,000			N/A Retired	

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RESULTS OF 103 INDIVIDUAL REVIEWS BY NIH HUMAN CAPITAL GROUP

		Individual	Position	Date Left NIH	IC	Number Reported	Number of Events	Events w/ Problem	Compensation Received	Infraction	Appt Type	Action	Date
18 Self-Reports for Phai	88	Park, Myung Hee	Research Chemist		DC	1	1	1	1,356	Failure to adhere to procedures before engaging on outside activities		Letter of Caution	12/21/05
	89	Schwartzberg, Pam	Senior Investigator		HG	1	1	1		Failure to adhere to procedures before engaging on outside activities		Letter of Caution	11/29/05
	90	Calzone, Toni	Computer Scientist		AA								
	91	Chesney, Margaret	Deputy Director, NCCAM		AT								
	92	Erdos, Michael	Staff Scientist		HG								
	93	Khan, Javed	Investigator		CA								
	94	Liotta, Lance[2, 3]		8/1/05	CA								
	95	Ma, Ge			DC								
	96	Pawlosky, Robert	Staff Scientist		AA								
	97	Rubin, Jeff	Research Biologist		CA								
	98	Shears, Stephen	Senior Investigator		ES								
	99	Turner, Maria	Senior Clinician		CA								
Other 3 L.A. Times	100	Gallin, John	Director Clinical Center		CC								
	101	Germain, Ronald	Senior Investigator		AI								
	102	Katz, Stephen[5]	Director NIAMS		AR	2	2	1	274,750			No Additional Action Warranted	
	103	Moshell, Alan[3]	Medical Officer Dermatology	4/30/06	AR								

[1] 11 individuals (Brewer, Cidlowski, Delaglio, Fojo, P. Murphy, Post, Sunderland, Walsh, Warach, Levy, and Pritchard) who were also part of the 29 self-reports.
[2] 4 individuals (Brewer, Klein, Sunderland, and Liotta) who were also part of the 7 who were mentioned in the media.
[3] 2 individuals (Liotta and Moshell) who were part of the June 2004 Congressional hearing.
[4] 2 individuals (Sunderland and Walsh) who were referred to the PHS Commissioned Corps.
[5] Employee remedied violation once it was brought to his attention
[6] ADA -- Alternative Disciplinary Action
Individuals who are no longer at NIH.
Individuals who were misidentified as NIH employees in the Congressional List.

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	Date	Activity	Organization	Location	Travel	Compensation
1	6/29/2006	Seminar	Lundbeck International Neuroscience Foundation	Copenhagen, DN	Withdrawn	Withdrawn
2	5/25/2006	Speaking	The Reading Hospital and Medical Center	West Reading, PA	$69.00	$1,500.00
3	5/3-7/2006	Speaking	Lundbeck International Neuroscience Foundation	Sicily, Italy	$3,087.50	$1,190.00
4	4 Yrs	Appointed	Society of Biological Psychiatry	Locally	Withdrawn	Withdrawn
5	3/1/2006	Speaking	Montefiore Medical Center	New York, NY	$551.00	$1,500.00
6	4/28/2006	Speaking	Office of Cont. Education, Baystate Health System	Holyoke, MA	$599.00	$2,500.00
7	11/16-18-2005	Speaking	Academy of Psychosomatic Medicine	Albuquerque, NM	$861.00	$1,000.00
8	11/14-18/2005	Speaking	Lundbeck International Neuroscience Foundation	Skodsborg, DN	$3,000.00	$1,000.00
9	11/11-12/2005	Speaking	Foundation for Advanced Education in the Sciences	Bethesda, MD	$0.00	$2,000.00
10	4/29/2005	Speaking	University of Texas Medical Branch	Galveston, TX	$960.00	$2,500.00
11	4/25/2005	Lecture	PREX Health Marketing Projects and Services	Washington, DC	$0.00	$1,750.00
12	3/4/2005	Symposium	American Association for Geriatric Psychiatry	San Diego, CA	$1,500.00	$2,000.00
13	2/24/2005	Lecture	Montefiore Medical Center	Bronx, NY	Withdrawn	Withdrawn
14	2/19/2005	Lecture	Nevada Psychiatric Association	Las Vegas, NV	$625.19	$2,500.00
15	11/2004-2005	Lecture	Lundbeck International Neuroscience Foundation	Skodsborg, DN	Withdrawn	Withdrawn
					$11,252.69	**$19,440.00**
	8/2005 - 8/2006		Private Practice			50-75k

Tab 4

Tab 5

	Departure	Return	Destination	Cost
1	6/2/2006	6/4/2006	Fort Lauderdale, FL	$632.59
2	5/21/2006	5/23/2006	Toronto, Canada	$1,218.00
3	5/16/2006	5/19/2006	Toronto, Canada	$1,491.40
4	4/26/2006	4/27/2006	Manhattan, NY	$609.11
5	12/9/2005	12/6/2005	Waikoloa, HI	$3,864.36
6	11/3/2005	11/5/2005	Pittsburgh, PA	$1,168.89
7	9/14/2005	6/18/2005	Geneva, Switzerland	$2,516.00
8	7/26/2005	7/27/2005	Kings Park, NY	$353.53
9	6/18/2005	6/18/2005	Washington, DC	$619.30
10	6/10/2005	6/12/2005	Palm Beach, FL	$745.80
11	5/18/2005	5/21/2005	Atlanta, GA	$622.43
				$13,841.41

Tab 6

Summary of the Office of Management Assessment's (OMA) Report on Dr. Trey Sunderland's Outside Activity Discrepancies

Factual Data:

The OMA's review of discrepancies between records provided by NIH and by Pfizer Inc. to the U.S. House of Representatives, Committee on Energy and Commerce, Subcommittee on Oversight Investigations, found that Dr. Sunderland:

A. Failed to Seek Prior Approval for Lectures, Honoraria and other Outside Consulting Activities, in Violation of Commissioned Corps Personnel Manual Chapter CC26 and the Code of Federal Regulations, 5 CFR 2635.02, and the NIH Manual Chapter 2300-735-4

1) Pfizer cited 140 dates in 1999-2004 when Dr. Sunderland gave lectures and received honoraria totaling $248,000. Dr. Sunderland cited 82 dates. Only 43 dates matched both lists. Dr. Sunderland did not obtain approval for any of these activities.

2) Pfizer reported consulting on 12 specific days. Dr. Sunderland's estimated list reports 25 dates. Only seven dates matched. Dr. Sunderland did not obtain approval for any of these activities.

3) After the NIH Director requested that scientists disclose any unreported outside activities with pharmaceutical or biotechnology companies, Dr. Sunderland reported consultations and lectures with 14 additional companies. Dr. Sunderland did not obtain approval for any of these activities.

B. Failed to disclose compensation he received from Pfizer and other companies on his OGE Form 450, *Executive Branch Confidential Disclosure* Reports from 1999-2003[1]

1) Pfizer cited that Dr. Sunderland was paid $248,000 in honoraria and lectures from 1999-2004. Dr. Sunderland did not report these earnings on his OGE 450 forms from 1999-2003.

2) Pfizer cited total payments of $228,500 to Dr. Sunderland for consulting services from 1999-2004. Dr. Sunderland did not report these monetary earnings on his OGE 450 forms from 1999-2003.

[1] OMA received different totals for payments to Dr. Sunderland for his outside activities from the Committee, Pfizer and Dr. Sunderland.

3) Dr. Sunderland reported consultations with monetary payments totaling $193,880 after being asked by the NIH Director to disclose unreported activities. Dr. Sunderland did not report these monetary earnings on his OGE 450 forms from 1999-2003.

C. Failed to Obtain Prior Approval for Outside Consulting Activities in Violation of Commissioned Corps Handbook, Section C.12.c, Use of Leave in Connection with Outside Activities

OMA determined that Dr. Sunderland was not on approved leave at least 34 days when he was engaging in outside activity. OMA notes that these numbers are likely higher but they were unable to verify specific additional activity dates.

D. Failed to Submit an OGE Form 278, *"Executive Branch Personnel Public Financial Disclosure Form"* for 2004

Dr. Sunderland has failed to submit his SF-278 Public Financial Disclosure Form for 2004. Despite being given several opportunities to complete the form, and the fact that his attorney was given specific information regarding why he was required to complete his SF-278 Public Financial Disclosure Form for 2004, as of this date, Dr. Sunderland still has not submitted the form.

E. NIH Office of Ethics' Review

1) Dr. Sunderland's unapproved outside activities with Pfizer was reviewed by the NIH Ethics Review Panel. The NIH Ethics Review Panel is composed of individuals with the expertise to evaluate matters related to ethical conflicts. The Panel documented in its memorandum dated April 1, 2005, that it found a direct overlap between the subject matter of Dr. Sunderland's official area of research and scientific subject matter of his Pfizer consultancies. The members of the panel concluded that Dr. Sunderland would not have been given approval for these consulting activities. The panel expressed concern over Dr. Sunderland's dual relationship with Pfizer and that he entered into a Material Transfer Agreement (MTA) with Pfizer in 1998 while he maintained an ongoing consulting relationship. The panel noted that his lecturing activities, both those related to Pfizer and those with other companies, would most likely have been approved as the lectures did not overlap with areas of research that Dr. Sunderland oversees at NIH.

2) In a memorandum dated October 12, 2005, the NIH Ethics Review Panel advised that Dr. Sunderland's official duties constituted an overlap with services he provided to Astra Zeneca, Cerebus, CNS Inc., Johnson and Johnson, Lilly, Merz, Novartis and Warner Lambert and the Panel concluded that his activities with these companies would not have been given approval, if he had sought it.

Analysis:

Dr. Sunderland, through his attorney and his interview with OMA, maintains that there was no effort at deception and that other scientists, doctors and administrators did not give the Forms 450 and 520 attention. Dr. Sunderland maintains that there was no conflict of interest in relation to the research he oversees at NIH and his activities with Pfizer. He maintains that administrators knew of his consulting and lecturing activities. Dr. Sunderland stated that he was open about his relationship at Pfizer and took care to avoid the appearance of a conflict. Dr. Sunderland maintains that some relevant documents were lost in the administrative approval process and he cites that his secretary for some time period was less than capable. Dr. Sunderland provided a letter with notes, which he states indicates he did submit outside activities for approval. He stated that he signed the HHS Forms 520, *Request for Approval of Outside Activity* and submitted them to his secretary to fill-in the relevant information concerning his outside activities with Pfizer and other companies. He said he did not think he had to resubmit approvals for ongoing activities for Pfizer. He further stated in his interview with OMA that he gave letters to his secretary, and he assumed the activities were approved unless he heard otherwise. He said that he knew he should not engage in activities before hearing that they were approved, but he was very busy with his science as well as other administrative work. He also maintains and provided evidence that leave slips were vetted through administrative channels, but often did not appear on the official time and attendance record.

Dr. Sunderland placed the NIH in a position where it had to respond to allegations of impropriety, which compromised faith in the Agency and trust in our research. Dr. Sunderland violated ethics rules with regard to his relationship with Pfizer and engaged in relationships with Pfizer and many other organizations that would not have been approved had he submitted them for approval in accordance with the process for seeking approval of outside activities. Dr. Sunderland violated NIH and Commissioned Corps procedures and policies on multiple occasions (Pfizer reported 140 activities for which there were no approvals) all of which cannot be dismissed as administrative oversights or anomalies. Given that he acknowledges that he had concerns about administrative support, he should have ensured that forms were submitted to the NIMH ethics office and that approvals were given. Dr. Sunderland was aware of the NIH ethics process through ethics training and was ultimately responsible for ensuring that all activities were approved and all financial disclosures were made. Not disclosing over $ 500,000 in income was not an oversight or lapse in judgment but appears to be a deliberate decision not to comply with the rules, policies and procedures that are necessary to protect the NIH, its scientists and most importantly, its science.

Although Dr. Sunderland has acknowledged that he now understands the importance of the NIH ethics outside activity approval process, he has recently failed to submit his *Executive Branch Personnel Public Financial Disclosure Form (SF-278)* for the year 2004, which causes us to question whether he will ever comply with the NIH ethics rules

and regulations. It also causes us to question whether or not he has been forthright regarding his activities with OMA investigators. Dr. Sunderland's continued misconduct has compromised public support of numerous other NIH scientists who, despite administrative challenges, have managed to follow proper procedure and receive proper approvals.

Dr. Sunderland maintains that there was no conflict of interest with respect to his relationship with Pfizer, the MTA and NIH. He maintains that he made great efforts to avoid the appearance of such including removing himself from some decision making processes. Dr. Sunderland may have felt that he was taking appropriate precautions to ensure that he was not in conflict; however, that was not an assessment for him to make. As an NIH scientist and especially in his role as Chief of one of its branches, he is obligated to engage in the process the agency has set forth for making such determinations. In a memorandum dated April 1, 2005, Holli Beckerman Jaffe, J.D., Director of the NIH Ethics Office outlines the NIH Ethics Panel's concerns with regard to Dr. Sunderland's relationship with Pfizer and notes that no documentation exists to the fact that Dr. Sunderland took every precaution necessary to avoid the appearance of a conflict. The precaution that Dr. Sunderland should have taken was to notify the National Institute of Mental Health (NIMH) Ethics Office to ensure that proper approvals had been given. However, the NIMH Ethics officials were unaware of Dr. Sunderland's activities.

It has been determined by the Office of Human Resources that if Dr. Sunderland were a civilian employee his actions would lead to a recommendation for his proposed removal. Dr. Sunderland's long years of service and dedication to the agency and the science, his significant contributions over time, have all been considered as mitigations, but they are not sufficient to outweigh the seriousness of his misconduct and its effect upon the agency.

Tab 7

Interview with Dr. Trey Sunderland
August 19, 2004

Persons Present:
Dr. Trey Sunderland, Chief, Geriatric Psychiatry Branch, NIMH
Mr. Robert Muse, Attorney, Stein, Mitchell & Mezines
Mr. Arthur Hainer, Office of Management Assessment, NIH
Ms. Patricia Quast, Office of Management Assessment, NIH

Dr. Sunderland said that he began work at NIH in July 1982 and joined the Commissioned Corps in 1987. He became the Chief of the Geriatric Psychiatry Branch in the mid-1990s.

Dr. Sunderland said that he is aware that there are rules governing disclosure of financial interests and approval of official duties and outside activities and has taken the ethics course in the past. He said that he understands the concept, but may not have paid proper attention to it in the past. He said that he is now aware of how important these matters are and has either resubmitted or cancelled all his current outside activities. Dr. Sunderland told us that he understands the principles of 450s and 520s and felt that he had always disclosed his outside activities to his constituency—his colleagues, supervisors, and patients. He added that he made no attempt to hide his work with Pfizer, and has disclosed his outside activities in all of his lectures so that the audience knows his potential biases.

Dr. Sunderland told us that he felt that he had disclosed all of his activities with Pfizer. He recalled submitting the appropriate 520s for speeches and consultations with Pfizer, and that the majority of the activities were lectures, not consultations. He said that he remembered applying in September 1997 for approval of consultation with Pfizer. Soon thereafter, he also requested an ongoing outside activity for a speaker's bureau for Pfizer. He said that he did not think that he needed to resubmit for ongoing activities, such as his private practice.

Dr. Sunderland said that when he needed approval of an outside activity, he gave the letter of invitation to his secretary for processing in the 520 package. He added that he assumed that the activity was approved unless he heard otherwise and that he cannot recall ever having an activity rejected. He added that he knew he shouldn't perform the activity until it was approved, but he hadn't been paying much attention to paperwork because he has been very busy with his science as well as with other administrative work, such as reviewing requests from patients, processing personnel papers, screening protocols, and writing papers. He said that he was also head of the NIMH Institutional Review Board during much of the period in question with the burden of tremendous additional administrative paperwork. He said that he enjoyed the lack of emphasis on

paperwork at NIH since it allowed him to put his time into other areas. He said that he had several secretaries in the last few years, including one that took him 2 years to transfer her into another position because of administrative weaknesses. He said that the new secretary who replaced this one found piles of paperwork under the desk, left by the old secretary.

Dr. Sunderland said that he does not know if he took annual leave for his outside activities because he doesn't track it, but that he works long, hard hours, like many of his colleagues.

We asked Dr. Sunderland about the process for completing his 450. He told us that, when he looks at them now, he realized that they are inadequate. He said that he takes the form home, reviews his stock portfolio and his wife's and children's financial interests, and fills out the first page of the form, including the signature. He said that he uses his past form as the template to fill out the new form. He then signs the form and gives it to his secretary to help gather his outside activities, since he doesn't keep copies of his 520s. He said that, since he has already signed the form, he doesn't review it again after she helps complete it. He said that everything that is on his past 450s is accurate, but not complete.

Dr. Sunderland said that he did not keep copies of his 520s and does not have the 520s for most of the activities in question. He said that the dates from Pfizer do not represent the dates of his activities and that he is trying to find the dates now for us.

We asked Dr. Sunderland about his Material Transfer Agreement with Pfizer. He said that he had a consulting arrangement with Pfizer Corporate and the MTA with Pfizer researchers in Connecticut. He said that the scientific collaboration was initiated by David Friedman, who was a basic researcher for Pfizer. He said that he sent spinal fluid to Dr. Friedman, and that he has shared spinal fluid in more than 30 other collaborations, including two with companies over the last 20 years and that this was his only MTA. He said that the scientific collaboration itself would not have required visits to Pfizer, as this was an exchange of material for analytical data, like many of his other collaborations. He said that he thought an MTA would protect him and Pfizer from issues of conflict because of his consulting arrangement with Pfizer. He said that part of the MTA had to do with proteomics and this project failed. The other part of the MTA has been a successful project.

Dr. Sunderland said that his consulting work with Pfizer has to do with drug development and lectures. He said that he has avoided studying Pfizer drugs in any of his NIH research protocols, although some patients may join his protocols already on Pfizer drugs clinically.

Dr. Sunderland said that he has studied a drug from Bristol Myers Squib in a clinical trial that was approved the end of 2001. He started work on the protocol

9 of 1

in 1999 based on a drug used in Europe that he thought was a generic medication. However, he found out only this August, from the pharmacist, that this was not a generic medication and that only BMS supplied it. He added that they do not buy the drug direct from BMS and that he has not had contact with BMS about this protocol. He said that the lectures he performed for BMS had nothing to do with this drug.

Dr. Sunderland said that he doesn't want his perspective to be biased and that he does not work with drug companies who try to insert their slides into his lectures. He said that all his lectures offer basically the same perspective no matter who is the sponsor and that people want to hear the most recent scientific information without bias.

We asked Dr. Sunderland about Karen Putnam's consulting work with Pfizer. He said that, in 2001, the proteomics project was in need of statistical help, and Pfizer asked if he knew anyone who could help. He said that he contacted Karen Putnam and John Bartko (ex-PHS officer, who had left the government) and discussed the consulting work with them and recommended them to Pfizer, who later contacted them.

When asked whether he had told Ms. Putnam that she needed to file a 520 for this activity, Dr. Sunderland said that he does not recall if he told her to file or not to file. He said that he does not think that she needed to file because she was a part-time employee on an IPA at the time and because her duties did not overlap with any decisions regarding drug or protocol development.

We asked Dr. Sunderland whether he knew if Ms. Putnam had taken leave for the time she was at Pfizer. He said that, although he is the approving official for Karen, he does not check to see if she has taken leave before he approves her time card, but he would probably have mentioned the need to take leave for the outside consulting work. Dr. Sunderland added that he looks for productivity, not hours in all his employees and only watches the leave records for people who do not work hard.

Dr. Sunderland said that he used to give the same types of lectures before Dr. Varmus allowed the scientists to personally keep honoraria, and that he contributed the honoraria to a government pool.

( ) These notes accurately summarize the interview.

(X) These notes, with indicated changes, accurately summarize the interview.

Signature

8/31/04
Date

IMC

Feb-15-2006 06:50pm From-Assistant Secretary for Legislation 202-690-7380 T-118 P.003 F-213

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892
www.nih.gov

April 1, 2005

Tab 8

TO: Colleen Barros
Deputy Director for Management, NIH

FROM: Holli Beckerman Jaffe, J.D.
Director, NIH Ethics Office

SUBJECT: Dr. Trey Sunderland's Unapproved Outside Activities with the Pfizer, Inc.

Between May 1998 and June 2004, Trey Sunderland, M.D., Chief, Geriatric Psychiatry Branch, National Institute of Mental Health (NIMH), engaged in a series of unapproved speaking and consulting activities with Pfizer, Inc. After a careful review of Dr. Sunderland's unapproved outside activities with Pfizer, the Panel finds a direct overlap between the subject matter of Dr. Sunderland's official area of research and the scientific subject matter of his Pfizer consultancies. The members of the Panel conclude that he would not have been given prior approval for the consulting activities. In addition, the panel expresses further concern over the Material Transfer Agreement (MTA) that Dr. Sunderland entered into with Pfizer in 1998 while he maintained an ongoing consulting relationship with the company in the same area. With regard to the one-time speaking events, however, the Panel concludes that the single lectures given by Dr. Sunderland would have been approved, because the topics of those lectures were general and lacked specific overlap with Dr. Sunderland's work at the NIH.

Unapproved Consulting

As the Chief of the Geriatric Psychiatry Branch at NIMH, Dr. Sunderland has been conducting research on Alzheimer's disease and studying depression in the elderly since 1982. As part of that research, he studies the development of potential biomarkers for Alzheimer's disease. From 1998 to 2004, Dr. Sunderland consulted for Pfizer on the development of central nervous system products, and according to his consulting agreements with the company he focused in particular on biomarkers for Alzheimer's disease. In a letter from Dr. Sunderland's attorney to the NIH Ethics Office, his attorney states that "Dr. Sunderland has been working with Pfizer as a consultant to consider alternative approaches [to traditional Alzheimer's disease medication trials] that would include different and multiple dependent variables, including surrogate markers, in medication and efficacy trials." The NIH Ethics Review Panel finds this type of consulting work to be directly related to Dr. Sunderland's research at the NIH and concludes that he would not have received approval to serve as a consultant with Pfizer in this area.

Dr. Sunderland however draws a distinction between the study of "surrogate markers", which he says are the subject of his consulting with Pfizer, and his study of "biomarkers" at the NIH. In a letter to the NIH Ethics Office, Dr. Sunderland's attorney states that "although these two terms (biomarkers and surrogate markers) may share semantic overlap and are often mistakenly interchanged in casual scientific discussion, the goals and techniques employed with biomarkers

research and surrogate marker trials are quite different." The Panel disagrees and does not find a significant distinction between "surrogate markers" and "biomarkers" for the purposes of the determination of overlap between the subject matter of the activities and Dr. Sunderland's official duties.

The Panel explains that a "surrogate marker" is a specific type of biomarker, and at the NIH, Dr. Sunderland studies a range of biomarkers related to Alzheimer's disease. Even if he did not study the same biomarkers as in his Pfizer consultancy – which it is not clear that he did not – the distinction that he draws between the study of different biomarkers is too fine to provide a meaningful basis to differentiate the subject matter of the unapproved consulting activities and his official duties. The study of surrogate markers for Alzheimer's disease constitutes the same area of research as his work at the NIH.

Furthermore, the Panel is deeply concerned by Dr. Sunderland's dual relationship with Pfizer. As noted above, Dr. Sunderland served as a consultant to Pfizer from 1998 to 2004. In 1998, Pfizer and Dr. Sunderland, on behalf of the NIMH (he signed the agreement as the authorized signatory for the NIMH), entered into a MTA. In his official capacity as Chief of the Geriatric Psychiatry Branch, Dr. Sunderland officially transferred coded clinical samples of cerebrospinal fluid to Pfizer. The samples were from subjects that took part in previous NIH clinical trials involving Alzheimer's disease. After obtaining the samples, Pfizer scientists studied them for Alzheimer's biomarkers and published the results in an April 2003 edition of the *Journal of the American Medical Association*. Dr. Sunderland, in his official capacity, appeared as co-author to the article along with the Pfizer scientists.

Dr. Sunderland contends that the MTA did not occur as a result of his prior relationship with Pfizer. In a letter from his attorney, Dr. Sunderland asserts that Dr. Friedman, a Pfizer scientist, initiated contact with Dr. Sunderland based upon his knowledge of Dr. Sunderland's published work in the field of Alzheimer's research and that the scientist works in a different division of Pfizer, unrelated to Dr. Sunderland's consulting work with the organization. In vetting the MTA for approval, Dr. Sunderland states that he took every precaution to avoid the appearance of a conflict. Despite his assertions, no documentation exists to that effect, and NIMH ethics officials have indicated that they were unaware of his activities with Pfizer. Whether the MTA was facilitated because of Dr. Sunderland's outside relationship with Pfizer is irrelevant. The ethics rules do not allow an employee to participate in an official duty matter involving the same company to which he serves as a consultant without authorization to do so. There is no record of such authorization.

Unapproved Lectures

In addition to Dr. Sunderland's consulting activities, he participated in (and received compensation for) numerous lectures for Pfizer from 1998 to 2004. The lectures were on the topics of Alzheimer's disease and depression in the elderly and could best be compared to continuing medical education lectures commonly attended by medical practitioners. Dr. Sunderland provided evidence that these lectures were of a general nature and did not involve the marketing of Pfizer products.

The Standards of Conduct prohibit an employee from receiving "compensation from any source other than the Government for teaching, speaking or writing that relates to the employee's

official duties." 5 C.F.R. §2635.807(a). A speech "relates to an employee's official duties if: . . . the subject of the activity deals in significant part with: (1) any matter to which the employee presently is assigned or to which the employee had been assigned during the previous one-year period." 5 C.F.R. §2635.807(a)(2)(i)(E).

According to this standard, the Ethics Review Panel concludes that the subjects of the lectures do not overlap with the areas of research that Dr. Sunderland oversees at the NIH. The Panel finds that the lectures are very general in nature and contain information for a wide audience. Although the numerous unapproved lectures for Pfizer represent a huge pattern of disregard for the prior approval rules by Dr. Sunderland, because the subject matter only involves information related to Dr. Sunderland's NIH research in a very general way, the members of the Review Panel conclude that the lecturing activities would likely have been approved if he had sought such approval.

The NIH Ethics Review Panel does note, however, that in a sample set of presentation slides provided by Dr. Sunderland, he appears to be referring audience members to clinical trials at the NIH. Recruiting for clinical trials as part of an outside activity is prohibited. In discussing an NIMH protocol relevant to one of his lectures, Dr. Sunderland provides the name and telephone number of a coordinator at the protocol. Presenting this type of information during a paid outside lecture may be contrary to NIH policy if the mentioning of the protocol is determined to be recruiting of patients.

Holli Beckerman Jaffe, J.D.

[redacted]
Tab 9

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of Mental Health
6001 Executive Blvd.
Bethesda, Maryland 20892

November 21, 2005

TO: Captain Denise Canton, Director
Office of Commissioned Corp Operations

THRU: Deputy Director, NIH _____ 12/2/5

FROM: Director, NIMH

Attached are an investigative file, determination on possible conflict of interest, and a summary of charges of misconduct as assembled by the NIH Office of Management Assessment in regards to Captain Trey Sunderland, M.D. According to the Office of Management Assessment investigation, Dr. Sunderland has engaged in serious misconduct, in violation of the Department's Standard of Conduct Regulations (45 CFR Part 73), and Federal law and regulation. The Office of Human Resources at NIH has informed me that the NIH has recommended removal for civilian employees who have engaged in misconduct of a similar type and gravity. As the Director of the NIMH, these findings are surprising and disappointing to me as Dr. Sunderland's service to this Institute, his colleagues, and his patients has been exemplary for over two decades. In the hopes of a fair and rapid resolution, I am referring this matter to the Assistant Secretary for Health, in accordance with Chapter CC46 – Conditions of Service, Subchapter CC46.4 – Officer's Responsibilities and Conduct, and Personnel INSTRUCTION 1 – Disciplinary Action.

Thomas R. Insel, M.D.

Attachments

NIMH
National Institute
of Mental Health

[redacted]
Tab 10

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DPT Reading File

National Institutes of Health
Bethesda, Maryland 20892
www.nih.gov

SEP 24 2004

Refer to: Case #2004-82-MH-106

TO: Mr. Patrick Doyle
Regional Inspector General for Investigations
Philadelphia Field Office

FROM: Director, Office of Management Assessment, OM

SUBJECT: Referral of Conflict of Interest Matter – Dr. P.Trey Sunderland

The purpose of this memorandum is to refer to the Office of Inspector General an allegation that Dr. P. Trey Sunderland, Chief, Geriatric Psychiatry Branch, National Institute of Mental Health, National Institutes of Health, may have conducted outside activities during Government work hours without charging leave. Those activities relate to Dr. Sunderland's consulting, lecturing and other work for Pfizer Inc. Dr. Sunderland is a Public Health Service Commissioned Corps officer.

NIH management requested a review after Dr. Sunderland's outside activities were discussed at a June 22, 2004, hearing on NIH ethics held by Chairman James Greenwood of the U.S. House of Representatives, Committee on Energy and Commerce, Subcommittee on Oversight and Investigations (see Attachment, Tab A). The subcommittee subsequently included Dr. Sunderland's activity with Pfizer on a list of discrepancies between records provided by NIH and by Pfizer to the subcommittee. In reviewing Dr. Sunderland's activity with Pfizer we found that he may have been participating in activities for Pfizer while he was not on approved leave, as required by NIH Policy Manual Chapter 2300-735-4, G. 1. a. (4), Use of Personal Time (Tab B).

The attached documents related to Dr. Sunderland's outside activities with Pfizer were discussed with Special Agent Tamila Miles in a meeting on September 20, 2004. They include a list Dr. Sunderland provided of the estimated dates and times of his lectures and consultations with Pfizer (Tab C), a list Pfizer provided of the dates of his lectures only (Tab D), a table matching those dates (Tab E), a summary of an August 19, 2004, interview with Dr. Sunderland (Tab F), and his leave records for the period May 1, 1998 to September 2, 2004 (Tab G).

The table comparing Dr. Sunderland's and Pfizer's activity dates shows that Dr. Sunderland should have taken 27 days of leave to perform outside activities with Pfizer. Using a conservative approach, we have only recommended that leave be charged when the dates from both parties matched and when Dr. Sunderland said that he spent a full day on the activity. We did not recommend that leave be charged for those days that Dr. Sunderland said the activity was "local" and took place in the evening or was "brief."

However, we are currently awaiting a clarification of the Commissioned Corps policy on leave for outside activities and this number may be revised upward.

In addition, we have requested a list from Pfizer of the dates Dr. Sunderland consulted with them and, since the original list from Pfizer contained only lectures, the number of days Dr. Sunderland should have taken leave may be revised upward. We will send you a copy of that list from Pfizer when we receive it.

If you have any questions, please call Mr. Kevin Wetmore at (301) 496-5586.

Suzanne J. Servis

Attachments

cc: *w/attachments*
Ms. Tamila Miles, OIG/OI

Attachment

Document Listing

Subject: **Dr. Trey Sunderland**

Tab	**Document**
A	June 22, 2004—Statements by Chairman Greenwood re Dr. Trey Sunderland at the House Energy and Commerce, Subcommittee on Oversight and Investigations, Hearing on Consulting Contracts and Ethics at NIH
B	NIH Policy Manual Chapter 2300-735-4, G. 1. a. (4), Use of Personal Time
C	Listing of estimated outside activities with Pfizer from 1/15/99 to 6/3/04 provided to NIH by Dr. Sunderland
D	Listing of honoraria paid to Dr. Sunderland and corresponding meeting dates from 3/15/99 to 6/9/04 provided to NIH by Pfizer
E	Table matching the dates provided by Pfizer to those provided by Dr. Sunderland
F	August 19, 2004 interview with Dr. Trey Sunderland, Chief, Geriatric Psychiatry Branch, NIMH
G	Dr. Sunderland's leave records ▪ 5/1/98-8/31/02 ▪ 8/31/02-9/2/04

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892
www.nih.gov

June 13, 2006

Carol J. Weil, J.D.
Division of Compliance
Compliance Oversight Coordinator
The Tower Building
1101 Wootton Parkway, Suite 200
Rockville, MD 20852

Dear Ms. Weil:

On Wednesday June 7, 2006, I spoke with Dr. Schwetz by phone to give him a preliminary report of the issues addressed in this letter. In keeping with the requirements of the NIH's Federal Wide Assurance (FWA # 00005897) and consistent with the OHRP Guidance on Reporting Incidences to OHRP (issued on May 27, 2005), I am providing a preliminary report in writing.

On June 13 and 14, 2006 the House Committee on Energy and Commerce is holding hearings on "Human Tissue Samples: NIH Research Policies and Practices." The hearings mainly address the research use of coded, stored samples of cerebrospinal fluid (CSF) collected by researchers in the National Institute on Mental Health (NIMH) from research subjects with dementia of the Alzheimer type (DAT), subjects with other neuro-psychiatric illnesses and healthy volunteers. Within the last few weeks, in preparation for the hearings, the IRP has uncovered some research activities that are not consistent with the policies and procedures of its Human Research Protection Program (HRPP). We have not completed our investigation but the current details and corrective actions to date are provided below.

1) The research use by some investigators in the Intramural Research Program (IRP) of coded human specimens and data collected previously under NIH IRB-approved protocols, but without continuing IRB review and approval of ongoing research data analyses.

The IRP's Office of Human Subjects Research (OHSR) reviewed 16 protocols which are among the congressional committee's interests. These 16 NIMH-IRB approved protocols authorized the collection and research use of cerebrospinal fluid from research subjects with DAT, subjects with other neuro-psychiatric illnesses or healthy volunteers. Eleven of the 16 protocols were terminated

(between the years 1993 and 1997) by Principal Investigators after subject enrollment, research-related interventions (including CSF collection) and subject follow up were complete but before completion of the research-related data analyses. Attachment 1 gives the list of these 11 protocols with additional information as requested in the May 2005 OHRP Guidance on Reporting Incidents (II.B). Therefore, the research analyses in these protocols did not receive continuing IRB review and approval.

Also, in its audit activities, OHSR reviewed all of the consent documents associated with these closed protocols to uncover if they could be construed as authorizing the research analyses of CSF for protein biomarkers (which is a main topic of the congressional hearings). The consent language on the research use of the samples was broad. It is a matter of judgment but the more sophisticated recent analyses of CSF protein biomarkers would seem to be in excess of what the patients signed on to. However, different observers could differ on this point. It is fair to say that because no continuing review was obtained of these terminated protocols, the NIMH IRB — which is responsible for assuring that consent language is appropriate – did not have the opportunity to engage in a discussion of what consent language was appropriate.

Action Items: IRP policy is that prospective and continuing NIH IRB review and approval are required when IRP researchers conduct research involving stored identified or coded samples, specimens or data when they can identify the sources. Recent and past actions which clarify and strengthen this policy are:

a) On June 12, 2006 I issued a memorandum accompanied by the revised OHSR Information Sheet #14 entitled "NIH Requirements for Research Use of Stored Human Specimens and Data." Please see Attachments 2 and 3. These documents went sent to all IRP Clinical Protocol Principal Investigators (PIs), Clinical Protocol Associate Investigators (AIs), Clinical, Scientific and Institute Directors, all NIH Principal Investigators, the 14 NIH IRB Chairs and IRB Administrators. My memorandum directs that IRP researchers stop any research activities involving the use of stored identifiable or coded specimens or data that are not consistent with IRP requirements.

b) On June 6, 2006, the Clinical Center's Medical Executive Committee (MEC) amended the NIH form 1195 which accompanies all requests to an NIH IRB for the continuing review of protocols. An action item was added to the revised form that allows the PI to "Renew protocol: enrollment complete; study and data analyses ongoing" (Attachment 4). The form will be in use as soon as it is approved by the CC Director.

c) In November 2005, during routine procedures to update its Information Sheets, OHSR revised its Information Sheet # 9 "Continuing Review of Research Involving Human Subjects" to include procedures for expedited review of

research where the only remaining research activities are limited to data analyses (see OHSR web site at <http://ohsr.od.nih.gov/info/sheet9.html>http://ohsr.od.nih.gov/info/sheet9.html)

2) Failure by an IRP investigator to obtain from OHSR an exemption under the requirements of 45 CFR 46.101(b)(4)

An NIMH PI previously collected samples of CSF under an NIMH IRB-approved protocol. The protocol was terminated and all research-related analyses were complete. The PI provided to another NIMH PI for his research use some of these stored samples in an anonymized manner (they were irreversibly stripped of personal identifiers). The NIMH PI was required to consult with OHSR to obtain an exemption but did not do so.

Action Items: In keeping with 45 CFR 46, NIH policy recognizes that some research involving stored unlinked or unidentified specimens or data may be exempt from the requirement for IRB review and approval. In the IRP, only the OHSR is authorized to determine whether a research activity is exempt.

a) My memorandum and the revised Information Sheet #14 clarify IRP procedures for determining and granting exemptions.

3) Incorrect signatures on some IRB administration forms.

During the review of records associated with 2 of the protocols listed in Attachment 1, incorrect signatures were noted on a few continuing review 1195 forms. The 1195 form includes signature lines for NIH officials including the IRB chair (see attached 1195). The IRB Chair signs the form after IRB approval and after all stipulations have been met. It signifies that the protocol meets the IRB's requirements and that it is ready to go forward to CC Office of Protocol Services. For protocol 91-M-0194, Dr. Trey Sunderland, who was the NIMH IRB Chair at the time, signed on the IRB Chair signature line in 1992, 1995 and 1996. This was incorrect because he was also an Associate Investigator on the protocol. Therefore, an Acting or Vice Chair should have signed on behalf of the Chair. On protocol 94-M-0007, Dr. Sunderland, who was the IRB chair signed on the IRB signature line in 1997. He was the PI of this protocol and he was requesting termination of the protocol.

Action Item: The IRP is currently revising its policies on conflicts of interest of IRB members. We will add language to the NIH IRB Standard Operating Procedures (SOPs) to address this issue. Current NIH IRB Chairs are aware that they are not authorized as Chair to take actions on protocols when they are a Principal or Associate Investigator. At the next meeting of the Human Subjects

Research Advisory Committee (HSRAC), we will discuss this prohibition and the SOP modifications.

I will provide you with updates of our ongoing investigation. Please contact me if you have any questions.

Sincerely,

Michael M. Gottesman, M.D.
Deputy Director for Intramural Research

Attachments

Cc: Dr. Kington
Dr. Wichman
Dr. Gallin

Attachment 1

List of protocols from which CSF fluid were obtained. "T" after a protocol number means Terminated

Protocol Number	IRB Approval Date	Date Protocol Closed	PI Name	Protocol Title
82-M-0171-T	9/29/1982	2/26/1986	Cohen, Robert	Slow Progressive Dementia: A Longitudinal Twin Study
82-M-0191-T	11/23/1982	2/26/1986	Cohen, Robert	The Evaluation Of Mood And The Effect Of L-Deprenyl In Slow Progressive Dementia
85-M-0207-T	12/19/1985	10/27/1994	Sunderland, Trey	The Evaluation And Long-Term Treatment Of Dememtia Of The Alzheimer Type
88-M-0008-T	12/18/1987	4/29/1994	Sunderland, Trey	Combination Drug Therapy In Dementia Of The Alzheimer Type
88-M-0009-T	2/11/1993	3/26/1993	Sunderland, Trey	Combination Pharmacotherapy In Dememtia Of The Alzheimer Type
88-M-0076-T	3/28/1988	5/17/1994	Sunderland, Trey	The Effect Of Trazadone And Buspirone On Behavorial And Cognitive Symptoms In Alzheimer's Disease
88-M-0126-T	6/9/1988	7/23/1993	Sunderland, Trey	Cognitive and Behavioral Effects of Dehyroepiandrosterone
91-M-0194-T	7/18/1991	9/18/1996	Molchan, Susan	The Evaluation of Lithium Treatment in Dementia of the Alzheimer Type, Major Depression, and Age-Matched Controls
94-M-0004-T	10/4/1993	1/14/1996	Sunderland, Trey	Cognitive and Behavioral Effects of Xanthines in Nueorpsychiatric Patients and Controls
94-M-0007-T	9/22/1993	11/7/1997	Sunderland, Trey	A Comparison of the Effects of Tacrine and Dextroamphetamine in Patients with Alzheimer's Disease
90-M-0181-T	6/18/1990	7/22/1997	Rapoport, Judith	Childhood Onset Schizophrenia: Characterization and Treatment with Typical and Atypical Neuroleptics

(6/13/06, OHSR)

Attachment 2

DATE: June 12, 2006

TO: Clinical Research Protocol Principal Investigators
Clinical Research Protocol Associate Investigators
NIH IRB Chairs

FROM: Deputy Director for Intramural Research, NIH

SUBJECT: Research Use of Stored Human Samples, Specimens or Data

This memorandum is to clarify and strengthen the NIH Intramural Research Program's (IRP) requirements for the research use of stored human samples, specimens and data consistent with DHHS requirements. Please review the attached OHSR Information Sheet. It has been updated to clarify these requirements and provides definitions that I use in this memorandum. I want to emphasize the following points:

1) NIH IRB-approved research protocols in which IRP researchers intend to collect and store human specimens or data: All such protocols must include a written description of the intended use of the samples; how they will be stored; how they will be tracked; what will happen to the samples/specimens/data at the completion of the protocol, and what circumstances would prompt the PI to report to the IRB loss or destruction of samples. New protocols should include this information at the time of initial review. For ongoing protocols, this information may be added at the time of the next continuing IRB review.

2) Research involving stored identified or coded samples, specimens or data when IRP investigator can identify the subjects: Such research must receive prospective and continuing NIH IRB review and approval. Continuing IRB review and approval is required as long as research analyses are ongoing. This means that: 1) even after a protocol's subject enrollment and research-related interventions are complete, continuing IRB review and approval are required for ongoing research analyses and, 2) the research use of stored specimens or data collected under now-terminated IRP protocols may occur only with prospective and continuing NIH IRB review and approval.

3) Research involving stored unlinked or unidentified specimens or data: Such research may be exempt from the requirement for IRB review and approval. NIH requirements for obtaining exemptions have not changed. The NIH Office of Human Subjects (OHSR) is authorized to determine whether a research activity is exempt. IRP investigators must submit a formal request to OHSR by completing Form #1 found on the OHSR website at http://ohsr.od.nih.gov/info/info.html.

4) Research collaborations involving sending or receiving stored specimens or data: For discussion of IRP guidelines on research collaborations, please review the

information in The Gray Booklet at http://ohsr.od.nih.gov/guidelines/guidelines.html. Prospective and continuing NIH IRB review and approval is required for research collaborations in which IRP researchers send coded samples (for which they maintain the key) to non-NIH investigator(s). The protocol must identify the names of the collaborating researchers and their affiliated institutions. Before sending the samples, IRP investigators should contact an IC technology development coordinator for guidance on an appropriate NIH transfer agreement. IRP researchers whose collaborations involve the receipt of samples collected and sent by non-NIH researchers from non-NIH subjects should contact OHSR for guidance.

Action Items:

1) All new IRP research activities must fulfill the requirements set forth in this memorandum.

2) IRP researchers are requested to stop research activities involving the use of stored identified or coded specimens or data that are not consistent with the requirements set forth in item 2), above. Please submit to the appropriate NIH IRB, a completed NIH form 1195 along with a written request (i.e., protocol or memorandum) containing the items outlined in Information Sheet #14 (IV. 3). Research may take place after IRB review and approval.

3) IRP investigators whose research activities involving unidentified or unlinked stored specimens or data that are not consistent with the requirements set forth in 3), above should contact OHSR as soon a possible to request an exemption from IRB review.

If you have questions, contact your NIH IRB Chair or OHSR. OHSR is located in Building 10, Room 2C146 and the phone number is 301-402-3444. For questions involving transfer of biological materials into and out of the NIH, please contact your IC technology development coordinator.

Michael M. Gottesman, M.D.

CC: Dr. Gallin
NIH IRB Administrators
NIH Principal Investigators
Institute Directors
Clinical Directors
Scientific Directors

Attachment 3

(Revised: June 12, 2006)

Sheet 14: NIH REQUIREMENTS FOR THE RESEARCH USE OF STORED HUMAN SPECIMENS AND DATA

I. INTRODUCTION

Research often involves the use of stored human specimens or data. Such use obliges research investigators and Institutional Review Boards (IRBs) to consider the rights and welfare of the individuals who provide them, especially when samples retain identifiers or codes. Individuals (sources) who provided specimens or from whom information was obtained in the past are no less deserving of protection than are prospective research subjects. The research use of existing specimens or data without the ability or intent to identify the source may pose little risk to the donors. However, when these sources can be identified, conflicts may arise between their rights and the scientific benefit that can be obtained from studying their stored samples.

This information sheet provides actions that must take place before IRP researchers may use stored specimens or data for research purposes. It is the policy of the NIH's Intramural Research Program (IRP) that prospective and continuing NIH IRB review and approval is required for the research use of stored human samples or data when IRP researchers or members of the research team can identify the sources.

The following definitions, policy and implementation discussion are consistent with the report of the National Bioethics Advisory Commission (NBAC) in August 1999, entitled "Research Involving Human Biological Materials: Ethical Issues and Policy Guidance." (Volume I. Report and Recommendations of the National Bioethics Advisory Commission, Rockville, Maryland, August 1999.), and the requirements of the Office of Human Research Protections (OHRP), DHHS.

II. DEFINITIONS

1) **Human Subject** means a living individual about whom an investigator (whether professional or student) conducting research obtains (a) data through intervention or interaction with the individual, or (b) identifiable private information (45 CFR 46.102(f)). At the NIH, the following research activities are not considered research involving human subjects: the collection and study of (1) samples from deceased individuals; (2) samples taken for diagnostic purposes only; (3) specimens or data that are available from commercial or public repositories or registries; (4) established cell lines that are publicly available to

qualified scientific investigators, and (5) self-sustaining, cell-free derivative preparations including viral isolates or cloned DNA.

2) **Human specimens/samples** include blood and other body fluids, tissues, DNA and other direct derivatives from human tissues.

3) **Human data** include responses to questionnaires or surveys, medical histories, records and diagnoses.

4) **Source** means the individual who provided the sample or from whom data were collected.

5) **Identified** means samples or data that are still attached to a readily available subject identifier such as a name, social security number, address, telephone number, medical record number, etc.

6) **Coded** means that collected samples or data are unidentified for research purposes by use of a random or arbitrary alphanumeric code but the samples may still be linked to their sources through use of a key to the code available to an investigator or collaborator.

7) **Unlinked** means human data or samples that were initially collected with identifiers but, before research use, have been irreversibly stripped of all identifiers by use of an arbitrary or random alphanumeric code and the key to the code is destroyed, thus making it impossible for anyone to link the samples to the sources. This does not preclude linkage with existing clinical, pathological, and demographic information before subject identifiers are removed.

8) **Unidentified** means that the samples or data were collected without identifiers of any kind. Samples or data may retain demographic or diagnostic information and still be considered unidentified if such information cannot be used to reveal the identity of the source.

9) **Exempt research** means research that is exempt from the regulatory requirement for prospective IRB review and approval. This includes "research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects" {45 CFR 46.101(b)(4)}.

III. POLICY

1) The research use of stored identified or coded specimens or data, when IRP researchers can identify the sources, must receive prospective and continuing

NIH IRB review and approval. This includes research protocols where the remaining research activities are limited to data analyses, and 2) the subsequent research use of specimens or data previously collected under now-terminated protocols.

2) The research use of stored coded samples when IRP researchers cannot identify subjects, such as the receipt of coded samples from non-NIH collaborators may or may not require NIH IRB review and approval. Before receiving such samples, IRP researchers must contact OHSR for guidance.

3) The research use of stored, unlinked or unidentified samples may be exempt from the need for prospective IRB review and approval. Exemption requests must be submitted in writing to OHSR. Only OHSR is authorized to determine whether a research activity is exempt.

IV. IMPLEMENTATION

Implementing the NIH requirements for research activities with stored human specimens involves addressing the following issues:

1) Is the proposed research activity "human subjects research"?

Researchers engaged in activities which are not considered research involving human subjects (see Definition 1., above) do not need IRB or OHSR review and approval; however, these activities may be subject to other requirements such as rules governing technology transfer.

For any other research use of human samples, specimens or data, only an NIH IRB or OHSR may make the determination of whether the research involves human subjects. The final responsibility rests with the OHSR.

2) How does an IRP investigator obtain approval to use stored anonymized specimens?

The research use of existing unidentified or unlinked samples or data is generally exempt from the requirement for prospective IRB review and approval. Exemptions are issued only by OHSR and may be sought by completing Form #1, "Request for Review of Research Activity Involving Human Subjects" available from that office or on the OHSR homepage http://ohsr.od.nih.gov/info/info.html. NIH investigators should not make determinations about exemptions without consulting OHSR.

Research involving stored identified or coded samples or data, when IRP investigators can identify the sources, must receive prospective and continuing NIH IRB approval.

3) What points must an NIH IRB consider in reviewing a request for the research use of stored identified or coded specimens or data when an IRP researcher can identify the source?

The investigator must submit a written request (i.e., a memorandum or protocol) to the IRB which includes the following:

a. The nature of the proposed research including a complete description of the samples or data;

b. A justification for retention of the identities or codes of the sources of samples or data, and, in the case of codes, a description of the ease or difficulty with which linkage can be made between the code and the source, and a description of who can make the linkage.

c. A description of the extent to which confidentiality of research data will be maintained;

d. The informed consent document to be utilized, or a request for waiver of informed consent. When research involves stored samples or data previously collected under now-terminated protocols, an important question is whether a consent signed in the collection protocol is sufficient for the proposed research activity. The IRB will pay special attention to requests for waiver of informed consent. In order to waive informed consent, Federal regulations currently require that an IRB must find and document in its minutes that all of the following four conditions have been met:

- the research involves no more than minimal risk;
- the waiver will not adversely affect the rights and welfare of the subjects;
- the research could not practicably be carried out without the waiver; and
- whenever appropriate, the subjects will be provided with additional pertinent information after participation.

e. In those cases where a waiver of informed consent is sought, a statement that a source will not be contacted by anyone connected with the research without prior approval by the IRB.

f. A description of how the samples, specimens and/or data will be stored; how they will be tracked; what will happen to the samples/specimens/data at the completion of the protocol; what circumstances would prompt the PI to report to the IRB loss or destruction of samples.

The IRB will review the research in keeping with the requirements of the NIH Human Research Protection Program (HRPP) and as set forth in the NIH IRP Standard Operating Procedures.

4) What happens after an NIH IRB approves the research?

Continuing IRB review and approval of the research must take place at least annually.

Research protocols that require full IRB review for their initial reviews generally require it for their continuing reviews. The expedited review process may be used when: (1) the protocol is permanently closed to enrollment of new subjects, all subjects have completed all research-related interventions, and the research remains active only for long-term follow-up of subjects; or (2) where no subjects have been enrolled and no additional risks have been identified; or (3) where the remaining research activities are limited to data analyses.

5) What review is necessary for research collaborations involving sending or receiving stored specimens or data?

For discussion of IRP guidelines on research collaborations, please review the information found in The Gray Booklet at http://ohsr.od.nih.gov/guidelines/guidelines.html. Prospective and continuing NIH IRB review and approval is required for research collaborations in which IRP researchers send coded samples (for which they maintain the key) to non-NIH investigator(s). The protocol must identify the names of the collaborating researchers and their affiliated institutions. Before sending the samples, IRP investigators should contact an IC technology development coordinator for guidance on an appropriate NIH transfer agreement. IRP researchers whose collaborations involve the receipt of samples collected and sent by non-NIH researchers from non-NIH subjects should contact OHSR for guidance.

If you have questions, contact your NIH IRB Chair or OHSR. OHSR is located in Building 10, Room 2C146, (p) 301-402-3444 and (fax) 301-402-3443. The web site is <ohsr.od.nih.gov>.

CLINICAL RESEARCH PROTOCOL CONTINUING REVIEW APPLICATION	PROTOCOL NO.	PRINCIPAL INVESTIGATOR (Name, Institute/Branch, Address, Telephone):

PROTOCOL TITLE:

PROTOCOL STATUS:
- ☐ Renew -Recruitment of participants has not yet begun.
- ☐ Renew -Participants are currently being recruited or enrolled.
- ☐ Renew -No longer recruiting or enrolling participants, follow-up only.
- ☐ Renew -Enrollment complete; study and data analyses ongoing.
- ☐ Renew -Clinical Hold/Recruitment or enrollment of participants suspended.
- ☐ Terminate -Study closed. Recruitment and data analysis complete.

SUMMARY OF PROTOCOL ENROLLMENT (Aggregate): *When NIH is the coordinating site, provide enrollment table for each site.

NIH Site	Other Sites	Total	
_____	_____	_____	Accrual ceiling by IRB
_____	_____	_____	Aggregate total reported w/ last CR
_____	_____	_____	New subjects accrued since last CR
_____	_____	_____	Aggregate total accrued*

*(If accrual has been less than expected, discuss in the attached narrative.)

REQUESTED ACCRUAL EXCLUSION (Check all that apply):
- ☐ None
- ☐ Male
- ☐ Female
- ☐ Children <18
- ☐ American Indian/ Alaskan Native
- ☐ Other: _____
- ☐ Asian
- ☐ Black or African American
- ☐ White
- ☐ Hispanic or Latino
- ☐ Native Hawaiian or Pacific Islander

ARE YOU CURRENTLY RECRUITING HEALTHY VOLUNTEERS? ☐ No ☐ Yes

PHASE 3 CLINICAL TRIALS WHICH HAVE COMPLETED RECRUITMENT MUST REPORT SEX, RACIAL/ETHNIC ANALYSIS AS REQUIRED BY THE NIH POLICY AND GUIDELINES ON THE INCLUSION OF WOMEN AND MINORITIES AS SUBJECTS IN CLINICAL RESEARCH.

Have analyses by sex, racial/ethnic subgroups been conducted?
☐ No ☐ Yes (answer a and b)
a. Have analysis been reported? ☐ No (explain in narrative) ☐ Yes
b. Have significant differences been found? ☐ No ☐ Yes

HAVE ANY NON-NIH INVESTIGATORS OR SITES BEEN ADDED SINCE THE LAST REVIEW?
- ☐ No
- ☐ Yes (Identify the persons or sites and describe the collaboration in the summary report)

WITH THIS REVIEW, I AM REQUESTING A CHANGE TO THE FOLLOWING:
PRINCIPAL INVESTIGATOR:
Delete: _____
Add: _____

ASSOCIATE INVESTIGATORS?
☐ No ☐ Yes (Identify in the attached narrative.)

LEAD ASSOCIATE INVESTIGATOR:
Delete: _____
Add: _____

MEDICAL ADVISORY INVESTIGATOR:
Delete: _____
Add: _____

RESEARCH CONTACT:
Delete: _____
Add: _____

IONIZING RADIATION USE (X-rays, e.g., CT; radioisotopes, e.g. PET, etc.):
- ☐ None
- ☐ Medically indicated
- ☐ Research indicated
  - ☐ Research usage HAS NOT changed.
  - ☐ Research usage HAS changed. (Explain in summary report)

INVESTIGATIONAL NEW DRUG/DEVICE: ☐ None ☐ IND ☐ IDE

FDA No. _____
Name: _____
Sponsor: _____
Who is the manufacturer of the above endy? _____

DOES THE PROTOCOL INVOLVE A DRUG/DEVICE/PRODUCT THAT MAY LEAD TO YOU OR THE NIH RECEIVING PAYMENT AND/OR ROYALTIES?
- ☐ No
- ☐ Yes*(Append a statement of disclosure)

HAVE THERE BEEN ANY CHANGES IN THE INFORMED CONSENT PROCESS OR DOCUMENTATION SINCE THE LAST REVIEW?
- ☐ No
- ☐ Yes (Describe in Summary report)

HAS THE NIH IRP COI GUIDE BEEN DISTRIBUTED TO NON-NIH INVESTIGATORS?
- ☐ No
- ☐ Yes

BASED ON THE CRITERIA AT THEIR INSTITUTION, HAS A CONFLICT BEEN REPORTED?
- ☐ No conflicts reported.
- ☐ Yes, conflict(s) reported. Describe in attached narrative.

CONFLICTS OF INTEREST REVIEW?
Date submitted to IC DEC:_____ Date cleared by IC DEC:_____

THE FOLLOWING ELEMENTS ARE REQUIRED IN THE ATTACHED SUMMARY REPORT ALONG WITH THE PROTOCOL, CONSENT DOCUMENT(S) AND SUMMARY OF FDA ANNUAL REPORT, IF APPLICABLE:

1) a brief narrative explaining current progress/finding from the research;
2) a summary of any amendments made to the research protocol since the last CR;
3) the number of subjects accrued, including a demographic table and a description of any changes in the subject population, recruitment or selection criteria;
4) a summary of adverse events and any unanticipated problems involving risks to subjects or others;
5) a summary of subject withdrawals from the research;
6) any reports of complaints about the research since the last IRB review;
7) any relevant multi-center reports;
8) any data and safety monitoring board reports;
9) any information from the literature or from this or similar research that might affect the IRB's evaluation of the risk/benefit analysis of human subjects involved; and
10) reason(s) for continuing the study.

SIGNATURE	Principal Investigator	Print/Type Name	Date	Send to Accountable Investigator
RECOMMENDATION	Accountable Investigator	Print/Type Name	Date	Send to Branch Chief, or CC Dept. Head of Accountable Investigator
	Br Chief/CC Dept. Head of Acct. Invest	Print/Type Name	Date	Send to Clinical Director
APPROVALS	Clinical Director	Print/Type Name	Date	Send to Chair, Institutional Review Board
	Chair, For Institutional Review Board	Print/Type Name	Date Protocol & Consent Approved Effective	Send to Office of Protocol Services, through IRB Protocol Coordinator
COMPLETION	Protocol Specialist	Date		

Tab 12

Summary of information obtained in response to question #8 of the June 20th letter from the Congressional Committee on Energy and Commerce

The indicated study is protocol 91 M 194 "The Evaluation of Lithium Treatment in Dementia of the Alzheimer Type, Major Depression, and Age-Matched Controls." The PI was Susan Molchan and the Branch Chief was Dennis Murphy. At the time of the protocol termination in August of 1996, the total subject accrual was listed as 25 (although see below).

According to the records of Dr. Sunderland, 14 patients with Alzheimer's disease and 12 controls participated in the protocol. With the exception of one control subject studied in 1993, all samples were collected in 1991-1992. Of the 12 controls, only 5 received lumbar punctures under both drug and placebo conditions (the protocol was a double-blind, crossover trial of three weeks of lithium compared with three weeks of placebo). Three of the five controls no longer have CSF available from **both** LPs. Ten of the 14 patient subjects received LPs under both conditions; two of these ten no longer have CSF from **both** LPs available. Reasons for the absence of sufficient sample may include the following: inadequate CSF collected at the time of the LP; use of the sample for assay reruns when equivocal results were obtained; loss of samples due to freezer malfunction. The database does not permit identification of the specific reason for the absence of sample for any of the individual five subjects. The samples sent in response to Dr. Molchan's request, then, included paired CSF on eight Alzheimer's disease patients and two controls. Put another way, of the 30 maximal possible CSF samples in paired LPs (10 AD patients and 5 controls), only 5 are no longer available thirteen years after the samples were collected.

Plasma samples were also obtained on subjects participating in this protocol. Of a total of 44 plasma samples collected as complete pairs on patients and controls, 41 are still available. Thus of a total of 74 CSF and plasma samples collected in pairs thirteen years ago, 66 are still available.

David R. Rubinow, M.D.
Clinical Director, NIMH

(Further details attached.)

Regarding Question # 8 of the request from the Congressional Committee on Energy and Commerce:

Attached please find a letter from Dr. Sunderland to me and a table (with redacted names) showing the numbers of paired CSF and plasma samples on and off lithium collected as part of protocol 91-M-194. The last column identifies the samples that were sent in response to Dr. Molchan's request. Page two of the table identifies the 7 assays for which CSF samples were previously pulled. Finally, please find several papers coauthored by Drs. Molchan and Sunderland that relate to either the lithium or other CSF samples. Please let me know what additional information would be helpful.

David

June 27, 2005

Dear David,

I have reviewed my CV and found that 50 papers were published with Dr. Molchan from 1988 through 1997 while we were both in Dr. Dennis Murphy's Laboratory of Clinical Science. Of these, 50 papers, 2 were directly involved with the Lithium Study (91-M-194) directly, and an additional 6 papers covered topics involved with either these or additional CSF samples from our collection as well as other lithium-related matters. I have attached these papers for your reference and can send them to you by .pdf if you would prefer.

There has been some question about the storage and maintenance of samples in NIH laboratories. Like many labs, our practice has been to immediately freeze our samples in a -70 degree centigrade freezer for later use in research assays. The freezers are monitored by our own staff, and there is an alarm system if there is any electrical or mechanical breakdown. I have personally supervised this process for the past 20 years and have been on call 24 hours a day in case of emergency. While there have been freezer failures during those many years, and some samples have been lost despite the best efforts to avoid such, the system has been quite cost-effective and efficient. Similarly, our sample tracking system is well organized and archival and should compare favorably to any other system used within the NIMH.

Concerning the lithium samples in question, I will point out that they have already been utilized for scientific publications several times in the past; and yet, when approached more than 11 years after the last sample was collected clinically, we were still able to retrieve, identify, label and produce the vast majority of the samples to an off-site investigator within two months. For those who know the normal pace of biological collaborations, this should be recognized as a very rapid pace, especially given the extremely long storage time. Let me also note that these samples were made immediately available for an unanticipated scientific use at the request of a researcher who had taken no interest in or responsibility for these samples in over a decade.

If there are other questions about these samples or our system of storing and tracking biological specimens, I would be happy to discuss them with you. In the meantime, as attachments, I am sending a summary of the available CSF and plasma samples from the Lithium Study (91-M-194) as well as a listing of the other assays that have been performed on this collection of samples in the past.

LITHIUM STUDY: 91-M-194

AD

	NAME:	NIHID:	STUDY:	DATES:	CSF (N/D)	PLASMA (N/D)	CSF SAMPLES SENT:
	AD-paired samples						
1	[redacted]	2432257	Lithium	10/9/1991	2/2	2/2	SM05-20, SM05-05
2	[redacted]	2498091	Lithium	11/24/1992	2/2	1/2	SM05-6, SM05-19
3	[redacted]	2472764	Lithium	9/1/1992	2/2	2/2	SM05-8, SM05-13
4	[redacted]	2161552	Lithium	6/14/1992	2/2	2/2	SM05-10, SM05-1
5	[redacted]	2366629	Lithium	11/17/1991	1/2	2/2	
6	[redacted]	2554355	Lithium	12/30/1992	2/2	2/2	SM05-4, SM05-14
7	[redacted]	2066099	Lithium	1/28/1992	2/2	2/2	SM05-15, SM05-7
8	[redacted]	2409070	Lithium	1/7/1992	2/2	2/2	SM05-17, SM05-9
9	[redacted]	2548355	Lithium	6/18/1992	2/2	2/2	SM05-12, SM05-2
10	[redacted]	2967957	Lithium	10/12/1992	1/2	2/2	
	AD-only one CSF tap during Lithium Study						
1	[redacted]	1945543	Lithium	5/11/1992	only pbo 1/1	2/2	
2	[redacted]	2488073	Lithium	11/1/1992	only pbo 1/1	1/1	
3	[redacted]	2425075	Lithium	2/3/1992	only pbo 1/1	1/2	
	AD-NO CSF done on Lithium Study						
1	[redacted]	2509465	Lithium	4/16/1992	0/0	2/2	

CONTROLS

	NAME:	NIHID:	STUDY:	DATES:	CSF (N/D)	PLASMA (N/D)	CSF SAMPLES SENT:
	CNL-paired samples						
1	[redacted]	2046842	Lithium	9/29/1991	1/2	2/2	
2	[redacted]	2495235	Lithium	12/1/1992	2/2	2/2	SM05-18, SM05-11
3	[redacted]	2087169	Lithium	5/18/1992	1/2	2/2	
4	[redacted]	2288527	Lithium	9/22/1991	1/2	1/1	
5	[redacted]	1955251	Lithium	2/10/1993	2/2	0/0	SM05-3, SM05-16
	CNL-NO CSFparticipation in Lithium Study						
1	[redacted]	2287365	Lithium	1/26/1992	0/0	2/2	
2	[redacted]	2465334	Lithium	2/13/1992	0/0	2/2	
3	[redacted]	2340951	Lithium	3/25/1992	0/0	2/2	
4	[redacted]	1542254	Lithium	10/9/1991	0/0	1/2	
5	[redacted]	1590923	Lithium	10/22/1991	0/0	2/2	
6	[redacted]	1612657	Lithium	9/23/1991	0/0	2/2	
	CNL-didn't complete Study & didn't do CSF Taps						
1	[redacted]	1703626	Lithium	2/7/1992	0/0	1/1	

Paired Sample data give to D.Rubinow 6/24/05

	CSF	Plasma
AD	18/20	24/26
CNL	7/10	17/18

* N/D= number available in June05/number acquired during Lithium 1991-1993

	Lithium Study 1991-1993 CSF ASSAYS- for PAIRED SAMPLES						
	MHPG	HVA	V HIAA	SLI	AB 40	AB 42	TAU
AD	20/20	20/20	20/20	19/20	20/20	20/20	20/20
CNL	10/10	10/10	10/10	10/10	10/10	10/10	10/10
AD Patients							
1	[redacted]						
2	[redacted]						
3	[redacted]						
4	[redacted]						
5	[redacted]						
6	[redacted]						
7	[redacted]						
8	[redacted]						
9	[redacted]						
10	[redacted]						
CNL Patients							
1	[redacted]						
2	[redacted]						
3	[redacted]						
4	[redacted]						
5	[redacted]						

Tab 13

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Trey Sunderland, M.D., Chief,
Geriatric Psychiatry Branch
National Institute of Mental Health
CRC 10/2-5360, MSC 1274
Bethesda, Maryland 20892
301-496-0948

December 21, 2004

Dear Friends in the Family Study,

It is with both excitement and some sadness that I write to inform you that I will soon be leaving the NIMH to start a research program as a Professor at the Albert Einstein School of Medicine in New York. The excitement arises from the great opportunity to continue and expand the best of what we have started together in the Family Study in a new environment. However, with that excitement comes sadness, as this move will bring much change and the end of an era for the Geriatric Psychiatry Branch.

Over twenty years ago, I came to the NIMH to begin a research fellowship with an interest in Geriatric Psychiatry. Together with Robert Cohen and others, we soon started the first of many studies of Alzheimer's disease. Specifically, we initiated a small descriptive study of identical and fraternal twins with and without the illness. Since then, the research group has grown steadily, and we have developed diverse research projects including treatment studies, pharmacologic challenge tests to understand some of the deficits associated with memory loss, brain imaging studies and biologic marker studies in groups of normal controls, elderly depressives and Alzheimer patients. In all, we have published more than 250 scientific papers during that time and have helped lead the field in several key areas.

One of the Geriatric Psychiatry Branch's most important developments over the last 20 years has been the ongoing BIOCARD family study in which you are currently a participant along with over 350 other individuals. This longitudinal study has very important scientific implications, and it is our top priority to foster its survival and expansion. In the short term, the study will remain at the NIMH after my departure to New York City, but the plans are for the Geriatric Psychiatry Branch to eventually close over the next year, probably by September of 2005.

As for the future of the study, my intention is to invite you to continue our work in the New York area. The new research site will be the Litwin-Zucker Center for Alzheimer's Disease and Memory Disorders at the North Shore-Long Island Jewish Health System. The Center is in Great Neck, NY, a part of Long Island that is

convenient to LaGuardia airport and downtown New York City. For those of you who cannot visit us in New York, we are also trying to establish an alternative clinical outpost in the Washington, D.C. metropolitan area, but those details are not yet finalized. We will contact you directly as soon as more information is available.

Any time a program changes dramatically or moves locations, there is bound to be significant disruption. In discussing this transition, I do not want to minimize the inconveniences associated with the move, either for you as participants or the many staff members whose lives are affected by this change. However, I want to emphasize that we will do everything possible to maintain and even improve upon the quality of research care you have experienced to date. As we have mentioned at the annual gathering each year in December,[1] this study represents an ongoing collaboration. We want that collaboration to continue and grow, and we will do everything necessary to make that possible.

There are a few practical details that you might like to review and keep handy with this letter as a reference. First, the study will continue at the NIMH for the next 6-8 months, and our telephone numbers are unchanged (George Chang: 301-435-6058, Administrative Staff: 301-496-0948; Imaging Program: 301-435-6059). Second, Robert Cohen, M.D., Ph.D. will lead the research group in my absence, and David Rubinow, M.D., the NIMH Clinical Director, will serve as the administrative back-up for Dr. Cohen. Third, the previously announced PET imaging collaboration with the University of Pittsburgh will proceed as planned, and a subgroup of approximately 20 subjects in your group will soon be contacted separately to consider participation in that study.

Finally, I would be remiss if I did not say how strongly I feel about your participation in the family study and the staff that make it possible. We have all created a family study together, but we have also created a family atmosphere that is quite unusual in the world of research. In moving the center of the study to the New York City area, I will try my best to recreate that atmosphere, but I realize that some individuals will not be able to make the transition. For those individuals, we will make every effort to keep you involved by phone. In the meantime, you should know that I am most grateful for everything that you and the staff have contributed over the years.

Thank you for all of your support. I look forward to our new challenges together and hope that you will be willing to make that transition with us.

---

[1] If you would like to have a DVD or VHS tape of this year's lecture (December 1, 2004), they are now available through George Chang, D.O. (301-435-6058).

Sincerely yours,

Trey Sunderland, M.D

Los Angeles Times

July 16, 2006 Sunday
Home Edition

A TIMES INVESTIGATION; Drug Trials With a Dose of Doubt; A National Institutes of Health researcher with ties to pharmaceutical firms helped test their new medications. Some scientists questioned the results of the studies.

BYLINE: David Willman, Times Staff Writer

SECTION: MAIN NEWS; National Desk; Part A; Pg. 1

LENGTH: 5932 words

DATELINE: BETHESDA, Md.

On Jan. 10, 2001, pharmaceutical giant Merck & Co. gathered its forces in a hotel conference room here with a clear-cut mission: Win a favorable vote for a new antifungal drug from a federal advisory committee -- a victory that would position the product for swift government approval and for hundreds of millions of dollars in sales.

But after hours of speeches and slides, the committee members, appointed by the U.S. Food and Drug Administration, had yet to vote. The members were focused on the quality of Merck's case for the new drug, which rested on the treatment of only 69 patients.

Merck summoned to the microphone one of its announced consultants, a man whose government job was nearby, at the National Institutes of Health. Dr. Thomas J. Walsh assured the committee that Merck's data describing the patients was "extremely robust and very, very rigorous." He said his government staff had assisted in vetting the company's data. About 30% of the patients were helped by the drug, he said.

The advisory committee voted unanimously to endorse the drug, called Cancidas. Sixteen days later, the FDA approved it. Doctors would later prescribe it for patients whose immune systems had been ravaged by chemotherapy and who were presumed to have a potentially deadly, invasive fungal infection. In its first five years on the U.S. market, Cancidas would generate $859 million in sales for Merck.

U.S. law generally prohibits a federal employee from representing an outside party before a government agency.

In building a career as an influential government scientist, Walsh has served as both a paid and unpaid advisor to pharmaceutical companies and has helped lead clinical trials that tested the effectiveness of their products. With his help, the companies have brought new antifungal drugs to market, but controversy has flared over whether results from two of the studies were misleading and whether some of the participating patients received adequate treatment.

In written comments for this article, Walsh said his advice to industry did not conflict with his position at the NIH's National Cancer Institute, or affect his scientific judgment.

"I am not and have never been a representative of, or advocate for, any pharmaceutical company," Walsh said.

Two drug makers involved with his federal research, Merck and Pfizer Inc., said they have paid fees to Walsh. Merck and another company, Fujisawa USA Inc., have made financial or other donations to support Walsh's federal research with the approval of his NIH superiors, interviews and government records show.

From 1997 to 2003, Walsh appeared at meetings with FDA committees or staff alongside representatives of Pfizer, Fujisawa and Merck, according to videotapes, transcripts and other government records. He also helped design, oversee

and interpret the results of major clinical studies of four antifungal drugs made by those companies. The studies helped win FDA approvals for three of the drugs.

In separate letters to a leading medical journal, other researchers criticized two of those studies. They questioned whether the studies artificially boosted the new products by comparing them to drugs that were given at doses that were too low.

More patients died who took the "comparator" drugs than those who got the new products.

Walsh, in journal articles and in remarks to medical leaders, noted the disparities in deaths while describing the advantages of the newer drugs. In published responses to the scientific critics, he said the doses of the comparator drugs reflected the general standard of care at the participating hospitals.

What led to the higher death rates of the control-group patients in the two major studies may never be known: A limited number of autopsies were performed, and factors other than fungal infections, such as the patients' cancer, could have caused the deaths.

No published study has established that a higher dose of an antifungal drug is more effective in treating suspected infection, and some studies have suggested that lower dosing may provide similar benefits. But the possibility that patients did not receive adequate doses, combined with Walsh's advisory role with the drug companies, adds a new dimension to the furor over NIH scientists' ties to industry.

Earlier revelations of the agency scientists' outside arrangements called into question their impartiality and the independence of the NIH, the nation's largest agency for experimental medical research, prompting congressional hearings, policy reforms and ethics investigations.

However, even as the NIH moved recently to ban some of the activities with industry, the agency's director said the arrangements had apparently not jeopardized patients in clinical studies.

"Thus far, we have not identified any situations where patients were harmed as the result of financial arrangements NIH employees had with outside parties," NIH Director Elias A. Zerhouni told a Senate subcommittee in 2004. "I will, however, reserve final judgment until all internal and external reviews are completed."

In response to questions from The Times regarding Walsh, Zerhouni responded generally in a prepared statement. "We revamped our rules last year, and continue to carry out a vigorous program of education, oversight and enforcement," he said, adding, "Violations of the ethics rules are unacceptable, and I remain determined to pursue any information brought to my attention."

Walsh, 54, heads a medical research and treatment unit within the pediatric branch of the National Cancer Institute, where he arrived in 1986. He said that collaborating with companies has been fundamental to his government work.

"My efforts are in service of the public interest in sound, reliable science concerning potentially effective agents for the treatment of life-threatening infections in children and adults with cancer," Walsh said in a statement to The Times. "This mission frequently includes collaboration with companies that research and develop new compounds in this area -- for example, utilizing my [staff's] expertise to ensure that clinical trials relating to these compounds are designed and implemented in a manner that elicits reliable and useful results."

He said he has appeared before the FDA only "as a government scientist providing information and/or evaluation" regarding clinical trials. Referring to studies he helped lead, Walsh said, "There is no conflict of interest, and the trials were well and appropriately designed."

The full extent of Walsh's ties with industry is not open to view by outsiders. His yearly financial-activity reports at the NIH are exempt from release under the Freedom of Information Act, as are the reports for most senior researchers at the agency.

None of Walsh's outside arrangements were listed in records that the NIH turned over to a congressional committee that had sought details of connections between agency scientists and the drug industry.

Although Walsh declined to answer a number of questions about his financial arrangements with the drug companies for this article, he said in a telephone conversation on May 18: "On the personal issues, I've made mistakes."

Walsh also said he preferred to let colleagues address questions regarding the dosages selected for the two major studies he helped design. Two private lawyers representing him, H. Bradford Glassman and Jeffrey D. Robinson, noted

in a letter to The Times that the dosages were chosen with the assent of other researchers, and not by Walsh, individually.

Walsh is well-known in his field, having written or cowritten more than 230 medical journal articles over the last decade. A medical graduate of Johns Hopkins University in Baltimore, he has won honors within the NIH as a mentor, receiving the agency's Distinguished Clinical Teacher Award. In 1996, he received an Outstanding Service Medal from the U.S. Public Health Service for "sustained and outstanding advances in the treatment, prevention and diagnosis of invasive fungal infection in children with cancer and HIV infection."

Three of Walsh's superiors at the National Cancer Institute contacted The Times by e-mail and defended as scientifically sound the two major studies that he helped lead. The officials noted that the designs of both studies were reviewed and approved by the FDA and by boards at the medical sites where patients were treated. Dosages for one of the studies, they wrote, were selected based on a consensus of participating researchers.

Eight doctors, including seven who participated in one or the other major study with Walsh and who are not employed by the NIH, also contacted the newspaper and said they stood behind the validity of the research. The study designs, they said, "were both scientifically and medically sound, reflect the state of the art in the field, and have advanced supportive care, improving the management of patients worldwide and saving lives."

Other researchers have said that doses of comparator drugs that are inadequate may endanger patients or make a new drug look more effective than it is.

"I can see why the companies are eager to get an easy comparison, a drug they can beat," said Dr. Curt D. Furberg, who formerly headed clinical research at the NIH's National Heart, Lung, and Blood Institute. "But for [scientific] investigators to go along with that, it's just a bad practice."

Picking the Patients

From the late 1950s to today, the drug of choice for many doctors treating potentially lethal fungal infections has been a powerful compound called amphotericin B.

Nurses and doctors have long dubbed the drug, derived from spores found in Venezuela's Orinoco River region, "ampho-terrible." Some patients tremble violently as the solution, infused intravenously, courses through their bodies. Fever and vomiting also can result. In some cases, the drug can cause fatal kidney damage.

Approved by the FDA in 1958, amphotericin gained greater acceptance in the United States in the 1980s after research conducted in Europe and at the National Cancer Institute suggested that the drug decreased patients' vulnerability to an internal fungal infection.

For decades, amphotericin has been available worldwide in relatively cheap, generic formulations. By the early 1990s, several firms were aiming to modify it into their own brand-name products -- agents that they hoped would be better and that could fetch far higher prices. The new products would deliver the amphotericin in fatty mixtures, changing the characteristics of the drug to reduce the risk of kidney damage.

The modified amphotericin products would cost as much as $800 a day, compared with about $16 per day for the older drug.

In order to get their reformulated drugs approved by the FDA, the companies had to conduct human studies. The FDA held two public meetings, in 1994 and 1995, to hear experts' opinions regarding design standards for the studies.

The FDA was under pressure to cooperate more closely with the pharmaceutical industry. Amid complaints that existing standards had stymied the development of new drugs, the agency had been directed by Congress and the White House to streamline its medical reviews.

For makers of the new antifungal drugs, less burdensome clinical-study standards could make it easier to get the products approved. For instance, some companies wanted to enroll cancer patients with suspected -- but unproven -- fungal infections. These would be patients who had abnormally low levels of infection-fighting white blood cells and fevers lasting at least four days, despite treatment with a standard antibiotic.

Walsh has stressed the need for treating suspected infections quickly, noting that persistent fever may be the only sign and that delaying treatment could lead to increased deaths. As envisioned by Walsh and others developing the new products, the drugs would be assessed on several factors, including whether the patients' fevers abated.

Some cancer and infectious-disease specialists questioned that approach. Every enrolled patient would have a fever, but would its disappearance mean that the drug had defeated a fungal infection?

Noting that fever can have many causes, the specialists stressed the importance of studying patients with proven, as opposed to suspected, infections. Eliminating fever in the patients with proven infections, they said, would provide better evidence of effectiveness.

But at the 1995 FDA meeting, Walsh said enrolling and treating more of the patients with proven fungal infections would pose "financial and logistical limitations," meaning the major studies would take longer and cost more. He estimated that it would take years to identify and enroll a sufficient number of patients with proven infections.

"I think it is appropriate to have a relatively low frequency of the proven infections," Walsh said.

Walsh also told the FDA committee it was essential to launch separate studies that would more directly examine a drug's effect on specific fungal infections.

The FDA accepted the approach of designing the major studies to enroll and treat patients with persistent fevers who had suspected but unproven infections. An FDA medical officer, Dr. Teresa Wu, said the approach "largely was motivated by" the ease of enrolling such patients.

Roughly half the patients would get new drugs, made by companies that helped pay for the research. The remaining "control" patients would get dosages of an older, comparator drug.

The choice of dose might determine patients' survival: If the dose of the comparator drug in the first study, amphotericin, was insufficient, patients could be left more vulnerable to an infection invading the lungs or other organs.

One of the fungal infections, aspergillus, typically kills 50% or more of the patients who develop it. And it is notoriously difficult to diagnose: Because the patients are so sick, doctors often are reluctant to collect a sample of lung tissue, which might confirm an underlying infection. Aspergillus often cannot be confirmed before autopsy.

Yet if the dose were set too high, patients, including those who turned out not to have a fungal infection, would be put at greater risk of kidney damage.

Walsh did not commit to an exact dosage of amphotericin at the 1995 FDA meeting. He did, however, say that a drug used in the new studies would need to be powerful enough to treat aspergillus or other devastating mold-type fungal infections, not just yeast-type fungal infections, such as candida, which are lethal less often and are commonly treated with lower doses. Since the early 1990s, experts in the U.S. and Europe had reported increases in the frequency of aspergillus.

"If we are really trying to protect the high-risk patients," he said, "we have to appreciate that there are more than just yeasts that we are trying to prevent or to impact upon."

Disputed Results

The first major study that Walsh helped lead compared one of the new, modified drugs, AmBisome, with conventional amphotericin.

The study was paid for by the developer of the new drug, Fujisawa USA Inc., and by a grant from the NIH. Walsh had conferred about the study design with Fujisawa and with a national network of other physicians who would carry out the project.

The dosage for patients who would be given amphotericin was 0.6 milligram per kilogram of body weight, daily.

One expert invited by the FDA advisory committee, Dr. John H. Rex of the University of Texas Medical School at Houston, said in April 1995 that the dosage in such a study "probably, actually, should be higher." Asked if he favored the higher dosage even for the yeast-based fungal infections, Rex added: "The general feeling is ... somewhere between 0.6 and 1 is the correct dose."

Walsh had foreshadowed concern about using low-dose amphotericin for suspected aspergillus. In a 1990 article published by Seminars in Oncology, Walsh and a colleague wrote: "When Aspergillus pneumonia is suspected or proven, higher doses of amphotericin B (1 to 1.5 mg/kg/d as opposed to the standard 0.5 mg/kg/d used in other infections) are indicated to optimize successful outcome."

A TIMES INVESTIGATION; Drug Trials With a Dose of Doubt; A National Institutes of Health researcher with ties to pharmaceutical firms helped test their new medications. Some scientists questioned the results of the studies. Los Angeles Times July 16, 2006 Sunday

A dose of 0.6 milligram per kilogram of body weight, daily, for patients with suspected but unproven infections "obviously is not sufficient against" aspergillus, Walsh and his co-authors wrote in a 1991 article published by Reviews of Infectious Diseases.

In the AmBisome study, Walsh supported using the 0.6-milligram dosage. Walsh had told the FDA committee in 1995, without referring to the ongoing study with Fujisawa, that he preferred "flexibility in dosage." This would allow increases if a patient faltered. He said that "some experimental data" suggested that higher doses of conventional amphotericin might be more effective.

The study treated 687 patients: 343 with AmBisome, at 3 milligrams per kilogram of body weight, daily; and 344 with conventional amphotericin, at 0.6 milligram.

The patients, treated at sites throughout the United States and ranging in age from 2 to 80, were enrolled within 16 months, at what Walsh later called "a remarkably rapid rate." He also would describe the patients as a "very high-risk population," vulnerable to fungal infections.

Of the patients given conventional amphotericin, 36, or 10.5%, died. Of patients given Fujisawa's drug, 25, or 7.3%, died.

Those who oversaw the treatments concluded that fungal infection was the primary or contributing cause of death for 11 who received conventional amphotericin and for four treated with the Fujisawa drug. The remaining deaths were attributed to other causes.

On July 16, 1997, Walsh anchored Fujisawa's presentation of AmBisome to the FDA advisory committee, which met in Silver Spring, Md. The FDA's agenda listed Walsh as part of the "Fujisawa USA Presentation."

Fujisawa's vice president for regulatory affairs, Jerry Johnson, told the FDA committee: "Our presentation will conclude with Dr. Walsh presenting the key results from the U.S. study."

Walsh narrated a series of slides and told the committee that AmBisome "was more effective in preventing proven invasive fungal infections and fungal-infection-related deaths" than conventional amphotericin.

Within hours, the advisory committee voted unanimously in support of the new drug.

On Aug. 11, 1997, the FDA approved AmBisome for treating presumed fungal infections in children and adults. The dose approved by the FDA -- 3 milligrams per kilogram of body weight, daily -- was the same as that used in the study.

The next month, Walsh told a conference of physicians and research scientists in Toronto that AmBisome was "the first agent shown to be superior to amphotericin B in reducing proven, invasive fungal infections in cancer patients." AmBisome, he said, was "a new standard" in treatment. Within days, Fujisawa began marketing AmBisome in the U.S.

In the FDA's final review of the new drug, statistician Thomas Hammerstrom wrote that although AmBisome was similar in effectiveness to amphotericin, there were "inadequate scientific grounds" to judge it superior.

In March 1999, Walsh appeared as the lead author of an article in the New England Journal of Medicine that reported detailed results from the study that had compared AmBisome with amphotericin. The article said the drug dosages were "deliberated upon and adopted by consensus of the investigators" who conducted the study.

Physician-researchers from Germany questioned the design of the study in a letter to the journal seven months later.

"We think that the design of this randomized trial was not adequate because the dose of conventional amphotericin B (0.6 mg per kilogram of body weight per day) that was used does not reflect widely used standards of care," wrote Drs. Thomas Fischer, Gudula Heussel and Christoph Huber of Johannes Gutenberg University. "Most institutions in Europe and the United States would agree that treatment of this patient population requires a dose of at least 1 mg."

The physicians said it seemed "very likely" that if Walsh and his collaborators had used a "normal," higher dose of conventional amphotericin, fewer patients who took that drug would have had fungal infections emerge or progress. (Fischer declined to be interviewed for this article; he said by e-mail that AmBisome had proved to be a useful drug.)

Skepticism about the dose of conventional amphotericin used by Walsh also was reflected in a 2001 medical reference book issued by the British Society for Haematology and other groups. The authors said that conventional amphotericin had been given to similar patients in Europe at doses up to twice as high as in the study that Walsh helped lead.

The lower dose, the authors wrote, "may bias the results in the favour of AmBisome" and "could entirely explain the differences observed."

Fujisawa had agreed to allow doctors conducting the study to double the dose of either drug, depending on patients' conditions. But doctors ultimately increased the dose for 17% of the patients who took amphotericin -- while doses were increased for 34% of the patients who took AmBisome. The New England Journal of Medicine report cowritten by Walsh described the study as "blinded," so that neither the doctors nor their patients were supposed to know which of the two drugs was being administered.

Walsh and two colleagues, in a reply published by the journal, said the dose of amphotericin reflected "the standards of care" at the participating research centers. Walsh also suggested that the toxicity of amphotericin had prevented the administration of "appropriate doses" to some patients.

The three officials who wrote to The Times on Walsh's behalf, including Robert H. Wiltrout, a research director at the National Cancer Institute, defended the dose of conventional amphotericin.

"There is no rational motivation for an investigator or sponsoring company to design a trial with a control arm that is not standard of care," wrote Wiltrout, along with Drs. Lee J. Helman and Frank Balis of the National Cancer Institute.

As Walsh defended his study in the New England Journal of Medicine, he was helping write new medical-practice guidelines suggesting far higher doses for some patients.

In a paper submitted for publication in October 1999, Walsh and other authors said that, following prompt and aggressive evaluations of the patients, doctors should consider "maximum tolerated doses" of conventional amphotericin if aspergillus infection, specifically, was suspected. They defined those doses as 1 to 1.5 milligrams per kilogram of body weight, daily.

Standing With Merck

By 1999, Walsh was collaborating with Merck & Co., on its new antifungal drug, Cancidas. One Wall Street firm predicted that Cancidas could generate annual sales of $330 million. But first Merck needed FDA approval.

AmBisome, the same drug that Walsh had just helped guide to FDA approval, was picked as the comparator.

Merck paid for the study. Walsh designed it in collaboration with Merck and one other researcher, who received fees from Merck. The initial dose selected for AmBisome -- 3 milligrams per kilogram of body weight, daily -- was the same as in the earlier study.

In a statement delivered to The Times last week, Walsh said "there was and is no evidence" that higher dosages of AmBisome would offer better effectiveness.

Previously, Walsh supported higher doses of AmBisome for patients with aspergillus.

At the 1997 conference in Toronto, Walsh said that a lower dose might suffice for a yeast-type infection. But for aspergillus or for other mold infections that resist treatment, he said, "I would submit that we probably should be using more.... There are good experimental data to show that more is better."

When choosing a dose, Walsh added, "I think it depends on what disease one is treating."

At a September 1999 conference in San Francisco, Walsh, along with Fujisawa's medical director and several other scientists, described having used AmBisome doses from 7.5 to 15 milligrams per kilogram of body weight per day in patients with possible, probable and proven infections.

A summary of their research said the high dosages "are safe, well-tolerated, and can provide effective therapy for aspergillosis" and similar infections. (Two years later, their full-length article on the study repeated that conclusion but also said the study did not have enough patients to prove which dosages worked best.)

At a symposium to discuss the treatment of aspergillus infections last October in San Francisco, Walsh was asked by a physician which maximum dose of AmBisome he recommended.

"Certainly, we want to think that more is better," Walsh replied, adding that while results from clinical trials did not support using more than 5 milligrams per kilogram of body weight, daily, there were data, based on safety and drug concentration in the blood, suggesting a benefit at 7.5 to 10 milligrams.

A TIMES INVESTIGATION; Drug Trials With a Dose of Doubt; A National Institutes of Health researcher with ties to pharmaceutical firms helped test their new medications. Some scientists questioned the results of the studies. Los Angeles Times July 16, 2006 Sunday

From January 2000 through August 2002, 116 hospitals and clinics worldwide carried out the study of Cancidas.

The 1,095 patients with suspected fungal infections received either Cancidas or AmBisome. The patients ranged in age from 16 to 83.

At around the same time, Merck persuaded the FDA to conduct a fast-track review of Cancidas for a more narrow use: treating aspergillus in patients who had either not tolerated or failed to improve while taking another antifungal drug.

On Jan. 10, 2001, representatives of Merck -- assisted by Walsh -- presented the company's case for approval of the drug to the FDA advisory committee in Bethesda.

Walsh, in his statement to The Times, said: "I did not appear as a consultant to Merck."

But that is how Merck identified him to the FDA committee, both orally and in a slide.

Tamara Goodrow, a Merck regulatory affairs official, said: "Merck has brought several consultants to the meeting today so that they are available to facilitate the advisory committee's discussion and deliberations." Goodrow then named the consultants, including "Dr. Thomas Walsh."

Another Merck official said Walsh served as the head of a company committee of three researchers who assessed how patients with aspergillus infections had responded to treatment with Cancidas in the smaller company study.

Several members of the FDA advisory committee voiced concern about the validity of the small study involving 69 patients. They pointed out that it lacked a "control" group of patients treated at the same time to gauge the comparative effectiveness of Merck's drug.

They questioned whether the study proved that Cancidas provided patients with a measurable benefit.

At that point, a videotape of the meeting shows, Merck's senior director of clinical research, Dr. Carole A. Sable, gestured to the audience and said: "Perhaps Dr. Walsh, who is actually the head of our expert panel, would like to make a comment."

Walsh strode to the podium, took the microphone and assured the FDA committee that Merck's case-by-case information for the 69 patients was reliable. "I think this was really the largest and most robust set of data that we've ever had on individuals," Walsh said. He said his "whole section" of NIH government scientists had assisted him in reviewing Merck's data.

A member of the FDA committee, biostatistician William Blackwelder, asked Walsh if he was "confident" that the patients with worsening aspergillus infections had benefited from Merck's drug. "Yes, indeed," Walsh concluded.

The committee endorsed the approval of Cancidas for treating patients with aspergillus who had not responded to other drugs. On Jan. 26, 2001, the FDA approved Merck's application to market it for that narrow use, although doctors were at liberty to prescribe Cancidas as they saw fit.

A Merck spokesman said recently that Walsh was paid a total of $3,000 in fees, in 1999 and 2001, not related to his involvement with the company's drug. Walsh said in his statement to The Times that Merck had not paid him for any appearance before the FDA.

U.S. conflict of interest law generally prohibits a federal employee from representing anyone before a government agency, regardless of whether outside compensation is paid.

"Outwardly, it looks like it could be a problem," said John M. Treacy, who formerly directed operations of the FDA's advisory committees.

Meanwhile, Merck's hopes for wider use of Cancidas -- in patients with presumed but unproven fungal infections -- rested with the large international study that continued through late 2002.

The results were published in the New England Journal of Medicine on Sept. 30, 2004, with Walsh listed first among the authors. Patients who were given AmBisome as a comparator fared somewhat worse than those who got Merck's Cancidas: Of the 539 patients given AmBisome, 75, or 13.9%, died. Of 556 patients given Merck's drug, 61, or 11%, died.

A TIMES INVESTIGATION; Drug Trials With a Dose of Doubt; A National Institutes of Health researcher with ties to pharmaceutical firms helped test their new medications. Some scientists questioned the results of the studies. Los Angeles Times July 16, 2006 Sunday

A sharper contrast was reported among 24 patients described as having an aspergillus infection: 11 of the 12 given the older drug died or were otherwise not treated successfully, compared with seven of the 12 patients who got Merck's drug.

Walsh and his co-authors, who included four Merck employees, noted the differences in their journal article: Among the patients with "baseline" fungal infections, "the rate of death during the study was lower in the [Cancidas] group." Overall, they said, Cancidas offered "improved survival."

On Sept. 29, 2004, the FDA approved Merck's application to market Cancidas for treating patients with presumed fungal infections. On Dec. 8, 2004, a Merck executive told stock-fund managers that the approval could "give us a great opportunity to increase sales in 2005."

A month later, Dr. Francisco Marty, a specialist from Brigham and Women's Hospital in Boston who also is an instructor at Harvard Medical School, voiced concern about the Walsh-led study in a letter published in the New England Journal of Medicine.

Patients with early fungal infections who were given AmBisome "may have received suboptimal doses of that drug at a time when frontloading of therapy is critical to gain control of the infection," Marty and a colleague wrote.

Although the initial dose selected for AmBisome was the same as in the earlier major study, Marty's letter pointed out a distinction:

In the newer study, the dose was not supposed to be increased until a patient had received treatment for five days on the original dose -- and had continued to deteriorate. (A patient also could be removed from the study and treated differently at the discretion of the physician.)

In an interview at his Boston office, Marty said that the patients whose infections were found early in the Merck study and who were given the lower dose of AmBisome may have been put at a disadvantage.

"You have a bad infection and you don't get enough drug, you may be dead," Marty said. He noted that the medical-practice guidelines -- cowritten by Walsh -- suggested a dose of 5 milligrams per kilogram of body weight for aspergillus.

For those patients, Marty said, "you're not doing a good job with 3 milligrams."

Other doctors who wrote to the New England Journal of Medicine raised questions. An unusually low percentage of patients in the AmBisome group responded favorably to treatment, wrote Dr. Dimitrios P. Kontoyiannis and a colleague from the University of Texas M.D. Anderson Cancer Center in Houston.

In reply, Walsh wrote in the journal that various groups had advocated both higher and lower dosages of AmBisome. The use of 3 milligrams per kilogram of body weight per day, he and two co-authors wrote in January 2005, was "the most tenable initial dosing strategy."

Walsh, responding to questions for this article, said that the five-day provision in the second study was intended to standardize the conditions for increasing the dosages. He said the provision was approved by consensus of the participating institutions on the belief that it would not put patients at added risk.

In his statement last week, Walsh pointed to results from a recently completed study, suggesting that a 3-milligram dosage of AmBisome was about as effective against aspergillus as was a 10-milligram dosage.

The points made on his behalf recently by his superiors and by other letter signers, Walsh said, "conclusively refute any possible contention that the two clinical trials violated a standard of care or otherwise called for inappropriate dosages of antifungal medications."

A 2005 book, "Fungal Infections in the Immunocompromised Patient," written for doctors caring for patients most at risk, concluded that "much controversy still surrounds the optimal timing, dosage and duration of therapy" for patients with the suspected infections.

Furberg, the former NIH clinical research specialist, said the two major antifungal studies fell short because they left unanswered which drug or dose was best against suspected infections.

"When you set up studies with controversial comparisons, you risk misleading everybody -- regulatory agencies, physicians and patients," said Furberg, now a professor at Wake Forest University.

Times researcher Janet Lundblad in Los Angeles contributed to this report.

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A deadly fungus

Dr. Thomas J. Walsh has led major studies that helped bring new antifungal drugs to market. One fungus, aspergillus, is widely found indoors and outside. It can cause deadly infections in people with compromised immune systems, such as those who have undergone cancer or AIDS treatment or bone marrow or organ transplants.

Aspergillus

Where found: Widely distributed in soil, household dust and damp building materials.

Structure: Microscopic stalks topped with spores called conidia; as they grow they form a mass of fungus fibers.

*

Infections

Aspergillus can spread rapidly through the lungs and often to the brain and kidneys.

Symptoms: Fever, chills, shock, delirium.

Results: Kidney and liver failure can occur, with death resulting quickly.

*

Inside the body

The infections often appear in the lungs as a mass of fungus fibers, blood clots and white blood cells. The fungus grows, destroying lung tissue.

*

Sources: Centers for Disease Control and Prevention, Merck & Co., Medline Plus

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Drug studies

Dr. Thomas J. Walsh of the National Cancer Institute helped design and lead major clinical studies of drugs that treat potentially lethal fungal infections. The studies supported FDA approval of the drugs, made by companies that helped pay for the research. When the results of two of the studies were published, other doctors questioned whether dosage levels were high enough for drugs used as comparators.

AmBisome

(liposomal amphotericin B)

Company: Fujisawa USA Inc.

When patients were enrolled and treated: January 1995 to May 1996

Comparison drug: amphotericin B (conventional amphotericin)

Number of patients: AmBisome, 343; amphotericin, 344

Daily dosage: AmBisome,

3 milligrams per kilogram of body weight; amphotericin,

0.6 milligram

Deaths in each group: AmBisome 25; amphotericin 36

Cost per daily dose: AmBisome $800; amphotericin $16 *

FDA approval: Aug. 11, 1997

Total U.S. sales: Exceeded $665 million through 2005

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Cancidas

(caspofungin)

Company: Merck & Co.

When patients were enrolled and treated: January 2000 to

August 2002

Comparison drug: AmBisome (liposomal amphotericin B)

Number of patients: Cancidas, 556; AmBisome, 539

Daily dosage: Cancidas,

50 milligrams per kilogram of body weight; AmBisome, 3 milligrams

Deaths in each group: Cancidas 61; AmBisome 75

Cost per daily dose: Cancidas $395; AmBisome $800 *

FDA approval: Jan. 26, 2001; for expanded use, Sept. 29, 2004

Total U.S. sales: Exceeded $859 million through 2005

* Costs per daily dose are approximate and have varied by year.

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Sources: New England Journal of Medicine; IMS Health; Credit Suisse; U.S. Food and Drug Administration; Times reporting

LOAD-DATE: July 16, 2006

LANGUAGE: ENGLISH

GRAPHIC: GRAPHIC: A deadly fungus CREDIT: Los Angeles Times GRAPHIC: Questionable role CREDIT: Los Angeles Times PHOTO: 'Thus far, we have not identified any situations where patients were harmed as the result of financial arrangements NIH employees had with outside parties. I will, however, reserve final judgment until all internal and external reviews are completed.' Dr. Elias A. Zerhouni NIH director, speaking to a Senate subcommittee in 2004 PHOTOGRAPHER: JIM WATSON AFP/Getty Images PHOTO: Appearing with Merck: Dr. Thomas J. Walsh of the National Cancer Institute arrives at the dais of a U.S. Food and Drug Administration advisory committee meeting in January 2001 after being called upon by Merck & Co.'s senior director of clinical research, Dr. Carole A. Sable. Walsh, introduced earlier as a Merck consultant, vouched for the company's data. The committee unanimously recommended approval of Merck's antifungal drug. PHOTOGRAPHER: Courtesy of FDC Reports PHOTO: 'I can see why the companies are eager to get an easy comparison, a drug they can beat. But for [scientific] investigators to go along with that, it's just a bad practice.' Dr. Curt D. Furberg, former head of clinical research at NIH's Heart, Lung, and Blood Institute PHOTOGRAPHER: Wake Forest University PHOTO: 'There is no rational motivation for an investigator or sponsoring company to design a trial with a control arm that is not standard of care.' Dr. Lee J. Helman (above), Dr. Frank Balis And Robert H. Wiltrout National Cancer Institute officials, in a letter to the Times PHOTOGRAPHER: National Cancer Institute

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A TIMES INVESTIGATION; Drug Trials With a Dose of Doubt; A National Institutes of Health researcher with ties to pharmaceutical firms helped test their new medications. Some scientists questioned the results of the studies. Los Angeles Times July 16, 2006 Sunday

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Ethics probe thwarts researcher's retirement

BY JAMIE TALAN
STAFF WRITER

March 22, 2005, 4:59 PM EST

Dr. Trey Sunderland is in an unlikely position: He wants to leave his job, but he can't.

After almost a quarter century conducting clinical research on Alzheimer's disease, Sunderland is at the center of a federal investigation into potential conflicts of interest at the National Institutes of Health. His lawyer insists Sunderland has done no wrong, that he was open with the agency about his consulting arrangement with the pharmaceutical industry, and that the only thing at issue is whether Sunderland submitted accurate paperwork.

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But last month, when NIH officials said the agency's investigation had found no evidence of wrongdoing in most of the cases under investigation, Sunderland's was one of dozens left open.

Sunderland, the branch chief for geriatric psychiatry at the National Institute of Mental Health, decided to leave in November because of the controversy. He put in his retirement papers and accepted the top position at the new Alzheimer's Research Center at the North Shore-Long Island Jewish Health System. But just weeks before he was set to start the new job, his retirement was denied by NIH deputy director Dr. Raynard S. Kington. The reason, according to Kington's letter to Health and Human Service officials: The investigation into potential conflicts of interest isn't complete.

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Bio, bibliography on Dr. Trey Sunderland

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Dr. Trey Sunderland

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Sunderland's position is part of the Public Health Service Commissioned Corps, one of the seven Uniformed Services; officers with between 20 and 30 years of service can't quit without approval from the director of the agency.

Last summer, Sunderland's name emerged along with those of 120 other federal scientists during congressional hearings. At issue was money and research -- and whether they had intersected in an unethical manner when federal scientists received payment from the pharmaceutical and biotech industries for after-hours consulting. The practice began in the mid-1990s, when then-NIH director Harold Varmus encouraged such collaboration. Similar arrangements are commonplace in universities and medical centers.

But current NIH director Dr. Elias A. Zerhouni responded to last summer's hearings by banning federal scientists from such arrangements. The ban took effect in February.

Congressional investigators found that Sunderland had received almost $500,000 in consulting fees and travel expenses over a 10-year period from Pfizer and other drug companies without submitting the required forms to NIH.

Health and Human Services spokesman Bill Pierce said that he could not speak about any individual case, but "one of the things that can impede retirement is an ethical cloud that's unresolved."

Sunderland has refused requests for an interview until the investigation is complete. His lawyer, Bob Muse of Stein, Mitchell and Mezines in Washington, D.C., said the issue centers on work done at the geriatric psychiatry branch of NIH in cooperation with Pfizer, which makes the Alzheimer's drug Aricept. Federal researchers were letting Pfizer scientists analyze spinal fluid samples obtained in a federal study.

Sunderland, who has been following at-risk patients for years in an effort to identify biomarkers for Alzheimer's, was doing consulting work for Pfizer during the same period.

Muse said that NIH officials had signed off on the arrangement, even after Sunderland reminded them of his consulting arrangements. He said Sunderland may be guilty of "bad housekeeping," because the paperwork he submitted to NIH didn't match up to the money he made. Rep. James C. Greenwood (R-Pa.) used Sunderland as an example of the potential for conflict and cited the absence of information on Sunderland's financial disclosure reports as required by federal ethics rules.

Sunderland runs clinical trials for experimental drugs, but has never studied a Pfizer drug, according to Muse, who said his client has been cooperating with federal investigators for eight months.

The story of Trey Sunderland bespeaks a growing concern in the research world. More than half of all scientists in universities throughout the country have done consulting work for industry, according to a study in the Journal of the American Medical Association.

Varmus, now the president of Memorial Sloan-Kettering Cancer Center, said in an interview in November that "it is quite important to intramural scientists who want the stimulation of interactions with industry and have a lot to offer, and not to feel they are less ethical for doing the same thing as other scientists (outside of NIH)." He did not return repeated telephone calls placed in recent weeks.

His retirement denied, Sunderland is stuck in limbo. He's already notified the patients in his studies that the research work will continue on Long Island. He travels to LIJ on his own time several times a week. He will co-direct the research center with Dr. Peter

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Davies, a top Alzheimer's scientist at Albert Einstein College of Medicine in the Bronx, where Sunderland will also have an appointment.

Sunderland was a favorite at medical meetings because of his intellect and boyish charm, his colleagues at NIMH said. In July, Zerhouni, the NIH director, made "special mention" of Sunderland's research during an advisory council meeting, according to a memo from Dr. Thomas Insel, Sunderland's boss and director of the NIMH intramural program.

Like Sunderland, many scientists have hired attorneys to iron out the conflict of interest issues. Zerhouni said that he could not comment on any of the investigations under way, but did say that "all of these issues came from the very relaxed rules set into place in 1995 ... We want to recover what we had for 100 years before that: Full integrity."

NIH's Kington said that the federal ban on consulting would not prevent scientists from collaborating with industry on NIH time, but no money would change hands.

Muse insists his client did nothing unethical. "At no time did Dr. Sunderland have any authority or influence in the awarding of any grants to Pfizer or any other pharmaceutical company," he wrote in a letter to Zerhouni.

Several other top NIH scientists have left the federal health agency since last summer, including two lab chiefs at NIMH, Dr. Michael Brownstein and Dr. Dennis Charney. Insiders say that many scientists are actively looking for jobs. "Morale has never been lower," said one branch chief. Zerhouni said that the agency will review its ability to recruit and retain employees with the new ban in place.

Meanwhile, Sunderland's lab at NIH has closed, and it's not clear whether clinical research on Alzheimer's will continue at the mental health institute, scientists there say.

"It's unfortunate that this is happening to such a fine man and an outstanding scientist," said Dr. John Kane, director of The Zucker Hillside Hospital, part of the North Shore health system. Kane, who offered Sunderland the job, defended the importance of collaborations with industry. "We need to preserve the ability of scientists to interact with industry," he said.

Kane said that officials at North Shore have no qualms about the investigation into Sunderland's activities.

"We are waiting for him," he said.

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TREY SUNDERLAND

Born and raised in Baltimore, Maryland, I went to Harvard as an undergraduate to study psychology. My special interest has always been in geriatrics. I then studied medicine at the George Washington University School of Medicine before doing a medical internship at Beth Israel Hospital in Boston. My residency was in psychiatry at Harvard's McLean Hospital in Belmont, Massachusetts where I further pursued my interest in geriatric psychiatry.

I went on to do a research fellowship in psychopharmacology at the National Institute of Mental Health. It was there that I started a research program in Alzheimer's disease and geriatric depression. Over the next twenty years, I was able to build my interests from small individual studies to the widely recognized and respected Geriatric Psychiatry Branch.

I am currently a member of many national organizations and was recently President of the Society of Biological Psychiatry besides serving on editorial boards for multiple scientific journals and as a regular reviewer for many others. From 1990-2000, I was Chair of the Institutional Review Board for the National Institutes of Health during a time of much change at the National Institute of Mental Health. I was also Chair of the Medical Advisory Board for the Washington, D.C. Alzheimer Association for many years, and I have published over 250 scientific papers in national and international journals. I am co-author of Aging and Mental Health with Robert N. Butler and Myrna Lewis.

I recently moved to the LIJ/Hillside/North Shore hospital system as the first recipient of the Litwin-Zucker Chair of Geriatric Psychiatry. I am currently the Director of the Litwin-Zucker Center for the Study of Memory Disorders and Alzheimer's disease along with the Scientific Director, Peter Davies, Ph.D., and my current studies focus on the longitudinal follow-up of older subjects and the use of biomarkers to help establish an early diagnosis of Alzheimer's disease. Early diagnostic strategies will employ genetic markers, structural and functional brain imaging, cognitive testing, blood tests and cerebrospinal fluid measures. It is hypothesized that these biomarkers will generate an early "fingerprint" of Alzheimer's disease. I am also interested in innovative treatment trials for early Alzheimer patients. The idea is that if the diagnosis can be made years before symptoms of memory disorder are evident, perhaps there are treatment strategies that might help delay or even prevent the first symptoms of this devastating illness. Together with the basic science of Dr. Peter Davies, we hope to quickly create a world-class research center within the LIJ/Hillside/North Shore hospital system.

Tab 17

UNDER THE MICROSCOPE

North Shore-LIJ Recruits Nation's Leading Alzheimer's Researchers

GREAT NECK — In a move that will position it as a national leader in Alzheimer's disease research, the North Shore-Long Island Jewish (LIJ) Health System recently recruited the National Institute of Mental Health's chief of geriatric psychiatry and the Albert Einstein College of Medicine's top Alzheimer's researcher.

Trey Sunderland, MD, and Peter Davies, PhD, will lead the health system's new Litwin-Zucker Center for the Study of Memory Disorders and Alzheimer's Disease. The center, located at 225 Community Drive in Great Neck, will focus on both clinical investigation and laboratory research to advance the understanding and treatment of Alzheimer's. As the population ages, the number of individuals with Alzheimer's could triple or quadruple in the next 50 years, according to the New York State Department of Health.

Trey Sunderland, MD

"Through the leadership of Trey Sunderland and Peter Davies, the Litwin-Zucker Center for the Study of Memory Disorders and Alzheimer's Disease will bring vital, cutting-edge research on this debilitating disease to the residents of Long Island and New York City, which ultimately will benefit people all around the globe," said John Kane, MD, vice president of behavioral health services for the North Shore-LIJ Health System and chairman of psychiatry at The Zucker Hillside Hospital.

Dr. Sunderland comes to North Shore-LIJ after a 23-year career in Alzheimer's research at the National Institute of Mental Health, part of the National Institutes of Health, in Bethesda, MD. There, he started a long-term study of the evolution of memory dysfunction to better understand risk factors for Alzheimer's disease and identify individuals who are destined to eventually develop it. He will serve as the director of the Litwin-Zucker Center, where he will continue to build the population in this long-term study to gain greater insights. His current emphasis is on identifying biological markers that predict the disease before it even develops.

Peter Davies, PhD

Dr. Davies moved to New York from Scotland in 1977 to join the faculty of the Department of Pathology at the Albert Einstein College of Medicine. A decade later he was named the college's Judith and Burton P. Resnick Professor of Alzheimer's Disease Research. In his research over the past few decades, Dr. Davies has identified several clues to what contributes to the development of the disease. He has also developed chemical compounds that may counter some of these processes. Dr. Davies will serve as the center's scientific director.

— *Christina Verni*

Scientists Find Schizophrenia Genes in Unrelated People

GLEN OAKS — Psychiatric researchers at The Zucker Hillside Hospital campus of the Institute for Medical Research, in collaboration with scientists at the National Institutes of Health (NIH) and Harvard Medical School, have identified two genes that contribute to schizophrenia in a large group of unrelated individuals from Long Island and New York City. Doctors have known for a century that the illness runs in families, but only recently had European researchers begun to link specific genes to schizophrenia by studying the genetic blueprint of related individuals. This is the first time the genes have been linked with the disease in unrelated people.

The findings were published in two seperate studies in the November issue of *American Journal of Human Genetics*. Both studies were led by Anil Malhotra, MD, associate investigator with the Institute for Medical Research and director of psychiatry research at The Zucker Hillside Hospital.

In one study, the Zucker Hillside/Harvard team looked at the DNA of about 1,100 unrelated individuals and found that specific variations in one of the genes increased risk for schizophrenia in whites and Hispanics. The gene was not associated with an increase in risk in the African-American sample. In the other study, the Zucker Hillside/NIH team looked at the DNA of almost 600 unrelated whites and found specific variations in another gene located elsewhere in the genetic blueprint that contributes to schizophrenia and two other common psychiatric disorders — bipolar disorder and schizoaffective disorder.

Doctor's Discovery May Help Patients Breathe Easier

NEW HYDE PARK — Long Island Jewish Medical Center pulmonologist Boris Medarov, MD, recently discovered that breathing, too, has a biological clock.

Anyone who has traveled has experienced jet lag — that groggy realization that while your day is beginning in New York, the night you just left in Los Angeles is hardly over. Jet lag is an inconvenient reminder that the body is set to a 24-hour clock, known by scientists as circadian rhythms, from the Latin *circa dies*: "about one day." An internal biological clock is fundamental to all living organisms, influencing sleep and wakefulness, metabolism, body temperature and now, breathing.

Dr. Medarov looked at more than 4,800 lung function tests performed throughout the day's nine typical "working" hours (8 a.m. to 5 p.m.) over a five-year period from almost 4,000 patients, including healthy individuals and patients with lung diseases such as asthma. He discovered that lung function was worst at noon and peaked at the end of the workday between 4 and 5 p.m.

Circadian rhythms of lung function may have implications for various medical and recreational activities. Some asthma patients may be able to use less medicine if they concentrate their doses at those times of day when they are needed most. Removing breathing tubes from patients who are being weaned from a respirator may be better tolerated if done in the late afternoon when the lungs are strongest. Because there was a 15- to 20-percent rise in lung function in the four hours following noon, Dr. Medarov said patients may achieve optimal performance during exercise or other physical activities in the late afternoon, especially if they have asthma. Dr. Medarov added that healthy people who have strong lungs would hardly notice the difference.

NURSING MISSION

continued from page 7

Patricia Whelan, RN, Receives Wholeness of Life Award

"A phenomenal nurse, a true-blue friend, a dedicated North Shore employee and a wonderful, beautiful, generous woman."

MANHASSET — Those words were used by a supervisor to describe Patricia Whelan, assistant director of patient care services at North Shore University Hospital (NSUH). Ms. Whelan recently received the Wholeness of Life Award from the HealthCare Chaplaincy. This organization provides pastoral care, education and research to its partner institutions, including North Shore.

The award is given to patient care professionals who in treatment of patients, their loved ones and staff colleagues demonstrate respect for human beings as whole persons; practice healthcare with an appreciation for the interrelated functioning of body, mind and spirit; realize and model the importance of promoting team work among various disciplines; and embody a substantial degree of wholeness in striving for a balance of physical, mental and spiritual well-being.

Patricia Whelan, assistant director of patient care services at North Shore University Hospital.

Ms. Whelan's citation states, in part: "You stand out as a leader — inspiring others to strive for excellence. The team you have built on 6 Tower loves your wit and watchful eye that will not let a good job go unnoticed. Your high expectations are as renowned as your ability to reach out with words or a hug."

Ms. Whelan has been with NSUH for 34 years.

New Employee Input Survey

continued from page 1

North Shore-LIJ facilities to work with administrative leaders in developing action plans to address employee concerns.

Facility leaders implemented a range of different solutions, including the construction of a cafeteria at Forest Hills Hospital for staff and visitors. A new café is scheduled to open in the coming months. While they differed from facility to facility, most of the action plans focused on improving communications with administrators, making managers more accountable, implementing employee recognition programs, giving employees more opportunities to share ideas and improving the physical work environment.

"The upcoming survey is part of an ongoing effort to improve our workplaces," Mr. Dowling said. "We want to hear from employees on what we can do differently to help them do their jobs better. All feedback, whether it be negative or positive, is extremely valuable."

Tab 18

The American Society of Clinical Psychopharmacology, Inc.

The National Institute of Mental Health

&

The Zucker Hillside Hospital
North Shore-Long Island Jewish Health System

present

A Workshop on Clinical Trials in Psychopharmacology

Tuesday, April 25 – Thursday, April 27, 2006

The New York Hilton
New York, NY

Course Director
John M. Kane, MD

2006 WORKSHOP

Background:

This course on psychopharmacological clinical trials is co-sponsored by The American Society of Clinical Psychopharmacology, Inc., The National Institute of Mental Health and the Zucker Hillside Hospital. It is intended for physicians, PhDs, and other interested researchers in the pharmaceutical industry, clinical research organizations, foundations, governmental agencies or academic settings who are involved in psychopharmacology clinical trials and CNS drug development.

The program focuses on the general problems and challenges of designing and implementing clinical trials with an emphasis on methodology. Topics include trial design, diagnosis, clinical assessment, patient ascertainment, and recruitment. It will also review recent developments in psychotropic drug research and ethical issues in the conduct of clinical trials. The organization of the course includes didactic sessions, discussion and interactive workshops.

PROGRAM

TUESDAY, APRIL 25, 2006

8:15 a.m. – 8:45 a.m.	Registration & Continental Breakfast
8:45 a.m. – 9:00 a.m.	Welcome and Introduction *John M. Kane, The Zucker Hillside Hospital*
9:00 a.m. – 11:00 a.m.	Panel Discussion on the Design, Conduct and Implementation of Clinical Trials *Thomas Laughren, FDA* *Matthew Rudorfer, NIMH* *Bill Potter, Merck*
11:00 a.m. – 11:15 a.m.	Coffee Break
11:15 a.m. – 12:00 p.m.	Why Clinical Trials Fail *John Kane, The Zucker Hillside Hospital*
12:00 p.m. – 1:00 p.m.	Lunch (on your own)
1:00 p.m. – 1:45 p.m.	Diagnostic Assessment and Methodology Issues in the Development of Antidepressants and Mood Stabilizers *William Z. Potter, Merck* *Craig Mallinckrodt, Lilly* *Andrew Nierenberg, Massachusetts General Hospital*
2:00 p.m. – 3:00 p.m.	Placebo Response in Clinical Trials *William Z. Potter, Merck* *Craig Mallinckrodt, Lilly* *John Kane, The Zucker Hillside Hospital*
3:00 p.m. – 4:30 p.m.	Workshop on Designing Clinical Trials, Antidepressants and Mood Stabilizers
4:30 p.m. – 5:30 p.m.	Panel Discussion: Drug Development in Affective Disorders *William Z. Potter, Merck* *Andrew Nierenberg, Massachusetts General Hospital* *Craig Mallinckrodt, Lilly*

WEDNESDAY, APRIL 26, 2006:

8:30 a.m. – 9:00 a.m.	Registration & Continental Breakfast
9:00 a.m. – 9:45 a.m.	The Role of Large Simple Trials *Robert Reynolds, Pfizer*
9:45 a.m. – 10:30 a.m.	Biostatistics *Eugene Laska, NYU School of Medicine*
10:30 a.m. – 10:45 a.m.	Discussion
10:45 a.m. – 11:00 a.m.	Coffee Break
11:00 a.m. – 12:00 p.m.	Ethics, Informed Consent, Patient Ascertainment and Recruitment *Donald Rosenstein, NIMH*
12:00 p.m. – 1:00 p.m.	Lunch (on your own)
1:00 p.m. – 2:00 p.m.	Diagnostic Assessment and Methodologic Issues in the Development of Antipsychotic Drugs *Bruce Kinon, Lilly* *John Kane, The Zucker Hillside Hospital*
2:00 p.m. – 3:30 p.m.	Workshop on Designing Clinical Trials: Antipsychotics
3:30 p.m. – 4:15 p.m.	Panel Discussion: Antipsychotic Drug Development *Bruce Kinon, Lilly* *John Kane, The Zucker Hillside Hospital*

THURSDAY, APRIL 27, 2006:

8:00 a.m. – 8:30 a.m.	Registration & Continental Breakfast
8:30 a.m. – 9:30 a.m.	Diagnostic and Assessment Issues in Pediatric Psychopharmacology *John March, Duke University* *Joseph DeVeaugh-Geiss, Duke University*
9:30 a.m. – 10:00 a.m.	Coffee Break
10:00 a.m. – 11:00 a.m.	Workshop on Designing Clinical Trials in Pediatric Psychopharmacology
11:00 a.m. – 11:45 a.m.	Panel Discussion: Drug Development in Pediatric Indications *Drs. March & DeVeaugh*
11:45 a.m. – 1:00 p.m.	Lunch (on your own)
1:00 p.m. – 2:00 p.m.	Diagnostic, Assessment and Methodologic Issues in Geriatric Psychopharmacology *Trey Sunderland, NIMH* *Robert Lasser, Janssen*
2:00 p.m. – 3:00 p.m.	Workshop on Designing Clinical Trials in Geriatric Psychopharmacology
3:00 p.m. – 3:45 p.m.	Panel Discussion: Drug Development in Geriatric Indications *Drs. Sunderland & Lasser*

LOCATION

The New York Hilton
1335 Avenue of the Americas
New York, NY
212-586-7000

Any questions concerning this course should be directed to:
Dr. John Kane
(718) 470-8141.

2004 HIGHLIGHTS (CONTINUED)

The prevention and treatment of Alzheimer's disease is the personal crusade of Leonard Litwin (left) and Donald Zucker (right). Longtime supporters Associate Trustee Leonard Litwin and Trustee Donald Zucker have spent decades devoting personal energy and resources to a myriad of important health system initiatives.

Together, Mr. Litwin and Mr. Zucker have created The Litwin-Zucker Research Center for the Study of Alzheimer's Disease and Memory Disorders with a gift of $10 million. Two of the nation's leading experts, Peter Davies, PhD, and Trey Sunderland, MD, will oversee research to advance the understanding and treatment of Alzheimer's. The center serves as a hub for research and related clinical services, including educational and supportive programs and clinical referrals for research participants and their families. By supplying the means to create such a research center, Mr. Litwin and Mr. Zucker's generosity and dedication will help bring cutting-edge research to the community and potentially help the estimated 4.5 million Americans who are affected by this disease.

For more than a decade, Susan and Herman Merinoff have been loyal supporters of the North Shore-Long Island Jewish Health System. They have been true philanthropists, generous with their time, spirit and resources. In 2004, Mr. Merinoff, a trustee, became the new chairman of the board of the Institute for Medical Research. He has been an active board member since the Institute was founded in the late 1990s. The Merinoffs recently gave a $5 million gift to the Center for Patient-Oriented Research, which is an important resource in the discovery and diagnosis of human diseases as well as the development of new treatments. The Center also houses the General Clinical Research Center where investigators can develop new ideas into practicality, bridging the gap between basic research and clinical patient care. In honor of their benevolence and continuing commitment to the health system, the Center has been named The Susan and Herman Merinoff Center for Patient-Oriented Research.

[redacted]
Tab 20

06/26/06 VOUCHER | Voucher: TR188591-1V1
PAGE 1 ** Read Privacy Act On Last Page ** | TA Num: A150607

) NAME: SUNDERLAND, PEARSON . EIN: 001-00-75074

ADDR: ADDRESS NOT AVAILABLE
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PHONE:
MAIL CD:
ORG: HN76V00000C
TITLE:
SEC CLR:
CARD: CARDHOLDER

DUTY: Bethesda,MD TZ: 0
RES: ,
HOURS: 8

2) FROM	TO	TA NUMBER	TA DATE	TRIP PURPOSE	TRIP TYPE
12/09/2005	12/16/2005	A150607	01/09/2006	Domestic Travel	SINGLE TRIP

3) GTR/TICKET NO	VALUE	CR	CLS	DATE	FROM	TO
TBD 1	1352.60		ECO		IAD-Washing	KOA-Kona,

4) ACCT CLASS CODE	TRIP 3	TRIP 2	TRIP 1
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109909.1.2151 CONFERENCE ATTENDANCE - D.1832.853.853.103.12/ 09/2005..PROJECTS			
			450.00
9909.1.252W TUITION & REG FEES VIA A-.1832.853.853.103.12/ 9/2005..PROJECTS			

5) FINANCE OFFICE

6) NON-REIMBURSABLE EXPENSES ---------- 1,376.10
TOTAL AMOUNT CLAIMED ---------- 2520.41
ADVANCE OUTSTANDING ----- 0.00
ADVANCE APPLIED --------- 0.00 0.00

NET TO TRAVELER (GOVT) ---------- 2520.41

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(11) ITINERARY AND TRANSPORTATION EXPENSES - TRIP NO 1

DATE	TIME	DEPARTED/ARRIVED LOCATIONS	MODE	COST	DESCRIPTION
12/09/2005					
		D-RES: ,			
12/09/2005			AIR	1352.60 *	Airline Flight
12/09/2005					
		A-ISLE OF HAWAII: OTHER,HI			
12/09/2005			CAB	45.00	Taxi
12/09/2005			TMC	23.50 *	TMC Service Fees
12/16/2005					
		D-ISLE OF HAWAII: OTHER,HI			
12/16/2005			CAB	45.00	Taxi
12/16/2005					
		A RES: ,			
12/16/2005			RENT	153.13	Rental Car
12/16/2005			FUEL	9.54	Gas-Rental/Govt Car
		TOTAL TRANSPORTATION EXPENSES		1628.77	

(12) SUBSISTENCE AND OTHER REIMBURSABLE EXPENSES

DATE	ACTUAL LODGING	LODGING ALLOWED	MEALS B L D	M&IE ALLOW	P-DIEM RATE	OTHER EXPENSES	AMOUNT
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	ACTUAL LDG:	0.00					
12/09						Registration Fees	450.00
12/10	195.00	195.00		92.00	150/92		0.00
	ACTUAL LDG:	195.00					
12/11	195.00	195.00		92.00	150/92		0.00
	ACTUAL LDG:	195.00					
12/12	195.00	195.00		92.00	150/92		0.00
	ACTUAL LDG:	195.00					
12/13	195.00	195.00		92.00	150/92		0.00
	ACTUAL LDG:	195.00					
12/14	195.00	195.00		92.00	150/92		0.00
	ACTUAL LDG:	195.00					
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12/15						Domestic Lodging Tax	40.60
12/15						Miscellaneous Expense	41.44
12/15						Domestic Lodging Tax	70.70
12/16	0.00	0.00		69.00	150/92		0.00
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(13) COMMENTS:
avel pending avail.of funds; approved as official duty 10/21/05. Request for
AEA for housing in conf. hotel: 1. Selection:Hilton Waikoloa Village@group ra

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===(13)COMMENTS (Cont'd):==========
te $195; 2. Vista Waikoloa@$214, 0.7 mi away; 3. ResortQuest Waikoloa Colony V
'llas@$195, 0.2 mi away, and 4.Outrigger Fairway Villas@$186, 4.7 mi away, but
not avail (gooked 12/15-05-2/15/06).Cost impact: Gov't standard lodging $150/
nightx6=900; AEA request rate@$195/nightx6=$1,170, diff=$270. Justification: N
o lodging avail at less costly accommodations w/out incurring xtra cost of tax
i/shuttle for daily excursions to and from meeting.
Official Duty approved 10/21/2005. No lodging claim for 12/9/05.

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* Expense not claimed for reimbursement.

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TRIP:	0	DATE: 01/09/2006	TIME: 10:32AM	ADJUSTOR:	EILEEN M NEFF
TRIP:	0	DATE: 01/09/2006	TIME: 3:06PM	ADJUSTOR:	SHEILA M JOHNSON
TRIP:	0	DATE: 12/30/2005	TIME: 11:14AM	ADJUSTOR:	EILEEN M NEFF
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TRIP:	0	DATE: 01/09/2006	TIME: 3:06PM	ADJUSTOR:	SHEILA M JOHNSON

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ACCT CLASS CODE			TRIP 1
COMCARRIER-G-			1,352.60
LODGING-O-			975.00
M&IE-O-			690.00
MISC EXP-O-			41.44
OTHER-O-			111.30
TMC FEES-G-			23.50
TRANSPORT-O-			252.67
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/2005..PROJECTS

REG FEES-O-			450.00
2	0.00	0.00	450.00

Organization: HN76000000C
109909.8337647.1.252W TUITION & REG FEES VIA A-.1832.853.853.103.12/09
/2005..PROJECTS

SPLIT PAY DISBURSEMENTS:

TOTAL EXPENSES		3,896.51
NON-REIMBURSABLE EXPENSES		1,376.10
TOTAL AMOUNT CLAIMED		2,520.41
GOV'T ADVANCE OUTSTANDING --	0.00	
GOV'T ADVANCE APPLIED ------	0.00	
		0.00
NET TO TRAVELER (GOVT)		2,520.41
GOV'T CHARGE CARD EXPENSES -	0.00	
GOV'T CHARGE CARD ATM ADV --	0.00	
ADD'L GOV'T CHARGE CARD PYMT	0.00	
TOTAL GOV'T CHARGE CARD AMT	0.00	
PAY TO GOV'T CHARGE CARD		0.00
PAY TO TRAVELER		2,520.41

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		DATE	DESCRIPTION	COST
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[]	5.	12/09/2005AIR	Airline Flight	1,352.60
[]	6.	12/09/2005	Registration Fees	450.00
[]	7.	12/09/2005TO 12/16/2005	Lodging Expenses	975.00

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STATUS	DATE	TIME	SIGNATURE NAME	TELEPHONE
CREATED	12/20/2005	5:10PM	DOROTHY M DRAKE	301 496 1338
REPARED	12/20/2005	5:29PM	DOROTHY M DRAKE	301 496 1338
REPARED	12/29/2005	3:27PM	DOROTHY M DRAKE	301 496 1338
ERTIFIED	12/29/2005	4:31PM	PEARSON SUNDERLAND	301 496 0948
ADJUSTED	12/30/2005	11:14AM	EILEEN M NEFF	301 496 4271
ADJUSTED	01/09/2006	10:32AM	EILEEN M NEFF	301 496 4271
REVIEWED	01/09/2006	10:36AM	EILEEN M NEFF	301 496 4271
ADJUSTED	01/09/2006	3:06PM	SHEILA M JOHNSON	301 594 8071
APPROVED	01/09/2006	3:07PM	SHEILA M JOHNSON	301 594 8071

I certify that the electronic signatures listed above are valid and on file.

SIGNED DATE

05 8212 0275

PASSENGER TICKET AND BAGGAGE CHECK

SUBJECT TO CONDITIONS OF CONTRACT

ISSUED BY

[redacted] A.R.C. DATE OF ISSUE 6DEC05 PASSENGER RECEIPT 1 OF 1 88022

[redacted] INC. CARRIER 5880/DBAYSE / 0DBABM ISSUE US

[redacted] TRAVEL ROCKVIL/ROCKVILLE MD ISS. OFF. CODE A21790156

NAME OF PASSENGER SUNDERLAND/PEARSON FARE BASIS TOUR CODE

FROM **NOT VALID FOR******RETAIN THIS RECEIPT*** CLASS/DATE TIME RES. INVALID AFTER

TO **TRANSPORTATION***THROUGHOUT YOUR JOURNEY* REVALIDATION

ENDORSEMENTS/RESTRICTIONS

ORIGINAL ISSUE

ISSUED IN EXCHANGE FOR

PNR CODE JNR68U /1V

CONJ. TKT. NO.

FARE CALCULATION

9DEC WAS UA LAX 164.65YCAIAD UA KOA 09.30 725.78BUAS UA LAX 239.93WDG UA WAS 136.74V(

AIAD USD1276.40END ZPIADLAXKOALAX XT 12.80ZP 10.00AY 16.50XFIAD4.5LAX4.5KOA3LAX4.5

FARE USD1276.40 EQUIV. FARE PAID FORM OF PAYMENT BAXXXXXXXXXXXX4543 EXP1205/ 028013

TAX/FEE/CHARGE US36.90 PCS. CK. WT. UNCK. WT. ********** SEQ. NO. ALLOW. PCS. CK. WT. UNCK. WT.

TAX/FEE/CHARGE XT39.30 STOCK CONTROL NUMBER TX DOCUMENT NUMBER

TAX/FEE/CHARGE 88936687494454 0 016 1544550692 0

TOTAL USD1352.60

B3D NIHSTAF 467 38921

IAD 5

LAX UA 193 Y 09DECYCAIAD

KOA UA 67 B 09DECBUAS

LAX UA 50 W 15DECWDG

IAD UA 204 V 15DECVCAIAD

TO

CARRIER/FLIGHT CLASS/DATE TIME

GATE BOARD TIME SEAT SMOKE

ADDITIONAL SEAT INFORMATION

PCS. CK. WT. UNCK. WT. SEQ. NO. PCS. CK. WT. UNCK. WT.

BAGGAGE ID. NO. NOT VALID FOR TRAVEL

DOCUMENT NUMBER 016 1544550692 0

IT IS UNLAWFUL TO PURCHASE OR RESELL THIS TICKET FROM/TO ANY ENTITY OTHER THAN THE ISSUING CARRIER OR ITS AUTHORIZED AGENTS.

Approved 1/9/06 SMJ

Sunderland

Document Summary for Voucher TR188591-1V1

Quick Tip
For specific information, click on a Details link. You can sign and stamp your document from the Document Status section.

For this Document you can:

Save | Document
Continue | Entering Document
Close | Current Document

Trip Number 1
Travel Authorization Number A150607

Itinerary Details **ISLE OF HAWAII: OTHER,HI 12/09/05 - 12/16/05**

Purpose Description To attend ann.mtg.of Amer.College of Neuropsychopharmacology to present CSF Peptides as Biomarkers for Presymptomatic AD in At-Risk Controls, Dec.12-16, 2005 in Waikoloa, HI

Ticketed Trans Details **$1,352.60**

Expense Details **Expense Summary**

Quick Expense

Edit	Delete	Date	Expense	Amount	Document Status / Pmt Method
		12/09/2005	Registration Fees	450.00	OTHER
		12/09/2005	Taxi	45.00	OTHER
		12/09/2005	TMC Service Fees	23.50	GTA
		12/15/2005	Domestic Lodging Tax	70.70	OTHER
		12/15/2005	Domestic Lodging Tax	40.60	OTHER
		12/15/2005	Miscellaneous Expense	41.44	OTHER
		12/16/2005	Gas-Rental/Govt Car	9.54	OTHER
		12/16/2005	Rental Car	153.13	OTHER
		12/16/2005	Taxi	45.00	OTHER
				Total: 878.91	

Lodging/M&IE Details **$1,665.00**

Accounting Code Details **Accounting Code Summary**

Label	Amount
109909/1	3,446.51
109909/1	450.00
Total:	3,896.51

Totals Details **Totals Summary**

Disbursement Type	Amount
Amount Claimed	2,520.41
Non-Reimbursable Expenses	1,376.10
Advance Applied	0.00
Pay To Charge Card	0.00
Pay To Traveler	2,520.41

Enter Comments Travel pending avail.of funds; approved as official duty 10/21/05. Request for AEA for housing in conf. hotel: 1. Selection:Hilton Waikoloa Village@group rate $195; 2. Vista Waikoloa@$214, 0.7 mi away; 3. ResortQuest Waikoloa Colony Villas@$195, 0.2 mi away, and 4.Outrigger Fairway Villas@$186, 4.7 mi away, but not avail (gooked 12/15-05-2/15/06).Cost impact: Gov't standard lodging $150/nightx6=900; AEA request rate@$195/nightx6=$1,170, diff=$270. Justification: No lodging avail at less costly accommodations w/out incurring xtra cost of taxi/shuttle for daily excursions to and from meeting. Official Duty approved 10/21/2005. No lodging claim for 12/9/05.

Document Status **Document Status**

Enter Status/PIN to stamp this document

Document Status: CREATED **Awaiting:** SUNDERLAND, PEARSON

☐ **Final Voucher**

Status To Apply | Remarks
PREPARED

Sunderland V
TR188591-1V1

Hilton
Waikoloa Village

425 Waikoloa Beach Drive • Waikoloa, HI 96738
Phone (808) 886-1234 • Fax (808) 886-2900
Reservations
www.hiltonwaikoloavillage.com or 1 800 HILTONS

Name & Address

RLAND, TREY
JMBERLAND AVE

CHEVY CHASE, MD 20815-5458
US

Room 1083/D2LP
Arrival Date 12/09/05 9:37PM
Departure Date 12/15/05

Adult/Child 1/0
Room Rate

RATE PLAN C-ACN

HH# 509624448 SILVER
AL: US #00820612030
BONUS AL: CAR:

Confirmation Number : 3222282741

12/15/05 PAGE 1

DATE	DESCRIPTION	ID	REF. NO	CHARGES	CREDITS	BALANCE
12/09/05	*BOATLANDING PAVILION	LINTR	3418590	$16.58		
12/10/05	*INTERNET ACCESS	LINTR	3420782	$10.36		
12/10/05	GUEST ROOM	IJUAN	3421973	$195.00		
12/10/05	STATE ROOM TAX 4.166%	IJUAN	3421973	$8.12		
12/10/05	ROOM OCCUPANCY TAX 7.25%	IJUAN	3421973	$14.14		
12/11/05	*BOATLANDING PAVILION	LINTR	3425206	$16.14		
12/11/05	WH SMITH ACCENTS	CMIRAN	3426004	$2.99		
12/11/05	GUEST ROOM	IJUAN	3426103	$195.00		
12/11/05	STATE ROOM TAX 4.166%	IJUAN	3426103	$8.12		
12/11/05	ROOM OCCUPANCY TAX 7.25%	IJUAN	3426103	$14.14		
12/12/05	*INTERNET ACCESS	LINTR	3427532	$10.36		
12/12/05	GUEST ROOM	IJUAN	3430433	$195.00		
12/12/05	STATE ROOM TAX 4.166%	IJUAN	3430433	$8.12		
12/12/05	ROOM OCCUPANCY TAX 7.25%	IJUAN	3430433	$14.14		
12/13/05	*INTERNET ACCESS	LINTR	3432157	$10.36		
12/13/05	GUEST ROOM	IJUAN	3434844	$195.00		
12/13/05	STATE ROOM TAX 4.166%	IJUAN	3434844	$8.12		
12/13/05	ROOM OCCUPANCY TAX 7.25%	IJUAN	3434844	$14.14		
12/14/05	*INTERNET ACCESS	LINTR	3436518	$10.36		
12/14/05	GUEST ROOM	IJUAN	3439482	$195.00		
12/14/05	STATE ROOM TAX 4.166%	IJUAN	3439482	$8.12		
12/14/05	ROOM OCCUPANCY TAX 7.25%	IJUAN	3439482	$14.14		

Zip-Out Check-Out®

Aloha & Good Morning ! We hope you enjoyed your stay. With Zip-Out Check-Out ® there is no need to stop at the Front Desk Cashier to check out.

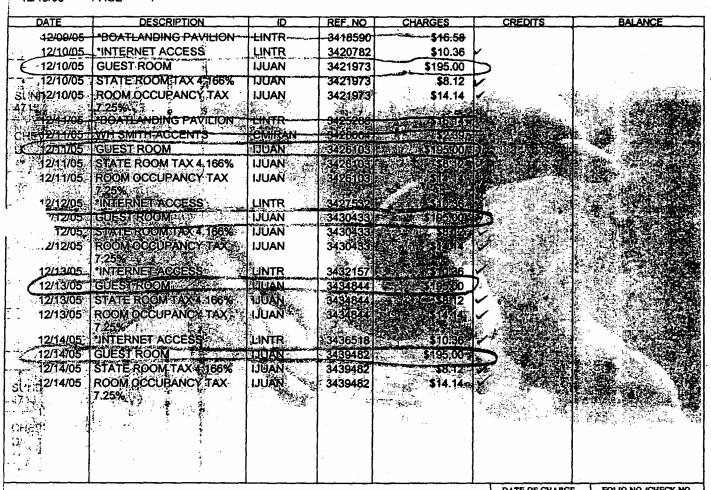
- Please review the enclosed statement. It is a record of your charges since late last evening.
- For any charges after your account was prepared, you may:
  + pay at the time of purchase.
  + charge purchases to your account, then stop by the Front Desk for an updated statement.
  + request an updated statement be mailed to you within two business days.
  ly dial 2737 from your room and tell us when you will be ready to depart. Your account e automatically checked out, and you may use this statement as your receipt.

e call the Front Desk at extension 2733 if you wish to extend your stay or if you have any questions about your account.

For luggage pick-up, please dial 52 and allow a minimum of 45 minutes prior to hotel departure to accommodate your request. For group movements, please contact your group coordinator, as actual delivery times will vary.

Thank you for choosing Hilton Waikoloa Village!

DATE OF CHARGE	FOLIO NO./CHECK NO. 431558 A
AUTHORIZATION	INITIAL
PURCHASES & SERVICES	
TAXES	
TIPS & MISC.	
TOTAL AMOUNT	



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Hilton
CONRAD
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Hilton Garden Inn
Hilton Grand Vacations Club
HOMEWOOD SUITES
USA
Official Sponsor

Sunderland P
TR188591-1V1

Meeting Confirmation Notice

Trey Sunderland, M.D.
Chief, Geriatric Psychiatry Branch
National Institute of Mental Health
Clinical Center CRC 2-5360
9000 Rockville Pike
Bethesda, MD 20892

Meeting: *ACNP Annual Meeting 2005*
Sunday, December 11, 2005 through Thursday, December 15, 2005

Hilton Waikoloa Village
Waikoloa, HI

Coordinators: Please contact Jerry Maher for further information at
ACNP Executive Office
545 Mainstream Drive Suite 110
Nashville TN 37228

Phone: 615-324-2360
Fax: 615-523-1715
jmaher@acnp.org

You are registered for the following:

Function	Quantity	Rate	Amount
Main Registration	1	450.00	450.00
		Total	450.00
		Payment	450.00
		Balance	0.00

Sunderland P
TR188591-1V1

[illegible] 9779661 [illegible]
Rent [illegible] 09 DEC [illegible] PM
Kona ARPT
Return 15-DEC 2005 01:04 PM
KONA ARPT

PEARS [illegible]
[illegible]
[illegible] Charged [illegible]CAR
[illegible] State/Province HI
[illegible] 248
[illegible] Out 61
[illegible] In 309

US GOVERNMENT TRAVEL OFFICE [illegible]
Contract [illegible]

Charge	[illegible] Unit	Price	Amount
T & M	[illegible]	[illegible]	[illegible]
UNLIM M/KM	[illegible]		[illegible]
CDW/LDW	[illegible] Days		0.00*
CONCESSION RECOUP FEE			9.73*
GOV ADMIN RT SPLMNT $5/D			30.00*
RNT MTR VH SC 3.00USD/DY			18.00
VEH REG.FEE & WEIGHT TX			0.00*
SALES TAX @4.166 %			5.40
Total Charges			USD [illegible].13
Paid By	AMEX [illegible]005		[illegible]53.13
Amount Due			USD 0.00

* Taxable Item.
Subject [illegible]
Customer [illegible] 1(800) 445-5664

Gas

WAIKOLOA BEACH SHELL#11
250 WAIKOLOA BEACH DR
WAIKOLOA, HI 967380000

TIME 7:55 PM DATE 12/14/05
TERM# 10025687 MER# 5514400761000000
TRAN TYPE SALE
#xxxxxxxxxxxx3005
CARD TYPE AMEX
SEQ # 155
TICKET # 0000107418
PROD CODE GENERAL MERCHANDISE
AUTH CODE 125708

TOTAL $9.54

CUSTOMER COPY

Neff, Eileen (NIH/NIMH)

Amendment Approved
by Pam 12/6/05

From: Johnson, Sheila (NIH/NIMH)
Sent: Wednesday, November 30, 2005 2:29 PM
To: Drake, Dorothy (NIH/NIMH)
Cc: Neff, Eileen (NIH/NIMH)
Subject: RE: Sunderland travel TR188591

No problem.

Sheila M. Johnson
Admin. Officer, NIMH
Bldg. 31, Rm. 2B34

From: Drake, Dorothy (NIH/NIMH)
Sent: Wednesday, November 30, 2005 1:18 PM
To: Johnson, Sheila (NIH/NIMH)
Cc: Neff, Eileen (NIH/NIMH)
Subject: Sunderland travel TR188591

Hi: Trey's airfare cost for ACNP increased from $885 to $1,362 and Omega is asking for an amended TO to cover the increase – I'm doing it now. He's traveling next Friday. Thanks. Dottie

TR-188591
Cond. Approved 11/25/05

NBS Travel Request Form

Note: This template is not an official form and its use is not required.

Instructions: This template is for Travel Planner or Traveler use ONLY. It is provided to assist in the communication of information and recommendations needed to complete official travel documents.

TAB to each grey field ( ) and type in the information pertinent to the trip. **SAVE document on your hard drive** and send as an e-mail attachment to the Recommending Official (Traveler's Supervisor) for concurrence. The form should then be returned to the Travel Planner via e-mail attachment or hard copy so travel documents may be prepared.

1. Traveler Information

Traveler Name (Last, First, MI)	SUNDERLAND, Pearson	NIH Employee ID Number	001-00-75074
Building / Room #	10 CRC, Room 2-5330	Office Phone	301-435-6050
Position / Title	Senior Investigator	Fax No.	301-402-2588

2. Trip Information

Travel Departure (BEGIN) Date (mm/dd/yy)	12/09/05	Travel Return (END) Date (mm/dd/yy)	12/15/05
Trip Description	To attend the ann.mtg.of the Amer.Coll.of Neuropsychopharmacology to present CSF Peptides as Biomarkers for Presymptomatic AD in At Risk Controls, Dec 12-16, 2005 in Waikoloa, HI.		

Trip Leg	Per Diem Location	Arrival Date (mm/dd/yy)	Arrival Time	Departure Date (mm/dd/yy)	Departure Time
1	Waikoloa, HI	12/09/05	4:35 PM	12/16/05	2:00 PM
5					

3. Sponsored Travel Information

Is this a Sponsored Trip?	☐ Yes ☑ No (If No, go to SECTION 4)		☐ Late Memo?
Do you have any conflicts of interest with this sponsor that will prevent you from answering "no" to all Sponsored Travel Checklist Questions?			☐ Yes ☐ No
Sponsored Expenses/Cost Breakdown	Airfare:	$	$
	Lodging:	$	$
	Meals:	$	$
			Additional:

Sponsor Name	Sponsor Contact Name	Sponsor Address	Sponsor Telephone

4. Travel Expenses (Other Than Per Diem)

Transportation Mode	☑ AIR ☐ POV ☐ TRAIN ☐ BUS ☐ GOV Vehicle
Terminal Information/routing	Comments:
Round Transportation to/from airport/depot	$ or Enter # of POV Miles:

Enter other anticipated expenses (e.g. Taxis, airfare, parking, telephone, rental car and other allowable miscellaneous expenses)	1. 2. 3.

Registration Fees should be paid using:
1. Direct Payment by the Government using the I.M.P. AIC Visa Purchase Card
2. Direct Payment by the Government with pre-Trip Direct Deposit
3. Pre-Payment by Traveler
4. Fixed Fee Events - When registration fees and other costs (e.g. airfare or lodging) are required in advance, the Government Visa Purchase Card should be used to pay for these expenses. Breaking down the costs of meals, lodging, etc. will no longer be a requirement.

Registration Fees	Lodging/Meals Included?	Comments: Travel pending availability of funds; approved as official duty activity on 10-21-05
$ 400.00	☐ Yes ☑ No	

5. TRAVEL PREFERENCES And SPECIAL TRAVEL CIRCUMSTANCES

Preferred HOTEL		
Is Gov. Per Diem being used?	☑ Yes ☐ No	
Is Conference Rate (CRA) required?	☐ Yes ☑ No	
Is an Actual Expense Authorization (AEA) required? (Justification required)	☑ Yes ☐ No	Comments:
If this is a foreign trip, has the Notification of Foreign Travel (NFT) been submitted to Equity? (Add URL)	☐ Yes ☐ No ☑ N/A	
Do you require exemption from the use of the government travel card?	☐ Yes ☐ No	
Do you require first class or other premium class transportation tickets?	☐ Yes ☐ No	
Will you be purchasing or paying for cruising personal funds > $100.00 USD?	☐ Yes ☐ No	
Will you use annual/personal leave while on this trip?	☐ Yes ☐ No	
Are you eligible to earn Compensatory Time for travel?	☐ Yes ☐ No	

Annual Leave Date(s)	Hours	Comments/Explanation

6. Accounting Information

Project Number (Direct Expenses)	109909
Project Number (Reimbursable Expenses)	

7. Travel Cash Advance

Employees and Commissioned Officers who travel frequently (Twelve or more times per year) on official business are responsible for meeting their travel expenses. However, these employees should not have to pay for official travel expenses entirely from personal funds unless they have elected not to use the Government contractor-issued travel card.

An ATM Cash Advance may be given up to a maximum of the estimated total of the trip, or $100.00 per day, or $500.00 for a week.

Cash/Direct Deposit Advance Requested?	☐ Yes ☑ No (If no, proceed to Section 8)

Reason for Cash Advance:	☐ Infrequent Traveler (One trip per year or fewer) ☐ Not Eligible for Travel Card ☐ Other (Please provide explanation)	Reason for Cash Advance (Other):
Other Trip Information:		
8. Recommending Signature		
Recommending Official:	I, David R. Rubinow (enter name) recommend this Travel. ☑ Yes ☐ No	

Drake, Dorothy (NIH/NIMH)

From: Omega Travel Itinerary [resfaxai@owt.net]
nt: Monday, October 31, 2005 4:24 PM
Drake, Dorothy (NIH/NIMH)
ect: Travel Itinerary 09DEC IAD SUNDERLAND

```
*****AIR PRICE SHOWN ON THIS PNR IS BASED PER PERSON****


**Please do not reply to this e-mail.**
**It will not go back to your travel counselor.**

SUNDERLAND/PEARSON                                    31Oct05   04:23pm

Booking locator: JNR68U
Fare: $885.49

09Dec05   12:14pm   Friday
Air   United Airlines        Flight# 498    Class:V Seat:20D
      From: Washington Dulles DC, 09Dec05   12:14pm   Friday
      To:   Denver CO, USA        09Dec05   02:04pm   Friday
      Meal: MEAL AT COST Equip: Boeing 757 200 Jet Status: Confirmed
      Stops: 0

      United Airlines locator: JNR68U

09Dec05   02:35pm   Friday
Air   United Airlines        Flight# 769    Class:V Seat:17D
      From: Denver CO, USA        09Dec05   02:35pm   Friday
      To:   Los Angeles CA, USA   09Dec05   03:57pm   Friday
      Meal: None Equip: Boeing 757 200 Jet Status: Confirmed
      Stops: 0

      LAX TERMINAL 7
      United Airlines locator: JNR68U

09Dec05   04:30pm   Friday
Air   United Airlines        Flight# 67     Class:V
      From: Los Angeles CA, USA   09Dec05   04:30pm   Friday
      To:   Kona/Kailua HI, USA   09Dec05   08:14pm   Friday
      Meal: FOOD TO PURCHASE Equip: Boeing 757 200 Jet Status: Confirmed
      Stops: 0

      LAX TERMINAL 7
      United Airlines locator: JNR68U

      SEATS ARE AIRPORT CHECK IN ONLY

09Dec05              Friday
Car   Pick Up City: Kona/Kailua HI, USA
      Alamo Rent A Car  Type: Inter Car Auto A/c
      Confirmation#: 525178325COUNT *   Rate: 90.00USD
      Drop Off: 15Dec Thursday   Kona/Kailua HI, USA

      Rate Info: USD90.00Weekly-Ulmtd FM Xtra Day15.00-Ulmtd FM
      Pick Up Address: KOAT71

15Dec05   02:15pm   Thursday
Air   United Airlines        Flight# 50     Class:W
      From: Kona/Kailua HI, USA   15Dec05   02:15pm   Thursday
      To:   Los Angeles CA, USA   15Dec05   09:26pm   Thursday
      Meal: FOOD TO PURCHASE Equip: Boeing 757 200 Jet Status: Confirmed
      Stops: 0
```

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health
National Institute of Mental Health
Geriatric Psychiatry Branch

Memorandum
301-496-13
FAX 301-402-2588

Date October 14, 2005

To William T. Fitzsimmons, Deputy Ethics Counselor

From Trey Sunderland, M.D., Geriatric Psychiatry Branch
Through: David Rubinow, M.D., Acting Chief, Geriatric Psychiatry Br.

Subject Request for Approval of Official Duty - Domestic Travel

This is to request that the following activity be approved as an official duty activity. I understand that no honorarium may be accepted.

Organization/ Address	American College of Neuropsychpharmacology (ACNP) 2014 Broadway, Suite 320, Nashville TN 37203
Meeting:	Annual meeting of the ACNP
Meeting location:	Waikoloa, Hawaii
Time frame involved:	December 11-16, 2005
Estimated time involved:	5 duty days (first day of meeting is Sunday)
Nature of Activity:	To attend the annual mtg of the ACNP to present "CSF Peptides as Biomarkers for Presymptomatic AD in At Risk Controls," Dec. 12-16, 2006 in Waikoloa, Hawaii. Attendance at this meeting will provide me with the latest information on topics relevant to my studies in the Geriatric Psychiatry Branch and allow for the exchange of information with others in the scientific community, which supports the mission of the NIH. I have no agreement or relationship with the College.
Travel expenses paid by:	NIH
Point of contact:	Sheila Johnson, Administrative Officer

Dottie Drake
Name of Requestor

✓ Approve ___ Disapprove
10/23/05
Supervisor Name Date

✓ Approve ___ Disapprove
Sr Advisor to CD 10/25/05
William T. Fitzsimmons
Deputy Ethics Counselor, IC Date

Administrative Officer Date

Shamba, Khari (NIH/NIMH)

From: Johnson, Sheila (NIH/NIMH)
Sent: Thursday, October 20, 2005 10:40 AM
To: NIMH Ethics (NIH/NIMH)
Subject: FW: Sunderland official duty

Good Morning,

I have reviewed and forwarding for final approval.

Thank you,

Sheila M. Johnson
Admin. Officer, NIMH
Bldg. 31, Rm. 2B34

From: Rubinow, David (NIH/NIMH)
Sent: Wednesday, October 19, 2005 12:14 PM
To: Johnson, Sheila (NIH/NIMH)
Subject: FW: Sunderland travel

travel approved. david
-----Original Message-----
From: Drake, Dorothy (NIH/NIMH)
Sent: Friday, October 14, 2005 2:41 PM
To: Rubinow, David (NIH/NIMH)
Subject: Sunderland travel

Hi: Attached please find travel request for Trey to approve and forward to Sheila Johnson, his AO. Thanks.
Dottie

The American College of Neuropsychopharmacology

Home | FAQs | Scientific Website | Search | Members Website | Conta

Main Menu

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Officers and Council

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President-Elect: Kenneth Davis, M.D.
Secretary: Oakley Ray, Ph.D.
Treasurer: Irwin J. Kopin, M.D.

— dress official duty with a waiver

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Raquel Gur, M.D., Ph.D. (04-06)
Michael Davis, Ph.D. (05-07)
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Ellen Frank, Ph.D. (2005)
Carol A. Tamminga, M.D. (05-06)
Dennis Charney, M.D. (04-05)

Executive Director
Ronnie D. Wilkins
ACNP Executive Office
E-mail: rwilkins@acnp.org

American College of Neuropsychopharmacology
545 Mainstream Drive Suite 110
Nashville TN 37228
Phone: 615-324-2360
Fax: 615-324-2361

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Published on: 2004-04-28 (1:

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Page Generation: 0.08 Seconds

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health
National Institute of Mental Health
Geriatric Psychiatry Branch

Memorandum
301-496-13
FAX 301-402-2588

Date October 14, 2005

To William T. Fitzsimmons, Deputy Ethics Counselor

From Trey Sunderland, M.D., Geriatric Psychiatry Branch
Through: David Rubinow, M.D., Acting Chief, Geriatric Psychiatry Br.

Subject Request for Approval of Official Duty - Domestic Travel

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Estimated time involved:	5 duty days (first day of meeting is Sunday)
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Travel expenses paid by:	NIH
Point of contact:	Sheila Johnson, Administrative Officer

Dottie Drake
Name of Requestor

✓ Approve ___ Disapprove
Supervisor Name 10/23/05
Date

✓ Approve ___ Disapprove
William T. Fitzsimmons
Deputy Ethics Counselor, IC Date 10/21/05

Administrative Officer Date

Shamba, Khari (NIH/NIMH)

From: Johnson, Sheila (NIH/NIMH)
Sent: Thursday, October 20, 2005 10:40 AM
To: NIMH Ethics (NIH/NIMH)
Subject: FW: Sunderland official duty

Good Morning,

I have reviewed and forwarding for final approval.

Thank you,

Sheila M. Johnson
Admin. Officer, NIMH
Bldg. 31, Rm. 2B34

From: Rubinow, David (NIH/NIMH)
Sent: Wednesday, October 19, 2005 12:14 PM
To: Johnson, Sheila (NIH/NIMH)
Subject: FW: Sunderland travel

travel approved. david
-----Original Message-----
From: Drake, Dorothy (NIH/NIMH)
Sent: Friday, October 14, 2005 2:41 PM
To: Rubinow, David (NIH/NIMH)
Subject: Sunderland travel

Hi: Attached please find travel request for Trey to approve and forward to Sheila Johnson, his AO. Thanks.
Dottie

```
==============================================================================
 06/22/06        AUTHORIZATION                    |DOC NO:      TR188591-1
  PAGE   1 ** Read Privacy Act On Last Page **    |TA NUM:      A150607
==============================================================================
 1) NAME: SUNDERLAND, PEARSON .                EIN:    001-00-75074

    ADDR: ADDRESS NOT AVAILABLE               PHONE:
                                              MAIL CD:
          ,                                   ORG:     HN76V00000C
                                              TITLE:
    DUTY: Bethesda,MD                TZ: 0    SEC CLR:
    RES:  ,                                   CARD:    CARDHOLDER
    HOURS:  8
==============================================================================
 2) TA NUM:   A150607             DATE: 11/30/2005     TYPE: SINGLE TRIP
==============================================================================
 3) TRAVEL PURPOSE:  Domestic Travel
 To attend ann.mtg.of Amer.College of Neuropsychopharmacology to present CSF
  Peptides as Biomarkers for Presymptomatic AD in At-Risk Controls, Dec.12-1
 6, 2005 in Waikoloa, HI
==============================================================================
 4) GENERAL ITINERARY

       DATE       TIME    DEPARTED/ARRIVED LOCATIONS     PER DIEM RATE
     --------    -------  --------------------------     -------------
     12/09/2005           D-RES: ,
     12/09/2005           A-ISLE OF HAWAII: OTHER,HI        150/92
     12/16/2005           D-ISLE OF HAWAII: OTHER,HI
     12/16/2005           A RES: ,

==============================================================================
 5) OTHER AUTHORIZATIONS                  |6)                EST COST     ADV AMT
  THER PRIVATELY-OWNED VEHICLE            |COMCARRIER-G       1362.60        0.00
 ACTUAL EXPENSE(1)                        |LODGING-O          1170.00        0.00
 CONTINUING RESOLUTION FUNDING(2)         |M&IE-O              690.00        0.00
 REGISTRATION FEES(3)                     |MILEAGE              24.26        0.00
 RENTAL CAR AUTHORIZED(4)                 |REG FEES-O          400.00        0.00
                                          |TMC FEES-G           23.50        0.00
                                          |TRANSPORT-O         194.00        0.00
                                                            ---------- ----------
                                          |TOTAL              3864.36        0.00
                                            ADVANCE AUTHORIZED               0.00
==============================================================================
 7) ACCT CLASSIFICATIONS                                              EST COST
 1 - 109909.8337647.1.2151 CONFERENCE ATTENDANCE - D.1832.853.853.103
 .12/09/2005..PROJECTS                                                 3464.36

 2 - 109909.8337647.1.252W TUITION & REG FEES VIA A-.1832.853.853.103
 .12/09/2005..PROJECTS                                                  400.00

==============================================================================
 8) REMARKS
Travel pending avail.of funds; approved as official duty 10/21/05. Request for A
EA for housing in conf. hotel: 1. Selection:Hilton Waikoloa Village@group rate $
195; 2. Vista Waikoloa@$214, 0.7 mi away; 3. ResortQuest Waikoloa Colony Villas@
$195, 0.2 mi away, and 4.Outrigger Fairway Villas@$186, 4.7 mi away, but not ava
==VERSION CIV===========Copyright 1998 Gelco Information Network GSD, Inc.======
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==============================================================================
 06/22/06        AUTHORIZATION                    | DOC NO:     TR188591-1
  PAGE   2 ** Read Privacy Act On Last Page **    | TA NUM:     A150607
==============================================================================
 1 (gooked 12/15-05-2/15/06).Cost impact: Gov't standard lodging $150/nightx6=90
   AEA request rate@$195/nightx6=$1,170, diff=$270. Justification: No lodging av
 _l at less costly accommodations w/out incurring xtra cost of taxi/shuttle for
daily excursions to and from meeting.
Official Duty approved 10/21/2005.
 (1)
 Travel on an actual subsistence basis may be authorized "when deemed warra
 nted", or under unusual circumstances when the applicable maximum per diem
  rate is insufficient.
 (2)
 This trip will be authorized pending funds availability.
 (3)
 Registration fees should be paid using (1) IMPAC Purchase Card  (2) NIHITS
   (3) NBS Travel advance or (4) GOV-issued Travel Card ($500 limit).
 (4)
 Travelers may rent a commercial government contract vehicle only when othe
 r methods of transportation will not be more advantageous to the Governmen
 t.  Use of a rental vehicle must be approved on the Travel Authorization.

==============================================================================
 9) AUTHORIZED BY                TITLE                DATE | INITIALS | DATE
                                                          |          |
                                                          |          |
==============================================================================
 10)FUNDS OBLIGATED

 ============================================================================
  1)  GTR/TICKET NO       VALUE   CR  CLS    DATE        FROM          TO
 --------------------  --------   --  ---  --------  ------------  ------------
 TBD 1                   1362.60     ECO            IAD-Washingt  KOA-Kona, HI
==============================================================================
 12) ITINERARY AND TRANSPORTATION EXPENSES - TRIP NO            1

  DATE      TIME   DEPARTED/ARRIVED LOCATIONS MODE      COST      DESCRIPTION
 -------- ------- -------------------------- -----  --------- ----------------
 12/09/2005
                  D-RES: ,
 12/09/2005                                  AIR      1362.60
                                                            * Airline Flight
 12/09/2005
                  A-ISLE OF HAWAII: OTHER,H
 12/09/2005                                  1POC       12.13 Private Automobil
                                                              Mileage: 25
                                                              Rate: .485

 12/09/2005                                  TMC        23.50
                                                            * TMC Service Fees
 12/16/2005
                  D-ISLE OF HAWAII: OTHER,H
 12/16/2005                                  1POC       12.13 Private Automobil
                                                              Mileage: 25
                                                              Rate: .485

 12/16/2005
                  A RES: ,
 .2/16/2005                                  RENT      138.00 Rental Car
```

06/22/06 AUTHORIZATION | DOC NO: TR188591-1
PAGE 3 ** Read Privacy Act On Last Page ** | TA NUM: A150607

12) ITINERARY AND TRANSPORTATION EXPENSES - TRIP NO 1

DATE	TIME	DEPARTED/ARRIVED LOCATIONS	MODE	COST	DESCRIPTION
12/16/2005			PARK	56.00	Parking Fees
		TOTAL TRANSPORTATION EXPENSES		1604.36	

13) SUBSISTENCE AND OTHER REIMBURSABLE EXPENSES

DATE	ACTUAL LODGING	LODGING ALLOWED	MEALS B L D	M&IE ALLOW	P-DIEM RATE	OTHER EXPENSES	AMOUNT
12/09	195.00	195.00		69.00			0.00
	ACTUAL LDG:	195.00					
						Registration Fees	400.00
12/10	195.00	195.00		92.00			0.00
	ACTUAL LDG:	195.00					
12/11	195.00	195.00		92.00			0.00
	ACTUAL LDG:	195.00					
12/12	195.00	195.00		92.00			0.00
	ACTUAL LDG:	195.00					
12/13	195.00	195.00		92.00			0.00
	ACTUAL LDG:	195.00					
12/14	195.00	195.00		92.00			0.00
	ACTUAL LDG:	195.00					
12/15	0.00	0.00		92.00			0.00
12/16	0.00	0.00		69.00			0.00
		1170.00		690.00			400.00

VRCIV=RATE TABLE DATE=11/18/05=Copyright 1998 Gelco Information Network GSD, Inc

* Expense not claimed for reimbursement.

Exception to GSA Form 87

In compliance with the Privacy Act of 1974, the following information is provided: Basic authority for requiring the requested information is contained in 5 USC 5701-5733, particularly sections 5721-5733, 30 USC 905 and Executive Order 9397. Disclosure of the data by you is voluntary. The principal purpose for collecting the data is to determine the amount to reimburse an employee for expenses incurred in connection with temporary duty travel. Information may be transferred to appropriate Federal, State, local or foreign agencies when relevant to civil, criminal or regulatory investigations or prosecutions. There is no personal liability to you if you do not furnish the requested information; however, we shall not be able to reimburse you for your expenses.

06/22/06 ACCT DETAIL | Doc No: TR188591-1
Copyright 1998 Gelco Information Network, Inc. | SUNDERLAND, PE 001-00-75074

CCT CLASS CODE			TRIP 1
COMCARRIER-G-			1,362.60
LODGING-O-			1,170.00
M&IE-O-			690.00
MILEAGE-			24.26
TMC FEES-G-			23.50
TRANSPORT-O-			194.00
1	0.00	0.00	3,464.36

Organization: HN76000000C
109909.8337647.1.2151 CONFERENCE ATTENDANCE - D.1832.853.853.103.12/09
/2005..PROJECTS

REG FEES-O-			400.00
2	0.00	0.00	400.00

Organization: HN76000000C
109909.8337647.1.252W TUITION & REG FEES VIA A-.1832.853.853.103.12/09
/2005..PROJECTS

6/22/06 DOCUMENT HISTORY | Auth: TR188591-1
pyright 1998 Gelco Information Network GSD, Inc. | SUNDERLAND, PE 001-00-75074

STATUS	DATE	TIME	SIGNATURE NAME	TELEPHONE
CREATED	11/30/2005	1:22PM	DOROTHY M DRAKE	301 496 1338
PREPARED	11/30/2005	1:24PM	DOROTHY M DRAKE	301 496 1338
ADJUSTED	11/30/2005	1:25PM	DOROTHY M DRAKE	301 496 1338
ADJUSTED	12/06/2005	10:50AM	PAMELA F KLEIN	301 496 4271
APPROVED	12/06/2005	10:50AM	PAMELA F KLEIN	301 496 4271
CLOSED	01/09/2006	3:07PM	TM System	

I certify that the electronic signatures listed above are valid and on file.

SIGNED DATE

Tab 21

06/22/06 AUTHORIZATION | DOC NO: TR169524
PAGE 1 ** Read Privacy Act On Last Page ** | TA NUM: A135470

1) NAME: SUNDERLAND, PEARSON . EIN: 001-00-75074

ADDR: ADDRESS NOT AVAILABLE
,

DUTY: Bethesda,MD TZ: 0
RES: ,
HOURS: 8

PHONE:
MAIL CD:
ORG: HN76V00000C
TITLE:
SEC CLR:
CARD: CARDHOLDER

2) TA NUM: A135470 DATE: 09/09/2005 TYPE: SINGLE TRIP

3) TRAVEL PURPOSE: Sponsored - Foreign
To participate in research planning conference on dementia to co-chair pres entation on Markers of Pathophysiology in Geneva, Switzerland, Sept 15-17, 2005.

4) GENERAL ITINERARY

DATE	TIME	DEPARTED/ARRIVED LOCATIONS	PER DIEM RATE
09/14/2005		D-Bethesda, MD	
09/14/2005		A-GENEVA,SUI	211/157
09/18/2005		D-GENEVA,SUI	
09/18/2005		A Bethesda, MD	

5) OTHER AUTHORIZATIONS
FOREIGN TRAVEL(1)
SPONSORED TRAVEL(2)

6)	EST COST	ADV AMT
TRANSPORT-O	70.00	0.00
TOTAL	70.00	0.00
ADVANCE AUTHORIZED		0.00

7) ACCT CLASSIFICATIONS EST COST
1 - 109909.8337647.1.2152 CONFERENCE ATTENDANCE - F.1832.853.853.103
.09/14/2005..PROJECTS 70.00

8) REMARKS
Approved as official duty on 9/7/05. NFT approved on 9/9/05.
(1)
A Notification of Foreign Travel (NFT) must be submitted to the Fogarty In ternational Center prior to travel departure.
(2)
Employees may not accept an honorarium or retain cash in excess of actual expenses. The acceptance of payment or in kind services from a nonfederal source should be the exception and not the rule.

9) AUTHORIZED BY TITLE DATE | INITIALS | DATE

==VERSION CIV==========Copyright 1998 Gelco Information Network GSD, Inc.======

06/22/06 AUTHORIZATION | DOC NO: TR169524
PAGE 2 ** Read Privacy Act On Last Page ** | TA NUM: A135470

10) FUNDS OBLIGATED

11) GTR/TICKET NO	VALUE	CR	CLS	DATE	FROM	TO
TBD 1	790.00				IAD-Washingt	GVA-Geneva,

12) ITINERARY AND TRANSPORTATION EXPENSES - TRIP NO 1

DATE	TIME	DEPARTED/ARRIVED LOCATIONS	MODE	COST	DESCRIPTION
09/14/2005					
		D-Bethesda, MD			
09/14/2005			AIR	790.00	
					* Airline Flight
09/14/2005					
		A-GENEVA,SUI			
09/14/2005			CAB	25.00	Taxi
09/15/2005			CAB	10.00	Taxi
09/18/2005					
		D-GENEVA,SUI			
09/18/2005			CAB	25.00	Taxi
09/18/2005					
		A Bethesda, MD			
09/18/2005			CAB	10.00	Taxi
		TOTAL TRANSPORTATION EXPENSES		860.00	

13) SUBSISTENCE AND OTHER REIMBURSABLE EXPENSES

DATE	ACTUAL LODGING	LODGING ALLOWED	MEALS B L D	M&IE ALLOW	P-DIEM RATE	OTHER EXPENSES	AMOUNT
09/14	211.00*	211.00		117.75#	211/157		0.00
09/15	211.00*	211.00		157.00#	211/157		0.00
09/16	211.00*	211.00		157.00#	211/157		0.00
09/17	211.00*	211.00		157.00#	211/157		0.00
09/18	0.00*	0.00		117.75#	211/157		0.00
		844.00		706.50			0.00

VRCIV=RATE TABLE DATE=09/01/05=Copyright 1998 Gelco Information Network GSD, Inc

* Expense not claimed for reimbursement.

M&IE calculation altered.

Exception to GSA Form 87

In compliance with the Privacy Act of 1974, the following information is provided: Basic authority for requiring the requested information is contained in 5 USC 5701-5733, particularly sections 5721-5733, 30 USC 905 and Executive Order 9397. Disclosure of the data by you is voluntary. The principal purpose for collecting the data is to determine the amount to reimburse an employee for expenses incurred in connection with temporary duty travel. Information may be transferred to appropriate Federal, State, local or foreign agencies when relevant to civil, criminal or regulatory investigations or prosecutions. There is no personal liability to you if you do not furnish the requested information; however, we shall not be able to reimburse you for your expenses.

06/22/06 ACCT DETAIL | Doc No: TR169524
Copyright 1998 Gelco Information Network, Inc. | SUNDERLAND, PE 001-00-75074

ACCT CLASS CODE			TRIP 1
TRANSPORT-O-			70.00
1	0.00	0.00	70.00

Organization: HN76000000C
109909.8337647.1.2152 CONFERENCE ATTENDANCE - F.1832.853.853.103.09/14
/2005..PROJECTS

06/22/06 DOCUMENT HISTORY | Auth: TR169524
Copyright 1998 Gelco Information Network GSD, Inc. | SUNDERLAND, PE 001-00-75074

STATUS	DATE	TIME	SIGNATURE NAME	TELEPHONE
CREATED	09/07/2005	5:56PM	DOROTHY M DRAKE	301 496 1338
PREPARED	09/08/2005	11:35AM	DOROTHY M DRAKE	301 496 1338
CERTIFIED	09/08/2005	11:42AM	PEARSON SUNDERLAND	301 496 0948
ADJUSTED	09/08/2005	1:41PM	EILEEN M NEFF	301 496 4271
REVIEWED	09/08/2005	1:44PM	EILEEN M NEFF	301 496 4271
ADJUSTED	09/09/2005	3:57PM	CARLITA R MARSH	301 496 4271
CONDITIONAL APPROVAL	09/09/2005	4:15PM	CARLITA R MARSH	301 496 4271
ADJUSTED	09/13/2005	8:54AM	SHEILA M JOHNSON	301 594 8071
ADJUSTED	09/13/2005	8:56AM	SHEILA M JOHNSON	301 594 8071
PREPARED	09/13/2005	8:57AM	SHEILA M JOHNSON	301 594 8071
ADJUSTED	09/13/2005	8:58AM	SHEILA M JOHNSON	301 594 8071
CONDITIONAL APPROVAL	09/13/2005	8:58AM	SHEILA M JOHNSON	301 594 8071
REVIEWED	09/13/2005	9:01AM	PAMELA F KLEIN	301 496 4271
REVIEWED	09/13/2005	9:01AM	PAMELA F KLEIN	301 496 4271
ADJUSTED	09/13/2005	5:44PM	BARBARA E VERMILLION	301 443 3836
APPROVED	09/13/2005	5:44PM	BARBARA E VERMILLION	301 443 3836
CLOSED	05/04/2006	2:28PM	TM System	

I certify that the electronic signatures listed above are valid and on file.

SIGNED DATE

REQUEST FOR APPROVAL TO ACCEPT PAYMENT OF TRAVEL EXPENSES FROM A NON FEDERAL SOURCE

06/22/2006
(date)

se this form to request, approve, and report acceptance of payments as provided in DHHS Travel Manual Chapter 1-70. Submit request to recom-
.nending official as soon as possible, but not later than 15 days before scheduled departure.

1. NAME AND TITLE OF TRAVELER
SUNDERLAND, PEARSON /

3. TRAVELER'S ORGANIZATION
HN76V00000C

2. NAME AND ADDRESS OF SPONSORING ORGANIZATION
AMERICAN PSYCHIATRIC
1000 WILSON BOULEVARD
SUITE 1000
ARLINGTON, VIRGINIA 22209, US

4. PURPOSE OF TRIP Sponsored - Foreign
To participate in research planning conference on dementia to co-chair presentation on Markers of Pathophysiology in Geneva, Switzerland, Sept 15-17, 2005.

5. AUTHORITY FOR TRAVEL

☒ 31 USC 1353 ☐ 42 USC 3506 ☐ 5 USC 7342
(See DHHS Travel Manual Chapter 1-70):

METHOD OF PAYMENT:

A. ☐ DIRECT REIMBURSEMENT TO PROJECT/TASK/EXP.TYPE $
PROJECT/TASK/EXP.TYPE

B. ☒ IN KIND. . . . . $ 2,340.50

** C. ☐ IN CASH for retention by traveler. . . . . $

**NOTE: CASH MAY ONLY BE ACCEPTED UNDER 42 U.S.C. 3506 AUTHORITY

INDICATE VALUE OF PAYMENT:

TRAVEL	$	790.00
LODGINGS	$	844.00
MEALS	$	706.50
OTHER	$	0.00

AYMENT TO BE USED FOR TRAVEL
☒ ROUND ☐ ONE WAY *(see itinerary below)*

STARTING DATE	ENDING DATE	FROM	TO
09/14/2005	09/14/2005	Bethesda, MD	GENEVA,SUI
09/18/2005	09/18/2005	GENEVA,SUI	Bethesda, MD

7. IS THE DEPARTMENT PAYING PART OF THE COST? *(If any, specify which part and amount)*

8. RECOMMENDATION

9. AUTHORIZATION (SEE DOCUMENT TRACKING AND HISTORY)

10. TRAVELER'S CERTIFICATION *(Complete after trip)*

I certify that while on official travel the above amounts are correct and I did not receive (1) any honoraria, or (2) any cash for my retention from the sponsoring organization. I further understand that any accommodations, meals or incidental expenses accepted that are not normally reimbursed by Government Travel Regulations, and not fully reimbursed by the sponsoring organization will have to be borne out of my personal funds.

DATE

-348 (Rev. 8/92)

BACKGROUND INFORMATION ON REQUEST FOR APPROVAL TO ACCEPT PAYMENT OF TRAVEL EXPENSES FROM A NON FEDERAL SOURCE

AVELER: Trey Sunderland

. Is the sponsoring organization using Federal Funds to defray the costs of this trip?

☐ YES ☒ NO *(If yes, reimbursement may NOT be accepted.)*

2. Does the offer of travel reimbursement include other compensation from the sponsor in (a) the form of an honorarium, or (b) payment for the travel of family members or (c) payment for travel beyond that allowed under Federal travel regulations?

☐ YES ☒ NO

(If yes at (b), family member's travel order # _____ *, at (c) justification attached.)*

3. Is the travel unrelated to official government business as prescribed in Manual Issuance 1500-8 REIMBURSEMENT FOR TRAVEL IN CASH OR IN KIND?

☐ YES ☒ NO

4. Why can't this trip be paid with DHHS funds?

It is customary for non-conflicting sponsors to offer support for travel of mutual benefit to the sponsor and the NIH.

5. Is the travel related to the development by the sponsor of a grant or contract proposal for submission to your ICD?

☐ YES ☒ NO

6. Are there current plans for the development of a CRADA with the sponsoring Organization?

☐ YES ☒ NO

7. Is the traveler an officer, director, trustee, partner or employee of the sponsoring-organization?

☐ YES ☒ NO

8. Do you or your spouse or minor child have financial interests or personal business relationship with the sponsoring organization?

☐ YES ☒ NO

9. Do you have any involvement in the review, approval, or monitoring or any active or potential or potential grant, cooperative agreement, or contract (for research, goods, or services) concerning the sponsoring organization? Further, does the acceptance of this sponsorship compromise the ICS or NIH with respect to its policies, procedures, and official positions on issues?

☐ ☒ NO

10. Is the sponsor involved in any NIH investigations of scientific fraud or misconduct or for any reason been disbarred from receipt of government grants, contracts or cooperative agreements? Is the purchase of the travel to participate in an activity involving scientific misconduct issues? If the answer to either question is 'yes', please discuss the circumstances with your Executive Officer before proceeding.

☐ YES ☒ NO

I hereby certify that the information above is accurate and complete to the best of my knowledge and in accordance with e policy in NIH Manual Chapter 1500-8.

DATE 09/08/2005

-S-348 (Rev. 8/92)

REQUEST FOR APPROVAL TO ACCEPT PAYMENT OF TRAVEL EXPENSES FROM A NON FEDERAL SOURCE

05/04/2006
(date)

Use this form to request, approve, and report acceptance of payments as provided in DHHS Travel Manual Chapter 1-70. Submit request to recommending official as soon as possible, but not later than 15 days before scheduled departure.

1. NAME AND TITLE OF TRAVELER
SUNDERLAND, PEARSON /

3. TRAVELER'S ORGANIZATION
HN76V00000C

2. NAME AND ADDRESS OF SPONSORING ORGANIZATION
AMERICAN PSYCHIATRIC
1000 WILSON BOULEVARD
SUITE 1000
ARLINGTON, VIRGINIA 22209, US

4. PURPOSE OF TRIP Sponsored - Foreign
To participate in research planning conference on dementia to co-chair presentation on Markers of Pathophysiology in Geneva, Switzerland, Sept 15-17, 2005.

5. AUTHORITY FOR TRAVEL

[X] 31 USC 1353 [ ] 42 USC 3506 [ ] 5 USC 7342
(See DHHS Travel Manual Chapter 1-70):

METHOD OF PAYMENT:

A. [ ] DIRECT REIMBURSEMENT TO PROJECT/TASK/EXP.TYPE $
PROJECT/TASK/EXP.TYPE

B. [X] IN KIND. . . . . $ 1,496.50

** C. [ ] IN CASH for retention by traveler. . . . . $

**NOTE: CASH MAY ONLY BE ACCEPTED UNDER 42 U.S.C. 3506 AUTHORITY

INDICATE VALUE OF PAYMENT:

TRAVEL	$	790.00
LODGINGS	$	0.00
MEALS	$	706.50
OTHER	$	0.00

PAYMENT TO BE USED FOR TRAVEL
[X] ROUND [ ] ONE WAY *(see itinerary below)*

STARTING DATE	ENDING DATE	FROM	TO
09/14/2005	09/14/2005	Bethesda, MD	GENEVA,SUI
09/18/2005	09/18/2005	GENEVA,SUI	Bethesda, MD

7. IS THE DEPARTMENT PAYING PART OF THE COST? *(If any, specify which part and amount)*

8. RECOMMENDATION

9. AUTHORIZATION (SEE DOCUMENT TRACKING AND HISTORY)

10. TRAVELER'S CERTIFICATION *(Complete after trip)*

I certify that while on official travel the above amounts are correct and I did not receive (1) any honoraria, or (2) any cash for my retention from the sponsoring organization. I further understand that any accommodations, meals or incidental expenses accepted that are not normally reimbursed by Government Travel Regulations, and not fully reimbursed by the sponsoring organization will have to be borne out of my personal funds.

DATE 09/28/2005

HHS-348 (Rev. 8/92)

Document Summary for Adjustment to Authorization TR169524 (View Only)

Quick Tip
For specific information, click on a Details link. You can sign and stamp your document from the Document Status section.

For this Document you can:

Continue Entering Document

Close Current Document

Authorization Number A135470

Itinerary Details **GENEVA,SUI 09/14/05 - 09/18/05**

Purpose Description To participate in research planning conference on dementia to co-chair presentation on Markers of Pathophysiology in Geneva, Switzerland, Sept 15-17, 2005.

Ticketed Trans Details **$790.00**

Expense Details

Expense Summary

Document Status

Edit	Delete	Date	Expense	Amount	Pmt Method
		09/14/2005	Taxi	25.00	OTHER
		09/15/2005	Taxi	10.00	OTHER
		09/18/2005	Taxi	25.00	OTHER
		09/18/2005	Taxi	10.00	OTHER
				Total: 70.00	

Lodging/M&IE Details **$1,550.50**

Other Authorizations Details **FOREIGN TRAVEL**
SPONSORED TRAVEL

Accounting Code Details

Accounting Code Summary

Label	Amount
109909/1	70.00
109952/1	0.00
Total:	70.00

Sponsor Details

Sponsor Summary

Sponsor Name	Reimbursable Amount	In-Kind Amount
AMERICAN PSYCHIATRIC ASSOCIATION, MINORITY FELLOWSHIPS PROGRAM	0.00	2,340.50
Total:	0.00	2,340.50

Totals Details

Totals Summary

Disbursement Type	Amount
Estimated Cost	70.00
Advance Requested	0.00

Enter Comments Approved as official duty on 9/7/05. NFT approved on 9/9/05.

Document Status

Document Status

Enter Status/PIN to stamp this document

Document Status: CLOSED **Awaiting:**

☐ **Final Voucher**

Status To Apply | Remarks

04/20/06 VOUCHER | Voucher: TR169524V1
PAGE 1 ** Read Privacy Act On Last Page ** | TA Num: A135470

1) NAME: SUNDERLAND, PEARSON . EIN: 001-00-75074

ADDR: ADDRESS NOT AVAILABLE
,
DUTY: Bethesda,MD TZ: 0
RES: ,
HOURS: 8

PHONE:
MAIL CD:
ORG: HN76V00000C
TITLE:
SEC CLR:
CARD: CARDHOLDER

2) FROM	TO	TA NUMBER	TA DATE	TRIP PURPOSE	TRIP TYPE
09/14/2005	09/18/2005	A135470	09/28/2005	Sponsored - Foreign	SINGLE TRIP

3) GTR/TICKET NO	VALUE	CR	CLS	DATE	FROM	TO
TBD 1	790.00				IAD-Washing	GVA-Geneva

4) ACCT CLASS CODE	TRIP 3	TRIP 2	TRIP 1
1			267.75
109909.1.2152 CONFERENCE ATTENDANCE - F.1832.853.853.103.09/14/2005..PROJECTS			

5) FINANCE OFFICE

6) NON-REIMBURSABLE EXPENSES

TOTAL AMOUNT CLAIMED		267.75
ADVANCE OUTSTANDING	0.00	
ADVANCE APPLIED	0.00	0.00
NET TO TRAVELER (GOVT)		267.75

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I certify that this Voucher is true and correct to the best of my knowledge and belief, and that payment or credit has not been received by me. I hereby assign the United States any right I may have against any parties in connection, with reimbursable transportation charges described above, purchased under cash payment procedures (41 CFR Part 301-10).

7) TRAVELER SIGNATURE DATE 4/19/06

8)
VOUCHER NO:
SCHEDULE NO:
CERTIFIED BY:
DATE:

This Voucher is approved. Long distance telephone calls, if any, are certified as necessary in the interest of the Government. (Note: If long distance telephone calls are included, the approving official must have been authorized in writing by the head of the department or agency to so certify (31 U.S.C. 680a)).

APPROVED, DATE

10)
CASH RECEIPT DATE
AMOUNT $
SIGNATURE

```
==============================================================================
04/20/06          VOUCHER                          |Voucher:       TR169524V1
PAGE   2  ** Read Privacy Act On Last Page **      |SUNDERLAND     001-00-75074

==============================================================================
 11)ITINERARY AND TRANSPORTATION EXPENSES - TRIP NO              1

 DATE      TIME   DEPARTED/ARRIVED LOCATIONS MODE     COST     DESCRIPTION
-------- ------- -------------------------- -----  --------  ----------------
09/14/2005
                 D-Bethesda, MD

09/14/2005                                  AIR      790.00
                                                          *  Airline Flight
09/14/2005
                 A-GENEVA,SUI

09/14/2005                                  CAB       45.00 Taxi
09/15/2005                                  CAB       30.00 Taxi
09/18/2005
                 D-GENEVA,SUI

09/18/2005                                  CAB       45.00 Taxi
09/18/2005                                  CAB       30.00 Taxi
09/18/2005
                 A Bethesda, MD

                                                   --------
                TOTAL TRANSPORTATION EXPENSES        940.00

==============================================================================
(12)SUBSISTENCE AND OTHER REIMBURSABLE EXPENSES

       ACTUAL  LODGING MEALS  M&IE  P-DIEM
 DATE  LODGING ALLOWED B L D  ALLOW RATE    OTHER EXPENSES                AMOUNT
----- ------- ------- - - -  ----- ------  -------------------------- --------
09/14     0.00
             *    0.00      117.75#211/157                                0.00
09/15     0.00
             *    0.00      157.00#211/157                                0.00
09/16     0.00
             *    0.00      157.00#211/157                                0.00
09/17     0.00
             *    0.00      157.00#211/157                                0.00
09/18     0.00
             *    0.00      117.75#211/157                                0.00
              -------        -----                                     --------
                 0.00       706.50                                        0.00

===(13)COMMENTS:==============================================================
 Approved as official duty on 9/7/05.  NFT approved on 9/9/05.

VERCIV=RATE TBL DATE=09/15/05=Copyright 1998 Gelco Information Network GSD, Inc.

  * Expense not claimed for reimbursement.

  # M&IE calculation altered.
==============================================================================
                         Exception to SF 1012

 E: Falsification of an item in an expense account works a forfeiture of
 aim (28 U.S.C. 2514) and may result in a fine of not more than $10,000 or
imprisonment for not more than 5 years or both (18 U.S.C. 287; i.d. 1001).

In compliance with the Privacy Act of 1974, the following information is prov-
```

04/20/06 ACCT DETAIL | Doc No: TR169524V1
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CCT CLASS CODE			TRIP 1
M&IE-O-			117.75
TRANSPORT-O-			150.00
1	0.00	0.00	267.75

Organization: HN76000000C
109909.8337647.1.2152 CONFERENCE ATTENDANCE - F.1832.853.853.103.09/14
/2005..PROJECTS

SPLIT PAY DISBURSEMENTS:

TOTAL EXPENSES		267.75
NON-REIMBURSABLE EXPENSES		0.00
TOTAL AMOUNT CLAIMED		267.75
GOV'T ADVANCE OUTSTANDING --	0.00	
GOV'T ADVANCE APPLIED ------	0.00	
		0.00
NET TO TRAVELER (GOVT)		267.75
GOV'T CHARGE CARD EXPENSES -	0.00	
GOV'T CHARGE CARD ATM ADV --	0.00	
ADD'L GOV'T CHARGE CARD PYMT	0.00	
TOTAL GOV'T CHARGE CARD AMT	0.00	
PAY TO GOV'T CHARGE CARD		0.00
PAY TO TRAVELER		267.75

06/22/06 VOUCHER | Voucher: TR169524V1
PAGE 1 ** Read Privacy Act On Last Page ** | TA Num: A135470

1) NAME: SUNDERLAND, PEARSON . EIN: 001-00-75074

ADDR: ADDRESS NOT AVAILABLE
,

PHONE:
MAIL CD:
ORG: HN76V00000C
TITLE:
SEC CLR:
CARD: CARDHOLDER

DUTY: Bethesda,MD TZ: 0
RES: ,
HOURS: 8

2) FROM	TO	TA NUMBER	TA DATE	TRIP PURPOSE	TRIP TYPE
09/14/2005	09/18/2005	A135470	05/04/2006	Sponsored - Foreign	SINGLE TRIP

3) GTR/TICKET NO	VALUE	CR	CLS	DATE	FROM	TO
TBD 1	790.00				IAD-Washing	GVA-Geneva

4) ACCT CLASS CODE	TRIP 3	TRIP 2	TRIP 1
1			150.00
109909.1.2152 CONFERENCE ATTENDANCE - F.1832.853.853.103.09/14/2005..PROJECTS			

5) FINANCE OFFICE

6) NON-REIMBURSABLE EXPENSES

TOTAL AMOUNT CLAIMED		150.00
ADVANCE OUTSTANDING	0.00	
ADVANCE APPLIED	0.00	0.00
NET TO TRAVELER (GOVT)		150.00

Copyright 1998 Gelco Information Network GSD, Inc.

I certify that this Voucher is true and correct to the best of my knowledge and belief, and that payment or credit has not been received by me. I hereby assign the United States any right I may have against any parties in connection, with reimbursable transportation charges described above, purchased under cash payment procedures (41 CFR Part 301-10).

7) TRAVELER SIGNATURE DATE

8)
VOUCHER NO:
SCHEDULE NO:
CERTIFIED BY:
DATE:

This Voucher is approved. Long distance telephone calls, if any, are certified as necessary in the interest of the Government. (Note: If long distance telephone calls are included, the approving official must have been authorized in writing by the head of the department or agency to so certify (31 U.S.C. 680a)).

9) APPROVED, DATE

10)
CASH RECEIPT DATE
AMOUNT $
SIGNATURE

06/22/06 VOUCHER | Voucher: TR169524V1
PAGE 2 ** Read Privacy Act On Last Page ** | SUNDERLAND 001-00-75074

11) ITINERARY AND TRANSPORTATION EXPENSES - TRIP NO 1

DATE	TIME	DEPARTED/ARRIVED LOCATIONS	MODE	COST	DESCRIPTION
09/14/2005					
		D-Bethesda, MD			
09/14/2005			AIR	790.00 *	Airline Flight
09/14/2005					
		A-GENEVA,SUI			
09/14/2005			CAB	45.00	Taxi
09/15/2005			CAB	30.00	Taxi
09/18/2005					
		D-GENEVA,SUI			
09/18/2005			CAB	45.00	Taxi
09/18/2005					
		A Bethesda, MD			
09/18/2005			CAB	30.00	Taxi
		TOTAL TRANSPORTATION EXPENSES		940.00	

(12) SUBSISTENCE AND OTHER REIMBURSABLE EXPENSES

DATE	ACTUAL LODGING	LODGING ALLOWED	MEALS B L D	M&IE ALLOW	P-DIEM RATE	OTHER EXPENSES	AMOUNT
09/14	0.00 *	0.00		117.75	#211/157		0.00
09/15	0.00 *	0.00		157.00	#211/157		0.00
09/16	0.00 *	0.00		157.00	#211/157		0.00
09/17	0.00 *	0.00		157.00	#211/157		0.00
09/18	0.00 *	0.00		117.75	#211/157		0.00
		0.00		706.50			0.00

===(13) COMMENTS:
Approved as official duty on 9/7/05. NFT approved on 9/9/05.

VERCIV=RATE TBL DATE=09/15/05=Copyright 1998 Gelco Information Network GSD, Inc.

* Expense not claimed for reimbursement.

M&IE calculation altered.

Exception to SF 1012

NOTE: Falsification of an item in an expense account works a forfeiture of claim (28 U.S.C. 2514) and may result in a fine of not more than $10,000 or imprisonment for not more than 5 years or both (18 U.S.C. 287; i.d. 1001).

In compliance with the Privacy Act of 1974, the following information is prov-

ided: Solicitation of the information on this form is authorized by 5 U.S.C. Chap. 57 as implemented by the Federal Travel Regulations (41 CFR 301-304), E.O. 11609 of July 22, 1971, E.O. 11012 of March 27, 1962, E.O. 9397 of Nov. 22, 1943 and 26 U.S.C. 6011(b) and 6109. The primary purpose of the requested information is to determine payment or reimbursement to eligible individuals for allowable travel and/or relocation expenses incurred under appropriate administrative authorization and to record and maintain costs of such reimbursements to the Government. The information will be used by officers and employees who have a need for the information in the performance of their official duties. The information may be disclosed to appropriate Federal, State, local, or foreign agencies, when relevant to civil, criminal, or regulatory investigations or prosecutions, or when pursuant to a requirement by this agency in connection with the hiring or firing of an employee, the issuance of a security clearance, or investigations of the performance of official duty while in Government service. Your Social Security Account Number (SSN) is solicited under the authority of the Internal Revenue Code (26 U.S.C 6011(b) and 6109) and E.O. 9397, Nov. 22, 1943, for use as a tax payer and/or employee identification number; disclosure is MANDATORY on vouchers claiming travel; and/or relocation allowance expense reimbursement which is, or may be, taxable income. Disclosure of your SSN and other requested information is voluntary in all other instances; however, failure to provide the information (other than SSN) required to support the claim may result in delay or loss of reimbursement.

06/22/06 DOCUMENT ADJUSTMENTS | Voucher: TR169524V1
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TRIP:	0	DATE:	09/28/2005	TIME:	11:35AM	ADJUSTOR:	DOROTHY M DRAKE
TRIP:	0	DATE:	04/20/2006	TIME:	11:11AM	ADJUSTOR:	DOROTHY M DRAKE
TRIP:	0	DATE:	04/26/2006	TIME:	5:22PM	ADJUSTOR:	DOROTHY M DRAKE
TRIP:	0	DATE:	05/02/2006	TIME:	10:47AM	ADJUSTOR:	EILEEN M NEFF
TRIP:	0	DATE:	05/04/2006	TIME:	1:47PM	ADJUSTOR:	ERIN M HALL
TRIP:	0	DATE:	09/28/2005	TIME:	11:35AM	ADJUSTOR:	DOROTHY M DRAKE
TRIP:	0	DATE:	04/20/2006	TIME:	11:11AM	ADJUSTOR:	DOROTHY M DRAKE
TRIP:	0	DATE:	04/26/2006	TIME:	5:22PM	ADJUSTOR:	DOROTHY M DRAKE
TRIP:	0	DATE:	05/02/2006	TIME:	10:47AM	ADJUSTOR:	EILEEN M NEFF
TRIP:	0	DATE:	05/04/2006	TIME:	1:47PM	ADJUSTOR:	ERIN M HALL

06/22/06 ACCT DETAIL | Doc No: TR169524V1
Copyright 1998 Gelco Information Network, Inc. | SUNDERLAND, PE 001-00-75074

ACCT CLASS CODE			TRIP 1
TRANSPORT-O-			150.00
1	0.00	0.00	150.00

Organization: HN76000000C
109909.8337647.1.2152 CONFERENCE ATTENDANCE - F.1832.853.853.103.09/14
/2005..PROJECTS

SPLIT PAY DISBURSEMENTS:

TOTAL EXPENSES		150.00
NON-REIMBURSABLE EXPENSES		0.00
TOTAL AMOUNT CLAIMED		150.00
GOV'T ADVANCE OUTSTANDING --	0.00	
GOV'T ADVANCE APPLIED ------	0.00	
		0.00
NET TO TRAVELER (GOVT)		150.00
GOV'T CHARGE CARD EXPENSES -	0.00	
GOV'T CHARGE CARD ATM ADV --	0.00	
ADD'L GOV'T CHARGE CARD PYMT	0.00	
TOTAL GOV'T CHARGE CARD AMT	0.00	
PAY TO GOV'T CHARGE CARD		0.00
PAY TO TRAVELER		150.00

06/22/06 RECEIPT CHECKLIST | Voucher: TR169524V1
Copyright 1998 Gelco Information Network, Inc. | SUNDERLAND, PE 001-00-75074

	DATE	DESCRIPTION	COST
[] 1.	09/14/2005CAB	Taxi	45.00
[] 2.	09/15/2005CAB	Taxi	30.00
[] 3.	09/18/2005CAB	Taxi	45.00
[] 4.	09/18/2005CAB	Taxi	30.00

06/22/06 DOCUMENT HISTORY | Voucher: TR169524V1
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STATUS	DATE	TIME	SIGNATURE NAME	TELEPHONE
CREATED	09/28/2005	11:30AM	DOROTHY M DRAKE	301 496 1338
PREPARED	09/28/2005	11:35AM	DOROTHY M DRAKE	301 496 1338
ADJUSTED	09/28/2005	11:35AM	DOROTHY M DRAKE	301 496 1338
PREPARED	02/06/2006	4:16PM	DOROTHY M DRAKE	301 496 1338
PREPARED	02/16/2006	3:29PM	DOROTHY M DRAKE	301 496 1338
PREPARED	04/19/2006	1:11PM	DOROTHY M DRAKE	301 496 1338
ADJUSTED	04/20/2006	11:12AM	DOROTHY M DRAKE	301 496 1338
ADJUSTED	04/26/2006	5:22PM	DOROTHY M DRAKE	301 496 1338
ADJUSTED	05/02/2006	10:47AM	EILEEN M NEFF	301 496 4271
REVIEWED	05/02/2006	10:48AM	EILEEN M NEFF	301 496 4271
ADJUSTED	05/04/2006	1:47PM	ERIN M HALL	301 496 4271
APPROVED	05/04/2006	2:28PM	ERIN M HALL	301 496 4271

I certify that the electronic signatures listed above are valid and on file.

SIGNED _____ DATE _____

REQUEST FOR APPROVAL TO ACCEPT PAYMENT OF TRAVEL EXPENSES FROM A NON FEDERAL SOURCE

06/22/2006
(date)

s this form to request, approve, and report acceptance of payments as provided in DHHS Travel Manual Chapter 1-70. Submit request to recom-
mending official as soon as possible, but not later than 15 days before scheduled departure.

1. NAME AND TITLE OF TRAVELER
SUNDERLAND, PEARSON /

3. TRAVELER'S ORGANIZATION
HN76V00000C

2. NAME AND ADDRESS OF SPONSORING ORGANIZATION
AMERICAN PSYCHIATRIC
1000 WILSON BOULEVARD
SUITE 1000
ARLINGTON, VIRGINIA 22209, US

4. PURPOSE OF TRIP Sponsored - Foreign
To participate in research planning conference on dementia to co-chair presentation on Markers of Pathophysiology in Geneva, Switzerland, Sept 15-17, 2005.

5. AUTHORITY FOR TRAVEL

[X] 31 USC 1353 [ ] 42 USC 3506 [ ] 5 USC 7342
(See DHHS Travel Manual Chapter 1-70):

METHOD OF PAYMENT:

A. [ ] DIRECT REIMBURSEMENT TO PROJECT/TASK/EXP.TYPE $
PROJECT/TASK/EXP.TYPE

B. [X] IN KIND. . . . . $ 1,496.50

** C. [ ] IN CASH for retention by traveler. . . . . $

**NOTE: CASH MAY ONLY BE ACCEPTED UNDER 42 U.S.C. 3506 AUTHORITY

INDICATE VALUE OF PAYMENT:

TRAVEL	$	790.00
LODGINGS	$	0.00
MEALS	$	706.50
OTHER	$	0.00

AYMENT TO BE USED FOR TRAVEL
[X] ROUND [ ] ONE WAY *(see itinerary below)*

STARTING DATE	ENDING DATE	FROM	TO
09/14/2005	09/14/2005	Bethesda, MD	GENEVA, SUI
09/18/2005	09/18/2005	GENEVA, SUI	Bethesda, MD

7. IS THE DEPARTMENT PAYING PART OF THE COST? *(If any, specify which part and amount)*

8. RECOMMENDATION

9. AUTHORIZATION (SEE DOCUMENT TRACKING AND HISTORY)

10. TRAVELER'S CERTIFICATION *(Complete after trip)*

I certify that while on official travel the above amounts are correct and I did not receive (1) any honoraria, or (2) any cash for my retention from the sponsoring organization. I further understand that any accommodations, meals or incidental expenses accepted that are not normally reimbursed by Government Travel Regulations, and not fully reimbursed by the sponsoring organization will have to be borne out of my personal funds.

DATE 09/28/2005

HS-348 (Rev. 8/92)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health
National Institute of Mental Health
Geriatric Psychiatry Branch

Memorandum

301-496-1338
FAX 301-402-2588

Date August 19, 2005

To William T. Fitzsimmons, Deputy Ethics Counselor

From Trey Sunderland, M.D., Geriatric Psychiatry Branch

Subject Request for Approval of Official Duty - Sponsored Foreign Travel

This is to request that the following activity be approved as an official duty activity. I understand that no honorarium may be accepted. An HHS-348 for sponsored foreign travel will be submitted via the appropriate channels.

Organization/ Address American Psychiatric Association (APA), c/o Ms. Rocio Salvador
1000 Wilson Blvd, Suite 1825, Arlington VA 22209-3901

Meeting: The Future of Psychiatric Diagnosis: Refining the Research Agenda - Diagnostic Issues in Dementia

Meeting location: Warwick Hotel Geneva, 14, rue Lauasanne, 1201 Geneva, Switzerland

Time frame involved: Wed, Sept 14 PM thru Sun, Sept 18, 2005
Estimated time involved: 16 duty hours plus Saturday and Sunday

Nature of Activity: To participate in this research planning conference on dementia to co-chair a presentation on "Markers of Pathophysiology." Attendance at this meeting will provide me with the latest information on diagnostic classifications in the area of dementia, which is my field of expertise, and allow for the exchange of information with others in the scientific community, which supports the mission of the NIH. I have no agreement or relationship with the APA.

Travel expenses paid by: APA: RT economy airfare(in-kind), 3 nights lodging (in-kind) and 4.5 days M&IE
NIH: Local expenses

Point of contact: Sheila Johnson, Administrative Officer

Dottie Drake B/for Dr. Sunderland
Name of Requestor

✓ Approve ___ Disapprove
9/7/05
Supervisor Name Date

___ Approve ___ Disapprove
William T. Fitzsimmons
Deputy Ethics Counselor, IC Date

9/8/05 per wt
Administrative Officer Date

9/8/05 Bill Fitzsimmons spoke with Dr. Rosier, APA. APA will not use federal funds for sponsored travel.

REQUEST FOR APPROVAL TO ACCEPT PAYMENT OF TRAVEL EXPENSES FROM A NON FEDERAL SOURCE

09/13/2005
(date)

Use this form to request, approve, and report acceptance of payments as provided in DHHS Travel Manual Chapter 1-70. Submit request to recommending official as soon as possible, but not later than 15 days before scheduled departure.

1. NAME AND TITLE OF TRAVELER
SUNDERLAND, PEARSON /

3. TRAVELER'S ORGANIZATION
HN76V00000C

2. NAME AND ADDRESS OF SPONSORING ORGANIZATION
AMERICAN PSYCHIATRIC
1000 WILSON BOULEVARD
SUITE 1000
ARLINGTON, VIRGINIA 22209, US

4. PURPOSE OF TRIP Sponsored - Foreign
To participate in research planning conference on dementia to co-chair presentation on Markers of Pathophysiology in Geneva, Switzerland, Sept 15-17, 2005.

5. AUTHORITY FOR TRAVEL

[X] 31 USC 1353 [ ] 42 USC 3506 [ ] 5 USC 7342
(See DHHS Travel Manual Chapter 1-70):

METHOD OF PAYMENT:

A. [ ] DIRECT REIMBURSEMENT TO PROJECT/TASK/EXP.TYPE $
PROJECT/TASK/EXP.TYPE

B. [X] IN KIND. . . . . $ 2,340.50

** C. [ ] IN CASH for retention by traveler. . . . . $

**NOTE: CASH MAY ONLY BE ACCEPTED UNDER 42 U.S.C. 3506 AUTHORITY

INDICATE VALUE OF PAYMENT:

TRAVEL	$	790.00
LODGINGS	$	844.00
MEALS	$	706.50
OTHER	$	0.00

PAYMENT TO BE USED FOR TRAVEL
[X] ROUND [ ] ONE WAY *(see itinerary below)*

STARTING DATE	ENDING DATE	FROM	TO
09/14/2005	09/14/2005	Bethesda, MD	GENEVA,SUI
09/18/2005	09/18/2005	GENEVA,SUI	Bethesda, MD

7. IS THE DEPARTMENT PAYING PART OF THE COST? *(If any, specify which part and amount)*

8. RECOMMENDATION

9. AUTHORIZATION (SEE DOCUMENT TRACKING AND HISTORY)
DEC, NIMH 9/13/05

10. TRAVELER'S CERTIFICATION *(Complete after trip)*

I certify that while on official travel the above amounts are correct and I did not receive (1) any honoraria, or (2) any cash for my retention from the sponsoring organization. I further understand that any accommodations, meals or incidental expenses accepted that are not normally reimbursed by Government Travel Regulations, and not fully reimbursed by the sponsoring organization will have to be borne out of my personal funds.

DATE

.S-348 (Rev. 8/92)

Boikess, Olga (NIH/NIMH)

m: Boikess, Olga (NIH/NIMH)
t: Tuesday, August 23, 2005 4:40 PM
Sunderland, Trey (NIH/NIMH)
Cc: Fitzsimmons, William (NIH/NIMH); Nakamura, Richard (NIH/NIMH)
Subject: FW: APA- Sept 14-18- trip to Switzerland for meeting on Future os Psychiatric Diagnosis - Dementia

The invitation materials that Ms Drake forwarded are helpful, but they don't answer the question - whether or not the APA is using NIH/HHS funds to sponsor your travel. Please establish the source of funds for your sponsored travel.

This activity is eligible for official duty approval - the question is whether or not NIMH can accept APA's sponsored travel. Note that even if APA is using its own non-federal resources, there may be conflict of interest concerns in accepting sponsored travel support from this group.

thank you Olga Boikess

-----Original Message-----
From: Drake, Dorothy (NIH/NIMH)
Sent: Tuesday, August 23, 2005 4:15 PM
To: Boikess, Olga (NIH/NIMH)
Subject: RE: APA- Sept 14-18- trip to Switzerland for meeting on Future os Psychiatric Diagnosis - Dementia

Hi Olga - I am sending you some info now for Dr. Sunderland's trip to Geneva. Dottie

---

From: Boikess, Olga (NIH/NIMH)
ent: Tuesday, August 23, 2005 12:30 PM
: Sunderland, Trey (NIH/NIMH)
Drake, Dorothy (NIH/NIMH); Tosten, Timothy (NIH/NIMH); Johnson, Sheila (NIH/NIMH)
ubject: APA- Sept 14-18- trip to Switzerland for meeting on Future os Psychiatric Diagnosis - Dementia

Since sponsored travel is involved, we need more information.

Among other matters, we need to be sure that APA isn't using HHS funds for this sponsored travel.

Please fax the invitation letter to 301-443-7840

Please provide more information. Who invited you? is this activity supported by NIH or HHS? who will be attending the meeting - types of attendees? how large is the group likely to be?

I tried to look this up on the APA website, but you need to have membership credentials to access the calendar.

thank you Olga Boikess

Sunderland
TR169524

Sunderland, Trey (NIH/NIMH)

From: Rocio Salvador [RSalvador@psych.org]
Sent: Friday, August 12, 2005 12:08 PM
To: Yu Xin; Barry Reisberg; Deborah Blacker; Dilip Jeste; Dr. Baiyewu; Dr. Hampel's Assistant; Dr. O'Brien Assistant; Gary Small; Harald Hampel ; Joao Machado; John Breitner; John O'Brien; John Saunders; Mary Sano; Masatoshi Takeda; Michael B. First; Olasgugun Baiyewu; Robert Terry; Ron Petersen; Simon Lovestone; Sunderland, Trey (NIH/NIMH); William Narrow; Darrel A. Regier, M.D; Erin Dalder; Jennifer Shupinka; Maritza Rubio-Stipec; Paul Sirovatka
Subject: Hotel and Air Logistics for Geneva
Importance: High

Dear Participants of the Research Planning Conference on Dementia,

After the disappointment of having to cancel our conference in Cairo, and the subsequent rush to find a new venue, I am pleased to inform you that we have secured a hotel for our conference in Geneva. I would like to thank each of you for your patience throughout this entire process, I really do appreciate it.

I realize that some of you had already made your travel arrangements through McNair. I have provided a new list to McNair, authorizing each of you to make your flight arrangements through them. If you had already booked a ticket, they will be able to change your flight to reflect our new destination. Please contact McNair Travel at (202) 496-9300 or toll free at (888) 662-2624. If you are calling from outside of the U.S. or Canada please dial + 1-202-496-9300.

For those of you who made your flight arrangements directly, the APA will reimburse you for any costs incurred because of changes to your flight itinerary. Please contact me so that I may answer any questions.

Finally, we have contracted with the Warwick Hotel Geneva, a four star hotel that is located near the main train station at 14, rue Lauasanne; 1201 Geneva Switzerland. Once you have decided on your travel plans, please inform me of your arrival and departure dates so that I may add you to our hotel reservation list directly.

I will be out of the office from August 15th until August 25th, so please copy my colleague Jennifer Shupinka on any response to me or if you have any questions. Her email is jshupinka@psych.org.

Thank you so much for your attention and assistance in this matter. I look forward to hearing from you soon.

With kind regards,
Rocio

Ms. Rocio Salvador
Psychopathology Program Coordinator for DSM V Development, Division of Research
American Psychiatric Association
1000 Wilson Blvd., Suite 1825
Arlington, VA 22209-3901
Phone: (703) 907-8655

Sunderland
TR169524

Sunderland, Trey (NIH/NIMH) * location changed to Geneva

From: Rocio Salvador [RSalvador@psych.org]
Sent: Monday, July 11, 2005 3:11 PM
To: Sunderland, Trey (NIH/NIMH); Barry Reisberg; Dilip Jeste; George Zubenko; John Bretner; Marilyn Albert; Mary Sano; Michael Weiner; Robert Terry; Rudy Tanzi
Cc: William Narrow; Erin Dalder; Jennifer Shupinka; Amy Porfiri
Subject: Air Travel Logistics for Dementia Workgroup Conference in Cairo

Thank you for agreeing to participate in the Dementia Workgroup Conference scheduled for September 14-16, 2005, in Cairo, Egypt.

Shortly you will receive more detailed logistical information for the conference. In the meantime, please use the information provided below to contact McNair Travel for your flight arrangements.

The following is a preliminary outline of the meeting to assist you with making your air reservations:

September 14, 2005: A Welcome Reception and Dinner will be held, starting at 6:00 p.m., location To Be Announced (TBA).

September 15, 2005: The meeting will occur at the hotel in Cairo from 8:00 a.m. to 5:30 p.m. with another Reception and Dinner at 6:00 p.m., location TBA.

September 16, 2005: The meeting will occur at the hotel in Cairo from 8:00 a.m.-5:30 p.m.

The APA will pay for your hotel room at the conference for up to four nights, and will allow one night before the conference (September 13th) and one night at the conclusion of the conference (September 16th) to help make your travel easier.

Please note that all times are tentative and subject to change. This is meant to serve as a guide so you can make your travel plans.

To book your air travel, please do the following:

An account has been set up with MacNair Travel so your airline bill will be paid directly by us. Please contact MacNair Travel at 1-888-662-2624 (Toll Free in the U.S. or Canada); For residents outside the U.S. or Canada, please call 00-1-202-496-9300, 8:30 a.m. – 6:00 p.m., Eastern Time, or you may fax your request to 00-1-202 496-9309. You may also e-mail your request to DLovell@macnairtravel.com. Identify yourself as a Dementia Workgroup Conference participant. Our airfare is based on an economy/coach rate.

If you have already booked air travel, please inform me. In addition, please retain your receipts so we may reimburse you after the conference. Once again, our air fare allowance is based on an economy/coach rate.

Hotel:

We are in the process of setting up our hotel account and will handle your hotel reservations directly. Once you have made your flight arrangements, please send me your arrival and departure dates so that I may add

Sunderland
TR16952

you to our hotel list accordingly.

Please note, again, that the APA will pay for your hotel room at the conference for up to four nights, and will allow one night before the conference (September 13th) and one night at the conclusion of the conference (September 16th).

I will send your confirmation number a few weeks before the conference.

Visas:

McNair Travel has graciously agreed to facilitate visa application for entry into Egypt. If you wish for McNair Travel to assist you in this process, please inform them at the time that you make your flight arrangements. You will need to submit the following:

- Your valid, signed Passport (passport must have at least 6 months validity remaining)
- 1 Application Form, fully completed and signed [Form Attached to this email]
- Completed Cover Page (print from browser) [Form Attached to this email]
- 1 recent passport-type photograph
- Copy of airline tickets or itinerary

If you wish to process your application on your own, please go to the following website to find instructions on how to apply for your visa.

http://www.egyptembassy.us/ On the menu bar on the left of you screen, click on "Consular Services." Several options will appear below this selection, click on "Visa and Consular Services."

You may use the invitation letter, sent earlier by Jennifer Shupinka on behalf of Dr. Regier, to meet the requirement for your visa application. A letter of financial responsibility is forthcoming and will be sent to you via email as soon as it is available.

Finally, my contact information is listed below; please feel free to contact me via this email or via telephone if you have any questions or if I may be of further assistance.

I will be in touch soon with further logistical information.

Cheers,

Rocio

Ms. Rocio Salvador
Psychopathology Program Coordinator for DSM V Development, Division of Research
American Psychiatric Association
1000 Wilson Blvd., Suite 1825
Arlington, VA 22209-3901
Phone: (703) 907-8653
Fax: (703) 907-1087

8/19/2005

Document Summary for Adjustment to Authorization TR169524 (View Only)

Quick Tip
For specific information, click on a Details link. You can sign and stamp your document from the Document Status section.

For this Document you can:
continue Entering Document
close Current Document

Travel Authorization Number

Itinerary Details GENEVA,SUI 09/14/05 - 09/18/05

Purpose Description To participate in research planning conference on dementia to co-chair presentation on Markers of Pathophysiology in Geneva, Switzerland, Sept 15-17, 2005.

Ticketed Trans Details $790.00

Expense Details

Expense Summary

Document Status

Edit	Delete	Date	Expense	Amount	Pmt Method
		09/14/2005	Taxi	25.00	OTHER
		09/15/2005	Taxi	10.00	OTHER
		09/18/2005	Taxi	25.00	OTHER
		09/18/2005	Taxi	10.00	OTHER
				Total: 70.00	

Lodging/M&IE Details $1,550.50

Other Authorizations Details FOREIGN TRAVEL
SPONSORED TRAVEL

Accounting Code Details

Accounting Code Summary

Label	Amount
109909/1	70.00
109952/1	0.00
Total:	70.00

Sponsor Details

Sponsor Summary

Sponsor Name	Reimbursable Amount	In-Kind Amount
AMERICAN PSYCHIATRIC ASSOCIATION, MINORITY FELLOWSHIPS PROGRAM	0.00	2,340.50
Total:	0.00	2,340.50

Totals Details

Totals Summary

Disbursement Type	Amount
Estimated Cost	70.00
Advance Requested	0.00

Enter Comments Approved as official duty on 9/7/05. NFT approved on 9/9/05.

Document Status

Document Status

Enter Status/PIN to stamp this document

Document Status: REVIEWED **Awaiting:** BARBARA E VERMILLION

☐ **Final Voucher**

Status To Apply Remarks

Vermillion, Barbara (NIH/NIMH)

From: Klein, Pamela (NIH/NIMH)
Sent: Tuesday, September 13, 2005 9:02 AM
To: Vermillion, Barbara (NIH/NIMH)
Subject: Travel Manager Correspondence

Travel Authorization TR169524 with first destination GENEVA,SUI departure date 09/14/05 purpose Sponsored - Foreign is now available.

If you are the TRAVELER (PEARSON SUNDERLAND) then click the URL provided below to review this Authorization and confirm your trip details:
<https://nbrssprod.cit.nih.gov:8920/evoucher/evMain.jsp?evParam=vchnum_TR169524 _doctype_Authorization>

If you are the travel APPROVER, please click http://my.nih.gov and access Gelco Route and Review Module to approve this document.

DATE: 09/09/2005
TO: Barbara Vermillion
FAX#: 301-443-6893
FROM: EILEEN NEFF
FAX#: 301-480-4533
PHONE: 301-594-8062

OF PAPERS INCLUDING COVER SHEET: 4

Please find attached the sponsor letters for Trey Sunderland's travel (TR169524) to Geneva, Switzerland on 09/14/2005.

Thank you very much, Eileen

Approved Trip Information

LastName	FirstName	Title	Employee status	Degree	Phone Number
SUNDERLAND	PEARSON	SENIOR INVESTIGATOR	PHS-CO	M.D.	301-496-0948

Agency	Center	Division	Cable	Additional Organization	Preparer	Preparer Phone	Preparer Email	Trip_D
NIH	NIMH		YES		Dottie Drake	301-496-1338	dorothydrake@mail.nih.gov	09/14/2

SecurityStatus	International Emergency Contact
APPROVED	Research Planning Conference on Dementia sponsored by American Psychiatric Association - contact is Rocio Salvador, APA, 1000 Wilson Blvd, Suite 1825, Arlington VA 22209, tel 703-907-8655; meeting and lodging at Warwick Hotel Geneva, 14, rue Lausanne, 1201 Geneva, Switzerland; Embassy of US (in Bern) Tel 031-357-7011

Dates	Locations	Purpose/Areas of activity/Explanation
09/15/2005 09/18/2005	Switzerland Geneva	**Meeting Speaker/Presenter -- gerontology/aging; mental health** Traveler will participate in APA-sponsored Research Planning Conference on Dementia to co-chair a presentation on "Markers of Pathophysiology"

FundingSource	FundingDetails	Amount
INDUSTRY	American Psychiatric Association	2,446.00
NIH	NIMH	70.00

Total Air Fare	Total PerDiem	Total ODC	Grand Total
790.00	1,656.00	70.00	2,516.00

MultilatOrg	Multilateral Meting Title	ML File	Business Class	Explanation
NONE		NONE	No	

Author	Action	Date	Time	LateJustification	Comment
HHS APPROVER	APPROVE	09/09/2005	10:45:34	NONE REQUIRED	NO COMMENTS MADE
NIH APPROVER	APPROVE	09/08/2005	17:14:10	OTHER	NO COMMENTS MADE
NIH APPROVER	AMEND	09/08/2005	17:13:50	NONE REQUIRED	JUSTIFICATION: LATE INVITATION
NIH SECURITY	SEC_APPROVE	09/08/2005	16:11:15	NONE REQUIRED	NO COMMENTS MADE
CIOB NIMH	APPROVE	09/08/2005	13:52:54	NONE REQUIRED	CARLITA MARSH 9/8/05
PREPARER	NEW	09/08/2005	13:11:46	LATE INVITATION	JUSTIFICATION: LATE INVITATION

Return to Main Menu

NIH Travel Request Form

RECEIVED
SEP 0 8 2005
Assoc. Dir. for Admin. Services

Note: This template is not an official form and its use is not required.

INSTRUCTIONS: This template is for Travel Planner or Traveler use ONLY. It is provided to assist in the communication of information and recommendations needed to complete official travel documents.

TAB to each field and complete the items pertinent to the trip. **SAVE document on your hard drive** and send as an e-mail attachment to the Recommending Official (Traveler's Supervisor) for concurrence. The form should then be returned to the Travel Planner via e-mail attachment or hard copy so travel documents may be prepared.

1. TRAVELER INFORMATION			
Traveler Name (Last, First, MI)	SUNDERLAND, P. Trey	NIH Employee ID Number	001-00-75074
Building/Room#	10 CRC, Room	Office Phone	301-496-0948
Position/Title	Senior Investigator	Fax No.	

2. TRIP INFORMATION			
Travel Departure (BEGIN) Date	09/14/2005	Travel Return (END) Date	09/18/2005
Trip Description	To participate in research planning conf. on dementia to co-chair presentation on Markers of Pathophysiology in Geneva, Switzerland, Sept 15-17,2005.		

Trip Leg	Per Diem Location	Arrival Date (mm/dd/yy)	Arrival Time	Departure Date (mm/dd/yy)	Departure Time
1	Geneva, Switzerland	09/15/04	10:00 AM	09/18/05	8:00 AM
2					
3					
4					
5					

3. SPONSORED TRAVEL INFORMATION				
Is this a Sponsored Trip?	x☐Yes ☐No (If No, go to SECTION 4)		☐ Late Memo?	
Do you have any conflicts of interest with this sponsor that will prevent you from answering "no" to all Sponsored Travel Checklist Questions?				☐Yes x☐No
Sponsored Expenses/Cost Breakdown	Airfare:	$ 790.00	$	Additional:
	Lodging:	$ 633.00	$	
	Meals:	$ 706.50	$	

Sponsor Name	Sponsor Contact Name	Sponsor Address	Sponsor Telephone
Amer.Psychiatric Association	Ms. Rocio Salvador	1000 Wilson Blvd., Arlington VA 22209	703-907-8655

NIH Travel Request Form

4. TRAVEL EXPENSES (OTHER THAN PER DIEM)

Transportation Mode	x☐AIR ☐ POV ☐TRAIN ☐ BUS ☐ GOV Vehicle
Terminal Information/routing	Comments:
Ground Transportation to/from airport or depot	$ or Enter # of POV Miles:
Enter other anticipated expenses (e.g. Taxis, parking, telephone, rental car and other allowable miscellaneous expenses.	1. $100 taxis/shuttles 2. 3.

Registration Fees should be paid using:

1. Direct Payment by the Government using the I.M.P.A.C Visa Purchase Card
2. Direct Payment by the Government with Pre-Trip Direct Deposit
3. Pre-Payment by Traveler
4. Fixed Fee Events - Where registration fees and other costs (e.g., one night of lodging) are required in advance, the Government-issued Purchase Card should be used to pay for these expenses. Breaking down the costs of meals, lodging, etc. will no longer be a requirement

Registration Fees	$	Lodging/Meals Included? ☐Yes ☐No	Comments:

5. TRAVEL PREFERENCES and SPECIAL TRAVEL CIRCUMSTANCES

Preferred HOTEL		
Is Gov. Per Diem being used?		☐ Yes x☐No
Is Conference Rate (CLA) required?		☐ Yes x☐No
Is an Actual Expense Authorization (AEA) required? (Justification memo)	☐ Yes x☐No	Comments:
If this is a foreign trip, has the Notification of Foreign Travel (NFT) been submitted to Fogarty? (Add URL)		☐ Yes ☐No x☐N/A
Do you require exemption from the use of the government travel card?		☐ Yes x☐No
Do you require First Class or other Premium Class transportation tickets?		☐ Yes x☐No
Will you be purchasing an airline ticket using personal funds (>$100.00 USD)		☐ Yes x☐No
Will you use annual or personal leave while on this trip?		☐ Yes x☐No
Are you eligible to earn Compensatory Time Off for Travel?		☐ Yes x☐No

Annual Leave Date(s)	Hours	Comments/Explanation

NIH Travel Request Form

6. ACCOUNTING INFORMATION	
Project Number (DIRECT EXPENSES)	109909
Project Number (REIMBURSABLE EXPENSES)	109952

7. TRAVEL CASH ADVANCE

Employees and Commissioned Officers who travel frequently (two or more trips per year) on official business are responsible for meeting their travel expenses. However, these employees should not have to pay official travel expenses entirely from personal funds unless they have elected not to use the Government contractor-issued charge card.

An ATM cash advance may be taken, not to exceed the greater of: the estimated out-of-pocket cost of the trip, $300.00 per day, or $600.00 per week.

Cash (Direct Deposit) Advance Requested	☐Yes x☐No (If no, proceed to Section 8)	
Reason for Cash Advance	☐Infrequent Traveler (One trip per year or fewer) ☐Not Eligible for Travel Card ☐Other (Please provide explanation)	Reason for Cash Advance (Other):
Other Trip Information:		

8. Recommending Signature

Recommending Official:	I, Timothy Tosten (enter name) Recommend this Travel. ☒Yes ☐No

Associate Director
for Administration, DIRP, NIMH

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health
National Institute of Mental Health
Geriatric Psychiatry Branch

Memorandum

301-496-1338
FAX 301-402-2588

Date August 19, 2005

To William T. Fitzsimmons, Deputy Ethics Counselor

From Trey Sunderland, M.D., Geriatric Psychiatry Branch

Subject Request for Approval of Official Duty - Sponsored Foreign Travel

This is to request that the following activity be approved as an official duty activity. I understand that no honorarium may be accepted. An HHS-348 for sponsored foreign travel will be submitted via the appropriate channels.

Organization/ Address American Psychiatric Association (APA), c/o Ms. Rocio Salvador
1000 Wilson Blvd, Suite 1825, Arlington VA 22209-3901

Meeting: The Future of Psychiatric Diagnosis: Refining the Research Agenda - Diagnostic Issues in Dementia

Meeting location: Warwick Hotel Geneva, 14, rue Lauasanne, 1201 Geneva, Switzerland

Time frame involved: Wed, Sept 14 PM thru Sun, Sept 18, 2005
Estimated time involved: 16 duty hours plus Saturday and Sunday

Nature of Activity: To participate in this research planning conference on dementia to co-chair a presentation on "Markers of Pathophysiology." Attendance at this meeting will provide me with the latest information on diagnostic classifications in the area of dementia, which is my field of expertise, and allow for the exchange of information with others in the scientific community, which supports the mission of the NIH. I have no agreement or relationship with the APA.

Travel expenses paid by: APA: RT economy airfare(in-kind), 3 nights lodging (in-kind) and 4.5 days M&IE
NIH: Local expenses

Point of contact: Sheila Johnson, Administrative Officer

Dottie Drake S/for Dr. Sunderland
Name of Requestor
9/9/05

✓ Approve ___ Disapprove
9/7/05
Supervisor Name Date

✓ Approve ___ Disapprove
William T. Fitzsimmons
Deputy Ethics Counselor, IC Date
per wt
9/8/05
Administrative Officer Date

Bill Fitzsimmons spoke with Dr. Rosier, APA. APA will not use federal funds for sponsored travel.

The Future of Psychiatric Diagnosis: Refining the Research Agenda
Diagnostic Issues in Dementia
September 15-17, 2005
Geneva, Switzerland

Thursday, September 15th

Welcome Dinner and Reception
Location TBA
Geneva, Switzerland
7:30-9:30 p.m.
Speakers:
Darrel Regier
Benedetto Saraceno (tentative)
Trey Sunderland
Dilip Jeste
Olusegun Baiyewu

Friday, September 16th

Buffet Breakfast to be served at the hotel
7:30-8:30 a.m.

Transport to the University of Geneva
(participants will meet in hotel lobby)
8:30 a.m.

Welcome and Aims
9:00-9:30 a.m.
Darrel Regier, Norman Sartorius,
Trey Sunderland, Dilip Jeste, Olusegun Baiyewu

The Neuropathology of Dementia
9:30-10:10 a.m.
Presenter: Robert Terry
General Discussion

Morning Break
10:10-10:30 a.m.

Differential Diagnosis of Dementia
10:30-11:10 a.m.
Presenter: Masatoshi Takeda
General Discussion

Mild Cognitive Impairment: Is it Real Yet?
11:10 a.m. -12:00 noon.
Presenter: Ron Peterson
Discussant: John O'Brien
General Discussion

Lunch
12:00-1:00 p.m.

Merging Differences Between DSM and ICD
1:00-1:50 p.m.
Presenter: Barry Reisberg
Discussant: Norman Sartorius (Benedetto Saraceno tentative)
General Discussion

Epidemiologic Considerations in Dementia
(and Cross-Cultural Differences in the Nomenclature)
1:50-2:30 p.m.
Presenter: John Breitner
General Discussion

Afternoon Break
2:30-2:50

Genetics of Dementia: Diagnostic vs. Prognostic
2:50-3:40 p.m.
Presenter: Deborah Blacker
Discussant: Simon Lovestone
General Discussion

Neuropsychological Testing
3:40-4:20 p.m.
Presenter: Mary Sano
General Discussion

Close and Adjournment
4:20-4:30 p.m.

Reception at World Health Organization
6:30-7:30 p.m.

Dinner
7:45-9:45 p.m.
Location TBA

Saturday, September 17th

Buffet Breakfast to be served at the Hotel Warwick
7:30-8:30 a.m.

Behavioral Complications +/- Prodromes
9:00-9:40 a.m.
Presenter: Dilip Jeste
General Discussion

Neuroimaging as a Surrogate Marker of Disease
9:40-10:20 a.m.
Presenter: Gary Small
General Discussion

Morning Break
10:20-10:40 a.m.

Markers of Pathophysiology
10:40-11:30 a.m.
Presenter: Trey Sunderland
Discussant: Harald Hampel

General Discussion
11:30 a.m. - 12:00 noon
Led by Trey Sunderland and Dilip Jeste
with special discussions from Joao Machado and Tarun Dua

Assignment of Disorder Groups and Description of Group Tasks
12:00- 12:15 p.m.

Disorder Workgroup tasks:

I. Identification of strengths and weaknesses of the current diagnostic criteria

II. Identification of promising hypotheses that could be tested in the next few years to make the criteria more valid and/or useful

III. Identification of hypotheses that are currently emerging but could only be addressed by significant technological breakthroughs over a longer time period

IV: Delegation of work group member to prepare brief power point presentation of results

12:15 -2:00 p.m.
Disorders Workgroup Collaboration

2:00-3:00 p.m.
Presentation of Summaries of Workgroup Collaborations
(Each workgroup will present a 15 minute summary of his/her workgroup's collaborations, followed by a 15 minute question and answer session)

3:00-3:30
Closing Comments:
Outlining a Future Research Agenda and Thanks
Dilip Jeste, Trey Sunderland

3:30
Adjournment

Trip Information

LastName	FirstName	Title	Employee status	Degree	Phone Number
SUNDERLAND	PEARSON	SENIOR INVESTIGATOR	PHS-CO	M.D.	301-496-0948

Agency	Center	Division	Cable	Additional Organization	Preparer	Preparer Phone	Preparer Email	Trip_D
NIH	NIMH		NO		Dottie Drake	301-496-1338	dorothydrake@mail.nih.gov	09/14/2

SecurityStatus	International Emergency Contact
------	Research Planning Conference on Dementia sponsored by American Psychiatric Association - contact is Rocio Salvador, APA, 1000 Wilson Blvd, Suite 1825, Arlington VA 22209, tel 703-907-8655; meeting and lodging at Warwick Hotel Geneva, 14, rue Lausanne, 1201 Geneva, Switzerland; Embassy of US (in Bern) Tel 031-357-7011

Dates	Locations	Purpose/Areas of activity/Explanation
09/15/2005 09/18/2005	Switzerland Geneva	**Meeting Speaker/Presenter -- gerontology/aging; mental health** Traveler will participate in APA-sponsored Research Planning Conference on Dementia to co-chair a presentation on "Markers of Pathophysiology"

FundingSource	FundingDetails	Amount
INDUSTRY	American Psychiatric Association	2,446.00
NIH	NIMH	70.00

Total Air Fare	Total PerDiem	Total ODC	Grand Total
790.00	1,656.00	70.00	2,516.00

MultilatOrg	Multilateral Meting Title	ML File	Business Class	Explanation
NONE		NONE	No	

Author	Action	Date	Time	LateJustification	Comment
PREPARER	NEW	09/08/2005	13:11:46	LATE INVITATION	JUSTIFICATION: LATE INVITATION

Select Action:

Please select an action to perform on the record detailed above and then press **Update Record.**

- ◉ **Approve:** Selecting this option will send the record to OIA for approval.
- ○ **Disapprove:** Selecting this option will notify the preparer that the trip request requires changes.
- ○ **Cancel:** Selecting this option will cancel the trip.

Add Comments:

Carlita Marsh 9/8/05

SUBMIT

NIH Travel Request Form

TR 169524

Note: This template is not an official form and its use is not required.

INSTRUCTIONS: This template is for Travel Planner or Traveler use ONLY. It is provided to assist in the communication of information and recommendations needed to complete official travel documents.

TAB to each field and complete the items pertinent to the trip. **SAVE document on your hard drive** and send as an e-mail attachment to the Recommending Official (Traveler's Supervisor) for concurrence. The form should then be returned to the Travel Planner via e-mail attachment or hard copy so travel documents may be prepared.

1. TRAVELER INFORMATION

Traveler Name (Last, First, MI):	SUNDERLAND, P. Trey	NIH Employee ID Number:	001-00-75074
Building/Room#:	10 CRC, Room	Office Phone:	301-496-0948
Position Title:	Senior Investigator	Fax No:	

2. TRIP INFORMATION

Travel Departure (BEGIN) Date:	09/14/2005	Travel Return (END) Date:	09/18/2005
Trip Description:	To participate in research planning conf. on dementia to co-chair presentation on Markers of Pathophysiology in Geneva, Switzerland, Sept 15-17,2005.		

Trip Leg	Per Diem Location	Arrival Date (mm/dd/yy)	Arrival Time	Departure Date (mm/dd/yy)	Departure Time
1	Geneva, Switzerland	09/15/04	10:00 AM	09/18/05	8:00 AM
2					
3					
4					
5					

3. SPONSORED TRAVEL INFORMATION

Is this a Sponsored Trip?	x☐Yes ☐No (If No, go to SECTION 4)	☐ Late Memo?	
Do you have any conflicts of interest with this sponsor that will prevent you from answering "no" to all Sponsored Travel Checklist Questions?			☐Yes x☐No
Sponsored Expenses/Cost Breakdown:	Airfare: $ 790.00	$	Additional:
	Lodging: $ 633.00	$	
	Meals: $ 706.50	$	

Sponsor Name	Sponsor Contact Name	Sponsor Address	Sponsor Telephone
Amer.Psychiatric Association	Ms. Rocio Salvador	1000 Wilson Blvd., Arlington VA 22209	703-907-8655

NIH Travel Request Form

4. TRAVEL EXPENSES (OTHER THAN PER DIEM)

Transportation Mode	x☐AIR ☐ POV ☐TRAIN ☐ BUS ☐ GOV Vehicle
Terminal Information routing	Comments:
Ground Transportation to/from airport or depot	$ or Enter # of POV Miles:
Enter other anticipated expenses (e.g. Taxis, parking, telephone, rental car and other allowable miscellaneous expenses)	1. $100 taxis/shuttles 2. 3.

Registration Fees should be paid using:

1. Direct Payment by the Government using the JMP A/C Visa Purchase Card
2. Direct Payment by the Government with Pre-Trip Direct Deposit
3. Pre-Payment by Traveler
4. Fixed Fee Events - Where registration fees and other costs (e.g. one night of lodging) are required in advance, the Government issued Purchase Card should be used to pay for these expenses. Breaking down the costs of meals, lodging, etc. will no longer be a requirement.

Registration Fees	$	Lodging/Meals Included? ☐Yes ☐No	Comments:

5. TRAVEL PREFERENCES and SPECIAL TRAVEL CIRCUMSTANCES

Preferred HOTEL		
Is Gov. Per Diem being used?		☐ Yes x☐No
Is Conference Rate (CLA) required?		☐ Yes x☐No
Is an Actual Expense Authorization (AEA) required? (Justification memo)	☐ Yes x☐No	Comments:
If this is a foreign trip, has the Notification of Foreign Travel (NFTrbee) submitted to Foreign? (Add URL)		☐ Yes ☐No x☐N/A
Do you require exemption from the use of the government travel card?		☐ Yes x☐No
Do you require First Class or other Premium Class transportation tickets?		☐ Yes x☐No
Will you be purchasing an airline ticket using personal funds (Cardholder Option)		☐ Yes x☐No
Will you use annual or personal leave while on this trip?		☐ Yes x☐No
Are you eligible to earn Compensatory Time Off for Travel?		☐ Yes x☐No

Annual Leave Date(s)	Hours	Comments/Explanation

NIH Travel Request Form

6. ACCOUNTING INFORMATION	
Project Number (DIRECT EXPENSES)	109909
Project Number (REIMBURSABLE EXPENSES)	109952

7. TRAVEL CASH ADVANCE		
Employees and Commissioned Officers who travel frequently (two or more trips per year) on official business are responsible for meeting their travel expenses. However, these employees should not have to pay official travel expenses entirely from personal funds unless they have elected not to use the Government contractor-issued charge card. An ATM cash advance may be taken, not to exceed the greater of: the estimated out-of-pocket cost of the trip, $300.00 per day, or $600.00 per week.		
Cash (Direct Deposit) Advance Requested:	☐Yes x☐No (If no, proceed to Section 8)	
Reason for Cash Advance:	☐Infrequent Traveler (One trip per year or fewer) ☐Not Eligible for Travel Card ☐Other (Please provide explanation)	Reason for Cash Advance (Other):
Other Trip Information:		

8. Recommending Signature	
Recommending Official	I, Timothy Tosten (enter name) Recommend this Travel. ☐Yes ☐No

JAMES P. MORAN
8TH DISTRICT OF VIRGINIA

COMMITTEE ON APPROPRIATIONS
SUBCOMMITTEES:
DEFENSE
INTERIOR

www.house.gov/moran

WASHINGTON OFFICE:
2239 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-4608
(202) 225-4376
FAX: (202) 225-0017

DISTRICT OFFICES:
51158 FRANCONIA ROAD
ALEXANDRIA, VA 22310
(703) 971-4700
FAX: (703) 922-8436

SUITE 312
1760 RESTON PARKWAY
RESTON, VA 20190
(703) 481-4339
FAX: (703) 481-4338

Congress of the United States
House of Representatives

July 5, 2005

Dr. Thomas R. Insel
Director
National Institute of Mental Health
6001 Executive Boulevard, 8235 NSC
Bethesda, MD 20892-9663

Dear Dr. Insel:

I am writing in reference to the Biocard Family Study, a longitudinal study on Alzheimer's disease that has been underway within the NIMH for a number of years. I understand from a constituent and also the national Alzheimer's Association, that this study is very important to help us better understand the origins of Alzheimer's disease and could be critical to someday bringing an end to this terrible disease. It is my understanding that the continuation of the Biocard Family Study may be in jeopardy.

I would hope that the Biocard Family Study would continue to completion, in part because of the wealth of data that has been collected on individuals with a family history of this illness. I realize there may be extenuating circumstances for this study centering on its long time principal investigator. Notwithstanding those issues, I would hope others could keep the study going and not waste the years of investment while the issues are resolved. It would be a shame to waste the investment and risk slowing progress on treatments, prevention and perhaps someday even a cure for Alzheimer's disease.

As a member of the Congressional Alzheimer's Caucus, I have worked with my colleagues to increase funding for the NIH in order to speed the progress on such devastating diseases as Alzheimer's. I am pleased with the reports I've been receiving on progress to date and will continue to fight for increased funding. I especially appreciate the work of the NIMH along with other institutes, such as the NIA and NINDS, on Alzheimer's research. Our nation cannot sustain the projected growth in numbers of Americans who will suffer from this disease if we do not end it or at least find ways to delay its onset and slow its progression.

I would appreciate hearing from you on NIMH's plans for the Biocard Family Study. If you have any questions, please do not hesitate to contact Renee McDonald of my office at (202) 225-4376.

Sincerely,

Jim Moran

James P. Moran

JPM/tm

223821

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of Mental Hea
6001 Executive Blvd.
Bethesda, Maryland 20892

AUG 5 2005

The Honorable James P. Moran
United States House of Representatives
Washington, DC 20515-4608

Dear Mr. Moran:

Thank you for your letter regarding the Biocard Family Study (Biomarkers in Older Controls at Risk for Alzheimer's Disease), a longitudinal investigation of individuals at risk for Alzheimer's disease. The National Institute of Mental Health (NIMH) is committed to reducing the burden of mental illness, including the behavioral manifestations of Alzheimer's disease, through research on etiology, prevention and treatment. The Biocard study has enrolled 350 participants and has been directed by Dr. Trey Sunderland as Principal Investigator (PI) since its inception in NIMH's Division of Intramural Research Programs in 1995. As you may know, Dr. Sunderland is planning to leave NIMH to take a new position as a professor of psychiatry at the Albert Einstein College of Medicine in New York. Typically, when a PI leaves a study, it either closes altogether or is continued by the PI in a new venue. So, in December 2004, all participants in the study were notified in writing of Dr. Sunderland's intention to continue this research from his new position in New York.

You may be assured that we at NIMH are very concerned with issues of mental health and mental illness in older adults and have recently established a new extramural branch to focus and coordinate research in this increasingly important area.

I very much appreciate having the benefit of your views; please do not hesitate to contact me if you require further information.

Sincerely yours,

Thomas R. Insel, M.D.
Director

NIMH
National Institute
of Mental Health

16

[redacted]
Tab 23

Slobodin, Alan

From: Hemard, Casey (HHS/ASL) [Casey.Hemard@HHS.GOV]
Sent: Wednesday, September 06, 2006 4:12 PM
To: Slobodin, Alan
Cc: Flamberg, Gemma (NIH)

Alan, in response to your question, please see below:
As you know, Dr. Joel Kleinman was recently named the Principal Investigator of the Biocard study. Please provide a list of the associate investigators (their names and affiliations) on this study and any changes in the listings of associate investigators since June 1, 2006. Thanks.

Currently, for Protocol #95-M-0096,
Principal Investigator: Joel Kleinman, MD (NIMH)
Associate Investigators: Blaine Greenwood, MD (North Shore Hospital System, NY)
John Kane, MD (North Shore Hospital System, NY)
William Klunk, MD (University of Pittsburgh)
Francois Lalonde, PhD (NIMH)
Karen Putnam (formerly NIMH)
P. Trey Sunderland, MD (NIMH)
These investigator changes were submitted to the IRB on 3/6/06 and approved on 7/6/06.

ey Hemard
..nselor on Oversight
U.S. Department of Health and Human Services
Office of the Assistant Secretary for Legislation
Casey.Hemard@hhs.gov
(202) 690-7627

Tab 24

Flamberg, Gemma (NIH/OD) [E]

From: Putnam, Karen T. (NIH/NIMH)
Sent: Wednesday, January 12, 2005 8:40 AM
To: Copenhaver, Brittany (NIH/NINDS) [C]
Cc: Sunderland, Trey (NIH/NIMH) [E]
Subject: LITHIUM CSF VIAL PULL

Follow Up Flag: Follow up
Flag Status: Flagged

Attachments: BRITTANY.SMCSF05.12JAN05.xls

Good morning Brittany,

Attached is an excel sheet with the 20 vials I described yesterday for the next CSF vial project. All of these samples will be pulled from the OLD system and realiquoted into the .5cc tubes. Then we will blind one tube for each CSF date, labeled with the corresponding label name listed in the excel sheet (SM05_01—SM05_20). The remaining sample will be filed w/the other old system realiquoted vials in the freezer. In columns Q & R you will see that some subjects already have some NEW system realiquoted vials, however we plan to use the older OLD system vials for this project.

These vials will probably be picked up directly and not need to be shipped out, however we will need a styrofoam box and dry ice for transport.
Please let me know which ones you cannot locate and if you have any questions.

Talk w/you later today or tomorrow

BRITTANY.SMCSF0
5.12JAN05.xls (...

Sincere thanks
Karen

SM Lit[illegible] CSF Project 11Jan05

CODENAME	CSFDATE	VISITNO	LABEL	TOT_CSF	V_1	V_2	V_2A	V_3	V_45	V_6A	V_6B	V_7	V_89	METHOD	OBS	V_BLUE	V_CLR
	25-Oct-91	1	SM05_20	9	.	3	3	3	.	.	.	.	.	OLD	1	.	.
	25-Nov-91	1	SM05_05	8.5	5	.	3	.	.	.	.	.	.	OLD	2	.	0.5
	16-Dec-92	1	SM05_06	10.5	.	.	3	.	.	.	.	.	1	OLD	3	1.5	5
	7-Jan-93	1	SM05_19	11	5	.	3	.	.	.	.	3	.	OLD	4	.	.
	15-Sep-92	1	SM05_08	10	.	3	.	3	3	.	.	.	1	OLD	5	.	.
	8-Oct-92	1	SM05_13	13	.	3	3	3	.	.	.	3	1	OLD	6	.	.
	30-Jun-92	5	SM05_10	13	.	3	3	3	.	.	.	3	1	OLD	7	.	.
	24-Jul-92	5	SM05_01	7	5	.	.	.	.	.	.	.	.	OLD	8	2	.
	13-Jan-93	2	SM05_04	8	5	.	.	.	3	.	.	.	.	OLD	9	.	.
	10-Feb-93	2	SM05_14	12	.	3	3	3	3	.	.	.	.	OLD	10	.	.
	14-Feb-92	7	SM05_15	13	.	3	3	3	.	.	.	3	1	OLD	11	.	.
	11-Mar-92	7	SM05_07	11	5	.	3	.	.	.	.	3	.	OLD	12	.	.
	17-Jan-92	2	SM05_17	12	.	3	3	3	.	.	.	3	.	OLD	13	.	.
	20-Feb-92	2	SM05_09	11	5	.	3	.	.	.	.	3	.	OLD	14	.	.
	13-May-92	1	SM05_12	6	.	3	.	3	.	.	.	.	.	OLD	15	.	.
	17-Jun-92	1	SM05_02	10.5	.	.	3	.	3	.	.	3	.	OLD	16	1.5	.
	16-Dec-91	0	SM05_18	2	.	.	.	.	.	.	.	.	.	OLD	17	.	2
	28-Jan-92	0	SM05_11	8	5	.	.	.	.	.	.	3	.	OLD	18	.	.
	10-Feb-93	0	SM05_03	5	5	.	.	.	.	.	.	.	.	OLD	19	.	.
	1-Apr-93	0	SM05_16	3	.	.	.	.	.	.	.	3	.	OLD	20	.	.

Flamberg, Gemma (NIH/OD) [E]

[redacted]:	Copenhaver, Brittany (NIH/NIMH)
[redacted]:	Tuesday, January 18, 2005 1:58 PM
To:	Sunderland, Trey (NIH/NIMH) [E]; Putnam, Karen T. (NIH/NIMH) [E]
Subject:	lithium CSF shipment
Follow Up Flag:	Follow up
Flag Status:	Flagged

Hi Trey & Karen,
For your records - FedEx just picked up the shipment of the 20 CSF lithium samples. It was sent to:

Virgina Lee
Maloney 3, HUP,
3600 Spruce Street
Philadelphia PA, 19104-4283

They said it will arrive by 10:30 tomorrow morning.

Have a great afternoon!
Brittany

Brittany R. Copenhaver
Geriatric Psychiatry Branch, NIMH
National Institutes of Health
copenhaverb@mail.nih.gov
301-435-6060

Flamberg, Gemma (NIH/OD) [E]

From: Putnam, Karen T. (NIH/NIMH)
Sent: Thursday, February 03, 2005 3:36 PM
To: Copenhaver, Brittany (NIH/NINDS) [C]
Subject: RE: ?

Follow Up Flag: Follow up
Flag Status: Flagged

Hello hello to you ☺

Lucky you w/the snow...enjoy

Good to her that merjud got dna; no problem about the entering. You can of course, just wait until next M or T and use MaryBeth machine.

The current 20 samples are not going w/the big shipment, they are a separate study. They will be going to NY.

Talk w/you soon
K

PS. We are still working on the ship date for the big shipment. What is the final number for that shipment--thanks

---

From: Copenhaver, Brittany (NIH/NIMH)
Sent: Thursday, February 03, 2005 2:27 PM
To: Putnam, Karen T. (NIH/NIMH)
Subject: RE: ?

Hello hello... good to hear you got snow, we are getting quite a bit right now!

Yes, merjud got dna done, I just haven't entered it yet. I'll get it entered today.

I just finished realiquoting everything, so let me know when to ship it all of. These extra 20 are going with the big shipment, right?

Talk to you later!
Brittany

From: Putnam, Karen T. (NIH/NIMH)
Sent: Thursday, February 3, 2005 12:31 PM
To: Copenhaver, Brittany (NIH/NIMH)
Subject: ?

Morning Brittany

Hope you are well today, Ohio got a lovely snow last night.

Quick question..did merjud get dna done when she was here in early Dec?
Thanks

Flamberg, Gemma (NIH/OD) [E]

From: Sunderland, Trey (NIH/NIMH)
Sent: Monday, February 07, 2005 10:05 AM
To: Copenhaver, Brittany (NIH/NINDS) [C]
Cc: Putnam, Karen T. (NIH/NIMH) [E]
Subject: CSF Shipment and Freezers
Follow Up Flag: Follow up
Flag Status: Flagged

Hi Brittany,

Here is the address for the CSF shipment.

Peter Davies, PhD
Dept of Pathology, F526
Albert Einstein College of Medicine
1300 Morris Park Ave
Bronx, NY 10580
718 430 3083 (phone)
718 430 8541 (fax)
davies@aecom.yu.edu

Also, I wanted you to see my correspondence with Terri Tolliver about the freezer space. We will see what happens on that front.

Hope you had a good weekend,

Trey

Hi Terri,

Thanks for the update. I certainly understand your situation, but please remember that the space your freezer is currently occupying a spot that has been our space for many years. The only reason it was vacant temporarily is because of a freezer breakdown of our own. You did what anyone would do in an emergency and found an available space...in this case, ours.

Now that the freezer has been repaired and ready to be returned, we need that, or an equivalent spot nearby. I don't really care if the space is slightly down the hall, but I do not think it is appropriate to ask us contact the SD office about where to put our freezer. After all, your freezer is borrowing our space at the moment.

I am sure we will be able to work something out. On the good side, we may be having space open up for you by the end of the summer, as we hope to move some of these freezers permanently, so the squeeze is really only temporary.

Let me know what plan you come up with.

Trey

PS Dennis, hope your flu is getting better...see you soon.

Good Morning Trey,

Dennis is sick with the flu. He emailed me this morning and asked me to tell you what was going on.

We are in the process of consolidating some of samples into our newer freezers on the N corridor but one of freezers went down. Rental brought a new freezer for us to use and plugged it in N corridor to help us out but it kept blowing the circuit breaker. The circuits need to be rotate to another circuit in the electrical panel before that freezer can be plugged in. We put in an emergency work request to have the power from some of freezers on the N corridor switched to a different circuit but there was no telling when they will get to us. To get the power checked on our corridor I had to call the Clinical Center maintenance 4 times and they finally showed up at 2:30 in the afternoon and told me that they would work on it until 3:30 because that was quitting time. They said to put in a work request, which we did. Eventually, we hope to surplus three old freezers and purchase one new freezer for our group and would like to have it located near our labs on the N corridor once all the work is completed.

Dennis said he wished he could help you out but under the present circumstances we can't really offer a quick solution to the space dilemma. Dennis suggested that you locate your freezer further down the D corridor near your lab or contact the SD office about where to put your freezer. We have already had one freezer damaged on the D with all the new construction and with the reduction in our budgets this year we can't afford to take such losses.

Teresa J. Tolliver

NIH, NIMH, LCS

10 Center Dr., Rm 3D41

Bethesda, MD 20892

Flamberg, Gemma (NIH/OD) [E]

From:	Copenhaver, Brittany (NIH/NIMH)
Sent:	Tuesday, April 05, 2005 2:37 PM
To:	Sunderland, Trey (NIH/NIMH) [E]
Cc:	Putnam, Karen T. (NIH/NIMH) [E]; 'davies@aecom.yu.edu'
Subject:	CSF shipment
Follow Up Flag:	Follow up
Flag Status:	Flagged

Good Afternoon Trey,

I just dropped off the shipment at the shipping dock, they said it should arrive tomorrow morning around 10am. Here is the address I shipped to:
Peter Davies
Dept. of Pathology
Albert Einstein College of Medicine
1300 Morris Park Ave
Bronx, NY 10461

This is a different zip code than the one you gave me, last time there were problems but this is the correct zip.

Hope all is well!
Brittany

Brittany R. Copenhaver
Geriatric Psychiatry Branch, NIMH
National Institutes of Health
nhaverb@mail.nih.gov
435-6060

Flamberg, Gemma (NIH/OD) [E]

From: Sunderland, Trey (NIH/NIMH)
Sent: Tuesday, April 05, 2005 8:34 PM
To: Copenhaver, Brittany (NIH/NINDS) [C]
Subject: Re: CSF shipment

Follow Up Flag: Follow up
Flag Status: Flagged

Hi Brittany,

Good work. We have already gotten a confirmatioin note from Dr. Davies.

Trey

Sent from my BlackBerry Wireless Handheld

-----Original Message-----
From: Copenhaver, Brittany (NIH/NIMH) <copenhaverb@mail.nih.gov>
To: Sunderland, Trey (NIH/NIMH) <trey@mail.nih.gov>
CC: Putnam, Karen T. (NIH/NIMH) <karenputnam@mail.nih.gov>; 'davies@aecom.yu.edu' <davies@aecom.yu.edu>
Sent: Tue Apr 05 14:37:28 2005
Subject: CSF shipment

Good Afternoon Trey,

Just dropped off the shipment at the shipping dock, they said it should arrive tomorrow morning around 10am. Here is the address I shipped to:
Peter Davies
Dept. of Pathology
Albert Einstein College of Medicine
1300 Morris Park Ave
Bronx, NY 10461

This is a different zip code than the one you gave me, last time there were problems but this is the correct zip.

Hope all is well!
Brittany

Brittany R. Copenhaver
Geriatric Psychiatry Branch, NIMH
National Institutes of Health
copenhaverb@mail.nih.gov
301-435-6060

Flamberg, Gemma (NIH/OD) [E]

From: Putnam, Karen T. (NIH/NIMH)
Sent: Tuesday, April 05, 2005 8:40 AM
To: Copenhaver, Brittany (NIH/NINDS) [C]
Cc: Sunderland, Trey (NIH/NIMH) [E]
Subject: FW: CSF Shipment and Freezers
Follow Up Flag: Follow up
Flag Status: Flagged

Morning Brittany

Below is the address to send the G04 shipment today. It is the same location we sent the smaller set in Feb05. Please email Trey (cc me also) to notify him when the shipment has left NIH etc.

Only include the blinded CSF vials (in boxes) with lots of dry ice- like previous shipments; do not include any of our excel lists that could identify the samples. Also please label the outside of each vial box on the top and side as 'T.Sunderland #/total boxes'.(1/4 boxes, 2/4 boxes and so forth).

Many thanks, call if this is unclear and I hope the inventory of the new system is going along swiftly.

Karen

From: Sunderland, Trey (NIH/NIMH)
Sent: Monday, February 07, 2005 10:05 AM
To: Copenhaver, Brittany (NIH/NIMH)
Cc: Putnam, Karen T. (NIH/NIMH)
Subject: CSF Shipment and Freezers

Hi Brittany,

Here is the address for the CSF shipment.

Peter Davies, PhD
Dept of Pathology, F526
Albert Einstein College of Medicine
1300 Morris Park Ave
Bronx, NY 10580
718 430 3083 (phone)
718 430 8541 (fax)
davies@aecom.yu.edu

Flamberg, Gemma (NIH/OD) [E]

[illegible]:	Putnam, Karen T. (NIH/NIMH)
[illegible]:	Thursday, April 07, 2005 4:12 PM
To:	'Dr Peter Davies'; Copenhaver, Brittany (NIH/NINDS) [C]
Cc:	't3mobile@yahoo.com'
Subject:	RE:
Follow Up Flag:	Follow up
Flag Status:	Flagged

Afternoon Dr. Davies,

THANK YOU for following up on our CSF shipment. I am very relieved to hear that the boxes arrived intact with lots of dry ice!

sincerely
Karen Putnam

-----Original Message-----
From: Dr Peter Davies [mailto:davies@aecom.yu.edu]
Sent: Thursday, April 07, 2005 1:10 PM
To: Copenhaver, Brittany (NIH/NIMH)
Cc: Putnam, Karen T. (NIH/NIMH); t3mobile@yahoo.com
Subject:
Importance: High

Of course, 30 minutes after I sent the last email, the package with 4 boxes of CSF was delivered safely. There was still tons of dry ice, and the samples are now in one of my -80oC freezers.
[illegible]er

Flamberg, Gemma (NIH/OD) [E]

From: Fitzsimmons, William (NIH/NIMH) [E]
Sent: Monday, July 10, 2006 3:53 PM
To: Flamberg, Gemma (NIH/OD) [E]
Subject: FW: CSF Samples

William T. Fitzsimmons
Executive Officer
National Institute of Mental Health (NIMH)
National Institutes of Health (NIH)
6001 Executive Boulevard; Room 8254
Bethesda, Maryland 20892
(Tel: 301-443-3877; Email: wf6q@nih.gov)

From: Copenhaver, Brittany (NIH/NINDS) [C]
Sent: Monday, July 10, 2006 11:54 AM
To: Fitzsimmons, William (NIH/NIMH) [E]
Subject: RE: CSF Samples

Mr. Fitzsimmons,

I am about to forward you many emails between myself and Karen and Trey regarding the CSF shipments. They contain excel spreadsheets showing which vials were in each shipment and other details about the process. Please let me know if I can assist you any further as you read through them.

Also, from reading through all of these emails I remembered that the database where this information was stored is called TITAN, and it could only be accessed through a few computers in the office. Every user had an individual password and we only had access to the databases that were specific to the work we did (for example, I could access the CSF and DNA databases but not the neuropsychological testing results databases).

Regards,
Brittany

> -----Original Message-----
> **From:** Fitzsimmons, William (NIH/NIMH) [E]
> **Sent:** Friday, July 07, 2006 5:30 PM
> **To:** Copenhaver, Brittany (NIH/NINDS) [C]
> **Subject:** CSF Samples
>
> Brittany,
>
> Could you please call me on Monday at the number below?
>
> Our records show that, while you were an NIMH IRTA fellow, in February and April 2005, you shipped Cerebrospinal Fluid from the NIMH's Geriatric Psychiatry Branch to a Dr. Peter Davies at the Albert Einstein College of Medicine in New York.
>
> You seem to have signed to approve the shipments in lieu of the local Administrative Officer, and these shipments are now part of a Congressional inquiry, so I need to chat with you to understand what happened.

Fitzsimmons, William (NIH/NIMH) [E]

From: Harris, John (NIH/NIMH) [E]
Sent: Monday, July 10, 2006 4:37 PM
To: Shirdon, Patrick (NIH/NIMH) [E]; Fitzsimmons, William (NIH/NIMH) [E]
Cc: Hermach, William (NIH/NIMH) [E]
Subject: RE: CSF Samples

Bill / Patrick,

A review of the site has revealed that there is no database integrated into the application architecture of the SILK site. All data is contained within HTML tables that are stored on the web site file system. Of those HTML tables that we located, we were not able to find any data related to tracking tissue samples. The tables contained primarily patient data, with no obvious reference to tissue.

We also spoke with Quang Tran from IRP to see if he was aware of any other databases that might be located on servers used by the branch, but he indicated that he was not aware of any. Bill also spoke with François in CIT (from whom he received access to the SILK site), but he was not aware of any databases either.

It would appear at this point that, if any tracking of tissue samples was done, it was likely through a spreadsheet or similar technology on a desktop computer or a laptop.

At this point, we are out of areas to search unless someone can provide us with more intelligence on the nature and location of this information.

John

From: Shirdon, Patrick (NIH/NIMH) [E]
Sent: Monday, July 10, 2006 2:24 PM
To: Fitzsimmons, William (NIH/NIMH) [E]; Harris, John (NIH/NIMH) [E]
Subject: RE: CSF Samples

John-- fairly certain that limits it to the SILK site.

From: Fitzsimmons, William (NIH/NIMH) [E]
Sent: Monday, July 10, 2006 1:56 PM
To: Harris, John (NIH/NIMH) [E]; Shirdon, Patrick (NIH/NIMH) [E]
Subject: FW: CSF Samples

See reference to TITAN.

Bill

From: Copenhaver, Brittany (NIH/NINDS) [C]
Sent: Monday, July 10, 2006 11:54 AM
To: Fitzsimmons, William (NIH/NIMH) [E]
Subject: RE: CSF Samples

Mr. Fitzsimmons,

I am about to forward you many emails between myself and Karen and Trey regarding the CSF shipments. They contain excel spreadsheets showing which vials were in each shipment and other details about the process.

Please let me know if I can assist you any further as you read through them.

Also, from reading through all of these emails I remembered that the database where this information was stored is called TITAN, and it could only be accessed through a few computers in the office. Every user had an individual password and we only had access to the databases that were specific to the work we did (for example, I could access the CSF and DNA databases but not the neuropsychological testing results databases).

Regards,
Brittany

-----Original Message-----
From: Fitzsimmons, William (NIH/NIMH) [E]
Sent: Friday, July 07, 2006 5:30 PM
To: Copenhaver, Brittany (NIH/NINDS) [C]
Subject: CSF Samples

Brittany,

Could you please call me on Monday at the number below?

Our records show that, while you were an NIMH IRTA fellow, in February and April 2005, you shipped Cerebrospinal Fluid from the NIMH's Geriatric Psychiatry Branch to a Dr. Peter Davies at the Albert Einstein College of Medicine in New York.

You seem to have signed to approve the shipments in lieu of the local Administrative Officer, and these shipments are now part of a Congressional inquiry, so I need to chat with you to understand what happened.

Thank you in advance for your assistance.

- Bill Fitzsimmons

William T. Fitzsimmons
Executive Officer
National Institute of Mental Health (NIMH)
National Institutes of Health (NIH)
6001 Executive Boulevard; Room 8254
Bethesda, Maryland 20892
(Tel: 301-443-3877; Email: wf6q@nih.gov)

Jun-27-06 12:57 From-NIH 301 402 1857 T-771 P.009/012 F-027

REQUEST FOR SHIPMENT

Serial No. 324179

Instructions:
Requesting Office sends the first two copies (white and yellow) to the Shipping Officer. Keep the third (pink) copy for reference.
Shipping Officer - After carrier has picked up the shipment, file this form to back up authorization for shipment.

NOTE: All dutiable international shipments (other than printed documents) must be accompanied by three copies of a commercial invoice (NIH 1884-1) for customs clearance.

1. We are requesting shipment of: [X] Government-owned property [ ] Other:

2. Date of request 4/5/05

3. Requester's Name (Consignor) Brittany Copenhaver

4. IOD NIMH/GPB

5. Building and Room 10/25-2335

6. Phone No. 301 435 6060

7. Shipment to be paid by [X] NIH [ ] Consignee (If consignee, complete item 8.)

8. Carrier's Name; Account No. to be Billed; Consignee's Phone No.

9. DESCRIPTION OF ARTICLES
When items of varying descriptions are to be shipped, seperate them and enter the quantity and value of each. If any item is hazardous or infectious to humans, note the amount (in milliliters or kilograms) and give a detailed description of the substance.

9. DESCRIPTION OF ARTICLES	10. HAZARDOUS or INFECTIOUS?	11. QTY.	12. DOLLAR VALUE
Cerebrospinal Fluid, packaged in Dry Ice DNA 14 ice	NO	4 boxes	$600.00
no DIM	TOTALS ▶		$ 600.00

13. Packaging: [X] Packed by requester [ ] To be packed by Shipping (Nonperishable, nonhazardous items only)

14. If material was packed by the requester, AND it is biological material, how was it packed? [X] Dry ice [ ] Ice packs [ ] Other: [ ] Wet ice [ ] Room temperature

15. SHIP TO (Consignee) (Name, street address, city, state or country, zip code, telephone number) (Do not use P.O. box addresses)
Peter Davies
Dept. of Pathology, F526
Albert Einstein College of Medicine
1300 Morris Park Ave
Bronx, NY 10461

16. Additional information, instructions, or justification
D.S.P 650

17. Date shipment must arrive at destination 4/6/05

18. Property clearance (Signature of Property Accountable Officer or other official)

19. Common Account Number (CAN) 8337647

20. Administrative Officer's name (Typed) Brittany Copenhaver

21. AO's signature Brittany Copenhaver

SHIPPING OFFICER COMPLETES THIS SECTION

22. Carrier Fed

23. Date shipped 4-5-05

24. GBL or ROC number NR062664

25. Airway bill or freight bill number 6755 3956 6587

26. UPS Charge

27. Packed by owner /

28. Packed by shipping

29. [ ] Internatl. [ ] Domestic

30. Mode

31. Total weight 32 #

32. Estimated cost $ 37.81 - 73.75

33. [ ] Pick up [X] Flat service charge

NIH 1884 (Rev. 10/90)

HZ. 4/5

Shipping Order Record

Fiscal Year 05	System Serial Number 10087	Shipping Date	04/05/2005
Carrier	FDE-	Govt Bill of Lading /Record of Call	NID62664
Shipper Serial Number	00324179	Sender	B.COPENHAVER
Sender Phone	5-6060	Institute/Center	NIMH
CAN	8337647	Bill Number (Air or Freight)	675539566587
State/Country	NY	International /Domestic	D
Packed by Owner	1	Packed by Shipping	0
Estimated Cost	$ 37.81	List Cost	$ 73.75
Pickup Reqd - No	Hazardous Inspection - Yes	Docd by RE	DELPRO by ST
Property Number		Shipping Bill	$ 73.00
Order Type Original	Notes		
Entered By VEH	Created 04/13/2005	Updated	Billed 04/13/2005

Billable Shipping Orders

Shipping Inquiry

Shipping Menu

Jun-27-06 12:57 From-NIH 301 402 1857 T-771 P.010/012 F-027

REQUEST FOR SHIPMENT

Serial No. 377793

Instructions:
Requesting Office sends the first two copies (white and yellow) to the Shipping Officer. Keep the third (pink) copy for reference.
Shipping Officer - After carrier has picked up the shipment, file this form to back up authorization for shipment.

NOTE: All dutiable international shipments (other than printed documents) must be accompanied by three copies of a commercial invoice (NIH 1884-1) for customs clearance.

1. We are requesting shipment of: [X] Government-owned property [ ] Other:

2. Date of request: 2·9·05

3. Requester's Name (Consignor): Brittany Copenhaver

4. ICD: NIMH/LPB

5. Building and Room: 10/2-8334

6. Phone No.: 301 435 6060

7. Shipment to be paid by: [X] NIH [ ] Consignee (If consignee, complete item 8.)

8. Carrier's Name; Account No. to be Billed; Consignee's Phone No.

9. DESCRIPTION OF ARTICLES
When items of varying descriptions are to be shipped, separate them and enter the quantity and value of each. If any item is hazardous or infectious to humans, note the amount (in milliliters or kilograms) and give a detailed description of the substance.

9. DESCRIPTION OF ARTICLES	10. HAZARDOUS or INFECTIOUS?	11. QTY.	12. DOLLAR VALUE
cerebrospinal fluid, packaged in dry ice	NO	1 box	$400.00
D.S.P.650			
NO Dry 4KG	TOTALS ▶		$400.00

13. Packaging: [X] Packed by requester [ ] To be packed by Shipping (Nonperishable, nonhazardous items only)

14. If material was packed by the requester, AND it is biological material, how was it packed? [X] Dry ice [ ] Ice packs [ ] Other: [X] Wet ice [ ] Room temperature

15. SHIP TO (Consignee) (Name, street address, city, state or country, zip code, telephone number) (Do not use P.O. box addresses)
Peter Davies, PhD
Albert Einstein College of Medicine
Dept. of Pathology, F526
1300 Morris Park Ave.
Bronx, NY 10461

16. Additional information, instructions, or justification: 3/

17. Date shipment must arrive at destination: 2·10·05

18. Property clearance (Signature of Property Accountable Officer or other official)

19. Common Account Number (CAN): 833 7647

20. Administrative Officer's name (Typed): Brittany Copenhaver

21. AO's signature: Brittany Copenhaver

SHIPPING OFFICER COMPLETES THIS SECTION

22. Carrier: Federal (P/S)

23. Date shipped: 2/9/05

24. GBL or ROC number: N1065213

25. Airway bill or freight bill number: 8755 3955 4528

26. UPS Charge

27. Packed by owner: 1

28. Packed by shipping

29. [ ] Internatl. [ ] Domestic

30. Mode

31. Total weight: 10#

32. Estimated cost: $ 32.32 / 68.25

33. [X] Pick up [ ] Flat service charge

NIH 1884 (Rev. 10/90)

DW 2/9

Shipping Order Record

Fiscal Year 05	System Serial Number 06886	Shipping Date	02/09/2005
Carrier	FDE-	Govt Bill of Lading /Record of Call	NID65213
Shipper Serial Number	00377793	Sender	BRITTANY COPENHAVER
Sender Phone	5-6060	Institute/Center	NIMH
CAN	8337647	Bill Number (Air or Freight)	675539554528
State/Country	NY	International /Domestic	D
Packed by Owner	1	Packed by Shipping	0
Estimated Cost	$ 32.32	List Cost	$ 68.25
Pickup Reqd - Yes	Hazardous Inspection - Yes	Doed by RE	DELPRO by ST
Property Number		Shipping Bill	$ 105.00
Order Type Original	Notes		
Entered By VEH	Created 02/17/2005	Updated	Billed 02/25/2005

Billable Shipping Orders

Shipping Inquiry

Shipping Menu

[redacted]
Tab 25

Slobodin, Alan

From: Flamberg, Gemma (NIH/OD) [E] [FlamberG@OD.NIH.GOV]
Sent: Tuesday, February 21, 2006 12:06 PM
To: Slobodin, Alan
Cc: Hernard, Casey (HHS/OS)
Subject: Answers regarding Karen Putnam

As a follow-up on Karen Putnam:

Is Karen Putnam known by any other name? NIH is not aware that Ms. Putnam is known by another name.

When was Karen Putnam's last day of NIH employment? Her resignation date was 7/22/2005. However, she has unpaid "special volunteer" status with the NIMH, which allows her to perform some statistical analyses for the Behavioral Epidemiology Branch of NIMH on an intermittent basis.

Does NIH have contact information on Karen Putnam? 1283 Sweetwater Drive, Wyoming, Ohio 45215

Can NIH confirm that Karen Putnam is at North Shore Hospital? If so, what department? The NIH has not confirmed that Ms. Putnam is at North Shore Hospital.

Does Karen Putnam have an attorney? If so, please provide name and number. In 2004, her attorney was David Schertler of Coburn and Schertler, 1100 Conn. Ave., N.W., Washington, D.C. (202) 628-4199. We do not know if he is still her personal attorney.

Gemma Flamberg
Senior Legislative Analyst
Office of Legislative Policy and Analysis
National Institutes of Health
(301) 496-3471
fax (301) 496-0840
flamberg@od.nih.gov

[redacted] Tab 26

n 08 05 12:22p Clara Kabore 301 402 2143

ORDER FOR SUPPLIES OR SERVICES

Mark all packages and papers with contract and/or order numbers.

OMB No. 0990-0115

1. Date of order	2. Contract no. *(if any)*	3. Order no.	Page
06/07/05		263-MD-511136	1 of

[redacted]isitioning NAME: VALERIE MASON
PHONE: 435-4348 CC:16008

5. Requisition no.
REQ#: QXT50015

.ounting and appropriation data
CAN: 58337647 OC: 252Z EFFDT: 06/08/05
BLDG:31 ROOM:2B34 INST: NIMH
CONTACT: SHEILA JOHNSON 301-594-8071

7. Ship to *(Name, address, and zip code)*
NATIONAL INSTITUTES OF HEALTH
TREY SUNDERLAND
ORDER # 263-MD-511136
BLDG 10CRS ROOM 2-5330
BETHESDA, MARYLAND 20892

8. To: Contractor *(Name, address, zip code)*
EIN: 154177993 2A1 SF37: XSXQ9
CRYONIX INC
12401 WASHINGTON AVE
ROCKVILLE, MD 20852

9. Type of order
☐ (a) PURCHASE. Reference your
WRT QUO
Please furnish the following on the terms specified on both sides of this order and on the attached sheets, if any, including delivery as indicated.
☐ (b) DELIVERY. Except for billing instructions as attached, this delivery order is subject to instructions contained on this side only of this form and is issued subject to the terms and conditions of the contract referenced in Block 2.

10. Issuing office *(Name and phone number of Purchasing Agent to call regarding this order.)*
PA: CLARA KABORE /CLK: CCK PA PHONE: 301-402-2143
NATL INST OF HEALTH,DHHS OPM,6011 EXEC BLVD,RM.536,ROCKVILLE, MD 20892

11. F.O.B. point	12. Inspection & acceptance	13. Government B/L no.	14. Delivery to F.O.B. point on or before	15. Prompt pay discounts
DESTINATION	SEE BLOCK 7		06/09/05	NET 30

16. SCHEDULE

Item No. (a)	Catalog No. (b)	Supplies or Services (c)	Quantity Ordered (d)	Unit (e)	Unit Price (f)	Amount (g)
		THIS ORDER REQUIRES INSIDE DELIVERY TO THE SHIP TO BUILDING AND ROOM SHOWN IN BLOCK 7 OF THIS ORDER.				
01	O	TRANSFER 5 FREEZERS FROM NIH TO LONG ISLAND NY STORAGE OF MATERIALS IN FIVE ULT FREEZERS FOR 5 TO 9 MONTHS	1	EA	16,823.70	16,823.70
02	O	TRANSPORTATION OF FREEZERS	5	EA	250.02	1,250.10
03	O	RELOCATION OF FREEZERS	1	EA	4,850.00	4,850.00

17. Classification: SB
SB — Small business W — Woman-owned
OTSB — Other than small business S — Sheltered workshop
M — Minority-owned I — American Indian-owned

18. Mail invoice to:
National Institutes of Health
Commercial Accounts, Room B1B39
31 Center Drive, MSC 2045
Bethesda, MD 20892-2045
Phone number for payment inquiries: 301-496-6088

16 (h) Total from continuation pages ▶
16 (i) Grand Total ▶ 22,923.80

19. FOR BILATERAL AGREEMENTS ONLY: *(When applicable, see attached Form NIH 2555-3.)*
Contractor's typed name and title | Contractor's signature | Date

Submit original and one copy of invoice. See attached invoice and payment provisions on Form NIH 2555-1.

[redacted]ited States of America
By *(signature)* ▶ Clara W. Kabore

21. Typed name and title of Government representative
CLARA KABORE
CONTRACTING OFFICER

NIH 2555 (Rev. 7/96) FRONT

MARKET REQUISITION - QXT50015 ACCELERATED?

RQM#: QXT50015 CAN: 58337647 INST: NIMH OC: 252Z SF37: XSXQ9
CC: 16008 PRO DEST: CEN JUST? N CLEARANCES? N FSS#:

VGST EIN: 1541779932A1 PAYEE: CRYONIX INC WORK RQST#:
VDOR: *CRYONIX INC RQM STAT: CERT ENTR DATE: 06/03/05
* UPDATED: 06/03/05
*12401 WASHINGTON AVE #ITEMS: 03 TOT$AMT: 22923.80
CITY/ST: *ROCKVILLE, MD ZIP: 20852 VEN TEL: 301-881-2045

SHIP TO: TREY SUNDERLAND BLDG: 10CRS ROOM: 2-5330 FPDS:
PANAME: VALERIE MASON BLDG: 31 ROOM: 2B34 TEL: 435-4348
FOR: TREY SUNDERLAND BLDG: 10CRS ROOM: 2-5330
PROJ OFFR: BLG: RM: TEL:
SUPPORT DOC:

A.O: CTT APPROV DATE: 06/03/05 ORDER TOL%: CLERK ID: VJM RQM CANCEL?
RMKS: SEE ATTACHMENT FOR APPROVAL BY SUE KEOSTER 06/03/05

PRO RCV DATE: 00/00/00 ACT DATE: 00/00/00 SECT CODE: SPA PA CODE:
AUTH CODE: TYPE: REF ORDER#: PRO STAT:
DLV DATE: EFF DATE: RMKS:

LINE ITEMS

ITEM#: 01 LAST ITEM? N QTY: 0001 UNIT: EA UPRICE: 16823.70 AMT: 16823.70
DISCOUNT%: LPRICE: 16823.70 TRADE-IN: TOL%: VAR%:
CAN: OC: LSTAT: MULTL#:
CAT#: 0 DESC: TRANSFER 5 FREEZERS FROM NIH TO LONG ISLAND NY
STORAGE OF MATERIALS IN FIVE ULT FREEZERS FOR 5 TO 9 MONTHS

ITEM#: 02 LAST ITEM? N QTY: 0005 UNIT: EA UPRICE: 250.02 AMT: 1250.10
DISCOUNT%: LPRICE: 250.02 TRADE-IN: TOL%: VAR%:
CAN: OC: LSTAT: MULTL#:
CAT#: 0 DESC: TRANSPORTATION OF FREEZERS

ITEM#: 03 LAST ITEM? Y QTY: 0001 UNIT: EA UPRICE: 4850.00 AMT: 4850.00
DISCOUNT%: LPRICE: 4850.00 TRADE-IN: TOL%: VAR%:
CAN: OC: LSTAT: MULTL#:
CAT#: 0 DESC: RELOCATION OF FREEZERS

MD511136

Mason-Yates, Valerie (NIH/NIMH)

m:	Koester, Susan (NIH/NIMH)
t:	Friday, June 03, 2005 3:36 PM
:	Fitzgerald, Pamela (NIH/NIMH)
Cc:	Sunderland, Trey (NIH/NIMH); Mason-Yates, Valerie (NIH/NIMH); Johnson, Sheila (NIH/NIMH)
Subject:	Re: Cryonixs

Yes, this is important to the Institute to provide reliable storage of these patient samples. -Su
---
Sent from my BlackBerry Wireless Handheld

-----Original Message-----
From: Fitzgerald, Pamela (NIH/NIMH) <fitzgerp@mail.nih.gov>
To: Koester, Susan (NIH/NIMH) <koesters@mail.nih.gov>
CC: Sunderland, Trey (NIH/NIMH) <trey@mail.nih.gov>; Mason-Yates, Valerie (NIH/NIMH) <yatesv@mail.nih.gov>; Johnson, Sheila (NIH/NIMH) <SheilaJohnson@mail.nih.gov>
Sent: Fri Jun 03 14:54:57 2005
Subject: Cryonixs

Hi Su:

I am in receipt of a Cryonix purchase request from Trey Sunderland to transfer material in five ULT Freezers to protect specimens, GPB has arranged to store them off NIH campus with Cyonix, Inc. The total amount of this order is $22,923.80.

we proceed?

mela Fitzgerald
Lead Administrative Officer
NIH, NIMH, IRP, ASB
31 Center Drive Suite 2B34
301-496-4271 (P)
301-480-4533 (F)
fitzgerp@mail.nih.gov

DATE RECEIVED (stamp here)

Requisition Worksheet

DIVISION/BRANCH APPROVAL (signature)

ORDER NO. (from Delpro System) 50015

Requester

NAME	DIV./BRANCH	CAN
Sunderland, Trey	GPB	5-8337647

OBJECT CLASS CODE	CUSTODIAL CODE	BUILDING/ROOM	PHONE NO.	DATE NEEDED
		10-CRC - 2-5330	301-496-0948	06/30/05

Source

NAME OF COMPANY	PHONE NO.
Cryonix Inc.	301-881-2045/ FX: 301-881-8306
ADDRESS	**COMPANY CLERK'S NAME**
12401 Washington Ave, Rockville, MD 20852	Lori Pearson

Order Information

Item No.	Back-order	CATALOG NUMBER	DESCRIPTION	QTY.	UNIT OF ISSUE	LIST PRICE	DISCOUNTED PRICE	TOTAL PRICE
1			Transfer 5 freezers from NIH					
			to Long Island, NY					
			Storage of material in					
			five ULT freezers					
			Total for 5 for 9 months	1	ea	16,823.70	16,823.70	16,823.70
			transportation of freezers	5	ea	250.02	250.02	1,250.10
			relocation of freezers	1	ea	4,850.00	4,850.00	4,850.00
						Total:		22,923.80

ORDER PLACED 6/3/05 VALERIE YATES

ARE THE ITEMS ORDERED AVAILABLE FROM THESE SOURCES?

Yes	No		Yes	No		Yes	No	
☐	X	1. NIH Surplus	☐	X	3. Blind/Severely Handicapped	☐	X	5. FEDERAL Supply Schedules
☐	X	2. UNICOR	☐	X	4. NIH or GSA Stock (catalog or store)	X	☐	6. OPEN-MARKET Suppliers

COMPANY NAME If order exceeds $2500, 2 more sources of supply must be contacted and listed below.	PRICE	AVAILABILITY	DATE CALLED
1			
2			

JUSTIFICATION *(Required for all orders: large business, ADP, personal appeal items, and sole source.)*

See attached

BACKORDER INFORMATION

GIN 154177993 2A1

BPA/IDC/TCO SOURCE NO.	FSS CONTRACT NO.	SHIPPING DATE	CLEARANCE REQUIRED? ☐ YES ☐ NO
Date ordered:	☐ Date sent to Central Procurement:	INSTITUTE PURCHASING AGENT	

NIH 1861-9 (10/92)

COPY DISTRIBUTION: White -Administrative Office; Canary -Requester's final copy; Pink -Requester's interim copy

With the general decrease in Geriatric Psychiatry Branch staff over the last several months the proper supervision of the biologic specimens is increasingly difficult. These NIH specimens have been collected over the last 15 years and reflect the end products of many research projects. To protect these specimens, we have arranged to store them off campus with Cryonix, Inc. The attached interact reflects the moving and secure storage of these samples.

Tab 27

Printed: [redacted]006 16:21

Transaction Activity Report

For the Month of November, 2005

NIH - Sunderland
10 Center Dr.
CRC, Rm. 2-5360
Bethesda, MD 20892

Sponser ID: 5110
Contact: Trey Sunderland
Phone: 301-435-6050

Request Date:	Trans Date Time:	MEMCO ID:	Location:	Material ID:	Quantity:	Description:	Picked By:
11/01/2005	Date: 11/01/2005 Time: 11:15	20740	H02	10315	1	Small Vials	Trey

Transaction Count: 1

Printed: .006 16:20

Transacti Activity Report

For the Month of July, 2005

NIH - Sunderland
10 Center Dr.
CRC, Rm. 2-5360
Bethesda, MD 20892

Sponsor ID: 5110
Contact: Trey Sunderland
Phone: 301-435-6050

Request Date:	Trans Date Time:	MEMCO ID:	Location:	Material ID:	Quantity:	Description:	Picked By:
07/21/2005	Date: 07/21/2005 Time: 11:04	20742	H04	10317	1	CSF & BLOOD SAMPLES	TS

Transaction Count: 1

Jun-27-06 12:56 From-NIH 301 402 1857 T-771 P.005/012 F-027

For Serial# 324592

TRANSPORTATION SERVICES ORDER *This government shipment is subject to the terms and conditions of 41 CFR 102-117 and 118*	TRANSPORTATION ORDER NUMBER 501583	DATE PREPARED (M/D/YYYY) 11/3/2005 [redacted]
	TSP (Complete mailing address) YELLOW FREIGHT SYSTEMS 7521 JEFFERSON AVENUE LANDOVER, MD 20785-1601 (301-772-2300) CARRIER REPRESENTATIVE: R. Sheets	SCAC YFSY Tab 28 DATE: 11/3/5

NAME AND MAILING ADDRESS OF REQUESTING AGENCY
NIH
9000 ROCKVILLE PIKE
BETHESDA, MD 20892 ISSUING OFFICER: SAMUEL TAYLOR

MODE
☐ TRUCK ☐ RAIL ☐ AIR ☐ IMPORT ☐ EXPORT ☒ DOMESTIC ☐ OTHER

COMMODITY DESCRIPTION (Give UFC, NMFC, number or a clear non-technical description; show number of packages as prepared for shipment (e.g. crated, uncrated, boxes, skids, loose, SU, KD)
1 SKID OF RESEARCH FILES

CARRIER WAY/FREIGHT BILL NO.:

CONSIGNOR (SHIPPER)	ORIGIN	CONSIGNEE (RECEIVER)
NIH 9000 ROCKVILLE PIKE BETHESDA, MD 20892 *Ph* 301-496-5921 *Fax* 301-402-1857	*Freight address of actual shipping point* SAME AS SHIPPER	DR TREY SUNDERLAND LITWIN ZUCKER CENTER A EINSTEIN COLLEGE OF MEDICINE *225 COMMUNITY DRIVE, SUITE 110* *GREAT NECK, NY 11021* *Ph* (516) 487-3492 *Fax*

CBL REQUESTED	TRANSPORTATION APPROPRIATION NUMBER TO BE SHOWN ON B/L	PAYING OFFICE OF REQUESTING AGENCY
☒ YES *(if yes, complete)* → ☐ NO	68337647 YELLOW SHIPPER'S COPY 501 WDC 519 264159 6	*Name* NIH / BLDG. 31, RM B1B31 9000 ROCKVILLE PIKE BETHESDA, MD, 20892

ADDITIONAL SHIPPING INFORMATION *(Descr... materials); special carrier service needed (e.g., exclusive... or high); special handling (e.g. hazardous*
ALTERNATE PHONE NUMBER CONT...

www.myyellow.com 1-800-610-6500 SINGLE SHIPMENT
This shipment is bound by the terms and conditions of the Uniform Straight Bill of Lading included in the NMFC 100 series.

RATE/ROUTE RESPONSE

TO: REQUESTING AGENCY Traffic data furnished below and/or on the back (item xx) is as of the date shown in item xx. If shipment is not made in a reasonable period a new request should be submitted with reference made to the control number in item xx below)

TRANSPORTATION SERVICE PROVIDER	APPLICABLE RATE INFORMATION			
Name , NON *Ph* (*Fax* (*Email*	RATE(S)	WEIGHT (LBS) 1,486	TARIFF OR OTHER RATE AUTHORITY	ESTIMATED COST

BILL OF LADING DESCRIPTION WHEN DIFFERENT FROM ITEM XX	REMARKS AND SPECIAL SERVICES

NIMH National Institute of Mental Health

According to Dottie Brake - all reprints, books, etc. that were cleared out of his office for the move

DATE ISSUED

...LICABLE DESTINATION INFORMATION

DELIVERED THIS CONSIGNMENT	COMPLETE & IN APPARENT GOOD ORDER EXCEPT AS MAY BE INDICATED HEREAFTER	STORAGE ☐
☐ TO STORAGE IN TRANSIT		DAMAGE ☐

...ME OF DESTINATION TSP | SIGNATURE OF TSP'S AUTHORIZED AGENT

Jun-27-05 12:56 From-NIH 301 402 1857 T-771 P.004/012 F-027

REQUEST FOR SHIPMENT

Serial No. 324592

Instructions: Requesting Office sends the first two copies (white and yellow) to the Shipping Office; keep the third (pink) copy for reference. Shipping Officer - After carrier has picked up the shipment, file this form to back up authorization for shipment.

NOTE: All dutiable international shipments (other than printed documents) must be accompanied by three copies of a commercial invoice (NIH 1884-1) for customs clearance.

1. We are requesting shipment of: ☐ Government-owned property ☑ Other: research files

2. Date of request: 10/31/05

3. Requester's Name (Consignor): Lottie Drake

4. ICD: NIMH

5. Building and Room: 10-3N218

6. Phone No.: 301 496 1338 *

7. Shipment to be paid by: ☑ NIH ☐ Consignee (If consignee, complete item 8.)

8. Carrier's Name; Account No. to be Billed; Consignee's Phone No.

9. DESCRIPTION OF ARTICLES (When items of varying descriptions are to be shipped, separate them and enter the quantity and value of each. If any item is hazardous or infectious to humans, note the amount (in milliliters or kilograms) and give a detailed description of the substance.)	10. HAZARDOUS or INFECTIOUS?	11. QTY.	12. DOLLAR VALUE
Research files	No	32 bx	-0-
TOTALS ▶		32	$ -0-

13. Packaging: ☑ Packed by requestor ☐ To be packed by Shipping (Nonperishable, nonhazardous items only)

14. If material was packed by the requester, AND it is biological material, how was it packed? ☐ Dry ice ☐ Ice packs ☐ Other: ☐ Wet ice ☐ Room temperature

15. SHIP TO (Consignee) (Name, street address, city, state or country, zip code, telephone number) (Do not use P.O. box addresses)
Dr. Trey Sunderland
Litwin-Zucker Center
A. Einstein College of Medicine
825 Community Drive, Suite 110
Great Neck, NY 11021

16. Additional information, instructions, or justification
West Entrance
Tel # 516-487-3492
* If no answer, call Ama Bowles 301 496 9675

17. Date shipment must arrive at destination: Not a rush → 11/10/05

18. Property clearance (Signature of Property Accountable Officer or other official): David Rubinow, MD

19. Common Account Number (CAN): 6-5337647

20. Administrative Officer's name (Typed): Sheila Johnson

21. AO's signature: AR Fuchs for

SHIPPING OFFICER COMPLETES THIS SECTION

22. Carrier: Yellow Trans.

23. Date shipped: 11/3/5

24. GBL or ROC number: 501 583

25. Airway bill or freight bill number

26. UPS Charge

27. Packed by owner: 1 Skid

28. Packed by shipping

29. ☐ Internatl. ☐ Domestic

30. Mode

31. Total weight: 1486 #

32. Estimated cost: $ 150.36

33. ☐ Pick up ☑ Flat service charge

NIH 1884 (Rev. 10/90)

* U.S. GOVERNMENT PRINTING OFFICE: 1987—418-811

RF 11/2

Shipping Order Record

Yellow Freight System

Fiscal Year 06	System Serial Number 04360	Shipping Date	11/03/2005
Carrier	YFSY	Govt Bill of Lading /Record of Call	501583
Shipper Serial Number	00324592	Sender	DOTTIE DRAKE
Sender Phone	301-496-1338	Institute/Center	NIMH
CAN	8337647	Bill Number (Air or Freight)	
State/Country	NY	International /Domestic	D
Packed by Owner	1	Packed by Shipping	0
Estimated Cost	$ 150.36	List Cost	$ 0.00
Pickup Reqd - No	Hazardous Inspection - No	Docd by JW	DELPRO by JW
Property Number		Shipping Bill	$ 42.00
Order Type Original	Notes		
Entered By TSY	Created 01/06/2006	Updated	Billed 01/13/2006

Billable Shipping Orders

Shipping Inquiry

Shipping Menu

JUN-24-00 12:00 FROM-NIH 301 402 1857 T-771 P.006/012 F-027

REQUEST FOR SHIPMENT

Serial No. YL 324590

Instructions:
Requesting Office sends the first two copies (white and yellow) to the Shipping Officer.
Keep the third (pink) copy for reference.
Shipping Officer - After carrier has picked up the shipment, file this form to back up authorization for shipment.

NOTE: All dutiable international shipments (other than printed documents) must be accompanied by three copies of a commercial invoice (NIH 1884-1) for customs clearance.

1. We are requesting shipment of: ☐ Government-owned property ☑ Other: files
2. Date of request: 10/28/05
3. Requester's Name (Consignor): Trey Sunderland
4. ICD: NIMH
5. Building and Room: 10CRC 2-5360
6. Phone No.: 301 435 6050
7. Shipment to be paid by: ☑ NIH ☐ Consignee (If consignee, complete item 8.)
8. Carrier's Name; Account No. to be Billed; Consignee's Phone No.

9. DESCRIPTION OF ARTICLES When items of varying descriptions are to be shipped, separate them and enter the quantity and value of each. If any item is hazardous or infectious to humans, note the amount (in milliliters or kilograms) and give a detailed description of the substance.	10. HAZARDOUS or INFECTIOUS?	11. QTY.	12. DOLLAR VALUE
Research files	No	21 bx	— 0 —
	TOTALS ▶	21	$ — 0 —

13. Packaging: ☑ Packed by requester ☐ To be packed by Shipping (Nonperishable, nonhazardous items only)
14. If material was packed by the requestor, AND it is biological material, how was it packed? ☐ Dry ice ☐ Ice packs ☐ Other: ☑ Wet ice ☐ Room temperature
15. SHIP TO (Consignee) (Name, street address, city, state or country, zip code, telephone number) (Do not use P.O. box addresses)
Litwin-Zucker Center
Albert Einstem College of Medicine
c/o Dr. Sunderland
225 Community Drive, Suite 110, West Entrance
Great Neck NY 11021
16. Additional information, instructions, or justification
Tel - 516-487-3492
NOTE: Office is locked - Call: Anne 301 496 9675 or Lothe 301 496 1338 for entry
17. Date shipment must arrive at destination: Not a rush - 11/7/05
18. Property Clearance (Signature of Property Accountable Officer or other official): David R Rubinow
19. Common Account Number (CAN): 6-8337647
20. Administrative Officer's name (Typed): Sheila Johnson
21. AO's signature: A R Rubinow

SHIPPING OFFICER COMPLETES THIS SECTION

22. Carrier: Express Air
23. Date shipped: 10-31-05
24. GBL or ROC number: 501576
25. Airway bill or freight bill number
26. UPS Charge
27. Packed by owner: 1 skid
28. Packed by shipping
29. ☐ Internatl. ☐ Domestic
30. Mode
31. Total weight: 1220 #
32. Estimated cost: $ 730.07
33. ☐ Pick up ☑ Flat service charge

RF 10/31

NIH 1884 (Rev. 10/90)

☆ U.S. GOVERNMENT PRINTING OFFICE: 1997—418-611

Shipping Order Record

Express Air

Fiscal Year 06	System Serial Number 03867	Shipping Date	10/31/2005
Carrier	EAFF	Govt Bill of Lading /Record of Call	501576
Shipper Serial Number	00324590	Sender	TREY SUNDERLAND
Sender Phone	301-435-6050	Institute/Center	NIMH
CAN	8337647	Bill Number (Air or Freight)	
State/Country	NY	International /Domestic	D
Packed by Owner	1	Packed by Shipping	0
Estimated Cost	$ 730.07	List Cost	$ 0.00
Picknp Reqd - No	Hazardous Inspection - No	Docd by KK	DELPRO by KK
Property Number		Shipping Bill	$ 42.00
Order Type Original	Notes		
Entered By TSY	Created 12/27/2005	Updated	Billed 01/13/2006

Billable Shipping Orders

Shipping Inquiry

Shipping Menu

Jun-27-06 12:57 From-NIH 301 402 1857 T-771 P.007/012 F-027

For Serial # 324540

TRANSPORTATION SERVICES ORDER *Government shipment is subject to terms and conditions of 41 CFR 102-117 and 118*	TRANSPORTATION ORDER NUMBER 501576	DATE PREPARED (M/D/YYYY) 10/31/2005
	TSP (Complete mailing address) EXPRESS AIR 23723 AIR FREIGHT LANE DULLES, VA 20166 CARRIER REPRESENTATIVE:	SCAC EAFF DATE:

NAME AND MAILING ADDRESS OF REQUESTING AGENCY
NIH
9000 ROCKVILLE PIKE
BETHESDA, MD 20892 ISSUING OFFICER: EDWARD CROCKETT

MODE
☐ TRUCK ☐ RAIL ☒ AIR ☐ IMPORT ☐ EXPORT ☒ DOMESTIC ☐ OTHER

COMMODITY DESCRIPTION (Give UFC, NMFC, number or a clear non-technical description; show number of packages as prepared for shipment (e.g. crated, uncrated, boxes, skids, loose, SU, KD)
RESEARCH FILES

CARRIER WAY/FREIGHT BILL NO.:

CONSIGNOR (SHIPPER)	ORIGIN	CONSIGNEE (RECEIVER)
NIH 9000 ROCKVILLE PIKE BETHESDA, MD 20892 *Ph* 301-496-5921 *Fax* 301-402-1857	*Freight address of actual shipping point* TREY SUNDERLAND NIH 10/2-5360 9000 ROCKVILLE PIKE BETHESDA, MD 20892	LITWIN-ZUCKER CENTER ALBERT EINSTEIN COLLEGE OF MED/225 COMMUNITY DR/STE *110/DR SUNDERLAND* *GREAT NECK, NY 11021* *Ph* (516) 487-3492 *Fax*

CBL REQUESTED	TRANSPORTATION APPROPRIATION NUMBER TO BE SHOWN ON B/L	PAYING OFFICE OF REQUESTING AGENCY
☒ YES *(if yes, complete)* → ☐ NO	8337647	*Name* NIH / BLDG. 31, RM B1B31 9000 ROCKVILLE PIKE BETHESDA, MD, 20892

ADDITIONAL SHIPPING INFORMATION *(Describe articles of unusual size or weight (e.g., 55' long, 8' wide or high); special handling (e.g. hazardous materials); special carrier service needed (e.g., exclusive use of vehicle or intransit cooling)*

RATE/ROUTE RESPONSE

TO: REQUESTING AGENCY Traffic data furnished below and/or on the back (item xx) is as of the date shown in item xx. If shipment is not made in a reasonable period a new request should be submitted with reference made to the control number in item xx below)

TRANSPORTATION SERVICE PROVIDER	APPLICABLE RATE INFORMATION			
	RATE(S)	WEIGHT (LBS)	TARIFF OR OTHER RATE AUTHORITY	ESTIMATED COST
Name , NON *Ph* (*Fax* (*Email*		1220 LBS		

BILL OF LADING DESCRIPTION WHEN DIFFERENT FROM ITEM XX *(include hazardous materials description if any)*	REMARKS AND SPECIAL SERVICES

TECHNICIANS NAME	DATE ISSUED

APPLICABLE DESTINATION INFORMATION

DATE *(mm/yyyy)*	ACTUAL DELIVERY POINT	DELIVERED THIS CONSIGNMENT ☐ TO STORAGE IN TRANSIT	COMPLETE & IN APPARENT GOOD ORDER EXCEPT AS MAY BE INDICATED HEREAFTER	STORAGE ☐ DAMAGE ☐

NAME OF DELIVERING TSP	NAME OF DESTINATION TSP	SIGNATURE OF TSP'S AUTHORIZED AGENT

Jun-27-06 12:57 From-NIH 301 402 1857 T-771 P.008/012 F-027

REQUEST FOR SHIPMENT

Serial No. 324591

Instructions:
Requesting Office sends the first two copies (white and yellow) to the Shipping Officer. Keep the third (pink) copy for reference.
Shipping Officer - After carrier has picked up the shipment, file this form to back up authorization for shipment.

NOTE: All dutiable international shipments (other than printed documents) must be accompanied by three copies of a commercial invoice (NIH 1884-1) for customs clearance.

1. We are requesting shipment of: [x] Government-owned property * [ ] Other:
2. Date of request: 10/27/05
3. Requester's Name (Consignor): Dottie Drake
4. ICD: NIMH
5. Building and Room: 10CRC 2-5330
6. Phone No.: 301 496 1338
7. Shipment to be paid by: [x] NIH [ ] Consignee (If consignee, complete item 8.)
8. Carrier's Name; Account No. to be Billed; Consignee's Phone No.

9. DESCRIPTION OF ARTICLES When items of varying descriptions are to be shipped, separate them and enter the quantity and value of each. If any item is hazardous or infectious to humans, note the amount (in milliliters or kilograms) and give a detailed description of the substance.	10. HAZARDOUS or INFECTIOUS?	11. QTY.	12. DOLLAR VALUE
Computers and accompanying peripherals	No	4 bx	
(1) 57# 6360 4334 8140			
(2) 22# 6360 4334 8150			
(3) 28# 6360 4334 8161			
50# 6360 4334 8172			
	TOTALS ▶	4 bx	$

13. Packaging: [x] Packed by requester [x] To be packed by Shipping (Nonperishable, nonhazardous items only) (1 pc)
14. If material was packed by the requester, AND it is biological material, how was it packed? [ ] Dry ice [ ] Ice packs [ ] Other: [x] Wet ice [ ] Room temperature

15. SHIP TO (Consignee) (Name, street address, city, state or country, zip code, telephone number) (Do not use P.O. box addresses)
Dr. Robert Cohen
Cedars-Sinai Bldg, Rm C300
8730 Alden Drive
Los Angeles CA 90048

16. Additional information, instructions, or justification
Please mark FRAGILE
*Property info attached
Tel # 310 423 4070

17. Date shipment must arrive at destination: 11-4-05
18. Property clearance (Signature of Property Accountable Officer or other official): David R. Rubinow
19. Common Account Number (CAN): 6-8337647
20. Administrative Officer's name (Typed): Sheila Johnson
21. AO's signature: DR Rubinow for

SHIPPING OFFICER COMPLETES THIS SECTION

22. Carrier: Fedl (P)
23. Date shipped: 10/28/5
24. GBL or ROC number: ~~NID 56033~~
25. Airway bill or freight bill number:
26. UPS Charge:
27. Packed by owner: 4
28. Packed by shipping: NID56003
29. [ ] Internatl. [ ] Domestic
30. Mode:
31. Total weight: 157#
32. Estimated cost: $ 175.00 / 339.15
33. [x] Pick up [ ] Flat service charge

NIH 1884 (Rev. 10/90)

81 WLW 10/28

☆ U.S. GOVERNMENT PRINTING OFFICE: 1997—418-511

Shipping Order Record

Fed-ex

Fiscal Year 06	System Serial Number 01435	Shipping Date	10/28/2005
Carrier	FDE-	Govt Bill of Lading /Record of Call	NID56003
Shipper Serial Number	00324591	Sender	DOTTIE DRAKE
Sender Phone	6-1338	Institute/Center	NIMH
CAN	8337647	Bill Number (Air or Freight)	636043348140
State/Country	CA	International /Domestic	D
Packed by Owner	4	Packed by Shipping	0
Estimated Cost	$ 175.36	List Cost	$ 339.15
Pickup Reqd - Yes	Hazardous Inspection - No	Docd by EH	DELPRO by ST
Property Number		Shipping Bill	$ 200.00
Order Type Original	Notes ALSO 636043348150/8161/8172		
Entered By VEH	Created 11/04/2005	Updated 11/07/2005	Billed 11/08/2005

Billable Shipping Orders

Shipping Inquiry

Shipping Menu

for pickup 10/28/05 (Sunday)

REQUEST FOR SHIPMENT

Serial No. 324591

Instructions:
Requesting Office sends the first two copies (white and yellow) to the Shipping Officer. Keep the third (pink) copy for reference.
Shipping Officer - After carrier has picked up the shipment, file this form to back up authorization for shipment.

NOTE: All dutiable international shipments (other than printed documents) must be accompanied by three copies of a commercial invoice (NIH 1884) for customs clearance.

1. We are requesting shipment of: [x] Government-owned property * [ ] Other:
2. Date of request: 10/27/05
3. Requester's Name *(Consignor)*: Dolfie Drake
4. ICD: NIMH
5. Building and Room: 10CRC 2-5330
6. Phone No.: 301 496 1338
7. Shipment to be paid by: [x] NIH [ ] Consignee *(If consignee, complete item 8.)*
8. Carrier's Name; Account No. to be Billed; Consignee's Phone No.

9. DESCRIPTION OF ARTICLES When items of varying descriptions are to be shipped, separate them and enter the quantity and value of each. If any item is hazardous or infectious to humans, note the amount (in milliliters or kilograms) and give a detailed description of the substance.	10. HAZARDOUS or INFECTIOUS?	11. QTY.	12. DOLLAR VALUE
Computers and accompanying peripherals	No	4 bx	
	TOTALS ▶	4 bx	$

13. Packaging: [x] Packed by requester [x] To be packed by Shipping *(Nonperishable, nonhazardous items only)* (1 pc)
14. If material was packed by the requester, AND it is biological material, how was it packed? [ ] Dry ice [ ] Ice packs [ ] Other: [ ] Wet ice [ ] Room temperature

15. SHIP TO *(Consignee)* *(Name, street address, city, state or country, zip code, telephone number)* *(Do not use P.O. box addresses)*
Dr. Robert Cohen
Cedars - Sinai Bldg, Rm C300
1130 Alden Drive
Los Angeles CA 90048

16. Additional information, instructions, or justification
Please mark FRAGILE
* Property info attached
Tel # 310 423 4070

17. Date shipment must arrive at destination: 11-4-05
18. Property clearance *(Signature of Property Accountable Officer or other official)*: David A Nelson
19. Common Account Number *(CAN)*: 6-8337647
20. Administrative Officer's name *(Typed)*: Sheila Johnson
21. AO's signature

SHIPPING OFFICER COMPLETES THIS SECTION

22. Carrier	23. Date shipped	24. GBL or ROC number	25. Airway bill or freight bill number
26. UPS Charge	27. Packed by owner	28. Packed by shipping	29. [ ] Internatl. [ ] Domestic — 30. Mode
31. Total weight	32. Estimated cost $		33. [ ] Pick up [ ] Flat service charge

NIH 1884 (Rev. 10/90)

* U.S. GOVERNMENT PRINTING OFFICE: 1987—418-511

JASON MCENTEE

Record of Personal Property Loan

To Non-Federal Government Organizations or Individuals
Please see instructions on reverse

2. Date 8/23/2005 (402)

3. NIH Loan No. L6-602

NIH Lender (IC organization and address)
NIMH INTRAMURAL OFFICE
BLG. 10 RM. 4N222/ 9000 ROCKVILLE PIKE
BETHESDA, MD

5. Borrowing Organization or Individual (name, address, phone and fax no.)
ROBERT M. COHEN
CEDARS-SINAI MEDICAL CENTER
8730 ALDEN DRIVE
LOS ANGELES, CA 90048
(310) 423-4070

6. IC Point of Contact (Name, phone and fax no.)
JASON MCENTEE
(301) 443-8931
(301) 443-6893

a. Cust Code	b. Decal No.	c. Description (serial no., manufacturer, model no.)	d. Qty.	e. Acq. Value	f. Acq. Date	g. Cond.
15008	See attached	See Attached listing	4			04
		h. Total Non-Acct.				
		i. Total Acct.	4	4,878.00		

8. Justification (include intended use, purpose, and Government benefit)
Dr. Robert will continue to collaborate on important structural and functional neuroimaging projects relating to aging and Alzheimer's [illegible]
He will be using this equipment to facilitate this collaboration on a great deal of this thus far unpublished data.

9. NIH Signatures:

a. Initiating Supervisor (Sign, and print name, title, phone no.) — Date 9/21/05
Tracy Sylvester, MD Chief, GSB

b. Approving Program Official. The signature of the Approving Program [illegible] constitutes confirmation that the loan's purpose has been reviewed and approved by any and all ethics, legal and appropriate review authorities; the loan is beneficial or will serve a useful purpose to the NIH; the property loaned is not excess; and the loan will not cause acquisition of similar [illegible] (Sign, and print name, title and phone no.) — Date 9.30 [illegible]

c. Property Management Representative — Date 10/6/05

d. NIH Property Acquisition Officer — Date 10/4/05

10. Terms for Borrower

a. The property of the United States Government described above is loaned for the period commencing 10/5/05, and ending on 10/6/10, unless terminated earlier at the discretion of the NIH. The property shall be used only for the purpose described above and in compliance with all applicable Federal, State, and local laws. This agreement shall terminate automatically upon any violation of the requirement in the preceding sentence. Borrower shall immediately notify NIH of any such unauthorized use of the property and, as directed by NIH, return all loaned property to the NIH at borrower's expense. Paragraphs b, c, e, f, g, h, and the first sentence of paragraph d shall survive any termination of this agreement.

b. The property listed above is being loaned to borrower with no warranties, express or implied, including any warranty of merchantability or fitness for a particular purpose.

c. The borrower assumes and shall bear the entire risk of loss, damage to, theft or destruction of all loaned property, from any and every cause whatsoever. The borrower's responsibility for that entire risk shall commence upon receipt to the property by the carrier contracted by the borrower. All transportation expenses incident to the delivery or return of the property will be at the borrower's expense. The borrower agrees to: (1) provide NIH with a verified inventory of the property received within ten (10) days of receipt; and (2) immediately notify NIH of any accident or event of loss or damage involving the property.

d. The borrower shall indemnify and hold the NIH and its employees harmless from any and all liability arising from the borrower's use of the property, whether that use is within or outside the purpose for which the property may be used. Upon request by the NIH, the borrower shall provide evidence of: (1) insurance fully covering the value of the property and liability for borrower's use of the property; and (2) a property management system that will ensure accountability for the property.

e. The borrower agrees to use the property carefully and in a manner reasonably contemplated to insure that the property will be usable during its entire economic life, which extends beyond the term of this loan agreement. Borrower agrees, at its sole expense, to keep the property in good repair, condition, and working order, reasonable wear and tear excepted, and to furnish any and all parts, mechanism, and devices needed to repair the property and keep it in good working order. All replacement parts and devices [illegible] repair or maintain the property shall [illegible] part of the property and shall be [illegible] NIH. The borrower shall not remove [illegible] otherwise tamper with any U.S. [illegible] property details or other identification [illegible] placed upon the property by the NIH.

f. Giving 24 to 48 hours prior notice [illegible] and other representatives of NIH [illegible] right at any time during normal [illegible] to enter the premises where the [illegible] located for the purpose of inspection [illegible] examining the property to ensure [illegible] borrower with its obligations under [illegible] agreement.

g. All notifications to NIH required to [illegible] immediately under this agreement [illegible] made by telephone call or fax to the [illegible] of Contact listed above. All other communications to NIH under this [illegible] shall be made by first class mail [illegible] the IC Point of Contact listed above [illegible] NIH Lender address listed above.

h. The borrower may not transfer [illegible] the property or borrower's obligations [illegible] this loan agreement.

11a. Signature of Borrower (agrees to terms above)	b. Printed Name	c. Title	d. Date

NIH 2489-2 (10/98)

Form NIH 2489 is no longer accepted. Use Form NIH 2489-1 for foreign [illegible]

PROPERTY

10/05/2005 09:54 6011

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

Tab 29

May 4, 2006

TO: CAPT Trey Sunderland

FROM: Commissioned Corps Liaison Office, NIH

SUBJECT: Medical Special Pay

This is to inform you that pursuant to the investigation by the National Institutes of Health Ethics Office, your Medical Special Pay is not being approved.

Kenneth C. Diepold

Kenneth C. Diepold

Cc: Dr. Thomas Insel, Director, NIMH

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE

MEDICAL SPECIAL PAY (MSP)
CONTRACT REQUEST
(Privacy Act Notice on Reverse)

DCP USE ONLY
DATE REC.:
CT. DATE:
EXP. DATE:

IDENTIFICATION

a. NAME (Last, First, Middle Initial)	b. GRADE/RANK	c. PHS SERIAL NUMBER
Sunderland, Pearson, T.	06	56247
d. ORGANIZATION	e. DUTY PHONE NUMBER	f. SSAN
NIH/NIMH/IRP	301·435·6050	1

2 **SPECIAL PAY(S) REQUESTED (Che**

☒ RETENTION SPECIAL PAY (RSP) (1, 2, 3, or 4 year contracts)	☐ MULTIYEAR RETENTION BONUS (MRB) (2, 3, or 4 year contracts, concurrent with RSP)	☒ INCENTIVE SPECIAL PAY (ISP) (1 year—If MRB contract, rate of concurrent ISP fixed for duration of MRB)

3 **CONDITIONS OF CONTRACT**

In consideration of payment of the above requested special pay for which I qualify under 42 U.S.C. 210(a)(2), 37 U.S.C. 302(a)(4), 302(b), and 301d, and implementing policies prescribed in INSTRUCTIONs 3, 9, and/or 10, Subchapter CC22.2, of the Commissioned Corps Personnel Manual (CCPM), I hereby agree to the following:

A. To remain on active duty in the Public Health Service (PHS) Commissioned Corps for 12, 24, 36, or 48 consecutive months from the effective date of this contract.
(CHECK ONLY ONE) ☒ 12 MONTHS ☐ 24 MONTHS ☐ 36 MONTHS ☐ 48 MONTHS

B. That the EFFECTIVE date shall be the DATE THE NOTARIZED CONTRACT IS RECEIVED in the Compensation Branch (CB), Division of Commissioned Personnel (DCP), except for conditions listed below:
(1) Effective date for initial contracts shall be the:
(a) Date I attain eligibility for MSP provided the completed contract is received in CB, DCP, within 60 days after I am initially eligible, and the contract bears my signature, notarized within 30 days after I am initially eligible for MSP; or
(b) Date the completed contract is notarized if received in CB, DCP, within 60 days of the date of eligibility but has not been notarized within 30 days of the date of initial eligibility; or
(c) Later date, if eligible, specified by me, which is _____ (Month) (Day) (Year).
(2) Effective date for subsequent contracts shall be the:
(a) Date following the date the preceding contract expires, provided the completed contract is received in CB, DCP, within 60 days after the date of expiration of the previous contract, and the contract bears my signature, notarized on or before the date following the date the preceding contract expired; or
(b) Date the completed contract is notarized if received in CB, DCP, within 60 days after the date of expiration of the previous contract, but has not been notarized on or before the date the previous contract expired.

C. If this contract is terminated prior to its expiration date for reasons other than as identified in F. below:
(1) I shall be required to refund a pro rata portion of any payment received pursuant to this contract. (For 1-year RSP and/or ISP and 2-year MRB contracts, that portion that represents 1/360 of the annual payment for each day of the year not served. In the case of 3-year and 4-year MRB contracts, the amount prorated will be the minimum bonus (2-year bonus amount)). The additional bonus amount for 3-year and 4-year contracts will not be prorated and must be repaid in its entirety;
(2) I shall be divested of entitlements for travel and transportation allowances for myself and my dependents, shipment of household goods, use of, transfer of, or payment for unused annual leave to my credit upon separation from the PHS Commissioned Corps;
(3) Any amount which I am obligated to refund because this contract is terminated shall be a debt due to the United States which I hereby agree to pay in full as directed by the appropriate collections officials. In accordance with Treasury Fiscal Requirements Manual (1 TFRM 6-8000, Cash Management), late charges may be assessed for payments made after the due date on amounts owed to the United States Government; and
(4) I shall have my commission terminated.

D. That a period of Absence Without Leave (AWOL) shall not be credited to fulfillment of the active-duty obligation incurred pursuant to this contract and that the period of such active-duty obligation shall be extended by the number of days of AWOL.

E. That the policies (INSTRUCTIONs 3, 9, and/or 10, Subchapter CC22.2, of the CCPM) which implement the MSP provisions of 42 U.S.C. 210(a)(2) and 37 U.S.C. 302(a)(4), 302(b), and 301d are incorporated into and made part of this contract.

F. That if I enter a long-term training program as defined in INSTRUCTION 1, Subchapter CC25.2, of the CCPM or medical internship or residency training program (i.e., training which is creditable toward board certification), this contract shall be terminated and I shall repay an amount as specified in C.(1) above.

G. That I am NOT ELIGIBLE for voluntary retirement for the duration of this contract.

4 **CERTIFICATION**

I certify that I understand and agree to the terms of this contract as stated above.

SIGNATURE [signature] DATE 12/30/05

VENUS V. ZVEIGENHAFT NOTARY PUBLIC MONTGOMERY COUNTY, MD

5 **NOTARIZATION**

Subscribed and sworn before me this 30th day of December (MONTH) A.D., 2005 (YEAR)
at City Bethesda State MD. Zip Code 20892.

SIGNATURE [signature] Date Commission Expires 8/8/09

6-8300-1 (FRONT) (Rev. 4/98) 1st Copy DCP 2nd Copy OPERATING DIVISION/ PROGRAM 3rd Copy OFFICER EF
Created by: PSC Media Arts (301) 443-3454

6	SUPERVISOR CERTIFICATION		
	(Check below as appropriate) ☒ This is to certify that the officer meets the following conditions: a. Will not be participating in long-term training or medical internship or first year of residency training as defined in INSTRUCTION 1, CC25.2 of the CCPM; b. Is performing at a satisfactory level; and c. Has received a competent or above performance rating on the current Commissioned Officers' Effectiveness Report as required by INSTRUCTION 1, CC25.1 of the CCPM. ☒ IS RECOMMENDED FOR: ☒ Retention Special Pay contract requested. ☐ Multiyear Retention Bonus contract requested. ☒ Incentive Special Pay contract requested. ☐ IS NOT RECOMMENDED for Medical Special Pay contract(s). A written explanation must accompany this contract.		
	SIGNATURE	TITLE Director, NIMH	DATE 1-11-06
7	OPERATING DIVISION/PROGRAM CERTIFICATION		
	I certify that this officer is eligible to receive this bonus and I recommend payment.		
	SIGNATURE	TITLE	DATE

Privacy Act Notice for
PHS Commissioned Corps Medical Special Pay (MSP) Contract
Form PHS-6300-1

General: This information is provided pursuant to the Privacy Act of 1974 (Public Law 93-579) for PHS commissioned medical officers applying for MSP.

Records System: 09-37-0002, "PHS Commissioned Corps General Personnel Records," HHS/OASH/OSG; 09-37-0003, "PHS Commissioned Corps Medical Records," HHS/OASH/OSG; 09-37-0005, "PHS Commissioned Corps Board Proceedings," HHS/OASH/OSG; 09-37-0006, "PHS Commissioned Corps Grievance, Investigatory, and Disciplinary Files," HHS/OASH/OSG; 09-37-0008, "PHS Commissioned Corps Unofficial Personnel Files and Other Station Files," HHS/OASH/OSG; and 09-90-0017, "Pay, Leave and Attendance Records," HHS/OS/ASPER.

Authority for Collection of Information: 37 U.S.C. 302(a)(4), 302(b), and 301d (Pay and Allowances of the Uniformed Services); 42 U.S.C. 202 et seq. (PHS Act Sec 201 et seq.); and Executive Order 9397 (Numbering System for Federal Accounts Relating to Individual Persons).

Purposes and Uses: The principal purpose for collecting this information is to determine your eligibility for MSP. If you are selected for award of MSP, the information collected will be used for issuance of personnel orders to authorize payment. These records, or information therefrom, may also be provided to other Federal agencies to which Corps medical officers are assigned. The information also may be used for study purposes and/or collection of statistical data for reports to other Federal agencies and the Congress. It may also be used for other lawful purposes including collection of a debt owed the Federal Government, law enforcement, and litigation.

Information Regarding Disclosures of Your Social Security Number (SSAN): Disclosure of the SSAN is mandatory under provisions of the Social Security Act, since Corps officers are under Social Security "covered employment" and taxes must be withheld from their salaries. The SSAN is also used as an identifier throughout an officer's career. It is used primarily to identify an officer's personnel, leave, and pay records and to relate one to the other. The SSAN is also used in connection with lawful requests for information from former employers, educational institutions, and financial or other organizations. The information gathered through the use of the number will be used only as necessary in personnel administration processes carried out in accordance with established regulations and published notices of systems of records. The use of the SSAN is made necessary because of the large number of present and former active, inactive, and retired officers and applicants who have identical names and birth dates, and whose identities can only be distinguished by the SSAN.

Effect of Nondisclosure: You are required to provide the information requested on this contract to receive MSP. Failure to supply complete and accurate information may result in delays and/or errors in determining eligibility and, therefore, result in late payment or nonpayment, or be cause for refund of pay if you receive an award based on erroneous information. All statements are subject to verification.

Tab 30

MRB/ISP VALIDATION RECORD

Name: **SUNDERLAND III, PEARSON**
SERNO: 56247 SSN:
Retention Pay DATE: 01/01/200-
Retirement Credit Date: 07/06/1982
Licensure: Y Exp: 09/30/2005
Specialty 1: 1701
Specialty 2:
Billet #: 12CC067 PRIMJOB: 92

Grade: 6 ADMINCOD: HN76V
Training Obligation Date:
Scholarship Obligation Date:
Limited Tour End Date:
Creditable Service Entry Date: 07/01/1983
BCERT1: Y
BCERT2:
MSPCSPEC: 9999 ROGSTAT: R

I. Attachments necessary to be submitted to the agency **BY THE OFFICER:**

- ✓ MSP Contract (Notarized)
- ____ Documentation of Training in Specialty or Board Certification (unless Board Certification listed above or on ISP-ROG contract)
- ✓ Copy of a current, unrestricted state license

If billet is **NOT** a clinical billet (PRIMJOB not = 81), officer **MUST** attach:

- ✓ ROG BILLET OR PREVENTIVE MEDICINE BILLET (No attachment needed)
- ____ Copy of billet, if PRIMJOB not = 81, but clinical privileges included in billet
- ____ Letter from clinical facility granting clinical privileges
- ____ Letter from clinical facility certifying previous year's completion of clinical time requirement (not necessary on initial contract)
- ____ Outside facility accreditation or description if not accredited.

I hereby certify that I (**DO**) or **WILL** (circle one) practice my

MRB/ISP Specialty of ROG

at NIH (Health Care Facility) (✓ Federal Facility ____ Non Federal)

40+ hours weekly OR ____ days monthly OR ____ days annually.

I certify that the above information is true and correct. Further, I understand that making a false statement or claim against the U. S. Government is punishable by a fine of not more than $10,000 or imprisonment for not more than five years or both, as written in 18 U.S.C. 287, 1001. I further understand that the information provided herein is subject to audit and that I will cooperate in such audit by providing the information requested.

I UNDERSTAND THAT IF MY CONTRACT PACKAGE IS INCOMPLETE, PROCESSING WILL BE DELAYED.

SIGNED: [signature]

PHONE: 301-435-6050 DATE: 12/29/05

I wish to have any contract problems reported to me on E-mail address [illegible]

II. AGENCY VERIFICATION

BY: ____

DATE: ____ TITLE: ____

Tab 31

Fitzsimmons, William (NIH/NIMH) [E]

From: Shirdon, Patrick (NIH/NIMH) [E]
Sent: Friday, December 30, 2005 1:15 PM
To: Fitzsimmons, William (NIH/NIMH) [E]
Subject: Retention bonus for Trey

HI Bill -- Hope you are feeling better.

Dr. N received the paperwork for a $15K bonus for Trey. To the best I can tell it is essentially a retention bonus based on his medical discipline. I don't see any reason we would want to not advise the front office to sign off on this, but there is some language that Trey has to sign off on about his time????????

Also - As I read the contract if he were to be able to retire, then he would have to repay a pro-rata share.

We can discuss on Tuesday.

Have a nice New Years Eve

Patrick Shirdon
Deputy Executive Officer, NIMH
NSC - Room 8102
6001 Exec Blvd
Rockville, Maryland 20892
301-443-3879

Fitzsimmons, William (NIH/NIMH) [E]

m: Nakamura, Richard (NIH/NIMH) [E]
t: Friday, January 06, 2006 9:24 AM
: Shirdon, Patrick (NIH/NIMH) [E]; Fitzsimmons, William (NIH/NIMH) [E]
Subject: Re: Trey and the contract bonus

This is clear and the next steps proposed are fine.

-----Original Message-----
From: Shirdon, Patrick (NIH/NIMH) [E] <shirdonp@mail.nih.gov>
To: Nakamura, Richard (NIH/NIMH) [E] <rnakamur@mail.nih.gov>; Fitzsimmons, William (NIH/NIMH) [E] <wfitzsim@mail.nih.gov>
Sent: Thu Jan 05 21:09:28 2006
Subject: Trey and the contract bonus

Good Evening Dr. Nakamura and Bill --

Richard Wyatt and I finally connected late this evening. He has been speaking directly with Trey on related matters concerning the "process" of his situation and they spoke of his contract.

Trey is not looking for a contract for calendar year 2006; but payment for calendar year 2005. Richard informed him that this cannot be done. However, he did suggest that as a part of a settlement, it could be negotiated.

I want to talk wiht Trey tomorrow to confim this with him. But beleive no further action necessary on this issue.

I would be glad to discuss further if you would like.

—Tab 32

Flamberg, Gemma (NIH/OD) [E]

From: Fitzsimmons, William (NIH/NIMH) [E]
Sent: Friday, September 08, 2006 2:27 PM
To: Flamberg, Gemma (NIH/OD) [E]; Smolonsky, Marc (NIH/OD) [E]
Subject: FW: North Shore

Fyi

From: Fitzsimmons, William (NIH/NIMH) [E]
Sent: Friday, February 10, 2006 5:54 PM
To: Sunderland, Trey (NIH/NIMH) [E]
Cc: Insel, Thomas (NIH/NIMH) [E]; Fitzsimmons, William (NIH/NIMH) [E]; Nakamura, Richard (NIH/NIMH) [E]
Subject: North Shore

Trey,

The institute continues to receive inquiries from people who think you have left Government employment and are now working at North Shore Hospital in New York. The most recent came today from a reporter in the New York area.

While I presume this is due to website stories from North Shore and other locations, which you have told me are incorrect, let me reiterate in writing what I have already explained to you several times:

1. Without a special waiver, NIH Ethics regulations do not permit you to have an outside activity (paid or unpaid) with North Shore, which is a grantee institution,
and at the moment no waivers are possible.

2. Your telework agreement is specific to you working at your home, here in the DC area, not in New York.

3. I understand that you intend to assume a position with North Shore once your Commissioned Corps retirement is approved, and that does allow you to travel to North
Shore without permission for limited purposes, essentially to work out details related to your future employment there. When you do this, you must take annual
leave, which I understand you have done.

4. But, please understand that, even with you taking annual leave, you cannot work at North Shore at this point in time.

Call me if you have any questions.

Bill

William T. Fitzsimmons
Executive Officer
National Institute of Mental Health (NIMH)
National Institutes of Health (NIH)
6001 Executive Boulevard; Room 8254
Bethesda, Maryland 20854
(Tel: 301-443-8877; Email: wf5a@nih.gov)

Tab 33

Flamberg, Gemma (NIH/OD) [E]

From: Fitzsimmons, William (NIH/NIMH) [E]
Sent: Friday, September 08, 2006 2:30 PM
To: Flamberg, Gemma (NIH/OD) [E]
Subject: FW: Can you please send me, RSK, and Holli ES #218136 as an email attachment? Thanks.

Sensitivity: Confidential

Re anonymous complaint.

From: Insel, Thomas (NIH/NIMH)
Sent: Wednesday, February 09, 2005 7:43 PM
To: Gottesman, Michael (NIH/OD)
Cc: Fitzsimmons, William (NIH/NIMH)
Subject: RE: Can you please send me, RSK, and Holli ES #218136 as an email attachment? Thanks.
Sensitivity: Confidential

Michael,
We will get Raynard a more complete response tomorrow, but the bottom line is that we have handled this much the way we handle the departure of any lab chief. One of the unique features here is that these "patients" are essentially healthy volunteers in a longitudinal study of aging. The NIMH will not continue this study without Trey. I suspect the letter to EZ is from a disgruntled former fellow of Trey's. She has already complained to me that she wants the CSF samples that she collected when she was a fellow in Trey's branch many years ago and she does not want him to take these samples with him. We cannot transfer samples to a university without re-consenting the subjects. In managing Trey's departure, we have asked what is best for the subjects as well as what is fair for him. I suspect this employee is interested in neither of these factors.
Tom

Thomas R. Insel, M.D.
Director, NIMH
6001 Executive Blvd. - Rm 8235- MSC 9669
Bethesda, MD 20892 - 9669
301-443- 3673 (phone)
301-443-2578 (fax)

From: Gottesman, Michael (NIH/OD)
Sent: Wednesday, February 09, 2005 7:34 PM
To: Insel, Thomas (NIH/NIMH); Kington, Raynard (NIH/OD)
Cc: Jaffe, Holli Beckerman (NIH/OD); Monarque, Brenda (NIH/OD); Fitzsimmons, William (NIH/NIMH)
Subject: RE: Can you please send me, RSK, and Holli ES #218136 as an email attachment? Thanks.
Sensitivity: Confidential

Moving the patients is a mixed blessing. The research program is important and cannot be continued at NIH without Dr. Sunderland. On the other hand, the kind of complaints raised in the letter deserve attention. Bill Fitzsimmons has been in touch about finding ways to facilitate the patient transfer and I have asked for a detailed plan which addresses the issue of continuity of care, patient safety, and fulfilling the initial commitment to the patients.
Michael

From: Kington, Raynard (NIH/OD)
Sent: Wednesday, February 9, 2005 1:51 PM
To: Gottesman, Michael (NIH/OD); Insel, Thomas (NIH/NIMH)
Cc: Jaffe, Holli Beckerman (NIH/OD); Monarque, Brenda (NIH/OD)
Subject: Fw: Can you please send me, RSK, and Holli ES #218136 as an email attachment? Thanks.
Sensitivity: Confidential

Can you take a look at this?

Raynard S. Kington, M.D., Ph.D.
Deputy Director, NIH
KingtonR@od.nih.gov
301-496-7322

-----Original Message-----
From: Gill, Tom (NIH/OD) <GILLT@od1tm1.od.nih.gov>
To: Kington, Raynard (NIH/OD) <KingtonR@OD.NIH.GOV>; Monarque, Brenda (NIH/OD) <MonarqueB@OD.NIH.GOV>; Jaffe, Holli Beckerman (NIH/OD) <JaffeHB@OD.NIH.GOV>
CC: Johnson, Dale (NIH/OD) <JOHNSOND@od1tm1.od.nih.gov>
Sent: Wed Feb 09 13:49:03 2005
Subject: RE: Can you please send me, RSK, and Holli ES #218136 as an email attachment? Thanks.
<<Error! Hyperlink reference not valid.>>
Here's the do cument, in .pdf format.

Thanks. --tom

From: Monarque, Brenda (NIH/OD)
Sent: Wednesday, February 09, 2005 1:40 PM
To: Johnson, Dale (NIH/OD); Gill, Tom (NIH/OD)
Cc: Jaffe, Holli Beckerman (NIH/OD)
Subject: Can you please send me, RSK, and Holli ES #218136 as an email attachment? Thanks.

Brenda Monarque
Staff Assistant
Office of the Director
National Institutes of Health
One Center Drive
Building 1, Room 126
Bethesda, MD 20892-0148
(301) 496-7322 Voice
(301) 402-2700 Fax
Email: monarqueb@od.nih.gov

—Tab 34

Flamberg, Gemma (NIH/OD) [E]

From: Fitzsimmons, William (NIH/NIMH) [E]
Sent: Friday, September 08, 2006 2:31 PM
To: Flamberg, Gemma (NIH/OD) [E]
Subject: FW: Sunderland

From: Insel, Thomas (NIH/NIMH)
Sent: Thursday, March 31, 2005 9:57 PM
To: Kington, Raynard (NIH/OD); Jaffe, Holli Beckerman (NIH/OD)
Cc: Fitzsimmons, William (NIH/NIMH); Gottesman, Michael (NIH/OD)
Subject: Sunderland

Raynard and Holli,
I spoke with Trey Sunderland tonight. He will not serve as P.I., care for patients, or sign charts. Robert Cohen has had primary responsibility for this research project for the past 2 months. He is eager to cooperate and even more eager to have all of this completed.
Tom

Thomas R. Insel, M.D.
Director, NIMH
Acting Director, NIMH, IRP
6001 Executive Blvd.
Bethesda, MD 20892
301-443-3673 (phone)
301-443- 2578 (fax)

[redacted]

Tab 35

Flamberg, Gemma (NIH/OD) [E]

From: Fitzsimmons, William (NIH/NIMH) [E]
Sent: Friday, September 08, 2006 2:54 PM
To: Flamberg, Gemma (NIH/OD) [E]
Subject: FW: confidential memo

From: Fitzsimmons, William (NIH/NIMH)
Sent: Thursday, January 20, 2005 2:03 PM
To: Gottesman, Michael (NIH/OD)
Cc: Wyatt, Richard G (NIH/OD)
Subject: RE: confidential memo

Okay. I will try to reach him.

Thanks,

Bill

---Original Message---
From: Gottesman, Michael (NIH/OD)
Sent: Thursday, January 20, 2005 1:55 PM
To: Fitzsimmons, William (NIH/NIMH)
Cc: Wyatt, Richard G (NIH/OD)
Subject: RE: confidential memo

Can we see a specific proposal from Trey about how much time he would need to be at Einstein to shepherd his protocols through the IRB process? I think a case can be made that this is essential for patient welfare, but we need to be honest about how much time this will actually take, and several days a week does not seem appropriate.
Michael

From: Fitzsimmons, William (NIH/NIMH)
Sent: Thursday, January 20, 2005 1:52 PM
To: Gottesman, Michael (NIH/OD)
Cc: Wyatt, Richard G (NIH/OD)
Subject: RE: confidential memo

Yes, he can start with these – but he thinks even this is hard to do long distance.

Thus – he wants to spend at least some (Government) time up there in NYC.

Also, of course, there is no clear end in sight to the current process. :)

bill

---Original Message---
From: Gottesman, Michael (NIH/OD)
Sent: Thursday, January 20, 2005 1:44 PM
To: Fitzsimmons, William (NIH/NIMH)
Cc: Wyatt, Richard G (NIH/OD)
Subject: RE: confidential memo

Bill,
Given that IRB approvals at Einstein will take months, why not start with these? Hopefully, his situation will be resolved by the time the Einstein IRB has approved the protocols.
Michael

From: Fitzsimmons, William (NIH/NIMH)
Sent: Thursday, January 20, 2005 1:28 PM
To: Gottesman, Michael (NIH/OD)
Subject: RE: confidential memo

Michael,

Mrs. Fitz and I are going on a little 35th anniversary "honeymoon" and will be back Tuesday.

I'll call you then.

In the meantime, Trey's argument essentially runs as follows:

1. He wants to assure that his patients are taken care of.

2. With Tom Chase retired and Stanley Rapoport not doing much, he is one of the few games in town for many of these patients, many of whom have cognitive problems.

3. People on his staff are already leaving, making it difficult for him to keep things intact here.

4. It will take him months to get IRB approvals etc at Einstein, so he needs to get up there at least on a part time basis to get started.

5. The NIH has a significant investment in his work, so it is important to that assure ongoing studies come to completion.

bill

---Original Message---
From: Gottesman, Michael (NIH/OD)
Sent: Wednesday, January 19, 2005 10:27 PM
To: Fitzsimmons, William (NIH/NIMH)
Subject: Re: confidential memo

Of course. Give me a call.
Michael

Sent from my BlackBerry Wireless Handheld

---Original Message---
From: Fitzsimmons, William (NIH/NIMH) <wfitzsim@mail.nih.gov>
To: Gottesman, Michael (NIH/OD) <MGottesman@nih.gov>
Sent: Wed Jan 19 12:41:23 2005
Subject: FW: confidential memo

fyi -

BTW, I talked to Trey yesterday re the rationale for moving patients to Einstein sooner rather than later. Worth discussing?

Bill

---Original Message---
From: Canning, Betty (NIH/OD)
Sent: Wednesday, January 19, 2005 12:22 PM
To: Fitzsimmons, William (NIH/NIMH)
Cc: Bolkess, Olga (NIH/NIMH)
Subject: RE: confidential memo

Thank you very much for your help. I'll be talking with the authors shortly to see if we can adopt some or

all of your suggestions. Appreciate it!

-----Original Message-----
From: Fitzsimmons, William (NIH/NIMH)
Sent: Wednesday, January 19, 2005 12:19 PM
To: Canning, Betty (NIH/OD)
Cc: Fitzsimmons, William (NIH/NIMH); Bolkass, Olga (NIH/NIMH)
Subject: RE: confidential memo

Betty,

The draft Kington memorandum looks pretty good, but I do have some comments and concerns:

1. I think it would be very helpful to have some estimated time frames associated with the various steps involved in the investigative/decision making process.
Things seem to be moving very slowly, which is exacerbating morale problems.

2. While paragraphs are okay, I think the use of "bullets" or a "flow diagram" would help the reader understand and follow the process better.

3. At the end of paragraph 3 on page 1, I would encourage allowing the IC DEC a chance to comment on the "conflicts analysis" performed by the NIH Ethics Office before
this analysis is sent to OMA. This will prevent errors and reduce misunderstandings.

4. I suggest the following as a substitute lead in:

This is to provide those NIH scientists and science administrators impacted by recent ethics investigations with some general information about ...

- Bill

-----Original Message-----
From: Canning, Betty (NIH/OD)
Sent: Wednesday, January 19, 2005 11:18 AM
To: Fitzsimmons, William (NIH/NIMH)
Subject: confidential memo
Importance: High

Here's the draft memo we'd appreciate your review/take on.

Thank you for helping.

<< File: 216918memo11905.wpd >>

TO: Addressees

FROM: Deputy Director, NIH

SUBJECT: Review of Outside Activities

The purpose of this memorandum is to provide you with some general information about the NIH review of certain outside activities of NIH employees. As you know, the House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, referred information about some outside activities to NIH for review, other activities were cited in news articles, and still others were self-reported by NIH employees in response to a request by Dr. Zerhouni. You are receiving this memorandum because one or more of your outside activities is being reviewed.

The NIH Office of Management Assessment (OMA) is conducting the fact-finding portion of each review. Each of you has met or will have the opportunity to meet with representatives from OMA. You have or will have had the opportunity to review and revise the summary of that interview prepared by OMA. You will

also have the opportunity to comment on the draft OMA report.

In addition to the fact-finding, some cases will also undergo a conflict analysis. When OMA finds that an outside activity was not approved as required by HHS and NIH policy, they will refer that activity to the NIH Ethics Office, which is coordinating a conflict analysis of the particular activity to determine if the subject of the outside activity substantially overlaps with the employee's official duties. The results of that analysis will be transmitted back to OMA.

When all work has been completed, OMA will transmit its final report, along with the conflict analysis, if any, to the Deputy Director for Management (DDM), NIH. OMA will also give a copy of its final report and the conflict analysis to you and to your Institute executive officer.

The DDM will deliberate and determine whether administrative action is appropriate, and if so, what action should be taken. The DDM will be advised by Human Resources and other experts in making these determinations to ensure fairness and consistency. Issues involving Commissioned Corps officers and calling for administrative disposition may be referred to or coordinated with the Office of the Surgeon General or other Commissioned Corps officials, as appropriate.

You will be informed by memorandum of any administrative action, as well as a description of the appeal process for any administrative action. You will also be informed if no administrative action will be taken.

Raynard S. Kington, M.D., Ph.D.

ADDRESSEES:
Employees (81) on the list provided by the House Subcommittee
Employees cited in 2 Los Angeles Times articles
Employees who reported activities with pharmaceutical and biotechnology companies
IC Executive Officers

NIH;OD;OM;OMA;SServis;1/3/05;doc#216916
Revised per NIH;OD;OM;PLenowitz;OIR;RWyatt;OGC/E;GWeaver;OGC;BMcGarey;bc;1/6&7/05
Revised per NIH;OD;OM;OMA;KWetmore;OGC;BDart;NIH;OD;ES;DJohnson;bc;1/11/05
Revised OGC/NIH;BMcGarey;1/12/05
Revised per NIH;OD;NEO;HBeckermanJaffe;OD;OM;OMA;KWetmore;1/19/05
Official file in OMA

[redacted]

Tab 36

Thank you for helping.

<< File: 216918memo11905.wpd >>

TO: Addressees

FROM: Deputy Director, NIH

SUBJECT: Review of Outside Activities

The purpose of this memorandum is to provide you with some general information about the NIH review of certain outside activities of NIH employees. As you know, the House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, referred information about some outside activities to NIH for review, other activities were cited in news articles, and still others were self-reported by NIH employees in response to a request by Dr. Zerhouni. You are receiving this memorandum because one or more of your outside activities is being reviewed.

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In addition to the fact-finding, some cases will also undergo a conflict analysis. When OMA finds that an outside activity was not approved as required by HHS and NIH policy, they will refer that activity to the NIH Ethics Office, which is coordinating a conflict analysis of the particular activity to determine if the subject of the outside activity substantially overlaps with the employee's official duties. The results of that analysis will be transmitted back to OMA.

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The DDM will deliberate and determine whether administrative action is appropriate, and if so, what action should be taken. The DDM will be advised by Human Resources and other experts in making these determinations to ensure fairness and consistency. Issues involving Commissioned Corps officers and calling for administrative disposition may be referred to or coordinated with the Office of the Surgeon General or other Commissioned Corps officials, as appropriate.

You will be informed by memorandum of any administrative action, as well as a description of the appeal process for any administrative action. You will also be informed if no administrative action will be taken.

Raynard S. Kington, M.D., Ph.D.

ADDRESSEES:
Employees (81) on the list provided by the House Subcommittee
Employees cited in 2 Los Angeles Times articles
Employees who reported activities with pharmaceutical and biotechnology companies
IC Executive Officers

NIH;OD;OM;OMA;SServis;1/3/05;doc#216918
Revised per NIH;OD;OM;FLenowitz;OIR;RWyatt;OGC/E;GWeaver;OGC;BMcGarey;bc;1/6&7/05
Revised per NIH;OD;OM;OMA;KWetmore;OGC;BDart;NIH;OD;ES;DJohnson;bc;1/11/05
Revised OGC/NIH;BMcGarey;1/12/05
Revised per NIH;OD;NEO;HBeckermanJaffe;OD;OM;OMA;KWetmore;1/18/05
Official file in OMA

Tab 37

Flamberg, Gemma (NIH/OD) [E]

From: Fitzsimmons, William (NIH/NIMH) [E]
Sent: Friday, September 08, 2006 2:38 PM
To: Flamberg, Gemma (NIH/OD) [E]; Smolonsky, Marc (NIH/OD) [E]
Subject: FW: Phone call with Trey

Fyi

From: Insel, Thomas (NIH/NIMH) [E]
Sent: Sunday, February 05, 2006 2:42 PM
To: Fitzsimmons, William (NIH/NIMH) [E]
Subject: Phone call with Trey

Bill,
I called Trey on Friday evening to define, once again, the importance of his recusing himself from any dealings with a future employer. He reiterated that he is not working at North Shore because he is not being paid, but he admitted that he has traveled there while on leave. He explained that he feels a clinical responsibility to the patients who are transferring from his NIH study to the North Shore study. He feels that after committing several years to this longitudinal study, he needs to be available to set up the program in New York and to ensure continuity for these patients. He reiterated that we told patients about this change over a year ago and that whatever problems exist now are due to the "unacceptable" delay he has endured in being able to leave the government and accept his new post. I reviewed the regulations with him (again) and told him that he is putting himself in jeopardy by interacting with a future employer while a government employee whether on official time or leave. I understand that you have already spelled this out for him very clearly on multiple occasions. I assume he has not requested a waiver for this activity. My sense from this conversation on Friday is that he does not recognize the seriousness of his situation. After 14 months of waiting to be released (I signed his retirement request in early Nov 2004!), one can understand his frustration. But if he flaunts the regs, he will make matters worse not better. I need to discuss this with Raynard (as NIH DEC) to decide next steps. Will let you know his recommendations.
Tom

Thomas R. Insel, M.D.
Director, NIMH/NIH
6001 Executive Blvd. Room 8235
Bethesda, MD 20892
301-443-3673 (ph)
301-443-2578 (fax)

Sep-11-2006 05:29pm From-Assistant Secretary for Legislation 202-690-7380 T-659 P.014/015 F-311

Tab 38

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

DATE: August 3, 2006

TO: Dr. Trey Sunderland, M.D.

FROM: Director, NIMH

SUBJECT: Workplace Restrictions

On December 2, 2005, you were informed that, after a lengthy investigation, it was determined that you had engaged in a number of serious incidences of misconduct. The matter was subsequently referred to the Commissioned Corps for further action. It is my understanding that the United States Attorney's office is looking into these issues as well.

Given the serious nature of the allegations, and the fact that the personnel matter is still pending with the Corps, I have decided to exercise my supervisory authority to restrict your workplace activities, as well as your official duty activities with outside groups and /or individuals, and any outside activities that involve your professional qualifications or scientific expertise and training (and which normally require prior approval).

The new restrictions, to be effective immediately, are as follows:

1. No official duty activities with outside entities, including teaching and lecturing, or any travel related to such activities, will be authorized, and any prior approvals for such activities are now cancelled.
2. No outside activities will be authorized, whether or not travel is involved, and any prior approvals are now cancelled (except as specified below).
3. Access to NIH materials deemed relevant by the Institute to the ongoing investigations will not be authorized.

You may continue your private medical practice so long as the standard restrictions related to separation of your private practice activities and your responsibilities as a Federal employee are observed. You, of course, may continue to write and edit scientific works related to your NIMH

assignments; however, these are subject to the normal pre-publication clearance procedures. Your tele-work agreement also remains in effect, which will allow you to work from your home several days per week.

Also be aware that, during this interim period, it is my intention to place you on a temporary duty assignment, effective August 6, 2006, to the Office of the Institute Director, in the Neuroscience Center on Executive Boulevard in Rockville, where you will assume Special Assistant to the Director duties, and assist me in the evaluation of the NIMH's extramural aging research programs.

You are also again cautioned that you cannot perform work for your prospective employer, North Shore Hospital, during this period, or take any official action on behalf of the Federal government that might benefit the financial status of North Shore.

If you have questions regarding these restrictions, or you would like to discuss the contents of this memorandum, I would be happy to meet with you.

Thomas R. Insel, M.D.
Director, NIMH

Acknowledgement of Receipt: _____

Date

Tab 39

HHSE-Mail
Response to
Slobodin
CC Questions
9/11/06

Slobodin, Alan

From: Hemard, Casey (HHS/ASL) [Casey.Hemard@HHS.GOV]
Sent: Monday, September 11, 2006 6:08 PM
To: Slobodin, Alan
Subject: Corps questions

Alan-

In response to your questions for Dr. Agwunobi and the Corps, please find answers below:

1. ***Can action be taken against a Commissioned Corps officer's retirement without the action of a Board of Inquiry (BOI)?***

   An officer's retirement pay and/or commission status cannot be compromised for misconduct without a Board's review, recommendation and a decision by the Assistant Secretary for Health. This would involve the convening of a Board of Inquiry, which affords due process by providing notice and an opportunity for the accused officer to appear at a hearing, present witnesses and cross examine the witnesses.

(2) ***What was the last case for which a BOI was convened? How long did it take? What were the allegations? Chronology of how long it took? Facts of the case?***

The most recent BOI case was in 1999, involving an officer assigned to the Food and Drug Administration (LCDR R. case).

The case took less than one year to complete. Special Agent within the FDA Office of Internal Affairs gathered facts on potential allegations for four months. A BOI was convened by the Surgeon General and a three-month investigation was conducted by a PHS Representative assigned to the BOI to develop the record and specification of the charges. The officer was formally notified and provided case documents, charges and specifications. The officer was afforded the required 30-day notification. The officer requested a one-month extension and was granted a 2-week extension. Prior to the hearing, the officer submitted a voluntary resignation and her commission was terminated by the Corps.

The case involved a total of seven charges including AWOL and misconduct for misappropriation of drugs.

(3) ***Can the Corps provide a list of all BOI cases for the last 30 years?***

The Commissioned Corps has records of Boards of Inquiry (BOI) dating back to 1983. The Corps' personnel policy governing disciplinary action including the BOI became effective in

April 1983. Since that time, there have been a total of 12 officers referred to a BOI. These cases represent the most serious types of misconduct that could not be adjudicated through other administrative remedies.

The BOI cases and their outcome are as follows.

#	Officer	Outcome
#1	LCDR B	Settled prior to the convening of the Board recommendation
#2	LCDR L	Involuntary termination as a result of the Board recommendation
#3	LT L	Reduced in rank/grade and not eligible for promotion for 5 years; officer retired from the Corps as an O-2 as a result of the Board recommendation
#4	LCDR L2	Reduced in rank/grade and not eligible for promotion for specified period; and reassigned as a result of the Board recommendation
#5	CDR S	Reduced in rank/grade as a result of the Board recommendation
#6	RADM W	Negotiated settlement prior to the convening of the Board hearing
#7	CDR S2	Negotiated settlement prior to the convening of the Board hearing
#8	CDR M	Summarily terminated for AWOL prior to the Board;
#9	CDR H	Involuntarily terminated commission as a result of the Board recommendation
#10	LCDR R	Voluntarily resigned commission prior to the convening of the Board hearing

#11	CAPT PS	Pending BOI – currently suspended
#12	CAPT TW	Pending BOI

(4) ***Can the Corps provide a list of all Boards of Involuntary Retirement over the last 30 years?***

During the period, 1991 to 2006, the Corps has referred a total of 45 officers to Involuntary Retirement Boards. The majority of these cases involved officers for whom the Corps was unable to identify suitable assignments, followed by issues involving professional licensure, performance, misconduct, and failure to promote. There are likely to have been additional cases, but officers elected to voluntarily retire when informed by supervisors that they were being considered for referral to an Involuntary Retirement Board.

(5) ***Is there a place on the HHS/OPHS website that relates to NIH the advantages of employing Commissioned Corps officers?***

There are a number of Departmental and Corps websites that contain information that relates the advantages of being a Commissioned Corps officer and employment opportunities for health professionals. Also contained on the Commissioned Corps Management Information System website is information for Departmental supervisors about employing and supervising Corps officers.

It appears to the Committee staff that the Commissioned Corps has different standards from agencies for participation in outside activities. Does the Corps enforce this differently from NIH?

The Standards of Ethical Conduct for employees in the Executive Branch and the Department's Supplemental Ethics Standards apply to both civil service employees and officers in the PHS Commissioned Corps. When an ethical question arises, the officer is referred to the agency Ethics Office.

(7) ***Why wasn't CAPT Sunderland deployed during Katrina?***

CAPT Sunderland did not participate in the Corps deployment during the Hurricanes Katrina, Rita and Wilma. Over 2,400 officers deployed in response to these three hurricanes, which means that approximately 3,600 officers were not deployed.

(8) ***In a situation where an officer retires from the Corps before an agency brings allegations of misconduct against this officer, can the Corps take away their retirement benefits (after they retire)?***

Although, the Corps' disciplinary policy does apply to both active duty and retired officers, there are practical limitations to recalling a retired officer who may be facing allegations of misconduct. It may be easy to recall a retired officer who voluntarily wishes return to active duty status, it may be difficult, or impossible to recall an officer who is facing allegations of misconduct and unwilling

(12) ***What is "station leave"? How does this differ from "annual leave"?***

What office maintains records on station leave? What office maintains records on annual leave? If paid outside consulting is permitted on annual leave but not station leave, how is this activity policed for proper leave usage?

Stations leave is defined as "absence from duty and station under the following conditions: (1) during off-work hours (i.e., the period between the normal completion and commencement of scheduled working hours) on two consecutive workdays; (2) on a non-workday unless the non-workday falls within a period of annual leave; and (3) for a period of less than one workday."

In contrast, annual leave is defined as "any period of one workday or more during which an officer is relieved from his/her scheduled working hours (other than sick leave) including all non-workdays falling within such period."

An officer's supervisor assigns the officer a leave maintenance clerk who maintains the officer's annual and station leave. Typically, the leave maintenance clerk is in the immediate office of the assigned officer.

Outside consulting may be permitted on annual leave as well as station leave provided the activity has been approved and is performed consistent with Subchapter CC26 listed in the previous question. Station leave may not be granted during normal duty hours for an officer to participate in an outside activity and earn compensation. For example, a nurse officer whose normal duty hours are Monday through Friday 0730 to 1700 would technically be on station leave during the weekend. Therefore, if the nurse officer wants to maintain clinical proficiency by working on the weekend, the officer would not be authorized to work and earn compensation unless approved for outside activity in accordance with Corps policy.

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Tab 40

United States General Accounting Office

GAO

Report to Congressional Requesters

May 1996

FEDERAL PERSONNEL

Issues on the Need for the Public Health Service's Commissioned Corps

GAO/GGD-96-55

GAO

United States
General Accounting Office
Washington, D.C. 20548

General Government Division

B-270284

May 7, 1996

The Honorable Lamar Smith
House of Representatives

The Honorable John R. Kasich
House of Representatives

This report responds to your request that we review the operations of the Public Health Service's (PHS) Commissioned Corps, whose officers carry out a variety of public health functions. You were interested in (1) whether there is a continuing need for the PHS Corps as a uniformed service with military-like pay, allowances, and benefits and (2) what the costs would be if federal civilian employees carried out the Corps' functions. You were also interested in the same issues regarding the National Oceanographic and Atmospheric Administration's (NOAA) Commissioned Corps. We plan to issue a separate report later on our findings on the NOAA Corps.

In working with your designated representative on the request, it was agreed that answers to seven specific questions would provide the information you were seeking. In general, the questions addressed why the Corps exists; Corps officers' duties; the rationale for their receiving military-like pay, allowances, and benefits; and any savings that might result from not using uniformed personnel to carry out Corps functions. Our findings are summarized below, and detailed responses to each question are presented in appendix I.

In doing our work, we interviewed and obtained documentation from officials of the Department of Health and Human Services (HHS), PHS, the Commissioned Corps, the Department of Defense (DOD), and other federal organizations that could provide insights into the Corps' functions, responsibilities, and costs. Appendix II describes in detail the objective, scope, and methodology of our review.

Results in Brief

The PHS Corps was established in the late 1800s to provide medical care to sick and injured merchant seamen. Over the ensuing years, the Corps' responsibilities have grown, and Corps officers are involved in a wide range of PHS programs, such as providing medical care to Native Americans at tribal and Indian Health Service facilities, psychiatric, medical, and other services in federal prisons, and health sciences research.

The functions of the Corps are essentially civilian in nature. In fact, some civilian PHS employees carry out the same functions as Corps members, and new employees hired for these functions are allowed to decide whether they will serve in a civilian capacity or as members of the Corps.

Members of the Corps were authorized to assume military ranks and receive military-like compensation, including retirement eligibility (at any age) after 20 years of service, as the result of their temporary service with the armed forces during World Wars I and II. The Corps has not been incorporated into the armed forces since 1952, and DOD has no specific plans for how the Corps might be used in future emergency mobilizations. Corps officers continue to receive virtually the same pay and benefits as the military, including retirement.

Generally, the PHS Corps does not meet the criteria and principles cited in a DOD report as justification for the military compensation system. According to the DOD report, the chief purpose of the military compensation system is to support the military services' mission readiness and sustainability. Military members can be assigned at any time to any locations the services see fit, regardless of the members' personal preferences or risks. Accordingly, the military compensation system is based on the premise that individual aspirations and preferences are subordinated to the good of the service. Other than officers who are detailed to the Coast Guard and DOD, Corps members are not subject to the Uniform Code of Military Justice, which underlies how military personnel are managed.[1]

Corps officials provided us their rationale for continuing the Corps as a uniformed service. In large part, the officials maintained that uniformed Corps members are needed as mobile cadres of professionals who can be assigned with little notice to any location and function where their services are necessary, often in hazardous or harsh conditions. We found that although some Corps assignments are of this nature, federal civilian employees are often also assigned to duties similar to those of the Commissioned Corps. Some PHS civilian employees—physicians, nurses, pharmacists, and others—have responsibilities that are identical to those of PHS Corps officers. Other agencies, such as the Environmental Protection Agency, the National Transportation Safety Board, and the

[1]Under a 1902 statute, the president can incorporate the Corps into the military service in the event of war or national emergency. Since all military personnel are subject to the Uniform Code of Military Justice, Corps officers, after being incorporated into the military, would be subject to the Code. This situation has not occurred since 1952.

Federal Emergency Management Agency, use civilian employees to respond quickly to disasters and other emergency situations.

According to our estimates, it would cost the government less to employ civilian workers than PHS Corps members. As of March 1995, PHS employed 6,276 persons on active duty in its Commissioned Corps. On the basis of 1994 costs, we estimate that PHS' annual personnel costs could be as much as $130 million, or about 22 percent, a year lower if civilian employees were used for the functions carried out by Corps members, once a transition to civilian employment were completed.[2] The components of this $130 million cost reduction include special pays, allowances, bonuses, Corps officers' advantage from paying no taxes on their housing and subsistence allowances, and retirement.

Agency Comments

HHS provided written comments on a draft of this report. Its specific comments on our responses to the seven questions are discussed at the end of the appropriate sections in Appendix I along with our responses to the comments.

HHS maintained that continuation of the Corps is essential to effective operations of the government's health programs. The primary argument advanced by HHS for retaining the Corps was an assertion that officers eligible to retire would, in fact, retire if the Corps functions were civilianized, and as many as 25 percent of the officers not eligible to retire would elect to leave their jobs, thereby creating immediate and long-term problems in the recruitment and retention of qualified health professionals and in the development of professional leadership for the future. HHS said it was informed by the agencies to which Corps officers are assigned that loss of the Corps would have an extremely detrimental effect on their programs and that they believed it would be very difficult to replace Corps officers with similarly qualified civilian employees.

We did not survey Corps officers to assess their potential actions if the Corps were civilianized. More importantly, there are a number of ways in which a transition to civilian employment could be accomplished if the Corps were eliminated, and the time period over which the transition

[2]The actual net cost reduction would differ, depending on various factors, including the method by which any changes are implemented, the accuracy of the data PHS and DOD provided us, the applicability of 1994 costs to future years, and how closely our underlying assumptions match actual relationships between Corps and civilian personnel costs. Cost reduction would result in budgetary savings only if Congress reduced appropriations by the amount of the cost reduction and lowered the discretionary spending caps.

would occur would have to be determined. In its comments, HHS presumed that the transition would be immediate and that all Corps officers would be required to decide whether to become civilian employees or leave their jobs. While such an approach is possible, nothing in our report suggested that it was the appropriate arrangement. It is also important to note that our report does not assess whether the Corps should be eliminated and reaches no conclusions nor makes any recommendations in this regard. Rather, we were asked to answer seven questions related to the Corps' history, costs, and operations. If a decision were made to eliminate the Corps, it is apparent that many considerations would be involved, not the least of which would be the manner in which a transition to civilian employment would be carried out and over what time frame.

We believe it is informative to again note that each professional category (medical, dental, nursing, etc.) in the Corps had civilian employee counterparts, often with more civilian employees than Corps officers serving in the professional category. Nothing came to light during our review or in the HHS comments to suggest that the civilian employees were incapable of carrying out their job responsibilities.

HHS took issue with our estimates of the comparative costs of employing Corps officers and civilian employees included in the draft report. After analyzing the HHS comments, including consideration of certain circumstances that had changed since our work was completed, we adjusted the cost comparisons accordingly. However, HHS also maintained that one-time transition costs amounting to at least $575 million could be incurred to convert the Corps to civilian employment. We found this estimate to be questionable because it consisted mostly of costs that would be incurred regardless of whether the Corps were continued or terminated.

DOD also provided written comments on the draft report. DOD stated that the number of Corps officers currently assigned to DOD was somewhat greater than indicated in the report. We did not change the report because the assignment data in the report reflected officer assignments as of a specific date. DOD also suggested some wording changes for clarification, particularly with regard to PHS' role in DOD's emergency mobilization plans. In consultation with a DOD official, we revised the wording to accommodate DOD's suggestions.

As agreed with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 7 days from the date of this letter. At that time, we will send copies to the Secretaries of HHS and DOD and other interested parties. We will also make copies available to others upon request.

If you have questions concerning this report, please telephone me at (202) 512-8676. Major contributors to this report are listed in appendix V.

L. Nye Stevens
Director, Federal Management
and Workforce Issues

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Abbreviations

CDC	Centers for Disease Control and Prevention
DOD	Department of Defense
EPA	Environmental Protection Agency
FEGLI	Federal Employees' Group Life Insurance
FEHB	Federal Employees' Health Benefits Program
FEMA	Federal Emergency Management Agency
FERS	Federal Employees' Retirement System
HHS	Department of Health and Human Services
IHS	Indian Health Service
NIH	National Institutes of Health
NOAA	National Oceanographic and Atmospheric Administration
NTSB	National Transportation Safety Board
OASH	Office of the Assistant Secretary of Health
OMB	Office of Management and Budget
OPM	Office of Personnel Management
PHS	Public Health Service
SGLI	Serviceman's Group Life Insurance
TSP	Thrift Savings Plan
UNICEF	United Nations Children's Fund

Information on the Public Health Service's Commissioned Corps

INFORMATION ON THE PUBLIC HEALTH SERVICE'S COMMISSIONED CORPS

1. When and why was the Public Health Service's Commissioned Corps established?

In 1798, Congress established the Marine Hospital Fund to maintain hospitals that would care for sick or disabled Navy and merchant seamen. The marine hospital system, the predecessor of the Public Health Service (PHS), consisted solely of civilian employees. In 1811, the Navy began its own hospital system, and the marine hospitals' responsibilities were limited to providing health care to merchant seamen.

Until the 1870s, the marine hospitals were locally administered with no central direction, and no merit requirements governed the selection of staff. To address this situation, in 1870, Congress established the Marine Hospital Service and created the position of Supervising Surgeon (later to be the Surgeon General) to oversee the newly created Marine Hospital Service. The new Supervising Surgeon required the Marine Hospital Service's physicians to wear uniforms. The stated objective of the uniform requirement was to professionalize health-care services. Two years later, the Department of the Treasury[3] issued regulations formally establishing the Commissioned Corps as a uniformed service. The literature suggests that the Commissioned Corps was created in the hope that the uniform requirement could deter patronage abuses in the Marine Hospital Service.

In 1878, in response to a yellow-fever epidemic, the Marine Hospital Service's scope was broadened to include quarantine authority. In 1889, Congress statutorily authorized the Commissioned Corps as part of the Marine Hospital Service. The Marine Hospital Service was renamed the Public Health and Marine Hospital Service in 1902, and in 1912, this organization became the Public Health Service. The Commissioned Corps continued its existence throughout these organizational changes.

The PHS Corps played a role during both world wars. During World War I, PHS Corps officers worked to combat disease in areas surrounding military camps in the United States. During World War II, some Corps medical, dental, engineering, and nursing personnel served with the U.S. Coast Guard in the North Atlantic, and other Corps officers were detailed to the military services.

Between the two world wars, PHS continued its prewar function of caring for sick and injured merchant seamen in its system of hospitals and clinics. PHS also expanded research that it had begun before World War I in areas such as venereal disease and mental hygiene, and its

[3]The Marine Hospital Fund, the Marine Hospital Service, and later the Public Health Service, were under the Treasury Department from 1798 until 1939.

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expanded research role was recognized by Congress in 1930 with a statute creating the National Institute of Health (later the National Institutes of Health). During the 1930s, PHS gained new responsibilities, including providing psychiatric, medical, and other services in federal prison hospitals and dispensaries. Other responsibilities included providing financial and technical assistance to state and local public health departments. PHS Corps officers were involved in these aspects of PHS' expanded role.

In 1981, the Omnibus Budget Reconciliation Act terminated the PHS Corps' original mission, which had broadened considerably over time. The automatic entitlement of merchant seamen to government-funded treatment was ended, and the PHS hospitals and clinics were closed.

Like other PHS employees, Corps officers are physicians, nurses, dentists, pharmacists, engineers, scientists, sanitarians, veterinarians, dietitians, and therapists. As of March 1995, PHS had 40,643 civilian General Schedule and Senior Executive Service employees and 6,276 Corps officers.

At the time of our review, the active duty Corps officers were carrying out functions in the various component agencies of PHS, as follows.

-- Indian Health Service (IHS) (2,401 officers). The officers' duties included providing medical care to Native Americans at tribal and IHS facilities.

-- Health Resources and Services Administration (997 officers, including 165 detailees who provided medical care to members of the Coast Guard; 429 detailees to the Bureau of Prisons, most of whom provided medical care to the inmates of federal correctional facilities; and 11 detailees who provided medical care to members of the Commissioned Corps at the National Oceanographic and Atmospheric Administration (NOAA)). Officers not detailed to other organizations served as project officers or grants administrators or provided technical support to clinical programs, such as those in public housing or for the homeless.

-- National Institutes of Health (NIH) (918 officers, including 2 detailees to the Uniformed Services University of the Health Sciences and 1 detailee to the United Nations Children's Fund (UNICEF)). The officers assigned to NIH carried out research in the health sciences or provided care to patients involved in NIH projects.

-- Centers for Disease Control and Prevention (CDC) (701 officers, including 9 detailees to the National Park Service; 6 detailees to the World Health Organization; 6 detailees to the U.S. Agency for International Development; 1 detailee to the Pan American Health Organization; 1 detailee to a congressional committee; and 3 detailees to private institutions, including The Johns Hopkins University, the

Rockefeller Institute, and the John Snow Institute. Officers in CDC carried out disease research, mostly in epidemiology.

-- Food and Drug Administration (519 officers). The officers appraised the efficacy and merits of proposed new drugs and medical devices.

-- Substance Abuse and Mental Health Services Administration (113 officers, including 71 detailees who provided medical care for patients at St. Elizabeth's Hospital). The other 42 officers were involved in mental health and substance abuse grant management.

-- Agency for Toxic Substances and Disease Registry (52 officers). The officers evaluated the health effects of toxic wastes in cooperation with community officials and local medical professionals.

-- Agency for Health Care Policy and Research (23 officers). The officers analyzed health-care policies and clinical treatment responses.

-- Office of the Assistant Secretary for Health (OASH)[4] (259 officers, including 2 detailees to the Department of Energy, 1 detailee to the Department of Defense (DOD), 38 detailees to the Immigration and Naturalization Service--where officers examined and provided health care to aliens seeking entry into the United States--and 1 detailee to the Peace Corps). OASH included the PHS regional offices, the National AIDS Program Office, the National Vaccine Program Office, the Office of the Surgeon General, the Office of Emergency Preparedness, and other health-related activities.

In addition, 13 officers were detailed to the Office of the Secretary of the Department of Health and Human Services (HHS), where they provided computer support for Corps and civilian HHS personnel systems. Further, 95 PHS Corps officers were detailed to the Health Care Financing Administration, where they served on medical peer review panels and conducted state nursing home evaluations, and 185 officers were detailed to the Environmental Protection Agency, where they carried out environmental research or regulatory functions.

AGENCY COMMENTS

HHS provided information to clarify the status of PHS in an October 1995 HHS reorganization. We incorporated the clarifying information. DOD noted that the number of Corps officers detailed to DOD had increased somewhat since we completed our work. So

[4]As the result of an October 1995 reorganization, OASH was eliminated. The Office of the Surgeon General was assigned to the newly created Office of Public Health and Science.

that the assignment information would consistently reflect all agency details as of the same date, we did not show the later DOD numbers.

2. When and why were members of the PHS Corps first covered by military-like pay, allowances, and benefits? What facts can be cited that are relevant to these justifications? In what ways is the Corps compensation program like, and unlike, the military compensation program?

Generally, the Corps compensation program is the same as the military compensation program.

Although the PHS Corps has been a uniformed service since the 1870s, it was not until World War I that Corps officers received military-like compensation. An executive order issued April 3, 1917, made PHS a part of the military forces during wartime. Several months later, Congress enacted legislation giving those PHS officers who were detailed to the Army or Navy or serving on Coast Guard vessels in wartime the same rights to pensions as those provided to Army, Navy, and Coast Guard officers. Officers not detailed to the military were not affected by this legislation.

The Joint Service Pay Act of 1920 extended the military pay system to the PHS Corps and explicitly set out the Corps rankings and their equivalent ranks in the Army and Navy. The debate on this act included the statement of one senator that the PHS Corps officers were placed in the same category as Army and Navy officers "[b]ecause the Army, the Navy, the Marine Corps, . . . and the Public Health Service are all regarded as a part of the Army or Navy . . . ." At the time the act was considered, this statement was true because the wartime mobilization of the PHS Corps was still in effect. (Although the actual combat in World War I ended with the Armistice of November 1918, the United States remained legally at war until Congress terminated the state of war by joint resolution in 1921.)

The PHS Corps was again integrated with the military services during World War II.[5] In 1944, Congress extended all military "rights, privileges, immunities, and benefits" to PHS Corps officers who were detailed to duty with the Army, Navy, or Coast Guard. In 1956, PHS Corps officers became eligible for certain veterans' and survivor benefits. In 1960, legislation made all Corps officers eligible for retirement after 20 years' service.

[5]The PHS Corps remained a part of the military services by executive order until July 3, 1952, when the order expired. The Corps has not been integrated with the military since that date.

AGENCY COMMENTS

Neither HHS nor DOD had any comments on our response to question 2.

3. What reasons does the Corps now give in support of the need for uniformed services personnel to carry out its functions? What facts can be cited that are relevant to these arguments?

The Corps provided us its rationale for continuing to be a uniformed service. Generally, officials cited (1) the need for officers to be mobile, like the military, and to respond quickly in emergency situations and (2) the fact that Corps officers can be called on to serve in arduous conditions and remote locations. The officials said the Corps' pay and benefits enabled them to attract the best professional medical talent.

Information we developed suggests that uniformed personnel are not necessary to carry out the Corps' functions. For example, civilian employees of the Federal Emergency Management Agency (FEMA) and the National Transportation Safety Board (NTSB) must quickly respond to emergency situations and also must work under arduous conditions at remote locations. Officials of these two agencies said agency employees serve under these conditions on a routine basis. Also, officials at NIH, the Agency for Health Care Policy and Research, and the Health Care Financing Administration said all positions in their agencies could be filled by civilians. These 3 agencies have about 1,000 PHS Corps officers assigned to them.

Several officials from IHS said it continues to be very difficult to get civilian medical personnel to serve in IHS medical facilities in remote sections of sparsely populated states, such as South Dakota. In an earlier report,[6] we noted that some geographic areas were experiencing shortages of IHS medical personnel in general. As we reported, the lack of available full-time physicians, whether Corps officers or civilian employees, had forced IHS medical facilities in North and South Dakota to use physicians from temporary-hire agencies.

On entering PHS, qualified new recruits were permitted to choose between a career in the Corps or to do the same jobs in a civilian capacity. PHS officials said some recent PHS recruits, especially physicians, had elected to work as civilian employees because entry-level civilian salaries were higher than the pay and allowances Corps officers receive in some professions.

We asked PHS Corps officials to provide their views on why the Commissioned Corps needs to exist. Table I.1 gives their stated rationales and our observations on those rationales.

[6] Indian Health Service: Efforts to Recruit Health Care Professionals (GAO/HEHS-94-180FS, July 1994).

Table I.1: PHS' Reasons for Maintaining the Corps and Our Observations

PHS' reasons for maintaining the Corps	Our observations
To attract the best professional talent into public service medical work through competition for available slots.	Tools such as recruiting bonuses and special pay are available to PHS to attract civilian medical talent. Qualified new entrants are given their choice of becoming PHS Corps officers or civilian employees.
To have a cadre of officers who can be assigned to serve in any position, consistent with their training, without regard to rank or officer preferences.	PHS officers can refuse assignments and leave the Corps without being court-martialed; many assignments are filled by officers who applied for them.
Corps officers are mobile and can be moved from assignment to assignment anywhere in PHS to meet critical needs.	According to a PHS official, Corps officers in most PHS agencies do not relocate regularly, and civilians are not necessarily harder to reassign than Corps officers. In fact, many officers stay at one geographic location throughout most or all of their careers.
Corps officers can be sent into emergency situations on short notice.	Many civilian federal employees are also subject to emergency call-up. NTSB and FEMA both order their employees to respond to emergency situations on short notice. Further, only 1 of the 61 disaster medical assistance teams run by PHS consisted solely of active duty Corps officers.
Corps officers are available for emergency mobilization into the armed forces in wartime. In such mobilization, they can replace military doctors needed for combat zones.	No such call-up has taken place since 1952, and the Assistant Secretary for Health opposed consideration of such a call-up during Desert Storm. An agreement exists between DOD and HHS that Corps officers can be called upon to augment DOD health-care activities in the continental United States and, on a limited basis, other activities, during a national emergency. However, according to a DOD official in charge of health services operations and readiness, no specific plans for PHS' participation have been developed, and the need for augmentation has been greatly reduced as the result of DOD's downsizing.
Corps officers provide services on detail to other agencies (Bureau of Prisons; EPA; Coast Guard; UNICEF; World Health Organization; Pan Am Health Organization; and the Departments of State, Energy, and Defense).	PHS has over 19,000 civilian employees in the same occupational specialties as the Corps officers. Employees in these occupations could be—and have been—detailed to these organizations.
The Corps proactively and consciously develops a multidisciplinary public health workforce that can be counted on to provide the necessary skilled and experienced leadership and infrastructure to manage, develop, and evaluate public health programs and policies into the future.	Civilians provide a significant leadership role in PHS agencies. Further, Corps officers' assignments and job responsibilities are determined by the agencies in which they serve, not by the Corps.

HHS COMMENTS

HHS stressed its view that the Corps was essential to accomplishing the missions of the agencies to which officers are assigned. According to HHS, officials of each of these agencies had indicated that the loss of Corps officers would have an extremely detrimental effect on their health-care delivery programs. HHS also said such elimination of the Corps could negate the gains that have been experienced in the employment of women and minority officers.

The premise behind HHS' comments and the statements of the agency officials was the presumption that, if the Corps were eliminated, the conversion to civilian employment would be immediate and that no transition period would be allowed. Using this premise, HHS stated in its detailed comments on the report that all retirement-eligible officers would retire immediately and 25 percent of all other officers would leave federal service rather than continuing in their positions as civilian employees.

The scope of our review did not include a survey of Corps officers to assess their potential actions if the Corps were civilianized. HHS told us its estimates of officer departures were based on informal surveys and discussions with dozens of officers. We agree that the sudden departure of Corps officers in the numbers assumed by HHS could have severe consequences on health-care delivery programs. However, nothing in our draft report suggested that complete civilianization of the Corps should necessarily be accomplished immediately or that it should be done in a manner that would compel Corps officers to leave federal employment. In fact, the report reaches no conclusions and makes no recommendations as to whether the Corps should be discontinued. However, it does note that many considerations would be involved in a decision on whether the Corps should be continued, particularly regarding the manner in which a conversion to civilian employment would be carried out and over what time frame.

HHS also stated that many agencies find it is more effective, efficient, and economical to have Corps officers detailed to them than to recruit health professionals from the private sector.

This comment is undoubtedly factual from the agencies' viewpoint. The processes involved in recruiting and hiring civilian employees can be time consuming and costly. However, this argument does not consider the fact that PHS incurs similar costs to recruit and hire Corps officers. Thus, regardless of whether PHS or the agencies do the actual recruiting and hiring of health professionals, the associated costs are borne by the government. Moreover, agencies to which Corps officers are detailed do not pay the costs of the officers' retirement benefits. We were told by a Coast Guard official that a major reason the Coast Guard continues to use Corps officers instead of employing its own medical staff is that the Coast Guard does not have to pay retirement costs. The official said the Coast Guard might review its practice of using Corps officers if it had to pay all compensation costs.

According to HHS, the loss of Corps officers could create immediate and long-term problems in the recruitment and retention of qualified health-care professionals and the development of professional leadership for the future. This position appears to be based primarily on HHS'

presumption that the Corps would be abolished immediately, causing large numbers of officers to leave federal service. It also does not take into account the fact that significant numbers of civilian personnel are already employed in the same professional categories as Corps officers. As the following average employment statistics for 1994 show, civilian employees outnumbered Corps officers in many of the occupations at issue.

Table I.2: Corps and Civilian Average Employment Statistics, 1994

Occupation	Number of Corps officers	Number of civilian employees
Medical	1,691	1,197
Dental	714	19
Nurse	1,006	3,060
Engineer	571	497
Scientist	284	11,566
Sanitarian	357	306
Veterinary	104	80
Pharmacist	733	86
Dietitian	86	111
Therapist	99	43
Health Service Officer	786	1,253
Total	6,431	18,218

Source: PHS data.

Finally, HHS said it is more advantageous to employ Corps officers than civilians because officers can be detailed easily to non-HHS agencies to meet special requirements for health personnel and, through these details, the officers gain expertise that is unmatched by any other group of health professionals in the government.

We were told by a senior HHS official that it is no more difficult to reassign civilian PHS employees than it is to reassign Corps officers. Our work also showed that a substantial number of Corps officers do not rotate among assignments.

DOD COMMENTS

In its comments, DOD suggested that some clarification was needed in our characterization of the Corps' potential role in wartime mobilization. In consultation with a DOD official, we revised the wording.

4. **What are the DOD-stated principles of uniformed services' compensation? In what way do the Corps functions conform to, or not conform to, these principles?**

According to a DOD report,[7] the sole purpose of the military is the continued safety of the nation, and the chief purpose of the compensation system for the military services is to ensure the services' mission readiness and sustainability. As in civilian employment, individual aspirations are often achieved through a military career, but it is expected that personal preferences will be subordinated to the good of the service. It is a way of life that is different from civilian life, according to the DOD report.

Generally, the PHS Corps does not meet the criteria stated in the DOD report for eligibility to receive military compensation. The Corps is not an armed service. Also, unlike the armed services, whose personnel are subject to the Uniform Code of Military Justice, PHS cannot press criminal charges or pass sentence against an officer who disobeys orders. Corps officers can quit the Corps without legal sanctions. Corps officers also are not required to face the hazards of field duty or maneuvers for training purposes, as military service members are required to do. Also, Corps officers usually are not transferred involuntarily and, as a practice, are not involuntarily separated from their families. PHS officers also can select their assignments by responding to job announcements.

The PHS Corps receives many of the same types of pay, allowances, and benefits that are paid to military personnel. DOD has articulated the following three major components of military compensation.

1. Regular Military Compensation. This component includes (a) basic pay, (b) housing allowances or housing, (c) subsistence allowance or actual subsistence, and (d) the associated tax advantages that occur because the housing and subsistence allowances are exempt from federal taxation.

2. Special and Incentive Pays. These include board-certified pay, retention special pay, and incentive pay for certain members based on their specialties.

3. Retirement and other supplemental benefits.

The Fifth Quadrennial Review of Military Compensation said the distinction between uniformed (military) and civilian service was that the uniformed service is subject to a

[7]The Fifth Quadrennial Review of Military Compensation, Department of Defense, January 1984. This publication included a detailed discussion of the criteria for the military compensation system.

"relatively complete, one-way control over the workforce, without internal debate and with the freedom to use it in any way judged necessary to serve the national interest."

The Review provided the following criteria as justification for the military compensation system. Following the criteria are PHS Corps officials' comments on how service in the Corps relates to the criteria.

1. The national leader (the president) must be able to

a. legally require the force to fight anywhere in the world, and have authority to punish those who disobey orders to do so;

PHS Corps Officials: The PHS Corps is not an armed service, although it is a uniformed one. PHS officers are not required to enter armed combat, although they do fight disease. Further, officers are asked at times to serve in distant locations such as New Delhi, India; Djakarta, Indonesia; or the island of Truk.

b. use the force when and as long as it is believed appropriate without undue regard to the personal preferences of individual military members, and at whatever tasks deemed necessary without rigid conformance to the occupational specialties of the individuals used;

PHS Corps Officials: Unlike military personnel, PHS officers do not sign up for a "tour" or enlistment period. Once an officer has passed a probation period, that officer can expect to serve 20 to 30 years, barring a large-scale reduction in strength. Corps officers can be and are assigned to slots not strictly in their occupational categories.

c. individually "fire" members, despite fully satisfactory performance, in mid-career for any momentary convenience to the government, while not allowing others to leave, even though they may desire to;

drawn-out hearings

PHS Corps Officials: Other than a separation for marginal or substandard performance (which is preceded by a series of prescribed steps) the only grounds for involuntary separation would be if there were no longer a billet for the officer (that is, his or her position would have been abolished) and a slot could not be found for the officer anywhere else in PHS.

d. force individual members to retire and retain the right to recall them to active duty when the need arises;

PHS Corps Officials: Annually, all PHS agencies receive a list of Corps officers eligible for retirement, along with an inquiry regarding whether the agency has any officers

it wishes to suggest for involuntary retirement. An agency may suggest candidates for involuntary retirement based on declining performance or on the lack of a position. During March 1995, there were about eight Corps officers who faced possible retirement because no positions were available for them. In most cases, an officer facing involuntary retirement will opt to voluntarily retire instead.

Retirees continue to hold commissions and can be called back to active service. Recall has occurred rarely because temporary needs usually are filled by members of the Corps' inactive reserve.

e. hold members in an idle status for indefinite and protracted periods and then cast them into whatever operational role is required.

PHS Corps Officials: The PHS Corps does not have an "idle" status. Officers are either carrying out specific assignments or on leave. However, officers can be--and have been--recalled from leave.

2. Service members have no control over

a. whether, when, or how long they will be exposed to the risks of combat;

PHS Corps Officials: Corps officers do not go into combat. They can be considered to be "in harm's way" in some foreign assignments--for example, nurses in Kuwait after Desert Storm, engineers looking into the supply of water for the Kurdish camps, or nurses and dietitians in Rwanda.

b. whether, when, or how often they will have to relocate themselves and their families;

PHS Corps Officials: Corps officers have some control over their relocation. Many positions in PHS are filled by taking applications and interviewing applicants. In some situations, both Corps officers and civilians may be interviewed. The selecting officials choose from among those who are interested in the job, rather than bringing in someone who is not.

In 1981, under the Omnibus Budget Reconciliation Act, PHS hospitals and clinics were closed. Some Corps officers were involuntarily separated, and others were given new assignments and told to report to them within 72 hours or separate. However, this type of mass involuntary reassignment is the exception rather than the rule.

c. when, how often, and how long they will have to work overtime and on weekends and holidays;

PHS Corps Officials: Corps officers, like many of their civilian counterparts, may work longer than an 8-hour day. On those occasions when extra work is required, Corps officers do not earn overtime pay or compensatory time, as can PHS civilians. Officers are considered to be on duty 24 hours a day, 7 days a week and must work whatever schedule their supervisors set to keep the functions operating.

d. when, how often, and how long they will have to work at a location separated from home and family;

PHS Corps Officials: When Corps officers are separated from their families, it is usually because the families chose not to accompany the officer or the officer chose not to bring them to the location. The only situation in which an officer cannot bring his or her family is when the officer is detailed to the Coast Guard or NOAA and is serving an "unaccompanied tour" aboard a ship. These details are usually filled by advertising the position and interviewing applicants--with the Coast Guard or NOAA, whichever organization has the advertised position, doing the interviews. Therefore, officers on these details have volunteered for these positions and know what they are getting into. (It should be noted that most Corps officers detailed to the Coast Guard do not serve aboard ships.)

e. when, how often, and how long they will be exposed to the conditions and hazards of field duty for training.

PHS Corps Officials: PHS does not have "field duty" in the sense of maneuvers as the armed services do. One of the 61 PHS Disaster Medical Assistance Teams is composed of Corps officers, and this team accompanies an Army unit on maneuvers every year.

3. Uniformed service requires the forfeiture of the individual's right to resign immediately if the situation is not satisfactory.

PHS Corps Officials: Corps officers can resign at any time, except if the Corps is incorporated into the Armed Forces by order of the president in a wartime situation. However, the officers must repay any government-incurred training costs that they have not worked off through service. PHS can sue for recovery of such costs. Otherwise, the Corps has no statutory authority to hold anyone who wants to leave.

4. Service members can also lose their jobs through failure to progress--known as "up-or-out."

PHS Corps Officials: The PHS Corps does not have statutory "up-or-out" authority--its officers cannot be forced to leave the Corps for failure to be promoted.[8] Officers are encouraged to take control of their own professional development. If they do not develop as the Corps desires and are not promoted, they can be given career counseling, which may refocus their goals or may lead to advice that their goals might be better achieved outside the Corps. However, some officers enter the Corps on a "program-limited tour," which is for a preset time, usually in increments of 1, 2, 3, or 4 years, depending on the needs of PHS. Such an officer automatically leaves the Corps at the end of the tour, unless PHS extends the tour. In August 1995, 214 officers were serving program-limited tours.

5. Uniformed service is a truncated career because of the need to maintain a young, vigorous, and mission-ready workforce.

PHS Corps Officials: Like the military retirement system, the Corps retirement system permits officers to retire at any age after completing 20 years of service. Corps officers must retire after 30 years of service unless they get permission from the Corps to continue. Such requests are tightly monitored. (Our comment: From calendar year 1991 through the first half of calendar year 1995, 92, or about 35 percent, of the 265 PHS Corps officers' requests to extend their service beyond 30 years were approved.)

6. A career in the uniformed services involves no choice in the selection of job, supervisor, or subordinates.

PHS Corps Officials: PHS Corps officers can select their assignments by applying for announced jobs. Except by deciding not to apply for a certain position, an officer cannot choose a supervisor. A supervisor can choose subordinates by selecting candidates to fill vacancies.

AGENCY COMMENTS

HHS stated that the DOD criteria we used to assess the appropriateness of providing a military-like compensation system to Corps officers were actually the criteria applicable to military combat personnel. HHS noted that the Corps did not have a combat mission and maintained that it would be more appropriate to compare the Corps with military health-care professionals, whose work and responsibilities were comparable to those of the Corps.

[8]In its response to a draft of this report, HHS said Corps officers can be dismissed for failure to be recommended for promotion after being eligible for promotion twice at a given grade level.

The DOD criteria used to justify the military compensation system, including retirement eligibility at any age after 20 years of service, apply to all military personnel, not combat personnel alone. Like any other members of the military, health-care personnel are subject to the Uniform Code of Military Justice, involuntary transfers or separations from service, inability to disobey orders or quit their jobs without legal sanctions, lack of control over their exposure to the risks of combat, and other conditions of employment that DOD cites in explaining why military members are managed and compensated in a manner different from other federal personnel or, indeed, unlike persons employed in the nonfederal sector.

We agree with HHS that Corps officers and military health-care professionals often do the same type of work. However, it is also the case that most Corps officers do much the same type of work as civilian health-care professionals in PHS. These civilian professionals, like Corps officers (other than the officers who are detailed to the Coast Guard and DOD), are not subject to military command or the Uniform Code of Military Justice. The civilians do not receive military-like compensation.

According to HHS, the Corps has provided personnel to serve in every major conflict involving American forces during this century, thereby demonstrating the Corps' ability to carry out military missions when needed.

It is true that Corps officers carried out some military functions in World Wars I and II. Because of that participation, they were covered by a military-like compensation system. However, according to information provided by the Corps Historian, Corps officers did not serve in combat areas during the Korean Conflict, and PHS' participation in Vietnam consisted of a small number of Corps officers and civilian employees working in civilian hospitals or participating in plague and malaria control efforts. As HHS acknowledged in its detailed comments on our draft report, the Corps' association with the Gulf War was limited, consisting of nursing care in a children's hospital in Kuwait, assessment of air pollution from burning oil wells, and efforts to improve the water supply on the Kurdish border with Iraq.

DOD had no comments on our response to question 4.

5. Would there be cost savings if the PHS Corps did not use uniformed services personnel to carry out its functions?

On the basis of PHS data, we estimated that, in 1994, personnel costs would have been approximately $130 million, or about 22 percent, lower if civilian employees, rather than commissioned officers, had carried out the Corps' functions.[9]

[9]The actual net cost reduction would differ, depending on various factors, including the method by which changes are implemented, the accuracy of the data PHS and DOD provided us, the applicability of 1994 costs to future years, and how closely our underlying assumptions match actual relationships between Corps and civilian personnel costs. Cost reduction would result in budgetary savings only if Congress reduced appropriations by the amount of the cost reduction and lowered the discretionary spending caps.

COMPARISON OF CORPS AND CIVILIAN PERSONNEL COSTS

In comparing the compensation costs of Corps officers and federal civilian employees, we asked PHS to determine the General Schedule salary grades that would be assigned to each member of the Corps if the positions were converted to civilian employment. We accepted the PHS determinations without independent evaluation or verification. Table I.3 shows the Corps' grade/civilian grade equivalents determined by PHS.

Table I.3: PHS Corps' Grade and Civilian Salary Grade Equivalents

Officer grade	Civilian grade	PHS Corps position
0-1	GS-5/6	Ensign, Junior Assistant
0-2	GS-7	Lieutenant (junior grade), Assistant
0-3	GS-9/11	Lieutenant, Senior Assistant
0-4	GS-12	Lieutenant Commander, Full Grade
0-5	GS-13	Commander, Senior Grade
0-6	GS-14/15	Captain, Director Grade
0-7	SES[a]	Rear Admiral (lower half), Assistant Surgeon General
0-8	SES	Rear Admiral, Assistant Surgeon General, Deputy Surgeon General
0-9	SES	Vice Admiral, Surgeon General

[a]Senior Executive Service member.
Source: PHS.

Comparative Pay and Allowances

PHS Corps officers are compensated under a pay-and-allowances system. Each officer receives a basic pay amount, determined by his or her grade and length of service, along with housing and subsistence allowances that vary by grade and number of dependents. Corps officers' basic pay and allowances amounts are determined under the same schedules as apply to the military services. Corps officers may also receive retention bonuses and special and incentive pays, depending on the positions they hold.

Table I.4 itemizes the pay, allowances, and bonuses paid to PHS Corps officers in grades 0-1 through 0-9 during calendar year 1994. Of the $451.7 million total, basic pay constituted $296.6 million, or 65.7 percent. Special pays and bonuses amounted to $74.6 million, or 16.5 percent, and housing, subsistence, and variable housing allowances together comprised the remaining $80.5 million, or 17.8 percent.

Table I.4: Pay, Allowances, and Bonus Costs Incurred for the PHS Corps, Calendar Year 1994

Category	Description	Total cost in 1994
Basic pay		$296,611,000
Variable special pay	Special pay to physicians and dentists	16,842,518
Category special pay	Special pay to veterinarians, optometrists, nurses, scientists, and engineers	494,413
Board-certified pay	Additional pay to medical officers and dentists for board certification	5,446,131
Additional special pay	Additional pay to dentists for 1-year retention	3,955,978
Incentive special pay	Incentive pay for certain physicians based on specialty	17,237,000
Multiyear retention bonus	Special retention bonus for medical officers	9,503,500
Retention special pay	Annual payment for physicians committing to remain on active duty for a fixed period	21,113,418
Basic subsistence allowance	Allowance for subsistence (food) costs	11,048,795
Basic housing allowance	Allowance for housing	52,569,773
Variable housing allowance	Allowance based on the cost of renting or purchasing a home at the officer's duty station	16,899,812
Total		$451,722,338

Source: PHS data.

Civilian employees at PHS are compensated under an entirely different system. Most receive annual salaries that are based on the General Schedule. Unlike Corps members, civilian employees do not receive housing and subsistence allowances or incentive pays. However, they can be eligible to be paid for any overtime they work, as well as for premium payments for working at night and on Sundays and holidays. (Corps members do not receive extra compensation for any overtime they may have to work or for working at night, on Sundays, or on holidays.) Like certain Corps officers, PHS civilians are eligible for retention bonuses, and civilian PHS physicians also receive the Physicians' Comparability Allowance, which is an additional amount paid to attract physicians to federal service.

We requested from PHS payroll data showing actual expenditures during calendar year 1994 for salaries and other payments to the civilian employees PHS had identified as having jobs comparable to PHS Corps officers. We averaged these amounts to get a "per person" cost at each salary grade and applied these averages to the comparable Corps positions to estimate the cost equivalent for a hypothetical civilianized Corps. As table I.5 shows, we estimate that Corps officers would have received total salary and other payments of about $375 million, as opposed to the over $451 million they actually received, if they had been paid as civilian employees during calendar year 1994.

Table I.5: Estimated Salaries, Allowances, and Bonuses That an Equivalent PHS Federal Civilian Workforce Would Have Received, Calendar Year 1994

Category	Estimated cost in 1994
Salary	$352,927,139
Overtime	2,496,783
Night pay	637,672
Sunday pay	555,397
Holiday pay	815,875
Post differential[a]	18,823
Cost-of-living allowance[b]	989,919
Uniform allowance[c]	86,902
Physicians' Comparability Allowance[d]	16,223,262
Retention bonus[e]	255,770
Total	$375,007,542

[a]Post differential is a percentage of salary that is based on the conditions of an environment that differ substantially from conditions in the continental United States, or an amount paid to an employee officially stationed in the United States who is on extended detail outside of the United States.

[b]A cost-of-living allowance is authorized in locations outside of the continental United States when living costs are substantially higher than in the District of Columbia.

[c]A uniform allowance is authorized for employees who are required by regulation or status to wear a prescribed uniform in the performance of official duties. (Corps officers also wear uniforms, but they do not receive recurring uniform allowances. They receive one-time allowances to purchase uniforms when entering the Corps.)

[d]A Physicians' Comparability Allowance is an allowance that civilian physicians receive to bring their pay closer to private physicians' incomes.

[e]A retention bonus of up to 25 percent of salary may be approved for an employee--who is otherwise likely to leave--to retain his or her services.

Source: GAO analysis of PHS data.

Because PHS Corps officers do not receive extra pay when they work outside the regular 40-hour work week, the above estimated costs of using civilian employees to carry out the Corps' functions could be understated. A Commissioned Corps official said there is no requirement that Corps officers record their time usage; thus, the extent to which individual officers may work overtime or on Sundays and holidays is unknown. Our estimates of the costs of civilianizing the Corps include the actual overtime and other premium pay amounts received by PHS civilian employees in jobs comparable to those in the Corps. If Corps officers actually work more such duty hours than civilians, the added costs that would be incurred are not reflected in our estimates.

Federal Income Tax Advantage

As is true for members of the military, PHS Corps officers pay no federal income taxes on their housing and subsistence allowances.[10] As DOD explained, the "cost" to the government arising from this tax advantage comes in the form of a loss to the U.S. Treasury of the federal income taxes that would otherwise have been paid if the allowances were taxable, rather than as payments to individuals.[11] Federal civilian employees receive no such tax advantages; they must pay their living expenses from their fully taxable salaries.

[10]As previously discussed, a major component of military and Corps compensation is termed "Regular Military Compensation." This component includes basic pay, nontaxable housing and subsistence allowances, and the tax advantage accorded to members through the nontaxable allowances.

[11]As actually calculated by DOD, the tax advantage is the amount of additional income military (or Corps) personnel would need to retain their take-home pay if their allowances were taxable.

A DOD publication[12] pointed out that the actual federal tax benefit an individual member realizes is governed by many considerations. These considerations include (1) the aggregate amount of a member's (and his or her spouse's) income, both earned and unearned; (2) the amount of the member's housing and subsistence allowances; (3) the member's marital status and number of dependents; (4) whether the member takes the standard deduction or itemizes deductions for federal income tax purposes; and (5) whether the member is entitled to other types of tax exclusions. The publication further noted that members do not actually receive the tax advantage in cash or in kind. Accordingly, it is not a cost item in DOD's budget, nor is it in PHS' budget.

DOD developed a series of numerical estimates of the tax advantages to members using certain assumptions related to the above factors. Since PHS Corps officers receive the same base pay and housing and subsistence allowances as military officers at the same ranks, we used DOD's tax advantage estimates to estimate the tax advantage afforded to Corps members. In 1994, the estimated tax advantage for Corps officers amounted to $27,516,188.

Comparative Retirement Costs

The retirement system for PHS Corps officers provides the same benefits as the system covering military personnel. They participate in the Social Security program, to which the officers and the Corps make equal contributions of 6.2 percent of base pay,[13] and they are also covered by a pension plan for which the government pays all costs. According to a PHS actuarial report, the annual accruing cost of the pension plan, calculated as of September 30, 1994, was 30.1 percent of base pay.[14]

Most federal civilian employees hired after 1983 are covered under the Federal Employees' Retirement System (FERS). Using Social Security benefits as a base, FERS provides a pension plan and a thrift savings plan (TSP). FERS-covered employees currently contribute 0.8 percent of their salaries toward FERS pension plan costs. Their employing agencies contribute 11.4 percent of salary to the pension plan.[15] The employing agency contributes 1 percent of each employee's salary into his or her TSP account. The agency also matches, dollar-for-dollar, an employee's contributions to TSP up to 3 percent of salary and 50 percent

[12]Military Compensation Background Papers: Compensation Elements and Related Manpower Cost Items, Office of the Secretary of Defense, Department of Defense, November 1991.

[13]In 1994, Social Security contributions were required on base pay amounts up to $60,600.

[14]The annual accruing cost of a pension plan is referred to as the "normal cost." It is expressed as a percentage of payroll and represents the amount of money that should be set aside during employees' working years that, with investment earnings, will be sufficient to cover future benefit payments. It applies to future retirement benefits being earned by current employees, not payments to current retirees.

[15]According to the Office of Personnel Management (OPM), the normal cost of the FERS pension plan is 12.2 percent of covered payroll.

of the employee contribution of the next 2 percent of salary.[16] Using the FERS Social Security, pension plan, and TSP cost factors, we calculated what the costs would have been in 1994 if PHS Corps officers were covered by FERS and compared these costs with the costs of the PHS retirement system. Table I.6 shows the results of this comparison.

Table I.6: Estimated Comparative Costs to the Government of FERS and the PHS Corps' Retirement System, Calendar Year 1994

Retirement system	Total salaries/Basic pay	Aggregate retirement cost factor	Total retirement costs
Civilians (FERS)	$352,927,139	21.3%[a]	$75,173,481
PHS Corps	296,611,000	36.1%[b]	107,076,571
Cost difference			$31,903,090

[a]Includes 11.4 percent FERS pension, 6.0 percent Social Security, and 3.9 percent TSP costs to the government. The actual Social Security contribution requirement in 1994 was 6.2 percent of pay up to $60,600. Because a number of individuals had pay rates higher than $60,600, OPM suggested that a 6.0 percent factor be used to estimate Social Security costs.

[b]Includes 30.1 percent PHS Corps pension and 6.0 percent Social Security costs to the government.

Source: GAO analysis of PHS, OPM, and TSP data.

Health Care and Life Insurance

PHS Corps officers do not participate in the Federal Employees Health Benefits (FEHB) program. Instead, Corps officers and their dependents receive free health care directly from PHS medical personnel or at DOD-operated facilities where available, and otherwise from contract health-care providers. The providers directly bill PHS for the care the officers and dependents receive. In contrast, FEHB is a health insurance program. A number of insurance plans are available to employees under FEHB, with various premium amounts depending upon individual plan provisions. The government pays as much as 75 percent of the premium in some plans, and employees pay the remainder. Seldom, if ever, does an FEHB plan pay all of an employee's health-care costs.

Corps officers and civilian employees are also covered by the Medicare program. They and PHS each contribute 1.45 percent of their basic pay/salaries toward Medicare costs.

[16]According to information provided by the Federal Retirement Thrift Investment Board, on average, agency contributions to TSP amounted to 3.9 percent of the FERS payroll in fiscal year 1994.

We compared the costs to PHS for active duty officers' health care during 1994 with the premium amounts PHS would have paid if the Corps officers had participated in FEHB.[17] As table I.7 shows, it would have been somewhat more costly to PHS if the Corps officers had participated in FEHB, rather than receiving free health care paid by PHS. Moreover, Medicare costs for civilian employees would be greater because of their higher salaries.

Table I.7: Estimated Comparative Costs to the Government of Health Care for PHS Corps Officers and Civilian Equivalents, Calendar Year 1994

Category	PHS Corps officers	Civilian employees	Difference
Health care/FEHB	$13,645,548	$18,256,103	$4,610,555
Medicare	4,326,963	5,117,444	790,481
Total	$17,972,511	$23,373,547	$5,401,036

Sources: GAO analysis of PHS and OPM data.

Civilian employees and Corps officers also receive group life insurance coverage unless the employee or officer waives coverage. Civilians are covered by the Federal Employees' Group Life Insurance (FEGLI) program, while Corps officers can receive Serviceman's Group Life Insurance (SGLI). While the government pays one-third of the premiums for employees covered by FEGLI, Corps officers covered by SGLI pay the full cost of such coverage. We estimate that if the PHS Commissioned Corps were covered by FEGLI, the cost to the government in 1994 would have been $480,321.

Other Benefits and Privileges

PHS Corps officers as well as federal civilian employees are afforded other benefits and privileges that are neither easily quantifiable nor readily susceptible to comparison. For example, Corps officers and retirees are eligible to purchase goods and services at military base commissaries and exchanges at prices generally lower than those charged by commercial establishments. This benefit is usable only if such facilities are located within a reasonable commute of an officer's home or duty station.

Corps officers also have access to military service clubs and other DOD-sponsored recreational facilities. Again, however, this is a usable benefit only when such amenities are nearby. Further, Corps officers can obtain free travel on government aircraft on a "space available" basis, but a Corps official said records are not kept of the actual availability of such flights, the frequency of usage by Corps members, or the value of this benefit. Corps officers can also qualify for a variety of veterans' benefits by virtue of their Corps service.

[17]We derived our estimates using OPM data for average FEHB program "self" and "family" premiums paid during 1994.

However, a Corps official said the extent to which Corps officers actually use such benefits as VA-sponsored tuition assistance or VA-guaranteed home mortgage loans is unknown.

Further, Corps officers, like military personnel, have the option of declaring a state of residence regardless of where they are actually stationed or the length of time they spent in that state. This can be of significant value to officers who select states with no personal income taxes as their states of residence. In contrast, civilian employees are subject to all taxes imposed by the states in which they actually reside.

Federal civilian employees can also receive benefits and privileges that are intangible or difficult to quantify in terms of direct costs to the government. For example, federal employees may have access to occupational health-clinic services at work without cost to themselves. There also may be such amenities as employer-provided or subsidized health-club memberships or exercising facilities.

While these benefits and privileges can be of considerable value to Corps officers and civilian employees, we did not attempt to estimate their comparative values or costs.

POTENTIAL REDUCED PERSONNEL COSTS AVAILABLE BY CIVILIANIZING THE PHS CORPS

Our analysis shows that, when all of the components of personnel costs discussed in this section are considered, PHS personnel costs could be reduced by civilianizing the PHS Corps. The extent to which actual net costs would be reduced would differ, depending on various factors, including the method by which any changes are implemented, the accuracy of the data PHS and DOD provided us, the applicability of 1994 costs to future years, and how closely our underlying assumptions match actual relationships between Corps and civilian personnel costs.

The amount of any cost reductions would also depend, in large part, on the manner in which any transition to civilian employment would be carried out, including the period of time over which the transition would occur. Any decision to replace Corps officers with civilian employees could be implemented in a number of ways. The possibilities range from requiring all officers to immediately convert to civilian employment to longer-range measures such as allowing all current officers to remain in place until retirement or other separation and requiring all new entrants to be civilian employees. Or, perhaps all officers with a specific number of years in the Corps could be allowed to continue in the Corps until retirement or other separation. It may even be found to be appropriate to retain a permanent smaller Corps to provide medical services in areas that are difficult to staff with civilian employees.

The amount of transition costs would also depend on how considerations such as the following are resolved.

(1) What retirement benefits or credits are given to officers for the time they spent in the Corps before converting to civilian employment and the civilian employee retirement system.

(2) What resources would be required to recruit, train, and retain civilian employees that might be needed to replace Corps officers who opt to leave federal service.

(3) The amount of additional resources, if any, that would be required to administer the civilian workforce at PHS after eliminating the Corps and its administrative personnel.

A plan of action that addresses the above factors and other possible considerations would be needed before estimates of the transition costs involved could be determined.

Table I.8 summarizes the estimated comparative costs in 1994.

Table I.8: Estimated 1994 Comparative Costs of Employing PHS Corps Officers and Federal Civilian Employees

Category	PHS Corps officers	Federal civilian employees	Difference
Basic pay/Salaries	$296,611,000	$352,927,139	($56,316,139)
Special pays, allowances, and bonuses	155,111,338	22,080,403	133,030,935
Tax advantage	27,516,188	0	27,516,188
Retirement	107,076,571	75,173,481	31,903,090
Health care	17,972,511	23,373,547	(5,401,036)
Life insurance	0	480,321	(480,321)
Total	$604,287,608	$474,034,891	$130,252,717

Source: GAO analysis of Corps and civilian personnel costs.

It should be again emphasized that the estimate of civilian employee costs could be somewhat understated if PHS were to incur added overtime and other premium pay costs from using civilian employees rather than Corps officers to carry out all functions now assigned to Corps officers.

AGENCY COMMENTS

Our draft of this report included an estimate that, based on 1994 costs, PHS' annual personnel costs could be as much as $162 million a year lower if civilian employees were used for the functions now carried out by Corps officers, once a transition to civilian employment were completed. HHS stated that a number of circumstances had changed since our work was completed that would cause the cost difference to be lower than our estimate. Also, HHS pointed out that we had understated the potential costs of certain elements of the civilian

employee compensation package. HHS said its analyses suggested that no savings were available from civilianizing the Corps.

After analyzing HHS' comments, we agreed that our original estimate of the cost savings available from civilianizing the Corps was overstated. A major contributing factor was a significant reduction in the cost of the Corps retirement system. Our estimate reflected the latest actuarial valuation available at the time we completed our work, which showed the retirement system's normal cost was 35.9 percent of base pay. However, HHS pointed out that a new actuarial valuation showed the normal cost had dropped to 30.1 percent of base pay through the application of revised economic assumptions. On the basis of HHS comments, we also recalculated the estimated amounts that would be paid to civilian employees for Physicians' Comparability Allowances and retention bonuses if the Corps were eliminated. With the recalculations of these compensation elements and the reduction in Corps retirement costs, our estimate of the difference between annual Corps and civilian personnel costs on the basis of 1994 data was reduced to about $130 million.

HHS stated that efforts were under way to compensate PHS civilian physicians and other categories of health-care personnel under the provisions of Title 38 of the United States Code that allow higher than normal federal compensation amounts for Veterans Administration health-care personnel. According to HHS, paying Title 38 amounts to civilian replacements for Corps officers would cost approximately $47 million a year more than we had assumed in our cost comparisons. However, information subsequently provided by HHS showed considerable uncertainty about the extent to which Title 38 would actually be applied in the PHS agencies. HHS acknowledged that use of Title 38 compensation had not been authorized for all of the agencies and some of the agencies for which it had been authorized had no plans to use it. HHS said Title 38 was being used to the greatest extent in NIH, but added that there were still uncertainties about how many employees would ultimately be covered in NIH. Since it was not possible to predict with any degree of certainty how much use might be made of Title 38, we did not change our cost comparison estimates.

We did not agree with other HHS comments that suggested we should make further changes to our cost comparison estimates. In large part, we felt the matters involved were too speculative to justify assigning dollar values to them. For example, HHS stated that it would incur over $15 million in additional moving costs each year if the Corps were civilianized because civilian employees receive greater reimbursement of their moving costs than do Corps officers. HHS told us this estimate was made using data on actual relocations of Corps officers during fiscal year 1994 and the assumption that the same number of moves would occur each year if the Corps positions were filled by civilian employees. While it is true that average civilian moving cost reimbursements have been higher, we believe there is simply too much uncertainty about how many moves might be made in the future to determine how much, if any, added cost would be incurred. Similarly, HHS stated that it might need to spend about $3.8 million a year in recruitment bonuses to attract civilian employees to positions now held by Corps officers. Again, we believe this is too speculative to allow a dollar value to be assigned because it is not possible to know at this point how many officers might leave their jobs if the Corps were civilianized or whether recruitment bonuses might be necessary to recruit civilian replacements. Moreover, HHS provided information showing

that, of almost 2,500 civilian employees who were recruited into PHS during 1994 and 1995 in positions in the same occupations as Corps officers, only 65 received recruitment bonuses.

It should be noted that, because of uncertainties about future events, our cost comparisons also did not include a significant benefit available to Corps officers. When officers retire, they are eligible to receive reimbursement of the cost of traveling and shipping their household goods to any home they select. The home of selection may be in any location in the world, but the cost reimbursement is limited to the amount that would have pertained if the home of selection was in the contiguous United States. According to HHS, in 1994, about 42 percent of the retiring officers received such payments, averaging about $9,000 each. Similarly, officers who separate before retirement may receive reimbursement of the cost of travel and transportation of household goods to their homes of record or the locations from which they entered the Corps. Similar benefits are generally not available to civilian employees.

HHS also maintained that civilian employees who replaced Corps officers would receive higher salary grades than assumed in the report. It stated that many officers were actually working at higher levels of responsibility than their ranks would indicate; thus, the equivalencies of Corps ranks to civilian salary grades used in the report understated the civilian salary grades that would be assigned if the Corps' positions were civilianized. As discussed on page 22, we did not independently determine what civilian salary grades were appropriate for each of the Corps' ranks. Rather, PHS provided the equivalent salary grades that it determined would be appropriate for the duties and responsibilities of Corps members at each rank. In the absence of any evidence that PHS erred in determining the equivalent ranks and grades it originally provided us, we did not change the report.

While our draft report recognized that some amount of transition costs would be involved in converting Corps positions to civilian employment, it did not attempt to estimate such costs because of the decisions that would be required on how such a conversion would be carried out and over what time frame. In its comments, HHS estimated that the one-time transition costs would amount to at least $575 million, assuming that the conversion caused all retirement-eligible officers to retire and 25 percent of the remaining officers to leave federal service.

As discussed previously, we see no basis for assuming that such significant departures of Corps members would occur if the Corps were civilianized. More importantly, much of the costs HHS included in its estimate of transition costs are not directly related to elimination of the Corps. These costs included (1) $20.8 million to retiring officers and $4.3 million to other departing officers for their unused annual leave, (2) $5.7 million to retiring officers for moving costs to their homes of selection, and (3) $4.4 million to other departing officers for moving costs to their homes of record. These are all costs that would be eventually paid to the officers regardless of whether the Corps were retained.

The greatest amount of transition costs cited by HHS was $489 million to cover the unfunded liabilities for benefits officers have accrued under the Corps retirement system if they were transferred to the retirement system for civilian employees. HHS reasoned that the amount should be included as transition costs since the civilian retirement system is fully funded.

In our opinion, it is inappropriate to include unfunded Corps retirement liabilities as part of the costs of converting the Corps to civilian employment. For one thing, this assumes that all Corps officers would be immediately removed from the Corps retirement system and included under the civilian retirement system. This assumption may or may not be the manner in which a conversion to civilian employment would be carried out. More importantly, the cost of retirement benefits earned in the past under the Corps system bears no relationship to the cost of future benefits the officers would earn under the civilian system. It would be PHS' responsibility to fund the past service costs regardless of whether the officers remained under the Corps system or were included under the civilian system.

On the basis of its assumption that 25 percent of the Corps' physicians would leave federal service if the Corps were civilianized, HHS stated that it would cost $12.1 million to recruit civilian replacements and additional amounts would be required to recruit replacements in other job categories. HHS also said recruitment bonuses amounting to $23.4 million would have to be paid to civilian employees hired to replace all officers it assumed would leave federal service because of a transition to civilian employment. Also on the basis of its assumptions about officer departures, HHS stated that the vacancies in clinical positions would have to be filled with temporary contractors at an added cost of $16.3 million until permanent employees were hired.

It is difficult to evaluate these cost estimates because they are based on HHS assumptions about the magnitude of Corps officer departures. If the assumptions were to prove valid, it is clear that added recruiting costs of some amount would be incurred to replace departing officers and contracts might be needed for interim replacements as well. However, because of the uncertainties involved in HHS' assumptions, we did not evaluate any added costs that might be incurred as the result of officers' departures.

DOD had no comments on our response to question 5.

6. What are the functions of the reserve officers in the PHS Corps? What is the federal budgetary obligation to the inactive reserves?

In addition to the regular PHS Corps, PHS also maintains a reserve corps. The reserve corps is divided into two components--active and inactive duty. Officers in the Corps' active reserve are actually on continuous active duty, like regular Corps officers. All officers enter the Corps in the active reserve and, after 4 years of service, are eligible to be "assimilated" into the regular Corps (which requires nomination by the president and confirmation by the Senate.) Statutory provisions limit the size of the regular Corps to 2,800 members, and its actual strength was at 2,391 as of March 1995. The active reserve, which has no statutory limit, had a March 1995 strength of 3,885.

The PHS Corps inactive reserve component consists of former active Corps officers and students receiving training in a health-care profession who serve in the Corps during school breaks. The inactive reserve numbered 7,543 as of May 1994, including about 2,500 students. Inactive reserve members can be--and occasionally have been--called up for brief periods but do not participate in training or other organized Corps activities when not on duty. Inactive reserve members do not receive pay or other compensation except when serving on active

duty. Therefore, the Corps has no budgetary obligation for the inactive reserve. Except for any periods that officers may spend on active duty, time on the inactive reserve list does not count toward retirement.

AGENCY COMMENTS

Neither HHS nor DOD commented on our response to question 6.

7. Have there been efforts to change the Corps' retirement system to the accrual basis? If yes, what has occurred as the result of those efforts?

The PHS Corps retirement system is not prefunded, although there have been efforts in the past to convert it to the accrual basis. The federal budgets for fiscal years 1991 through 1993 contained proposals to change the Corps retirement system to the accrual basis. These proposals did not advance.

The 1996 federal budget proposed to require that agencies fully account for the costs of retirement benefits as they accrue. According to an Office of Management and Budget (OMB) official, this action would also convert the Corps retirement system from pay-as-you-go to the accrual basis. At the time we completed this report, no legislation to implement the proposal had yet been forwarded to Congress.

It has long been our position that the costs of federal retirement programs should be recognized as they accrue rather than when they are paid. When done properly, recognizing costs as they accrue reflects the full costs of providing retirement benefits to federal personnel at the time their services are rendered.

Until 1984, the military retirement system was funded on a pay-as-you-go basis in the same manner that the Corps retirement system is currently funded. The 1984 change required the military system to switch to the accrual basis.

The proposal to convert the Corps retirement to the accrual basis includes a plan to eliminate the system's unfunded liability. This liability amounted to $3.7 billion as of September 30, 1994, the last date for which a liability figure was available. The legislation that converted the military retirement system to the accrual basis also required that annual appropriations be made to the retirement fund to amortize the system's unfunded liability. The DOD Retirement Board of Actuaries established a 40-year amortization schedule for the liquidation of the unfunded liability. An OMB official said the proposal discussed above will call for the unfunded liability of the Corps' system to be amortized in a similar manner.

AGENCY COMMENTS

Neither HHS nor DOD commented on our response to question 7.

Appendix II

Objective, Scope, and Methodology

The objective of this report is to provide information on the operations of the Public Health Service's (PHS) Commissioned Corps. We were asked to provide answers to seven questions regarding PHS Corps officers' duties; the rationale for their receiving military-like pay, allowances, and benefits; and any savings that might result from not using uniformed personnel to carry out Corps duties. One of the questions asked about efforts to fund the Corps retirement system on the accrual basis.

The seven questions were as follows:

1. When and why was the PHS Corps established?

2. When and why were members of the Corps first covered by military-like pay, allowances, and benefits? What facts can be cited that are relevant to these justifications? In what ways is the Corps' compensation program like, and unlike, the military compensation program?

3. What reasons does the Corps now give in support of the need for uniformed services personnel to carry out its functions? What facts can be cited that are relevant to these arguments?

4. What are the DOD-stated principles of uniformed services' compensation? In what way do the Corps functions conform to, or not conform to, these principles?

5. Would there be cost savings if the PHS Corps did not use uniformed services personnel to carry out its functions?

6. What are the functions of the reserve officers in the PHS Corps? What is the federal budgetary obligation to the inactive reserves?

7. Have there been efforts to change the Corps' retirement system to the accrual basis? If yes, what has occurred as a result of those efforts?

To gather information on the Corps' history and officers' duties, we reviewed PHS historical material and interviewed and obtained documentation from officials of the Office of the Secretary of the Department of Health and Human Services (HHS); PHS, including Corps officials; the Indian Health Service; the Department of Defense (DOD), including the Departments of the Army and Navy; the National Transportation Safety Board; the Federal Emergency Management Agency;

the Environmental Protection Agency; the Coast Guard; and the Bureau of Prisons.

Since the Corps' compensation system is very similar to the compensation system for military personnel, we identified the criteria DOD uses to justify the military compensation system. These criteria were articulated in a report entitled The Fifth Quadrennial Review of Military Compensation.[1] We then obtained the views of PHS Corps officials on how service in the Corps related to these criteria. We also interviewed officials of HHS component agencies, such as the National Institutes of Health and the Health Care Financing Administration, to determine whether positions occupied by Corps officers in those organizations could be filled by civilians.

To compare the costs of using uniformed personnel or civilian employees to carry out Corps duties, we identified the different types of pay, allowances, bonuses, and benefits that officers receive in the Corps and obtained data from PHS that showed the cost to the government of providing each type of pay, allowance, bonus, and benefit during calendar year 1994. We used 1994 data because that was the most recent full year for which data were available. We obtained from PHS the equivalent General Schedule salary grades for civilian employees that would be appropriate for the duties and responsibilities of Corps members at each Corps grade. We then obtained from PHS and applied the average annual compensation (total pay, allowances, bonuses, and benefits) costs for PHS civilian employees in these grades during the same time period to estimate what the cost would have been if civilian employees had carried out the Corps functions.

We also obtained information on other types of benefits and privileges available to Corps members, such as military commissary and exchange privileges; access to military service clubs, health clubs, and other recreational facilities; and occupational health clinical services. Some of these benefits and privileges, such as the commissaries and exchanges, recreational facilities, and occupational health clinics, involve some measure of cost to the government, although not necessarily to PHS. However, because of the difficulty in determining the value of these benefits and privileges and the lack of information on the extent to which PHS personnel actually used them, we did not include these elements in our cost-comparison estimates.

[1]The Fifth Quadrennial Review of Military Compensation, Department of Defense, January 1984.

To gather information on the methods used to finance the Corps' retirement program, we interviewed officials from HHS and the Office of Management and Budget.

We did our work in Washington, D.C., and Oklahoma City, Pawnee, and Claremore, OK, between November 1994 and January 1996. Our work was done in accordance with generally accepted government auditing standards.

HHS and DOD provided written comments on a draft of this report. Copies of their comments are included as appendixes III and IV. HHS' comments included both a summary of HHS' positions on the matters discussed in the report and an appendix providing elaboration and details supporting the summary comments. Because we found that the summary comments captured the essence of the information contained in the appendix, only the summary comments are included in appendix III.

Appendix III

Comments From the Department of Health and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

JAN 17 1996

Mr. L. Nye Stevens
Director, Federal Management
and Workforce Issues
United States General
Accounting Office
Washington, D.C. 20548

Dear Mr. Stevens:

Enclosed are the Department's comments on your draft report, "*Federal Personnel: Issues Related to the Need for the Public Health Service's Commissioned Corps.*" The comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

The Department appreciates the opportunity to comment on this draft report before its publication.

Sincerely,

Michael Mangano
for June Gibbs Brown
Inspector General

Enclosure

The Office of Inspector General (OIG) is transmitting the Department's response to this draft report in our capacity as the Department's designated focal point and coordinator for General Accounting Office reports. The OIG has not conducted an independent assessment of these comments and therefore expresses no opinion on them.

RESPONSE OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
TO THE GAO DRAFT REPORT RELATING TO
THE COMMISSIONED CORPS OF THE PUBLIC HEALTH SERVICE

The General Accounting Office's (GAO) draft report, "Issues Related to the Need for the Public Health Service's Commissioned Corps," contains no specific recommendations; however, the report does contain several "conclusions" that are addressed below.

1. The GAO draft report concludes that: "Based on 1994 costs, we estimate that PHS' annual personnel costs could be as much as $162 million a year lower if civilian employees were used for the functions now carried out by Corps members, once a transition to civilian employment were completed."

   The Department non-concurs. The Department conducted its own analysis (Appendix) which indicates that there is no cost advantage to converting Commissioned Corps officers to the Federal civil service. Equally important, the Department's cost analysis concludes that the Government would incur one-time transition costs, conservatively estimated at more than $575 million, if PHS officers were replaced with civil service employees. No transition cost estimates were included in the GAO cost analysis.

   The Department has a serious concern that without a clear statement of the methodology used by GAO in its analyses, we do not believe the draft report presents credible evidence to show that the Public Health Service (PHS) could successfully replace Corps officers by offering health professionals less compensation through the Federal civil service system.

   We believe the GAO cost analysis includes substantial, material errors. For example, the draft report concludes that PHS medical officers, if converted to the civil service, would receive a total of only $1,529,941 in Physician Comparability Allowances (PCA), an average of only $956 annually for each of the 1,612 Corps medical officers. This amount is far less than is the current civil service experience.

   A serious omission in the cost analysis is the fact that the average cost to relocate geographically a civil service employee is substantially higher, largely because personal residence sale and purchase expenses are reimbursable to civil service employees but not to Corps officers. In 1994, this additional outlay would have been $15,165,800, a substantial additional cost for relocating civil servants.

The Department of Veterans Affairs (DVA)--the only Federal agency other than the Department of Defense (DoD) and this Department that employs large numbers of health professionals--has its own higher special pay rates as noted in the Appendix. DVA relies on these special pays extensively to secure qualified health personnel. However, the draft report contains no analysis using the DVA special pay system.

It would be decidedly detrimental to the Federal Government's health programs to submit to the Congress large savings estimates related to conversion of the Corps to the civil service without making certain that those estimates are reasonably correct and without including a thorough discussion of all the potential ramifications of such action.

In addition, the draft report does not contain any discussion about the private sector market for health professionals in which the Department must compete for personnel. As indicated in the Appendix, health professionals command considerably more compensation in the private sector than either in the Corps or civil service.

2. The GAO draft report concludes that the Department and other Federal agencies could fulfill their missions solely using civil service employees.

The Department non-concurs. Each of the agencies to which officers are assigned has indicated that the loss of Corps officers would have an extremely detrimental impact on their programs (see Appendix). These clear and unequivocal comments from agency officials about the importance of the Corps to program mission are in stark contrast to the statements in the GAO report that were attributed to unidentified personnel. Particularly hard hit would be the major health care delivery programs that rely heavily on PHS officers--the Indian Health Service, Bureau of Prisons, Coast Guard, and the Health Resources and Services Administration. These programs utilize about half of the active duty officers and provide health services to some of the country's most disadvantaged populations that are often located in geographically remote areas.

A review of the long list of Federal agencies that have utilized and continue to utilize PHS officers demonstrates beyond a doubt the value of the Corps as a unique and valuable national health resource. With the exception of DVA and DoD, many Federal agencies rely on the PHS

Commissioned Corps as the de facto Federal personnel system for procuring health expertise. Agencies rely on the quality and mobility of Corps officers. Moreover, non-PHS agencies have found that it is far more effective, efficient, and economical to have PHS officers detailed to them than it is to try to recruit health professionals from the private sector.

For more than 120 years, the Corps has provided PHS with a flexible, mobile, dedicated, well-trained contingent of health professionals who have agreed to serve in accordance with the needs of PHS. The special attributes of the Corps as a personnel system are set forth in more detail in the Appendix. For example, the Appendix includes information about the highly-successful efforts of the Corps that increased the number of women and minority officers by 64.1 percent and 83.1 percent, respectively, since 1987. There are now more than 2,000 female officers, about one-third of the Corps, and more than 1,200 minority officers, about one-fifth of the Corps. Should the Corps be abolished, a significant number of women and minorities would be forced to convert to the civil service or separate from PHS because they are not retirement eligible.

One of the great advantages for the Department is the fact that Corps policies are developed internally to meet the changing needs of the agencies to which officers are assigned. Another notable advantage of the Corps is the fact that officers can be detailed easily to non-Departmental agencies to meet their special requirements for health personnel. The rotation of Corps officers through a variety of assignments, in many different agencies, creates a body of expertise that is unmatched in any other group of health professionals in the Federal Government.

Finally, as referenced in the Appendix, the Chief Professional Officers for the professional categories in PHS have indicated that loss of the Corps would create immediate and long-term problems in the recruitment and retention of qualified health professionals and the development of professional leadership for the future.

3. The GAO draft report concludes that PHS officers do not meet the criteria and principles cited in a Department of Defense report as justification for receipt of military compensation.

The Department non-concurs. The GAO draft report applies the rationale for payment of military combat personnel to the PHS Commissioned Corps. This analysis is based on

inappropriate comparisons and assumptions. The Corps does not have a combat mission. A more realistic comparison would have been between the health professional components of the military services and the PHS Commissioned Corps. This type of comparison, as set forth in the Appendix, clearly shows that PHS officers engage in much the same type of work and with most of the same types of responsibilities and liabilities as their health professional counterparts in the military services. The fact that the Corps provides personnel to the Coast Guard and that the Corps has provided personnel to serve in every major conflict involving American forces during this century clearly demonstrates the Corps' ability to carry out military-related missions when needed.

In 1988, PHS and DoD entered into an agreement by which PHS officers can be assigned to the military services in times of national emergency. DoD officials consider this agreement to remain in effect as indicated in the Appendix.

In addition, the President continues to have authority to militarize the Corps pursuant to 42 U.S.C. 217. It should be emphasized that the Corps is not in a standby mode pending advent of an emergency; rather, every active duty officer is engaged in full-time duties with the agency to which he or she is assigned, but these officers can be deployed should events so dictate.

Two important technical corrections need to be made in the draft GAO report relative to the organizational status of the PHS and the Office of the Surgeon General (OSG) pursuant to Departmental reorganization activities. The PHS continues to exist and is constituted by the 8 PHS agencies and the Office of Public Health and Science (OPHS). The OSG is located organizationally in the OPHS. This reorganization was approved by Secretary Shalala on October 31, 1995.

One last point deserves emphasis. At best, one can only hypothesize whether this Department and other agencies could replace Corps officers by employing health professionals through the Federal civil service. Should that hypothesis be tested and found wanting, major Federal health programs and their beneficiaries will suffer. Moreover, substantial amounts of funds and resources over currently budgeted levels would be required to procure the services formerly provided by Corps officers. This additional funding requirement would occur in an atmosphere of fiscal austerity.

Given these observations and analyses, the Department would oppose any action which would undermine its ability to provide the health professionals necessary to fulfill its mission through the use of the PHS Commissioned Corps.

Appendix IV

Comments From the Department of Defense

HEALTH AFFAIRS

THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D. C. 20301-1200

0 5 DEC 1995

The Honorable Charles A. Bowsher
Comptroller General of the United States
441 G Street, NW, Room 7100
Washington, D.C. 20548

Dear Mr. Bowsher:

Thank you for the opportunity to review the GAO draft report entitled, "Issues Related to the Need for the Public Health Service's Commissioned Corps." The following comments are provided to assist in preparing the final report.

The Department of Defense (DoD) and the Department of Health and Human Services signed a memorandum of understanding (MOU) covering the utilization of commissioned corps officers of the U.S. Public Health Service (PHS) in DoD during periods of national emergencies. It was indefinitely extended in 1989. We feel that a reference to the MOU should be included in the final report.

We also note that the numbers of PHS personnel working in the DoD is understated. Four officers are assigned to Health Affairs, the Joint Staff, and the Office of Civilian Health and Medical Program of the Uniformed Services. Additionally, there are 12 PHS faculty members and 34 students assigned to the Uniformed Services University of the Health Sciences. PHS personnel assignments procedures used to detail personnel to governmental agencies who are subsequently detailed to DoD may not provide immediate visibility of these personnel.

In Table I-1, page 14, reference is made to a statement made by an official in charge of health services operations and readiness that "...PHS' participation is not contemplated in DoD emergency mobilization plans." Recommend that this phrase be deleted. Although there are no formal plans which assign specific tasks and missions for PHS officers, the Department still considers the MOU viable and contemplates utilization of PHS officers in times of national emergencies. There have been a number of occasions as recently as the Persian Gulf War, relief operations in Rwanda, and others, when PHS officers materially participated. These were clearly identified by your auditors elsewhere in the draft report.

We appreciate the opportunity to participate in this study. We are ready to provide any further assistance that you may need.

My point of contact for this action is COL Don Curry. He can be contacted at (703) 697- 8233.

Sincerely,

Stephen C. Joseph, M.D., M.P.H.

cc:
DoDIG

Appendix V

Major Contributors to This Report

General Government Division, Washington, D.C.

Robert E. Shelton, Assistant Director, Federal Management and Workforce Issues
Nancy A. Patterson, Assignment Manager
Philip Kagan, Technical Advisor
Steven J. Berke, Evaluator-in-Charge
Marlene M. Zacharias, Evaluator Assistant

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[redacted]

_Tab 41

ONE HUNDRED NINTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515–6115

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JAY INSLEE, WASHINGTON
TAMMY BALDWIN, WISCONSIN
MIKE ROSS, ARKANSAS

July 28, 2006

The Honorable Elias Zerhouni, M.D.
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

Dear Dr. Zerhouni:

Public records show that Dr. Thomas J. Walsh, a scientist at the National Cancer Institute (NCI), appeared at meetings before Food and Drug Administration (FDA) Advisory Committees and/or meetings with FDA held during the 1997-2003 time period. Transcripts and/or other records of some of these meetings raise questions as to whether Dr. Walsh served as either: (1) a paid outside consultant to a drug company sponsor; (2) an unpaid outside consultant to a drug company: (3) an unpaid consultant to a drug company sponsor in his official capacity as an NCI scientist: (4) a collaborator with a drug company as part of a Cooperative Research and Development Agreement (CRADA); and/or (5) a paid consultant to a drug company sponsor in his official capacity as an NCI scientist. Further, it appears that some scientists have questioned whether Dr. Walsh adequately dosed control-group patients in studies involving comparison trials with drugs manufactured by companies that Dr. Walsh later assisted at FDA Advisory Committee meetings and/or FDA staff meetings. The Committee is seeking to determine if there is a sufficient factual basis to formally investigate questions about National Institutes of Health (NIH) policy, the adequacy of NIH oversight, or other issues that may be raised by the conduct of this NIH scientist.

To assist our evaluation on whether these questions warrant further Committee scrutiny, some non-public information and records are needed. Pursuant to Rules X and XI of the U.S. House of Representatives, please provide the following by Friday, August 11, 2006:

1. All records relating to the financial disclosure reports (and amendments to such reports) of Dr. Thomas J. Walsh for the calendar years 1995 through 2005.

2. All records relating to any NIH reviews (including any reviews and/or reports by the Office of Management Assessment) of Dr. Thomas J. Walsh's activities with drug or biotechnology companies.

3. Copies of all NIH or NCI policy that permits its scientists as part of their official duties to assist drug companies with presentations to FDA Advisory Committees or FDA staff, if any.

4. Copies of all NIH or NCI policy that permits its scientists to accept directed monetary donations from a drug company as part of a consultancy, in lieu of or in addition to direct, personal compensation.

5. Copies of any and all Material Transfer Agreements, CRADAs, and/or any other records of NCI or NIH-approved official collaborations between Fujisawa U.S.A., Merck, or Pfizer and NCI that directly or indirectly involves the research work of Dr. Walsh, if any. Please provide all records relating to such collaborations.

Please note that, for the purpose of responding to these requests, the terms "records" and "relating" should be interpreted in accordance with the attachment to this letter. In addition, we are requesting that following production of the records to the Committee, you make available NIH employees for Committee staff interviews as requested by Committee staff.

If you have any questions, please contact Alan Slobodin of the Majority Committee staff at (202) 225-2927 or David Nelson of the Minority Committee staff at (202) 226-3400.

Sincerely,

Joe Barton
Chairman

John D. Dingell
Ranking Member

Ed Whitfield
Chairman
Subcommittee on Oversight
and Investigations

Bart Stupak
Ranking Member
Subcommittee on Oversight
and Investigations

Attachment

ATTACHMENT

1. The term "records" is to be construed in the broadest sense and shall mean any written or graphic material, however produced or reproduced, of any kind or description, consisting of the original and any non-identical copy (whether different from the original because of notes made on or attached to such copy or otherwise) and drafts and both sides thereof, whether printed or recorded electronically or magnetically or stored in any type of data bank, including, but not limited to, the following: correspondence, memoranda, records, summaries of personal conversations or interviews, minutes or records of meetings or conferences, opinions or reports of consultants, projections, statistical statements, drafts, contracts, agreements, purchase orders, invoices, confirmations, telegraphs, telexes, agendas, books, notes, pamphlets, periodicals, reports, studies, evaluations, opinions, logs, diaries, desk calendars, appointment books, tape recordings, video recordings, e-mails, voice mails, computer tapes, or other computer stored matter, magnetic tapes, microfilm, microfiche, punch cards, all other records kept by electronic, photographic, or mechanical means, charts, photographs, notebooks, drawings, plans, inter-office communications, intra-office and intra-departmental communications, transcripts, checks and canceled checks, bank statements, ledgers, books, records or statements of accounts, and papers and things similar to any of the foregoing, however denominated.

2. The terms "relating," "relate," or "regarding" as to any given subject means anything that constitutes, contains, embodies, identifies, deals with, or is in any manner whatsoever pertinent to that subject, including but not limited to records concerning the preparation of other records.

Tab 42

PFIZER PAYMENTS TO DR. THOMAS WALSH – NIH

Date	Payment	Description
03/14/1996	$750.00	Honorarium – Sales Force (speaker program)
01/07/1997	$4,726.00	Meeting in UK – Sales Force
01/07/1997	$1,750.00	Meeting in UK – Sales Force
07/29/1997	$1,000.00	Honorarium – Sales Force
07/29/1997	$1,000.00	Honorarium – Sales Force
09/25/1997	$1,000.00	Honorarium – Sales Force
11/12/1997	$1,000.00	Honorarium – Sales Force
12/24/1997	$1,000.00	Honorarium – Sales Force
02/11/1998	$2,071.15	Expense Reimbursement – Sales Force
02/11/1998	$27.15	Expense Reimbursement – Sales Force
04/20/1999	$394.45	Expense Reimbursement – Sales Force
04/20/1999	$1,000.00	Honorarium – Sales Force
08/17/2001	$260.00	Expense Reimbursement – train and taxis – attendance at Vfend Mock Advisory Committee Meeting in New York
08/17/2001	$244.20	Expense Reimbursement – train and taxis – trip to Groton, CT
10/23/2002	$12,000.00	Three mock advisory board meetings at $4,000.00 per meeting.
02/11/2003	$1,000.00	Honorarium – Speaker program
03/11/2003	$1,000.00	Honorarium – Speaker program
TOTAL	**$30,222.95**	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892
www.nih.gov

[redacted]

Tab 43

TO: Captain Denise Canton, Director
Office of Commissioned Corp Operations

THRU: Deputy Director NIH 12/2/5

FROM: Acting Director, NCI

Attached are an investigative file, determination on possible conflict of interest and a summary of charges of misconduct on Thomas Walsh, M.D. Dr. Walsh has engaged in serious misconduct, in violation of the Department's Standards of Conduct Regulations (45 CFR Part 73), and Federal law and regulation. The Office of Human Resources has informed me that the NIH has recommended removal for civilian employees who have engaged in misconduct of a similar type and gravity. Therefore, in accordance with Chapter CC46--Conditions of Service, Subchapter CC46.4--Officer's Responsibilities and Conduct, Personnel INSTRUCTION 1--Disciplinary Action, the National Institutes of Health is referring this matter to the Assistant Secretary for Health for action.

John Niederhuber, M.D.
11-17-05

Attachments

Summary of the Office of Management Assessment's (OMA) Report on Dr. Thomas Walsh's Outside Activity Discrepancies

Factual Data:

The OMA's review of a discrepancy of records between NIH and Merck & Co., Inc. to the U.S. House of Representatives, Committee on Energy and Commerce, Subcommittee on Oversight Investigations, found that Dr. Walsh:

A. Failed to Obtain Prior Approval for Outside Consulting Activities in Violation of Commissioned Corps Personnel Manual Chapter CC26

1) Dr. Walsh failed to obtain approval for a Merck sponsored "Anti-Fungal Opinion Leader Summit" on September 14-26, 2000.

2) Dr. Walsh failed to obtain approval for a Merck sponsored conference on April 17, 2001.

3) Dr. Walsh self reported, after being asked by the NIH Director to disclose all outside activities, that he engaged in 36 other activities with 24 additional pharmaceutical or biotechnology firms, between January 1999-August 2004. He did not receive approval for any of these activities for which he received a total of $97,970.

B. Failed to Disclose Compensation Received on His OGE Form 450, Executive Branch Confidential Disclosure Report

1) Dr. Walsh did not report on an OGE Form 450 the $2,100 he received for participating in the Merck sponsored "Anti-Fungal Opinion Leader Summit" on September 14-26 2000.

2) Dr. Walsh did not report on an OGE Form 450 the $1,000 dollar honorarium for participating in the Merck sponsored activity on April 17, 2001.

3) Dr. Walsh did not report on the $ 97, 970 he received from outside activities from January 1999-August 2004 on the OGE Form 450s he filed from January 1999-August 2003.

C. Failed to Obtain Prior Approval for Leave for Outside Consulting Activities in Violation of Commissioned Corps Handbook, Section C.12.c, Use of Leave in Connection with Outside Activities

1) Dr. Walsh failed to request leave on September 15, 2000 while he engaged in an outside activity with Merck.

2) Dr. Walsh failed to request leave on April 17, 2001 while he engaged in an outside activity with Merck.

3) Dr. Walsh was not on approved leave for at least 10 days during the self-reported activities from January 1999-August 2003.

D. Violated the Code of Federal Regulations, 5 CFR 2635.02

Dr. Walsh was the principal investigator in a Cooperative Research and Development Agreement (CRADA) between the National Cancer Institute (NCI) and Merck in 2000-2001. During that time, he engaged in two unapproved outside activities with Merck. 5 CFR 2635.02 states that "where the employee determines that the circumstances would cause a reasonable person with knowledge of the relevant facts to question his impartiality in the matter, the employee should not participate in the matter unless he has informed the agency designee of the appearance problem and received authorization from the agency designee." Despite the fact that this situation is one in which a reasonable person could question Dr. Walsh's impartiality, Dr. Walsh did not inform an agency designee about the appearance of a problem nor did he obtain permission.

E. Violated the NIH Manual Policy Chapter 2300-735-4

Dr. Walsh was the principal investigator in a CRADA between NCI and Merck in 2000-01, at the time he engaged in two unapproved outside activities with Merck. Dr. Walsh violated the NIH Manual Policy Chapter 2300-735-4 which states that an employee may not engage in official duty activities while at the same time engaged in outside activities with the same organization. Furthermore, employees are prohibited from engaging in activities with any outside organization with which they have direct official business dealings as government employees.

F. NIH Ethics Office Review

The NIH Office of Ethics concluded in its June 1, 2005, memorandum to Colleen Barros, Deputy Director for Management, NIH, that Dr. Walsh's "outside activities present a serious ethical problem with respect to his official relationship with Merck and its competitor Fujisawa." The memo states, "Further it is highly unlikely that Dr. Walsh would have been granted approval to engage in outside activities with the company with which he dealt in his official capacity on a CRADA."

Analysis:

Dr. Walsh fails to acknowledge that the reason for the "complex set of rules" governing NIH staff in regards to real or potential conflicts of interest is to prevent the integrity of the agency and its science from being called into question. His assertions that his reputation is sufficient to dismiss any questions about his impartiality cannot be the standard that he or the agency use in deciding to adhere to well-publicized rules – regardless of how burdensome, time-consuming, or cumbersome an employee may find them to be. Clearly, Congress did and any reasonable outside party, reviewing the record and the failure to adhere to agency requirements, could question Dr. Walsh, including his impartiality with regard to his relationship with Merck while participating in a CRADA, whether or not that was clearly spelled out in the regulations. The NIH Ethics Office concluded there were serious ethical problems and his participation in the outside activities likely would not have been approved.

Dr. Walsh states that he has taken the on-line training each year; he is sent a reminder from the Commissioned Corps about its Standards of Conduct; he has sought prior approval in some instances and, by his own admission, been denied approval on at least one occasion, thus it is clear that he knew or should have known the process and its importance. Indeed, as a principal investigator held in high regard, it was even more incumbent upon him that he adheres to the requirements of the Corps and the agency. Staff has been advised that the purpose of the internal review and prior approval requirements is to avoid these very situations; further staff has been advised and should know to err on the side of caution.

Dr. Walsh failed to recognize and acknowledge these realities. His conduct continued over time and involved at least 38 separate instances where he chose not to follow agency procedures. He actively chose not to adhere to policies because it was inconvenient or time-consuming; he knew it was likely his participation would have been disapproved. His actions reflected negatively upon the agency. It has been determined by the Office of Human Resources that if he were a civilian employee his actions would lead to a recommendation for his proposed removal. Dr. Walsh's long hours of service and dedication to the agency and the science, his significant contributions over time, his recognition that he should have been more careful, and his regret have all been considered as mitigations but they are not sufficient to outweigh the seriousness of his misconduct and its effect upon the agency.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892
www.nih.gov

15 MAR 2005

Refer to Case #2004-82-CA-24

TO: Ms. Colleen Barros
Deputy Director for Management, NIH

FROM: Director, Office of Management Assessment, OM

SUBJECT: Review of Outside Activities at NIH—Dr. Thomas Walsh

PURPOSE. The Office of Management Assessment (OMA) has completed its review of a discrepancy between records provided by NIH and by Merck & Co., Inc., (Merck) to the U.S. House of Representatives, Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, related to an outside activity by Dr. Thomas Walsh, Chief, Immunocompromised Host Section, Pediatric Oncology Branch, NCI. Dr. Walsh is a commissioned officer.

ALLEGATION. The committee cited a payment of $2,000 to Dr. Walsh from Merck for a consultant meeting on October 18, 2000.

FINDINGS. The activity cited by the Committee was a Merck-sponsored "Anti-Fungal Opinion Leader Summit" on September 14-16, 2000, in Montreal, Canada. Dr. Walsh did not obtain prior approval to participate by filing an HHS Form 520, *Request for Approval of Outside Activity*, a violation of Commissioned Corps Personnel Manual Chapter CC26, Subchapter CC26.1, Personnel Instruction 1, *Standards of Conduct*, Sections D.1 and D.2.

Dr. Walsh received $2,100 (a $2,000 honorarium and $100 for incidentals) for participating in the meeting. He failed to report the income on his OGE Form 450, *Confidential Financial Disclosure Report*, for that fiscal year.

Although Dr. Walsh stated he was consistent in submitting leave slips for outside activities, no leave slip for that activity was found, and the record shows that Dr. Walsh was not on annual leave on September 15, 2000, as required by the Commissioned Corps Officer's Handbook (1998), Section C.12.c., *Use of Leave in Connection with Outside Activities*, and as reiterated in the annual Standards of Conduct memorandum sent to active-duty commissioned officers of the U.S. Public Health Service.

NCI-Merck CRADA. Dr. Walsh was the principal investigator in a Cooperative Research and Development Agreement (CRADA) between NCI and Merck in 2000-01, when he also engaged in two unapproved outside activities with Merck—the one cited by the Committee and an activity on April 17, 2001, for which he received a $1,000 honorarium. Again the record shows that Dr. Walsh was not on approved annual leave on one day for the second activity, and he did not report it on his OGE Form 450.

The CRADA, titled "Study of Intravenous MK-0991 in Treatment of Invasive Pulmonary Aspergillosis in Persistently Granulocytopenic Rabbits" (CRADA 00665), was executed on October 2, 1998, and expired on October 1, 2004. Dr. Walsh's involvement in the CRADA and in outside activities with Merck creates the appearance of a conflict of interest because, according to federal regulations,[1] Dr. Walsh should not have participated in the outside activity while engaged in the CRADA unless he informed NIH and received prior authorization to do so. Under the circumstances, a reasonable person with knowledge of the relevant facts would question Dr. Walsh's impartiality in the CRADA.

In addition, NIH policy[2] states that an employee generally may not engage in official duty activities while at the same time engaged in outside activities with the same organization (the policy notes one exception that is not applicable in this case). Furthermore, while intramural employees may engage in activities with outside organizations, they are prohibited from engaging in activities with any outside organizations with which they have direct official business dealings as government employees.[3] We therefore referred the information to the Office of the Deputy Director, NIH, for a conflict of interest analysis.

SELF REPORTED OUTSIDE ACTIVITIES. After the NIH Director requested that scientists disclose all outside activities with pharmaceutical or biotechnology firms, Dr. Walsh reported 36 other activities with 23 additional pharmaceutical or biotechnology firms, between January 1999 and August 2004. He did not obtain prior approval to participate in any of these activities, for which he received $96,970. Dr. Walsh was not on approved annual leave for at least 10 days while participating in the activities for which he was able to provide specific dates. He did not report any of the activities in his OGE Forms 450 for 1999 through 2003.

CONCLUSION. Dr. Walsh engaged in two unapproved outside activities with Merck without official prior approval. He was not on approved annual leave for at least two days to participate in the activities, and he did not report the two activities, for which he received honoraria, on his OGE Form 450. His participation in outside activities with Merck, a party to a CRADA of which he was principal investigator, created the appearance of a conflict of interest.

Additionally, Dr. Walsh reported performing an additional 36 unapproved outside activities with pharmaceutical and biotechnology firms. He was not on approved annual leave for at least 10 days during those activities and did not report them on his OGE Form 450.

RECOMMENDATION. We recommend that you take appropriate administrative action, on the basis of our findings and of the results of the conflict of interest analysis, and consult with the Office of Commissioned Corps Operations to determine the appropriate disciplinary action.

---

[1] 5 CFR § 2635.502 (a) and (d).
[2] NIH Policy Manual Chapter 2300-735-4, G.2.a.(7).
[3] NIH Policy Memorandum, *Changes in NIH Policies on Outside Activities*, dated November 3, 1995.

COMMENTS ON OMA'S REVIEW AND OMA'S RESPONSE. Dr. Walsh's comments focused on whether his outside activities with Merck while he was engaged in a CRADA constituted a conflict of interest, emphasizing that he was diligent in requesting annual leave when participating in outside activities, and that he believed that OMA was incorrect in saying that he could not recollect whether 40 activities were official duty activities.

We took Dr. Walsh's comments into account and incorporated then into our report, as appropriate. They did not change our recommendation.

Dr. Walsh's comments are reprinted in their entirety in the attachment.

Suzanne J. Servis

Attachment

cc:
Mr. David Elizalde, NCI
Dr. Thomas Walsh, NCI

BAACH
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&LEWIS
PLLC

WASHINGTON | LONDON

Confidential Communication
FOIA Exemption Requested

February 17, 2005

VIA ELECTRONIC MAIL

Ms. Mary Jane Myers
Office of Management Assessment
National Institutes of Health
Bethesda, MD 20892

Re: Review of Outside Activities at NIH –
Dr. Thomas Walsh Case #2004-82-CA-24

Dear Ms. Meyers:

We represent Dr. Thomas Walsh in connection with the above referenced matter. This is in response to Suzanne J. Servis's memorandum of February 14, 2005 to Dr. Walsh inviting his response to the draft memorandum from the Director of OMA to Ms. Colleen Barros. We appreciate the opportunity to comment on the memorandum.

OMA has found that Dr. Walsh's outside activities with Merck & Co. ("Merck") during a period in which he had a CRADA with Merck created the appearance of a conflict of interest. We respectfully disagree with this finding and request that it be modified for the reasons set forth below.

First, as explained in detail in earlier correspondence to the OMA officials conducting this inquiry, the CRADA with Merck concerned subject matter that was entirely distinct from the subject matter of the outside activities. (Additional copies of those communications can be provided if doing so would assist your review of this matter.)

Second, the amounts of the honoraria in question were relatively small, totaling only $3,000 (not including travel and lodging expenses paid for by Merck) over a two-year period. Unlike circumstances where individuals receive

1201 F Street, NW | Suite 500 | Washington, DC 20004-1225 | 202.833.8900 | 202.466.5738 fax | baachrob@barol

substantial sums from an outside source, payments of this amount are unlikely to be viewed as impacting a professional's impartiality. We would add that anyone familiar with Dr. Walsh and his reputation would dismiss out of hand the notion that his impartiality would be compromised in these circumstances.

Third, the Merck CRADA was funded in large measure by Merck. Moreover, Dr. Walsh had no funding or grant-making authority with respect to any aspect of the NCI-Merck relationship. This is not a circumstance where a company was providing payment to someone in a position to grant it a financial benefit. It is also not a circumstance where questions could be raised about the diversion of NIH resources. Merck was providing the funding.

The memorandum also makes reference to regulations and policy guidelines that allegedly make clear the impermissibility of engaging in a CRADA and in unrelated outside activities with the same company during the same time period. We have been unable, however, to find such a clear prohibition in the cited rules. The regulations at 8 C.F.R. § 2635.502(a) and (d) speak broadly to apparent conflicts of interest, and do not mention CRADAs at all. Similarly, we have been unable to find the November 3, 1995 NIH policy guidance cited in the memorandum on your website or through a general Google search.

The absence of clarity in this regard is a significant mitigating factor. Dr. Zerhouni's Blue Ribbon Panel last year "found an extremely complex set of rules governing conflicts of interest at NIH [which are] widely misunderstood by some of the people to whom they are intended to apply, thereby creating uncertainty as to allowable behavior and adversely affecting morale." Blue Ribbon Panel Rep. 1. In the absence of a clear, published prohibition of engaging in a CRADA and in unrelated outside activities with the same company, it is unfair to Dr. Walsh to find him in violation of the appearance-of-conflict rules on this basis.

As to other matters raised in the draft memorandum, we take exception to the statement that "Dr. Walsh did not take at least 18 days of annual leave." OMA Mem. 2; *see also id.* ("He did not take 18 days of annual leave for these activities."). As explained in previous correspondence, Dr. Walsh was extremely diligent with respect to the submission of leave requests and is certain that leave slips were submitted for these activities but for whatever reason failed to make their way into the official leave records. These are paper slips that are routed to different offices. Dr. Walsh submitted his leave slips consistently, among other reasons, to eliminate any conceivable question of his being absent without leave so that, in the event of a life-threatening injury while traveling, his family would

not be left with an insurance dispute regarding his duty status at the time of the accident. Indeed, he often took leave for official duty activities though not required to do so for this reason. His usual workweek is a minimum of 80 hours. Dr. Walsh takes few vacations, has forfeited substantial leave in recent years under the "use or lose" regime, and hence would have absolutely no reason not to take leave for an outside activity. We would therefore ask that the memorandum make note of Dr. Walsh's explanation and conclude only that the relevant leave slips were not found in NIH records.

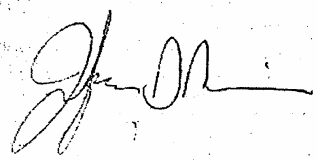
In addition, we question the statement that "40 activities were unidentified (Dr. Walsh said he could not recollect whether they were outside activities or official duties.)." OMA Mem. 2. Dr. Walsh clearly identified the 40 activities in question as official duty activities with outside organizations in a chart appended to his October 4, 2004 submission. In an abundance of caution, and in view of the long periods of time in issue, the chart noted that it was not intended as *definitive* as to whether certain activities were outside or official duty. (A similar proviso is included in the table of outside activities). We would therefore ask that the language of the memorandum be amended to state that Dr. Walsh identified the 40 activities as official duty activities (although he stated that the characterization could not be definitive in view of the difficulty of reconstructing events over a five-year period).

As you are aware, Dr. Walsh takes the process now underway within OMA and NIH very seriously. He has spared no effort in gathering all available information requested of him in order to make his activities with outside organizations an open book, and he has been entirely forthcoming and candid with OMA's investigators. Dr. Walsh is painfully aware that he should not have neglected to file the necessary forms in respect of his outside activities, and he is ready and willing to discuss and accept appropriate administrative action for this error of judgment. We would respectfully request, however, that the above issues be reconsidered and/or addressed as appropriate so that Dr. Walsh's actions can be evaluated in the most accurate possible light.

BAACH ROBINSON & LEWIS

We are grateful for OMA's courtesy during this very difficult period for Dr. Walsh. Please do not hesitate to contact us if we can be of any further assistance.

Respectfully submitted,



Jeffrey D. Robinson
H. Bradford Glassman
Baach Robinson & Lewis, PLLC
Counsel for Dr. Thomas Walsh

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&LEWIS
PLLC

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892
www.nih.gov

June 1, 2005

Tab 45

TO: Colleen Barros
Deputy Director for Management, NIH

FROM: Director, NIH Ethics Office

SUBJECT: Dr. Thomas Walsh's Unapproved Outside Activities with Merck

The NIH Ethics Review Panel examined two unapproved outside activities between Merck and Thomas J. Walsh, M.D., Head, Immunocompromised Host Section, Pediatric Oncology Branch, National Cancer Institute (NCI). The Review Panel finds that the scientific subject matter of the activities overlap directly with Dr. Walsh's research at NIH. In addition, while Dr. Walsh was a paid speaker for Merck on two occasions, he was collaborating with Merck, and one of its competitors, in his official capacity. Accordingly, the Panel finds his unapproved outside activities with Merck to be highly problematic.

During 2000 and 2001, Dr. Walsh received two honoraria for lectures that he gave for Merck. The first event took place on September 14, 2000, where Dr. Walsh gave a lecture at Merck's "Anti-Fungal Opinion Leaders Summit" in Montreal, Canada. His presentation was on the topic of the "salvage study" – the efficacy of Merck's compound caspofungin. On April 17, 2001, Dr. Walsh gave another presentation at a Merck-sponsored event where he lectured on "susceptibility testing," or the methods for determining the resistance of particular organisms to certain antimicrobial compounds.

As Head of the Immunocompromised Host Section, Dr. Walsh's laboratory program focuses on the study of opportunistic fungal pathogens in patients with cancer. He studies antifungal pharmacology, augmentation of mucosal and systemic host defenses, and early molecular detection. Such studies provide the foundation for clinical trials and a model for approaching emerging infectious pathogens in patients with cancer.

At the time of the two speaking events with Merck, his program had an active Cooperative Research and Development Agreement (CRADA) with Merck to study the compound caspofungin, which is used to combat advanced invasive fungal infections in adult patients that do not respond to other therapies. In 2000, he served in his official capacity on a data review committee for the caspofungin salvage study – the same study on which he gave a paid lecture for Merck at the 2000 Montreal conference. Dr. Walsh also chaired a pediatric study of caspofungin that enrolled four patients between November 2001 and November 2002. His program also had another CRADA with a competitor of Merck, Fujisawa, which also involved the study of an antifungal compound.

The Ethics Review Panel finds substantial overlap with his official duties and his unapproved outside activities with Merck. The CRADAs and the other research that Dr. Walsh oversees in his lab overlap directly with the subject matter of the outside activities. In one instance, Dr. Walsh was paid to give a presentation on a study, the "salvage study," which he was involved in as an official duty matter. Furthermore, it is highly unlikely that Dr. Walsh would have been granted approval to engage in outside activities with the company with which he dealt in his

official capacity on a CRADA. In addition, the CRADA with the company's competitor would have precluded him from obtaining approval for the outside activity, as well. The Panel finds that, in addition to the direct overlap with his official duties, his outside activities present a serious ethical problem with respect to his official relationship with Merck and its competitor Fujisawa.

Holli Beckerman Jaffe, J.D.

cc: Suzanne Servis, OMA
Charles Palmer, OHR

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892
www.nih.gov

SEP 09 2005

Refer to Case: #2004-82-CA-24

Tab 46

TO: Ms. Chris Steyer
Acting Director, Office of Human Resources, OM

FROM: Director, Office of Management Assessment, OM

SUBJECT: Review of Outside Activities at NIH—Dr. Thomas Walsh

PURPOSE: The Office of Management Assessment (OMA) has completed its review of a discrepancy between records provided by NIH and by Merck & Co., Inc., (Merck) to the U.S. House of Representatives, Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, related to an outside activity by Dr. Thomas Walsh, Chief, Immunocompromised Host Section, Pediatric Oncology Branch, NCI. Dr. Walsh is a commissioned officer.

ALLEGATION: The committee cited a payment of $2,000 to Dr. Walsh from Merck for a consultant meeting on October 18, 2000.

FINDINGS: The activity cited by the Committee was a Merck-sponsored "Anti-Fungal Opinion Leader Summit" on September 14-16, 2000, in Montreal, Canada. Dr. Walsh did not obtain prior approval to participate by filing an HHS Form 520, *Request for Approval of Outside Activity*, a violation of Commissioned Corps Personnel Manual Chapter CC26, Subchapter CC26.1, Personnel Instruction 1, *Standards of Conduct*, Sections D.1 and D.2.

Dr. Walsh received $2,100 (a $2,000 honorarium and $100 for incidentals) for participating in the meeting. He failed to report the income on his OGE Form 450, *Confidential Financial Disclosure Report*, for that fiscal year.

Although Dr. Walsh stated he was consistent in submitting leave slips for outside activities, no leave slip for that activity was found, and the record shows that Dr. Walsh was not on annual leave on September 15, 2000, as required by the Commissioned Corps Officer's Handbook (1998), Section C.12.c., *Use of Leave in Connection with Outside Activities*, and as reiterated in the annual Standards of Conduct memorandum sent to active-duty commissioned officers of the U.S. Public Health Service.

NCI-Merck CRADA: Dr. Walsh was the principal investigator in a Cooperative Research and Development Agreement (CRADA) between NCI and Merck in 2000-01, when he also engaged in two unapproved outside activities with Merck—the one cited by the Committee and an activity on April 17, 2001, for which he received a $1,000 honorarium. Again the record shows that Dr. Walsh was not on approved annual leave on one day for the second activity, and he did not report it on his OGE Form 450.

The CRADA, titled "Protocol of Study of Intravenous MK-0991 in Treatment of Invasive Pulmonary Aspergillosis in Persistently Granulocytopenic Rabbits" (CRADA 00665), was executed on October 2, 1998, and expired on October 1, 2004. Dr. Walsh's involvement in the CRADA and in outside activities with Merck creates the appearance of a conflict of interest because, according to federal regulations,[1] Dr. Walsh should not have participated in the outside activity while engaged in the CRADA unless he informed NIH and received prior authorization to do so. Under the circumstances, a reasonable person with knowledge of the relevant facts would question Dr. Walsh's impartiality in the CRADA.

In addition, NIH policy[2] states that an employee generally may not engage in official duty activities while at the same time engaged in outside activities with the same organization (the policy notes one exception that is not applicable in this case). Furthermore, while intramural employees may engage in activities with outside organizations, they are prohibited from engaging in activities with any outside organizations with which they have direct official business dealings as government employees.[3] We therefore referred the information to the Office of the Deputy Director, NIH, for a conflict of interest analysis.

SELF REPORTED OUTSIDE ACTIVITIES: After the NIH Director requested that scientists disclose all outside activities, Dr. Walsh reported 36 other activities with 24 additional pharmaceutical or biotechnology firms, between January 1999 and August 2004. He did not obtain prior approval to participate in any of these activities, for which he received $97,970. Dr. Walsh was not on approved annual leave for at least 10 days while participating in the activities for which he was able to provide specific dates. He did not report any of the activities in his OGE Forms 450 for 1999 through 2003.

CONCLUSION: Dr. Walsh engaged in two unapproved outside activities with Merck without official prior approval. He was not on approved annual leave for at least two days to participate in the activities, and he did not report the two activities, for which he received honoraria, on his OGE Form 450. His participation in outside activities with Merck, a party to a CRADA of which he was principal investigator, created the appearance of a conflict of interest.

Additionally, Dr. Walsh reported performing an additional 36 unapproved outside activities with pharmaceutical and biotechnology firms. He was not on approved annual leave for at least 10 days during those activities and did not report them on his OGE Form 450.

RECOMMENDATION: We recommend that you take appropriate administrative action, on the basis of our findings and of the results of the conflict of interest analysis, and consult with the Office of Commissioned Corps Operations to determine the appropriate disciplinary action.

---

[1] 5 CFR § 2635.502 (a) and (d).
[2] NIH Policy Manual Chapter 2300-735-4, G.2.a.(7).
[3] NIH Policy Memorandum, *Changes in NIH Policies on Outside Activities*, dated November 3, 1995.

COMMENTS ON OMA'S REVIEW AND OMA'S RESPONSE: Dr. Walsh's comments focused on whether his outside activities with Merck while he was engaged in a CRADA constituted a conflict of interest, emphasizing that he was diligent in requesting annual leave when participating in outside activities, and that he believed that OMA was incorrect in saying that he could not recollect whether 40 activities were official duty activities.

We took Dr. Walsh's comments into account and incorporated then into our report, as appropriate. They did not change our recommendation.

Dr. Walsh's comments are reprinted in their entirety in the attachment.

Suzanne J. Servis

Suzanne J. Servis

Attachment

cc:
Mr. John Hartinger, NCI
Dr. Andrew Von Eschenbach, NCI
Dr. Thomas Walsh, NCI

[redacted]

Tab 47

10-15-2002 7:02PM FROM P. 1

6006 Roosevelt St.
Bethesda, MD 20817
November 12, 2001

Ms Brenda R. Brown
Pfizer Global Research and Development
MS 6025-A5167
50 Pequot Ave
New London, CT 06320
1-860-732-4278

Dear Ms Brown:

Enclosed is an invoice for the three mock advisory ~~meetings in which~~ I participated during this year @ of $4,000 per session for a total of $12,000.

Okay to pay

Please contact me if you have nay questions.

Sincerely,

Thomas J. Walsh, MD

Payment Address: 6006 Roosevelt Street
Bethesda, MD 20817

Purchase Order No.: 140-R-242854

Okay to Pay
Amount: $12,000

If you have any questions regard
ing this invoice, please call me at (860) 732-4278.

Thank you,
Brenda R. Brown
Pfizer Global Research & Development
Development Operations, New London

C-2

WASHINGTON | LONDON

[redacted]

Tab 48

AACH
ROBINSON
&LEWIS
PLLC

H. BRADFORD GLASSMAN
brad.glassman@baachrobinson.com

CONFIDENTIAL COMMUNICATION
FOIA EXEMPTION REQUESTED

Analysts' note:
No documentation from outside organizations was provided to confirm dates of activities.

October 4, 2004

BY HAND DELIVERY

Mr. Kevin Wetmore
Division of Program Integrity
Office of Management Assessment
National Institutes of Health
6011 Executive Boulevard, Suite 601
Rockville, MD 20852

Re: Dr. Thomas Walsh/Outside Activities

Dear Mr. Wetmore:

You have requested that Dr. Thomas Walsh provide information relating to his activities with outside organizations for the period January 1, 1999 through December 31, 2003. Relevant information is provided herewith. We have made our best efforts to provide responsive, complete, and accurate information in the circumstances and will make Dr. Walsh available to answer any questions you might have regarding this information.

Activities with Outside Organizations

Dr. Walsh's activities with outside organizations are set forth in several attachments to this letter. Outside activities are listed at Tab A by year, with the name of the organization, any compensation received, the date of the event where available, and a brief description of the nature of the event. In a number of cases, the nature of the event is uncertain, typically where the name of an organization did not trigger any memory of the event. We believe that these organizations are likely to be private companies in the business of organizing Continuing Medical Education (CME) conferences and similar events. Listed at Tab B are activities with outside organizations that relate to Dr. Walsh's

CA. 24.8a

1201 F Street, NW | Suite 500 | Washington, DC 20004 | 202.659.7210 | 202.466.5738 fa

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official duties.[1] Dr. Walsh's *curriculum vitae* setting forth his faculty positions, professional associations, publications, and other pertinent information is at Tab C.

Approvals for Outside Activities

During the five-year period, there are occasions on which Dr. Walsh neglected to request NIH approval for outside activities. Dr. Walsh did seek and obtain official approval for his faculty positions with the University of Maryland, Johns Hopkins University, and the Massachusetts Institute of Technology. The unapproved outside activities were primarily Continuing Medical Education lectures and similar events sponsored by organizations with no relationship to NIH. These CME and similar activities do not raise substantive conflict of interest concerns.

Dr. Walsh is now painfully aware that he should not have neglected to seek proper approvals for his outside activities. Under the press of his work, and simply to expedite matters, Dr. Walsh exercised his own judgment to avoid actual and apparent conflicts of interest. *Cf.* Blue Ribbon Panel Rep. 1 ("[T]he panel found an extremely complex set of rules governing conflicts of interest at NIH. These rules are widely misunderstood by some of the people to whom they are intended to apply, thereby creating uncertainty as to allowable behavior and adversely affecting morale."). The record amply demonstrates that Dr. Walsh was not impelled by venal motives. There were many consulting and similar fees he turned down. For the activities he did undertake, he received relatively small amounts of compensation, and it was his frequent practice to pay for travel himself and/or not to seek travel reimbursements to which he was entitled. These points are discussed in greater detail below.

General Nature of Outside Activities

Dr. Walsh's remunerations during the five-year period were modest. Indeed, in terms of the dollar amounts, Dr. Walsh's aggregate income for outside activities was less than 25% of his NIH income in four of the five years during the 1999-2003 period.[2] Similarly, Dr.

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[1] We assume that routine interactions relating to matters such as obtaining antimicrobial agents and seeking information regarding organisms or compounds are not the subject of the present inquiry.

[2] Dr. Walsh's outside income amounted to 25.7% of his NIH income in 1999.

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Walsh is confident that he spent less than 400 hours performing outside work in each of the five years. While the guidelines restricting outside activity to less than 25% of NIH income and less than 400 hours were not in effect at the time, the fact that Dr. Walsh met them should give some comfort concerning the limited nature of his outside activities.

During the five-year period Dr. Walsh turned down many hundreds of thousands of dollars in lucrative consultancy offers (often including stock option packages) that he viewed as encroaching on the domain of his official responsibilities, requiring excessive time commitments, or simply involving sums so large as to seem inappropriate. If the outside activities were driven by a motive of financial gain, Dr. Walsh could easily have doubled or even tripled his annual income over the salary he received from NIH. Although Dr. Walsh did sometimes accept compensation for the value of his outside work, it is clear from the activities he undertook – as well as those he did not – that these decisions were guided by scientific and educational rather than financial objectives.

As noted in previous correspondence, Dr. Walsh had no grant-making or similar funding authority that might raise particular concerns regarding influence by private companies. In most official interactions between the Immunocompromised Host Section and private companies, it is not NCI but rather the companies themselves that provide the bulk of the funding and resources. Moreover, most activities such as clinical trials or research under a CRADA involve large groups of scientists, often at various institutions throughout the country, who generally operate by consensus, thus eliminating any real possibility that a company could improperly influence a scientific study. Finally, we have no doubt that your conversations with persons who have worked with Dr. Walsh will confirm that he simply would not abide any attempt to influence scientific data or the scientific studies entrusted to him.

Particular Outside Activities

We would like to bring the following outside activities specifically to your attention, based on our correspondence and discussions to date and our understanding of the issues of concern to you.

Merck

See correspondence of September 2, 2004 (Tab D).

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Schering-Plough

See correspondence of September 20, 2004 (Tab E).

Pfizer

Dr. Walsh received $1,000 from Pfizer Inc. ("Pfizer") in 1999, $12,000 in 2002, and $2,000 in 2003. Dr. Walsh does not recall the event for which he was paid $1,000 but believes it was probably a general-expertise CME lecture, *e.g.*, his standard lecture on antifungal therapy for oncology patients. The $12,000 in 2002 was for a general-expertise consultation in 2001 relating to vorconizole and other antifungal compounds. Dr. Walsh believes he met with Pfizer scientists on April 11, 2001, July 10, 2001, August 22, 2001. The $2,000 in 2003 was for preparing a general-expertise Power Point presentation that was not ultimately given because the symposium never occurred. The lecture was to be on the general subject of antifungal therapy for oncology patients. Dr. Walsh does not recall the date when he submitted the Power Point presentation.

As you are aware, conferences and symposia are often held by universities and professional conference organizers and supported by private companies. NIH guidelines provide that the conference organizer is the relevant party for purposes of conflicts analysis and approval if it is responsible for the invitations and agenda. *See* Instructions for Completing HHS-520. Nevertheless, in the interest of providing complete information, Dr. Walsh is aware that another organization that provided him with compensation, PPSI, organized at least some of its CME conferences with support from Pfizer. Dr. Walsh received $5,000 from PPSI in 2000, $3,500 in 2001, and $2,000 in 2002. These payments were compensation for CME lectures drawing from Dr. Walsh's general expertise. Dr. Walsh does not have event programs, invitations, or similar materials for these events, as it was not his practice to retain such documents for general CME lectures.

The Immunocompromised Host Section has had a relationship with Pfizer to varying degrees during the five-year period. The laboratory conducted four clinical trials with Pfizer, two of them chaired by Dr. Walsh. All of the trials were closed by 2000, and activity relating to the trials was concluded by that year with one exception: publication of one of the trials, a pediatric study, did not occur until this

year.[3] Dr. Walsh is confident that the outside activity with Pfizer in 1999 had no substantive overlap with any of the clinical trials. Similarly, the 2001 consultation and the 2002 Power Point presentation drew from Dr. Walsh's general expertise and had no significant overlap with the clinical trials. There are no CRADAs between Dr. Walsh or his Section and Pfizer.

Aronex

Dr. Walsh received $2,000 from Aronex Pharmaceuticals, Inc. ("Aronex") for a general-expertise consultation in 2000 relating to its compound liposomal nystatin, and particularly its activity against cryptococcosis. Dr. Walsh's laboratory has done essentially no work on cryptococcosis, which has been studied extensively by other well-regarded laboratories. Neither Dr. Walsh nor the Immunocompromised Host Section has participated in either clinical trials or CRADAs with Aronex. The Section did, however, study liposomal nystatin informally and published three papers on the compound in the 1998-1999 period and one in 2003. The paper published in 2003 drew from the work done in the late 1990s and was delayed on account of more pressing priorities. All of these papers were authored by NCI, and Aronex was not a co-author.

Enzon

Dr. Walsh received $7,000 from Enzon Pharmaceuticals ("Enzon") in 2003 for a consultation regarding a salvage therapy protocol using certain compounds including one known as ABLC. The actual payment was from the Spellman Group, which has organized events in the past for Enzon. Dr. Walsh was invited to participate on account of his general expertise and experience in protocol design. Dr. Walsh received an additional $3,500 from Enzon in 2003 for a consultation regarding various compounds being considered by the company for licensure (not including ABLC). At the time of these activities, neither Dr. Walsh nor the Immunocompromised Host Section had any formal relationship with Enzon. A CRADA has since been discussed and is now pending approval with Dr. Maureen Wilson's office to study ABLC. The CRADA was not specifically envisioned at the time of the above consultations and, to the best of Dr. Walsh's recollection, was not discussed at the meetings.

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[3] In addition, an informal compassionate release protocol (*i.e.*, for patients who had failed to respond to all other therapies) involving vorconizole was opened in 2001; Dr. Walsh believes it concluded the same year, and few patients were enrolled.

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Leave Requests

Dr. Walsh submitted leave requests not only for travel relating to outside activities but also on a number of occasions for official duty travel, although in the latter case he was not required to do so. He did this mainly to eliminate any conceivable question of his being absent without leave so that, in the event of an accident such as an airplane crash, his family would not be left with an insurance dispute regarding his status at the time of the accident. Our review of leave records, however, indicates that for whatever reasons a number of Dr. Walsh's leave slips did not make their way into the records system. Dr. Walsh does not know why this is the case, as he did not pay close attention to the processing of leave forms after he submitted them.[4]

Financial Disclosure

Dr. Walsh is not required to file public annual financial disclosure reports but does file confidential annual financial disclosure reports. The disclosures on these forms follow essentially the same pattern as with Dr. Walsh's filing of Form 520, with disclosure of university faculty positions but no disclosure for single-event and similarly limited lecture and consulting engagements. It should be noted that the relevant category on the form is entitled "Outside Positions" and does not appear to require the listing of such limited outside activities. We are attaching Dr. Walsh's 2001, 2002, and 2003 disclosure forms. *See* Tab F. Dr. Walsh has not retained the 1999 and 2000 forms. We presume that the forms for the earlier years are on file with NIH and available to your office. To the extent that Dr. Walsh's authorization is necessary for you to access these forms, you are authorized to obtain them if you should wish to do so. Please forward a copy of these forms to us if you do decide to obtain them.

Travel Reimbursement

Dr. Walsh sometimes handled reimbursements for official duty travel in the same manner as he would for outside activities. That is, rather than pay for the travel from his laboratory's budget and ask the outside organization to reimburse the government, he would pay for the travel himself and accept the reimbursement directly. Alternatively, the organization sometimes purchased Dr. Walsh's ticket and/or accommodations directly. Dr. Walsh proceeded in this way because he

[4] It should be noted that Dr. Walsh takes few vacations and has forfeited leave in recent years under the "use or lose" regime. Hence, he would have no reason not to take leave for an outside activity.

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found the official reimbursement process so cumbersome and time-consuming as to be non-viable within the laboratory's administrative staffing constraints, and he believed the practice of accepting reimbursements directly in this manner was acceptable. In any event, the bottom-line result is the same, resulting in no income and no cost either to the individual or the government.

FOIA Exemption Request

In complying with your request, Dr. Walsh is necessarily providing your office with a substantial body of confidential personal financial information. We therefore request that the information being submitted with this letter and our previous correspondence of September 2, 2004, September 20, 2004, and September 21, 2004, as well as the information disclosed in the September 8, 2004 interview and any subsequent interviews, be withheld from disclosure in response to any request presented under the Freedom of Information Act, 5 U.S.C. § 552, or otherwise. Such non-disclosure is required pursuant to 5 U.S.C. § 552(b)(4) and (b)(6) and related provisions. Dr. Walsh requests that this information be withheld from disclosure permanently, or until this request is overcome by final adverse judicial determination, after notice and an opportunity for Dr. Walsh to defend the requested exemption. Dr. Walsh is the "submitter" for purposes of this request, but we would ask that all inquiries and communications relating to the request be directed to this law firm on his behalf.

The Way Forward

As noted above, Dr. Walsh realizes that he has neglected to follow certain NIH procedural requirements and understands that a sanction is likely to be imposed upon him. As a sanction is considered, however, it is fair and appropriate that Dr. Walsh's conduct be viewed not in a vacuum but against the backdrop of his reputation, accomplishments, and dedication to NIH over nearly two decades of distinguished service.

We would welcome the opportunity at any stage of the process to address both the specific question of Dr. Walsh's activities with outside organizations and the more general context of his career and contributions to NIH. We have had little insight, however, into the process ahead and are not certain what opportunity we will have, if any, to be heard on these issues. Out of an abundance of caution, we would therefore like to address the broader context briefly in order to provide a framework for evaluating the issues presented by the outside activities.

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Dr. Walsh is an exceptionally dedicated scientist and physician and a leader in his field. He has devoted his career to the work of the Immunocompromised Host Section and NCI and NIH more broadly. He typically works 80- to 100-hour weeks, takes little vacation, and gives generously of his time to patients in need of his expertise, many of whose lives he has saved. He is exceptionally productive of original scientific research and literature (appearing on the masthead of more than 500 publications), serves on numerous committees and working groups, and devotes himself to an unusual degree to the mentoring of junior scientists. He has received the Surgeon General's Physician-Scientist of the Year award, NIH's Distinguished Clinical Teacher award, and other prestigious awards and recognition. Under Dr. Walsh's leadership, the laboratory's clinical research over the past 15 years has advanced the field and changed the management of immunocompromised patients worldwide. Dr. Walsh has also rendered services to the public in times of national emergencies including the September 11, 2001 World Trade Center attacks and the anthrax bioterrorism at the Brentwood postal facility. There is without question a great benefit to the public that NIH serves in allowing Dr. Walsh to continue to do the science at which he excels.

It must also be observed that activities with outside organizations are critical to Dr. Walsh's work and to the mission of the Immunocompromised Host Section. As the NIH Blue Ribbon Panel on Conflict of Interest Policies recently stated, "increasingly the translation of fundamental knowledge into practical solutions to health needs requires integrated teams of specialists from numerous disciplines in the public, academic, and commercial sectors." Blue Ribbon Panel Rep. 8 (June 22, 2004). To take but one concrete example, Dr. Walsh interacts almost constantly either in an official capacity or through outside activities with companies developing new antimicrobial compounds. The state-of-the-art knowledge derived from that contact is essential when he is consulted (as he is on a regular basis) by practitioners throughout the country confronting life-threatening invasive infections in immunocompromised patients. Remaining on the cutting edge of drug development is thus critical to fulfilling NIH's mandate of translating basic research into meaningful therapies for patients.

We hope that the foregoing is responsive to your information requests and helpful to your analysis. Please feel free to call either of us if questions arise or if there is need of clarification.

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FOIA EXEMPTION REQUESTED

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We are very grateful for your courtesy during this very difficult period for Dr. Walsh. We would welcome the opportunity to meet with you to discuss this information and the way forward.

Very truly yours,

Jeffrey D. Robinson
H. Bradford Glassman

Enc.: (6)

cc: Mr. Rocky LaMonaca

Ms. Susan R. Cornell
NIH FOIA Officer

Tab A

A-1

1999

Date	Organization	Description	Amount
79 Possibly 4/15-4/16/1999	Pfizer	Probably general expertise CME lecture.	$1,000 honorarium. Not certain re: travel costs.
38 May-99	American Society of Clinical Oncology	Obtained approval for this activity. ASCO is major oncology organization with close association to NCI.	~~$1,000 honorarium. Not certain re: travel costs.~~ $ not added
101 8/7/1999	University of Texas SW Medical Center	General expertise CME lecture to fellows in training.	$2,500 honorarium. Not certain re: travel costs.
92 Possibly 9/25/1999	TG Worldwide	Probably general expertise lecture or conference participation.	$2,100 honorarium. Not certain re: travel costs.
88	Schering Plough	Probably general expertise CME lecture or advisory panel.	$1,000 honorarium. Not certain re: travel costs.
90	Scientific Therapeutics Info	Probably a general expertise lecture or consultation.	$1,500 honorarium. Not certain re: travel costs.
32	ER Squibb & Sons	Possibly consultant panel re: treatment of otitis media in children.	$1,300 honorarium. Not certain re: travel costs.
94	The Liposome Company	General expertise consultation. Reviewed series of reports re: clinical activity of various compounds.	$19,000 honorarium. Not certain re: travel costs.

$28,400

2000

Date	Organization	Description	Amount
19 2/22/2000	Children's Hospital of Philadelphia	General expertise lecture and attended to patients in Philadelphia, PA.	No honorarium or travel costs.
16 3/11/2000	Aronex	General expertise consultation in Houston, TX on crypyococcal meningitis.	$2,000 honorarium. Not certain re: travel costs.

4-2

Date	Organization	Description	Amount
40 3/29/2000	Imedex	General expertise lecture "Infections" to physicians & microbiologists; "Focus 10" meeting.	$1,050 honorarium. Not certain re: travel costs.
93 09/14/2000-09/16/2000	(merck) TG Worldwide	"Anti-Fungal Opinion Leaders Summit," sponsored by Merck in Montreal, Canada.	$2,000 honorarium. Dr. Walsh also received $100 for incidentals and believes he received travel costs from conference organizer.
77 9/22/2000	Network for Medical Communication & Research	General expertise lecture in Atlanta, Georgia, entitled "Infections in the Cancer Patient," to group of oncologists for CME.	$3,000 honorarium. Not certain re: travel costs.
24 10/12/2000	Connecticut Infectious Disease Society	General expertise lecture in Windsor Locks, CT.	Possibly related to Medical Research Associates or Jobson Ed.
106 10/18/2000	Westchester Memorial Hospital Department of Pediatric Oncology	General expertise lecture in New York.	No honorarium. Not certain re: travel costs.
3 11/29/2000	American Society for Hematology	Probably general expertise CME lecture.	No honorarium or travel costs.
14	Armand Scott	General expertise lecture re: pharmacology of anti-microbials for CME.	$2,500 honorarium. Not certain re: travel costs.
30	EB Squibb	Informal general expertise consultation re: various compounds.	$1,000 honorarium. Not certain re: travel costs.
44	Impact Communication	Probably general expertise CME lecture in Atlanta, GA.	$1,000 honorarium. Not certain re: travel costs.

4-3

Date	Organization	Description	Amount
57	Jobson Education	Probably general expertise CME lecture.	$1,500 honorarium. Not certain re: travel costs.
95	The Liposome Company	Probably several general expertise CME lectures. Cannot recall specifically.	$6,500 honorarium. Not certain re: travel costs.
67	Medical Research Associates	Probably general expertise CME lecture.	$1,800 honorarium. Not certain re: travel costs.
? 76	NCI Advertising	Probably general expertise CME lecture.	$1,500 honorarium. Not certain re: travel costs.
84	PPSI	Probably general expertise consultation, advisory panel, or lectures.	$5,000 honorarium. Not certain re: travel costs.

P 28,950 + travel costs

2001

Date	Organization	Description	Amount
98 2/26/2001	University of Buffalo Foundation	General expertise lectures and rounds.	$1,500 honorarium. Not certain re: travel costs.
91 3/29/2001	Summit on Infectious Diseases; Strategic Research Institute	General expertise keynote lecture entitled "Experimental and Clinical Anti-Infective Therapeutics" to large group (industry/academia) in Trenton, NJ. Open to public.	No honorarium. Not certain re: travel costs.
98 April-01	Intermune	General expertise consultation re: general immunology issues.	$750 honorarium. Not certain re: travel costs.
80 4/11/2001; 7/10/2001; 8/22/2001	Pfizer	General expertise consultation re: Pfizer compounds.	$12,000 honorarium. Not certain re: travel costs.
68 4/17/2001	Merck	Attend conference and general expertise comments on presentations re: "susceptibility testing."	$1,000 honorarium. Merck may have paid travel costs.
15 5/4/2001	Armand Scott	General expertise pharmacology lecture in Washington, DC (same as 2000).	$2,500 honorarium. Not certain re: travel costs.

work activity

Duty day - No leave taken [CA. 24.86. F.1; p. 2]

Date	Organization	Description	Amount
13 5/12/2001	American Society of Transplantation	General expertise lecture on "Infections in Solid Organ Transplant Recipients."	$1,000 honorarium. Not certain re: travel costs.
85 6/1/2001 9/22/2001	PPSI	General expertise lectures in Washington, DC and Chicago, IL.	$5,000 honorarium. Not certain re: travel costs.
2 7/11/2001	American Academy of Pediatrics	General expertise lectures to pediatric infectious disease fellows in training.	No honorarium. AAP paid travel costs.
107 9/29/2001	Zarix	"Think Tank" session re: treatments of infections and general expertise lecture on infections in cancer patients.	$2,670 honorarium. Not certain re: travel costs.
103 December-01	Versicor	General expertise consultation, advisory panel to review company's portfolio of compounds.	$1,500 honorarium. Not certain re: travel costs.
25	Cooper Medical	CME provider. Probably several general expertise CME lectures.	$5,000 honorarium. Not certain re: travel costs.
36	Healthcasts	Possibly general expertise CME lecture.	$2,500 honorarium. Not certain re: travel costs.
83	Pharmedica	CME provider. Possibly general expertise lecture or consultation.	$1,500 honorarium. Not certain re: travel costs.
35	Health Research	CME provider. Probably general expertise lecture.	$1,000 honorarium. Not certain re: travel costs.

$37,720

2002

Date	Organization	Description	Amount
27 2/26/2002	Cubist	General expertise lecture in Waltham, MA entitled "Antifungal Therapy" and discussion of compounds under consideration for licensures.	$1,500 honorarium. Not certain re: travel costs.
22 3/15/2002	CME Group-not certain re: name	General expertise lectures (public domain) in Paris, France to group of physicians.	No honorarium. CME group paid travel costs.
96 3/16/2002	The Spellman Group	General expertise lecture to physicians in Atlanta, GA.	$2,500 honorarium. Not certain re: travel costs.

A-5

Date	Organization	Description	Amount
92 3/23/2002	Imedex	"Focus 12" meeting in Phoenix, AZ on fungal infections (general expertise).	No honorarium. Not certain re: travel costs. 8
100 4/23/2002	University of Texas	General expertise lecture at Univ. Texas in San Antonio, TX.	No honorarium. UT paid travel costs. 9
87 6/13/2002	Public Health Research Institute	General expertise lecture on "Invasive Fungal Infections in Immuno-compromised Hosts" at opening symposium (called "Frontiers in Infectious Diseases") to general audience of physicians & scientists in Newark, NJ.	$1,000 honorarium. Believes PHRI paid for Amtrak.
86 6/20/2002	PPSI	General expertise lecture in Dublin, Ireland on therapeutic approaches to Irish and English doctors.	$2,000 honorarium. PPSI paid travel costs.
49 6/25/2002	International Immuno-compromised Host Society (ICHS)	General expertise lecture at large international meeting held in Bergen, Norway.	No honorarium. ICHS paid travel costs. 10
Same 102 8/2/2002	Univ. Texas Southwestern	General expertise CME lecture to fellows in training at Whistler, Canada.	$2,500 honorarium. UTS paid travel costs.
61 12/13/2002	Mayo Clinic	General expertise lectures at Mayo Clinic in Rochester, MN as visiting professor re: infections in immuno-compromised patients.	No honorarium. Entitled to travel costs, but did not follow up. 11
17	Baxter Healthcare Corp.	General expertise consultation on setting up animal models in lab, interpreting animal data, etc.	$3,000 honorarium. No travel costs paid.
26	Corbett Healthcare	Probably CME organizer. Possibly general expertise lecture.	$1,500 honorarium. Not certain re: travel costs.

+14,000

2003

Date	Organization	Description	Amount
18 Periodic	Ceptyr	General expertise consultation. Reviewed proposed patent. Paid by hour.	$4,350 honorarium. Not certain re: travel costs.
34 1/16/2003	Gray Springs	General expertise CME lectures and grand rounds at UCLA on pediatric infections.	$6,067, including travel.
60 1/29/2003	Massachusetts General Hospital	"Grand rounds" in Boston, MA (general expertise).	No honorarium. No travel costs paid. 12

Date	Organization	Description	Amount
41 3/18/2003	Imedex	Several general expertise lectures. May be the Focus 13 meeting held in San Francisco, CA.	$4,050 honorarium. Imedex paid travel costs.
59 4/23/2003	Kansas City Hematology and Oncology Society	Gave Ludwina Knapp lecture (general expertise) in pediatric oncology at Children's Mercy Hospital and Clinics in Kansas City.	$1,000 honorarium. Organization paid travel costs.
97 5/13/2003	Spellman Group	Amount reflects several different events: general expertise protocol working group dealing with compound ABLC in Saint Louis, MO; general expertise CME lectures; and general expertise consultation re: design of epidemiological observational study.	$7,000 honorarium. Not certain re: travel costs.
6 5/20/2003	American Society for Microbiology	General expertise lecture in New York City.	No honorarium or travel costs. 13
28 6/25/2003	Design Write	General expertise consultation with Johnson & Johnson on antimicrobials and sepsis.	$2,000 honorarium. Not certain re: travel costs.
81 scheduled 7/24/2003	Pfizer	Prepared for general expertise lecture on treatment of infectious disease in oncology patients for symposium that did not occur. Submitted Power Point presentation.	$2,000 honorarium. No travel costs paid.
31 8/5/2003	Enzon	General expertise consultation in Newark, NJ. Participated in meeting to discuss various compounds company might license and their potential utility.	$3,500 honorarium. Not certain re: travel costs.
29 11/9/2003	East PA Society of the American Society for Microbiology	General expertise lecture in Philadelphia, PA.	$250 honorarium. $250 travel costs paid.
78 11/19/2003	NY Society for Medical Mycology	General expertise lecture.	No honorarium. No travel costs paid. 14
58 12/11/2003	Jules Bordet Hospital, Univ. of Brussels	General expertise keynote address to doctors, scientists, fellows, and students.	No honorarium. Travel costs paid. 15

Tab B

B-1

1999

Date	Association	Description of Activity	Travel Costs	
71 1/9/1999	National Committee for Clinical Laboratory Standards (NCCLS)	Served on committee and presented research.	NCCLS paid for travel.	1
7 3/1999	American Society for Microbiology	Presented research and served as co-chair of Conference on Candida and Candidiasis: Biology, Pathogenesis, and Management.	None.	2
62 5/22/1999	Medical Mycology Society of the Americas	Attended meeting and lectures.	None.	7
52 9/1999	Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC)	Co-convener, "New Frontiers in Antifungal Resistance." Research presentation.	None.	4

2000

Date	Association	Description of Activity	Travel Costs	
72 1/8/00	NCCLS	Served on committee. Research presentation.	NCCLS paid for travel.	5
70 3/24/00	Multinational Association for Supported Care in Cancer	Research presentation at International Symposium on Supportive Care in Cancer.	None.	6
April-December 69 4-12/2000	Merck	Chaired Data Review Committee in Philadelphia, PA for caspofungin. Participated in meeting in early 2000 and participated in follow-up meeting 12/07/00 in Philadelphia.	None.	7
63 5/20/00	Medical Mycology Society of the Americas	Attended annual meeting. Served as council member, officer, and president.	None.	8
8 5/22/2000	American Society for Microbiology	Research presentation.	None.	9
50 6/21/2000	International Immunocompromised Host Society	Research presentation.	None.	10

Duty Day - No leave taken [CA. 24.86.F.1; p.1]

B-2

Date	Association	Description of Activity	Travel Costs	
45 9/7/2000	Infectious Disease Society of America	Research presentation in New Orleans, LA.	None.	11
53 9/21/2000	ICAAC	Probably research presentation in Toronto, Canada.	None.	12
99 10/5/2000	University of Illinois	Received Harry F. Dowling Award and Lectureship in Infectious Diseases, non-cash or in range of $250.	None.	13

2001

Date	Association	Description of Activity	Travel Costs	
73 1/5/2001	NCCLS	Committee member for NCCLS. Meeting held in Tampa, FL.	NCCLS paid for travel.	14
9 5/21/2001	American Society for Microbiology	Research presentation.	None.	15
68 5/22/2001	Medical Mycology Society of the Americas	Attended meeting and lectures. Served as Chair of Award Committee.	None.	16
21 10/18/2001	Children's Oncology Group	Lecture, part general public domain and part protocol concepts and ideas, in San Antonio, TX.	None.	17
54 12/15/2001	ICAAC	Presentation in Chicago, IL.	None.	18

2002

Date	Association	Description of Activity	Travel Costs	
74 1/3/2002	NCCLS	Committee member for NCCLS. Meeting held in Tampa, FL.	NCCLS paid for travel.	19
10 1/13/2002-1/17/2002	American Society for Microbiology	Research presentations and general expertise lecture at Conference on Candida and Candidiasis: Biology, Pathogenesis, and Management.	None.	20
89 4/29/2002	Schering-Plough	Chaired Data Review Committee for protocol. Meeting took place in Newark, NJ.	Dr. Walsh paid for travel.	21
37 5/2002	American Society for Clinical Oncology	Symposium chair, Infections in Pediatric Cancer Patients.	ASCO paid for travel.	
11 5/19/2002	American Society for Microbiology	Research presentation in Salt Lake City, Utah.	None.	22

Sponsored Travel from SPB

B-5

Date	Association	Description of Activity	Travel Costs	
65 5/21/2002	Medical Mycology Society of the Americas	Attended lectures and meeting; served as Chair of Award Committee; President-elect of Society.	None.	23
33 5/30/2002	European Society for Pediatric Infectious Diseases	Research presentation in Vilnius, Lithuania. Chaired general symposium; spoke with members of ESPID concerning future international collaborative trials.	ESPID paid for travel.	24
55 9/25/2002	ICAAC	Co-Chair, Joint ICAAC-EORTC Symposium "Infections in Neutropenic Patients." Research presentations (recently abstracted work) in San Diego, CA.	None.	25
46 10/27/2002	Infectious Disease Society of America	Research presentation on recently abstracted work in Chicago, IL.	None.	26
4 12/5/2002	American Society for Hematology	Board meeting in Philadelphia, PA. Trying to set up clinical trial. Co-chair for protocol.	None.	27

2003

Date	Association	Description of Activity	Travel Costs	
75 1/11/2003	NCCLS	Review data for anti-microbial testing and set standards for determining if microorganisms are resistant. Meeting held in Tampa, FL.	NCCLS paid for travel.	28
82 3/29/2003	Pfizer	Assisted with designing protocol, Boston, MA.	Pfizer paid for travel.	29
66 5/20/2003	Medical Mycology Society of the Americas	Attended lectures and meeting. Served as President of MMSA.	None.	30
51 05/27/2003-05/30/2003	International Society for Human and Animal Mycology (ISHAM)	Lecture/research presentation in San Antonio, TX.	None.	31
104 6/11/2003	Vicuron	Investigator's meeting in Henderson, NV. Assisted with designing protocol.	Vicuron paid for travel.	32
23 6/19/2003	Commissioned Officers Association	Physician/Scientist of the Year Award from Surgeon General in Scottsdale, AZ.	None.	33
56 9/13/2003	ICAAC	Research presentations in Chicago, IL. Co-Chair, Focus session: "Pediatric Fungal Infections."	None.	34
44 10/12/2003	IDSA	Research presentation in San Diego, CA.	None.	35

B-4

Date	Association	Description of Activity	Travel Costs
5 12/4/2003	American Society for Hematology	Research presentation in San Diego, CA.	None.

2004

Date	Association	Description of Activity	Travel Costs
43 3/26/2004	Imedex	Research presentation at "Focus 14" meeting in New Orleans, LA.	None.
105 3/31/2004	Vicuron	Discussed anidulafungin pediatric pharmacokinetic data in Philadelphia, PA.	Vicuron paid for travel.
12 5/1/2004	American Society for Pediatric Hematology and Oncology	Three general expertise lectures (included general information and recent advances) in San Francisco, CA. Event was partially a research presentation, although there was some public domain information in the lecture.	None.
20 8/13/2004	Children's Hospital of Philadelphia	Traveled to CHOP, located in Philadelphia, PA, for emergency care and bedside consultation of 5-year boy with invasive fungal infection.	Dr. Walsh paid for travel.

We are setting forth the above information in order to assist the inquiry, and it is not our intention to characterize activities definitively as "outside activities," "official duty activities," or otherwise, particularly in view of the limited information and uncertain recollections underlying the reconstruction of many of the events. Rather, the tables should be viewed simply as a practical means to organize a large amount of complex information and as an effort to cooperate with the inquiry as fully as possible. Dr. Walsh will be happy to discuss any particular events in further detail if that would be helpful.

40
+ 1 Sponsored Travel HHS 348 5/2002
41

latimes.com Los Angeles Times

Tab 49

http://www.latimes.com/news/printedition/front/la-na-nih10sep10,1,42849.story?coll=la-headlines-frontpage&track=crosspromo

NIH Audit Criticizes Scientist's Dealings

A researcher received more than $100,000 from drug firms. The agency calls it 'serious misconduct' but has issued no penalty.

By David Willman
Times Staff Writer

September 10, 2006

WASHINGTON — A senior researcher at the National Institutes of Health engaged in "serious misconduct" by entering into dozens of unauthorized private arrangements with drug companies and failing to report annually the outside income, totaling more than $100,000, a confidential internal review by the agency has found.

Officials at the NIH concluded late last year that the actions of Dr. Thomas J. Walsh, who has helped lead major clinical trials involving cancer patients, might result in dismissal from federal government service. No disciplinary action has been taken.

The internal review, conducted by lawyers and other ethics specialists within the office of the NIH director, found that from 1999 to 2004, Walsh received fees totaling $100,970 from pharmaceutical and biotechnology companies. He accepted fees from 25 companies and has led government-sponsored research involving some of those companies' drugs.

"Dr. Walsh has engaged in serious misconduct, in violation of the Department's Standards of Conduct Regulations … and federal law and regulation," the review concluded.

The previously unreported findings shed light on the depth of conflict-of-interest problems that have persisted at the NIH — the government's preeminent agency for medical research on humans. The NIH's handling of disciplinary decisions related to Walsh and other senior scientists is expected to be a focus of a congressional hearing scheduled for Thursday.

In written comments to NIH ethics officials, private attorneys for Walsh said that the agency's rules were complicated and that his motives were beyond reproach. NIH officials said the rules were well known and should have been followed.

"Dr. Walsh fails to acknowledge that the reason for the 'complex set of rules' governing NIH staff in regards to real or potential conflicts of interest is to prevent the integrity of the agency and its science from being called into question," the summary said. "His assertions that his reputation is sufficient to dismiss any questions about his impartiality cannot be the standard that he or the agency use in deciding to adhere to well-publicized rules."

The summary, dated in December, also said that Walsh's "conduct continued over time and involved at least 38 separate instances where he chose not to follow agency procedures. He actively chose not to adhere to policies because it was inconvenient or time-consuming; he knew it was likely his participation [with the drug companies] would have been disapproved. His actions reflected negatively upon the agency."

The Los Angeles Times obtained copies of the internal findings and conclusions last week. Based on interviews

and documents gathered earlier, the newspaper reported in July that Walsh had appeared alongside company representatives at public and private meetings held by the U.S. Food and Drug Administration and that he received ;es from Merck & Co. and Pfizer Inc., with whom he has collaborated in his government work. Clinical trials he nelped lead influenced FDA approvals of three antifungal drugs.

Walsh's appearances at the FDA meetings — with representatives of Merck, Pfizer Inc., and Fujisawa USA Inc. — are the subject of a newly opened inquiry by the NIH director's Office of Management Assessment, according to people familiar with the matter.

U.S. conflict-of-interest law generally prohibits a federal employee from representing an outside party before a government agency, regardless of whether the employee accepts payment for the appearance.

Another NIH review, which ended three months ago, "did not identify issues of concern with the design or methodology" used in two clinical trials overseen by Walsh. When results of those trials were published, in 1999 and 2004, other research physicians had questioned in letters to the New England Journal of Medicine whether cancer patients with suspected fungal infections were given "control" drugs at dosages that were strong enough to be effective.

Reached briefly by phone on Friday, Walsh referred questions to NIH press aides. He earlier declined to answer questions from The Times regarding details of his arrangements with several companies, but also said that he had never served as a representative or advocate for any pharmaceutical company.

Members of the House Energy and Commerce Committee's investigative subcommittee are expected to question officials at the hearing this week about their handling of ethics matters, including the cases of Walsh and another senior NIH researcher, Dr. P. Trey Sunderland III.

Sunderland, who has specialized in researching Alzheimer's disease, accepted hundreds of thousands of dollars in drug-company fees — including about $612,000 from Pfizer — without obtaining required advance approval. In June, Sunderland asserted his 5th Amendment right against self-incrimination while declining to answer questions before the congressional subcommittee.

Neither Sunderland nor Walsh has been publicly disciplined, and each maintains his senior government position. Directly or through their lawyers, Sunderland and Walsh have said that they aimed to advance research that benefits patients. Both have worked for more than 20 years at the NIH as members of the U.S. Public Health Service Commissioned Corps, a uniformed branch of the service that is led by the surgeon general.

Officials at the NIH have said recently that they lack authority to discipline members of the corps — several of whose members have drawn scrutiny related to conflict of interest. The summary of the NIH internal report on Walsh noted, implicitly, his status within the corps: "It has been determined by the Office of Human Resources [at NIH] that if he were a civilian employee, his actions would lead to a recommendation for his proposed removal."

The Bush administration official that oversees the surgeon general and the corps, Assistant Secretary for Health John O. Agwunobi, said through an aide that he could not discuss details of the pending cases because of privacy concerns.

"The commissioned corps is very concerned about these allegations and will take appropriate action should wrongdoing be found," said Christina Pearson, a Health and Human Services Department spokeswoman. "However, our review must be coordinated with other reviews already in process."

Walsh was referred to a corps administrator nine months ago "for action" by a deputy NIH director, Dr. Raynard S. Kington, and by Dr. John Niederhuber, the then-acting director of the National Cancer Institute.

Walsh, 54, a medical graduate of Johns Hopkins University, arrived at the National Cancer Institute in 1986 and now heads a pediatric research and treatment unit. Walsh is well recognized in his field and has won government honors. Along the way, he collaborated with drug companies in his official role and, privately, as a paid advisor or speaker.

The industry compensation received by Walsh and Sunderland came to light because of a series of events over the past three years: After The Times reported in December 2003 that ranking NIH officials had received hundreds of company consulting payments or grants of stock or stock options, the House committee asked the agency to disclose all such transactions over a five-year period. When the NIH was slow to respond to the committee's broad request, lawmakers elicited information from 21 drug companies.

The companies' responses identified scores of NIH researchers who were not previously known to have received payments. One company, Merck, listed fees to Walsh that had not been reported to the NIH. Meanwhile, NIH Director Elias A. Zerhouni also was urging employees to report any previously undisclosed outside arrangements.

For Walsh, the first questions from NIH ethics officials centered on his arrangements with Merck. The NIH's internal review found that, at the same time Walsh accepted $3,000 in fees for attending separate Merck-sponsored events in 2000 and 2001, he was leading a formal "cooperative research and development agreement" between Merck and the National Cancer Institute.

Months before his case was referred for possible disciplinary action, the NIH ethics review panel concluded privately that Walsh should not have engaged in the simultaneous government and paid arrangements with Merck.

"The review panel finds that the scientific subject matter of the activities overlap directly with Dr. Walsh's research at NIH," the agency's chief ethics lawyer, Holli Beckerman Jaffe, wrote in June 2005.

"In addition, while Dr. Walsh was a paid speaker for Merck on two occasions, he was collaborating with Merck, and one of its competitors, in his official capacity," Jaffe said. "Accordingly, the panel finds his unapproved outside activities with Merck to be highly problematic."

A subsequent summary of the NIH's internal review added, "this situation is one in which a reasonable person could question Dr. Walsh's impartiality."

The new documents show that when Merck paid Walsh a $2,000 fee in September 2000, it was to discuss the company's new antifungal drug, Cancidas, at a company-sponsored meeting with medical-opinion leaders in Montreal.

Four months later, Merck identified Walsh as a consultant at an FDA advisory committee meeting at which the company made its case for the drug's approval.

Walsh told the FDA committee on Jan. 10, 2001, that, based on his and his government staff's review of data from a Merck study, Cancidas effectively combats a fungal infection called aspergillus. The committee unanimously recommended approval.

Later that month, FDA staff approved Merck's application to market Cancidas. Through 2005, the drug had generated $859 million in U.S. sales.

And, in the months leading up to an October 2001 FDA advisory committee meeting on Pfizer's antifungal drug, Walsh received $12,000 in fees for conferring three times with company representatives, the internal NIH documents show. Walsh has said he did not accept company payment for appearing at any FDA meeting.

Walsh's lawyers have said in letters to NIH officials that his government decisions were not swayed by the compensation from Merck or any other company. They also have stressed Walsh's diligence throughout his career.

Jaffe, the NIH ethics lawyer, told officials in a memo that if Walsh had sought permission to accept compensation from Merck, "it is highly unlikely that Dr. Walsh would have been granted approval."

*

david.willman@latimes.com

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PARTNERS: ktla tv Hoy

Tab 50

September 10, 2006

MEMORANDUM:

TO: OLPA, NIH

FROM: Executive Officer, NIMH, NIH

RE: Request from House Energy and Commerce Committee Staff

On behalf of the NIMH, I have previously provided both detailed responses and a large number of documents to the House Energy and Commerce Committee in reply to Mr. Slobodin's e-mail request of June 23, 2006 (See below). I have also provided additional information regarding what I learned in researching the answers to Mr. Slobodin's questions during two conference calls with both Mr. Slobodin and Mr. Nelson.

In response to Mr. Slobodin's recent request for a written summary of the information provided to him during these conference calls, as well as any new information collected on the issues discussed, I am providing the following:

Cryonix-Thermo Contract:
Institute records clearly show that, in May 2005, following some damage to one of the six freezers he used for the storage of tissue samples, Dr. Sunderland requested a quote from a firm called Cryonix (now Thermo) for a proposed contract to move his five functioning freezers (with tissue samples) to Cryonix's facility in Rockville, Maryland and to eventually (after 5 to 9 months, as stated in the contract) move these same freezers to Long Island, New York. On June 7, 2005, a contract was signed with Cryonix for the purposes stated, in the amount of $22,923. My investigation into this issue convinces me that the local administrative officer did not understand the import of the proposed shipment of the freezers to New York, and that the Scientific Director's office (which knew of the damaged freezer) was unaware that the proposed contract with Cryonix involved the shipment of freezers beyond Rockville, Maryland. It is noted that the freezers were, in fact, never shipped to New York, and that Dr. Sunderland no longer has access to these freezers.

Boxes Sent to New York:
Records show that Dr. Sunderland made two shipments (October 31, 2005 and November 3, 2005) of 60 boxes to himself at North Shore Hospital in New York. Shipping requests associated with these shipments appear to have been approved by Dr. David Rubinow, the Clinical Director of the NIMH, in lieu of the local administrative officer. Contacted at his current job, at a university in North Carolina, Dr. Rubinow could not at all recall signing these documents, and could only guess as to why he may have signed them. Two senior NIMH administrative staff members were sent to North Shore Hospital on July 18, 2006 to examine the boxes sent there. They report finding four categories of items: 1) Dr. Sunderland's personal effects, including photos, awards, and various memorabilia; 2) Reprints of various research papers he had published; 3) Books; and 4) Research related materials (about 30 boxes), many of which seem to relate to old studies, some conducted as far back as the early 1980's. Some of the latter materials contained patient specific information, raising questions about possible violations of Human Research Subject regulations and also possibly the Privacy Act. At my request, all 60 of these boxes are being shipped back to the NIMH.

Boxes Shipped to Cedar-Sinai Hospital in Los Angeles:

Records show that, on September 28, 2005, Dr. Rubinow signed off on the shipment of 23 boxes of materials to Dr. Robert Cohen (who retired from his position as a NIMH scientist in the Geriatric Psychiatry Branch in August 2005). These boxes were sent to Dr. Cohen at his new position at Cedar-Sinai Hospital in Los Angeles. Reached by phone, Dr. Cohen assured me that the materials he received included only books, reprints, and personal memorabilia. He has been asked to sign a written statement to that effect.

Records also show that, on October 28, 2005, Dr. Sunderland shipped four boxes of computer equipment (2 personal computers and 2 monitors) to Dr. Cohen in Los Angeles. This equipment was sent to Dr. Cohen as part of an equipment loan approved by the Office of the Scientific Director. At my request, Dr. Cohen has returned this equipment. It is noted that an inventory of the equipment assigned to Dr. Sunderland's branch showed that no equipment was missing.

Tissue Sample Inventory:
My staff and I have not been able to provide the requested inventory of Dr. Sunderland's stored tissue samples for specific time periods. Dr. Sunderland has indicated that only his former employee, Ms. Karen Putnam, has the ability to locate and access the management data required to provide this information and, with this in mind, he requested that Ms. Putnam's previously terminated access to NIH's computer systems be restored. My attempts to secure the information required without Ms. Putnam have been unsuccessful to date, and as a result, I have asked the Department's Office of General Counsel to enter into negotiations with Ms. Putnam's attorney to seek her assistance. These negotiations are ongoing.

I would note that, in trying to respond to the Committee's requests, I examined a password protected Geriatric Psychiatry Branch database, but found that, while this database provided specific information on tissue samples obtained from individual patients, it failed to provide the information required to explain the fate of each and every portion of the samples obtained.

Committee staff has already been provided with a series of emails I obtained from a former temporary staff member of Dr. Sunderland's branch. Based on these emails as well as telephone discussions with this individual, I feel certain that a database with an accurate accounting of the Geriatric Psychiatry Branch's tissue samples does exist, and that Ms. Putnam can access it for us.

Status of Geriatric Psychiatry Branch (GPB):
The Director, NIMH, Dr. Thomas Insel, began dismantling the GPB, headed by Dr. Sunderland, shortly after Dr. Sunderland announced his proposed retirement in December 2004. At the moment, Dr. Sunderland is essentially the only employee in this Branch, which is in the process of being organizationally abolished. On August 3, 2006, Dr. Insel assigned Dr. Sunderland to new duties, using his scientific expertise to evaluate the Institute's research grant portfolio in aging related research.

CSF Tissue Samples Sent to Albert Einstein College of Medicine in the Bronx, New York:
Records show that a temporary staffer working for Dr. Sunderland sent two shipments of cerebrospinal fluid (CSF) to Dr. Peter Davies at the Albert Einstein College of Medicine on February 9, 2005 and April 5, 2005. These tissue samples were returned to the Institute, apparently untouched.

Tissue Samples Sent to Pfizer:
Representatives of Pfizer have returned to the NIH a large number of unused tissue samples that the company had received from Dr. Sunderland in 2003.

William T. Fitzsimmons

From: Slobodin, Alan [mailto:Alan.Slobodin@mail.house.gov]
Sent: Friday, June 23, 2006 4:14 PM
To: 'marc.smolonsky@nih.hhs.gov'
Cc: Nelson, David
Subject: Human Tissue Samples

On behalf of the Committee and the Chairman, please forward the following:

1. All records relating to Dr. Sunderland's travel for 2005 and 2006, including the September 2005 trip to Geneva and the December 2005 trip to Hawaii.

2. All records relating to Dr. Sunderland's outside activities for 2005 and 2006.

3. Did Dr. Sunderland ever seek prior approval for activities with the Lundbeck Institute?

4. All records relating to NIMH contracts with Cryonix-Thermo or under whatever name they are operating under. How much is NIMH paying in 2006 for storage generally and for freezers specifically? How many freezers? How many freezers are dedicated for Dr. Sunderland's samples? Same questions for 2005.

5. All records relating to any shipments from NIMH of spinal fluid samples and other tissue samples sent by or on behalf of Dr. Sunderland or his branch to Cryonix-Thermo or some other name since June 2004.

6. Copies of audiotapes or audios for Dr. Sunderland's annual meetings with his study participants, including the one held in December 2004. These meetings were usually held in Natcher auditorium.

7. Who was involved in boxing up Dr. Sunderland's materials? Did the boxes include computers, laptops, and equipment? Where are the boxes?

8. Dr. Sunderland's leave records for 2004, 2005, and 2006.

9. Why does NIH allow Dr. Sunderland to retain the title, "Chief, Geriatric Psychiatry Branch," even though Dr. Insel maintained in yesterday's phone call that this Branch has reassigned or detailed all of the NIH employees from this Branch, except Dr. Sunderland, and this Branch has no ongoing clinical trials?

10. When did NIH deny Dr. Sunderland his bonus and/or physician comparability pay? Why? Please provide records relating to that action.

11. How many samples did Dr. Sunderland have stored at NIH in 2003, in 2004, in 2005, and in 2006?

12. Did Dr. Sunderland send any samples from NIMH to a non-NIH recipient in 2004? in 2005? in 2006?

13. All records relating to the OMA investigation (or referral to the OIG) of Dr. Sunderland and his possible activities with the Litwin-Zucker Center at Long Island Jewish Hospital.

14. Any records relating to any intra-NIH websites (www.silk.nih.gov) that were accessible to Dr. Sunderland and Karen Putnam.

15. Any records relating to Maryland relocation work orders for Dr. Sunderland.

Thanks.

Natio ancer Institute
Walsh Conditional Gifts
(in whole dollars)

Div	Lab/Branch	PI	Gift #	Donor	FY 1993 Collections	FY 1998 Collections	FY 1999 Collections	FY 2000 Collections	FY 2001 Collections	TOTAL
CCR	Pediatric Oncology Branch	Walsh	CG#019	Bristol Myers Squibb	38,167					**38,167**
CCR	Pediatric Oncology Branch	Walsh	CG#020	SmithKline Beecham	16,357		811			**17,168**
CCR	Pediatric Oncology Branch	Walsh	CG#085	Fujisawa USA, Inc.		40,000				**40,000**
CCR	Pediatric Oncology Branch	Walsh	CG#095	Aronex Pharmaceuticals, Inc.			40,000	30,000		**70,000**
CCR	Pediatric Oncology Branch	Walsh	CG#109	Ortho Biotech Critical Care/Surgery					200,000	**200,000**
				TOTAL	**54,524**	**40,000**	**40,811**	**30,000**	**200,000**	**365,335**

Tab 51

Quast, Patricia (NIH/OD) [E]

[redacted]

Tab 52

From: Fitzsimmons, William (NIH/NIMH)
Sent: Tuesday, November 23, 2004 4:44 PM
To: Quast, Patricia (NIH/OD)
Subject: FW: from Jamie

Oh, Patty! Are you in the middle of this part of it???

bill

-----Original Message-----
From: Diepold, Kenneth (NIH/OD)
Sent: Tuesday, November 23, 2004 3:03 PM
To: Fitzsimmons, William (NIH/NIMH)
Subject: RE: from Jamie

They are in Bldg 1.

I have advised Trey NOT to look for a Jan 1 retirement date.

My impression is they are going to hold up his retirement. For how long I do not know.

Dr. Wyatt is my point of contact in Bldg 1 on this matter.

-----Original Message-----
From: Fitzsimmons, William (NIH/NIMH)
Sent: Tuesday, November 23, 2004 12:44 PM
To: Diepold, Kenneth (NIH/OD); Fitzsimmons, William (NIH/NIMH)
Subject: FW: from Jamie

Ken,

Are Trey's retirement papers still moving forward?

bill
==========
Marc Stern
Contractor
301-435-7841
sternma@od.nih.gov
-----Original Message-----
From: Jamie.Talan@newsday.com [mailto:Jamie.Talan@newsday.com]
Sent: Tuesday, November 23, 2004 11:30 AM
To: Stern, Marc (NIH/OD)
Subject: from Jamie

I request an interview (by phone) with Dr. Raynard Kington, deputy director of NIH, to discuss conflict of interest problems at the federal health agency. Also, I want to talk about the Monday meeting that I read about in Science. **I also heard that Trey Sunderland is set to resign, and I would like to talk to you about this as well. Thanks. Jamie Talan, Newsday**

MR. WHITFIELD. The Chairman of the full committee, it is my understanding, is on his way and I am sure he will want to make an opening statement when he arrives, but in the meantime, I want to go and introduce our panel of witnesses today and I want to thank you for coming, and you can tell by the opening statements the concerns that we have and we do look forward to your testimony and answers to our questions.

The first witness today is the Honorable John Agwunobi, who is the Assistant Secretary of Health at the Department of Health and Human Services. We also have Dr. Raynard Kington, who is the Deputy Director of the National Institutes of Health. We have Dr. John Niederhuber, who is the Director of the National Cancer Institute. We have Dr. Thomas Insel, who is the Director of the National Institute of Mental Health, and then we have Mr. William Fitzsimmons, who is the Executive Officer at the National Institute of Mental Health at the National Institutes of Health. We welcome all of you. Thank you for being here.

As you know, this is an Oversight and Investigations Subcommittee hearing and we always take our testimony under oath, and I assume you do not have any objection to testifying under oath. And I would also say you are always entitled to legal counsel. I am assuming none of you have legal counsel here today, but if you do--do any of you have legal counsel? Okay. Well, if you would stand raise your right hand I will swear you in.

[Witnesses sworn]

MR. WHITFIELD. Thank you very much. At this time all of you are under oath, and what we are going to do, Mr. Agwunobi, we are going to allow you to give your testimony first. Here comes the Chairman now. So what we will do, before you begin your testimony, we will recognize Chairman Barton for any opening statement that he may have at this time.

CHAIRMAN BARTON. Thank you, Chairman Whitfield. I was downtown at a luncheon for the Boy Scouts and former Chairman Tauzin was the master of ceremonies, so it took a while. I apologize to our witnesses.

I think this is a very important oversight hearing as we begin to move towards reauthorization of the National Institutes of Health. We released a bill yesterday and we are getting great reviews on it, and hopefully we have a legislative hearing next week and go to markup very soon.

At our last NIH oversight hearing in June, Dr. Thomas Insel, the Director of the National Institute of Mental Health, told us that when it comes to ethics, NIH has to be better than clean. In his words, it has to be Camelot. Unfortunately, one of the scientists at his institute, a multiple and serious violator of the ethics rules in the eyes of the NIH, Dr. Trey Sunderland, still comes to work at NIH every day and collects his salary. Until recently, Dr. Sunderland was going on taxpayer-funded trips to Hawaii and other locales, was making thousands of dollars in outside income, all with the blessings of Dr. Insel and his managers. Although he proposed Dr. Sunderland's termination to the Commissioned Corps in November of 2005, Dr. Insel also recommended

a $15,000 retention bonus for Dr. Sunderland in January of 2006. That just doesn't make sense. Dr. Sunderland continues to have access to confidential data. Dr. Sunderland continues to have access to NIH staff and property. We now know that Dr. Sunderland has shipped his personal effects to his future employer at taxpayer expense. Without any waiver or approval from NIH, he took tissue samples and patient-related records and used NIH staff to help box it and send it to the future employer in New York State.

Everybody here remembers Dr. Sunderland's visit when he invoked his Fifth Amendment right under the Constitution against self-incrimination. That is his right, and we honor it, but we believe that he is the first scientist to ever take the Fifth Amendment rather than tell Congress what he has been doing. He refused to answer questions about what he did with spinal fluid samples from his patients who participated in a taxpayer-funded study. That seems to have made relatively little difference to Dr. Insel. Before the committee staff raised questions, did Dr. Insel or other supervisors treat Dr. Sunderland differently after the hearing? Apparently not. Dr. Sunderland is also a Commissioned Corps medical officer. Did the Corps do anything to uphold its high ethical standards? There is little evidence to suggest that they have done so.

Now we have another case of an NIH scientist, Dr. Thomas Walsh of the National Cancer Institute, whom NIH found to be a serial violator of ethics rules. Following the same road as Dr. Insel of the NIMH, the director of the NCI, Dr. John Niederhuber, has proposed Dr. Walsh's termination, but he has done little else that would reflect the changed circumstance. The Corps likewise so far has failed to act at the beginning of this year when it had a chance to do so. That is not Camelot. It is not even close.

This is really an ethical Potemkin village where a hollow system appears to provide the illusion of integrity, but transgressors never leave. Of the over 100 individuals who were identified by the NIH itself several years ago as violating NIH's policies, not one of them, according to information I have, has been terminated, not one. The vast majority have had nothing worse happen to them than get a reprimand and continue in their current jobs. Some have voluntarily left the agency and sought employment in the private sector. Only two are still under serious investigation so far as we can tell. The NIH has changed its rules, and that is a good thing, but they don't appear to really be doing anything to enforce the old rules against their most serious transgressors. So while NIH leaders like Dr. Insel acknowledge the ethics rules to the subcommittee, apparently behind closed doors at NIH there is a very different message that has been communicated, one that appears to look past or even encourage these transgressions. The shenanigans involving

Dr. Sunderland using NIH resources and NIH staff to further his post-NIH employment do not occur in a vacuum. They occur in an environment of support where he felt comfortable enough to operate openly. Dr. Insel did finally take some steps to restrict Dr. Sunderland but only after the committee staff raised questions and concerns.

I think it is time to tear down the illusions of ethics and build up a real information and management structure that protects the integrity of NIH and the Commissioned Corps. It may also be time to revisit the question of whether we need a uniformed Public Health Service at all. The GAO in 1996 reported that the functions of the Commissioned Corps are essentially civilian and could be performed efficiently and well by doctors and scientists without uniforms at much less cost to the taxpayers.

This is a time for serious rethinking of our ethics and management structure at the NIH. There should be and must be evidence of real enforcement. I think it is absurd that taxpayers have been footing the bill for nearly 2 years for Dr. Sunderland, even though he wants to leave and the NIH wants him out. We are going to reauthorize hopefully the NIH and help make it a stronger scientific agency in the very near future. It really does deliver for the American people, but NIH needs to regain the public trust. This is only going to happen if there is meaningful enforcement. Sensible and decisive leadership on such enforcement is a much-needed first step and I hope that we can see the seeds of that at this hearing.

With that, Mr. Chairman, I yield back, and thank you for your leadership.

[The prepared statement of Hon. Joe Barton follows:]

PREPARED STATEMENT OF THE HON. JOE BARTON, CHAIRMAN, COMMITTEE ON ENERGY AND COMMERCE

Thank you, Mr. Chairman, for holding this important oversight hearing as this Committee moves on NIH reauthorization legislation for the first time in over a decade.

At our last NIH oversight hearing in June, Dr. Thomas Insel, the Director of the National Institute of Mental Health, told us that when it comes to ethics, NIH has to be better than clean. In Dr. Insel's words, "It has to be Camelot."

Unfortunately, one of the scientists at his institute, a multiple and serious violator of the ethics rules in the eyes of the NIH, Dr. Trey Sunderland, still comes to work at NIH and collects his salary. Until recently, Dr. Sunderland was going on taxpayer-funded trips to Hawaii and other locales, and making thousands of dollars in outside income – all with the blessing of Dr. Insel and his managers. Although he proposed Dr. Sunderland's termination to the Commissioned Corps in November 2005, Dr. Insel also recommended a $15,000 retention bonus for Dr. Sunderland in January 2006. Dr. Sunderland continues to have access to confidential data. Dr. Sunderland continues to have access to NIH staff and property. We now know that Dr. Sunderland shipped his personal effects to his future employer at taxpayer expense. Without any waiver or approval from NIH, he took

tissue samples and patient-related records, and used NIH staff to help box it and send it to his future employer in New York.

Everybody here remembers Dr. Sunderland's visit, when he invoked his Fifth Amendment right under the Constitution against self-incrimination before this Subcommittee. This is his right and we honor it, but we believe he is the first NIH scientist to ever take the Fifth rather than tell Congress what he's been doing. He refused to answer questions about what he did with spinal fluid samples from his patients who participated in a taxpayer-funded study. That seems to have made relatively little difference to Dr. Insel. Before the Committee staff raised questions, did Dr. Insel or other supervisors treat Dr. Sunderland any differently after the hearing? Apparently not.

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This isn't Camelot, not even close. This is really an ethical Potemkin village where –a hollow system provides the illusion of integrity, but transgressors never leave. The Corps and the NIH present an elaborate structure of rules and regulations on ethical standards which, when tested by reality, just doesn't seem to work.

Even worse, while NIH leaders like Dr. Insel acknowledge the ethics rules to the Subcommittee, behind closed doors at NIH a different message seems to be informally communicated -- one that appears to look past or even encourage these transgressions. The shenanigans involving Dr. Sunderland using NIH resources and NIH staff to further his post-NIH employment did not occur in a vacuum. They occurred in an environment of support, where he felt comfortable to operate openly. Dr. Insel did finally take some steps to restrict Dr. Sunderland, but only after the Committee staff raised questions and concerns.

Mr. Chairman, it's time to tear down the illusion of ethics and build up a real information and management structure that protects the integrity of NIH and the Commissioned Corps. It may also be time to revisit the question of whether we need a uniformed public health service at all. The GAO in 1996 reported that the functions of the Commissioned Corps are essentially civilian and could be performed efficiently and well by doctors and scientists without uniforms, at less cost to the taxpayers.

This is a serious time for rethinking ethics and management. There must be evidence of real enforcement. It is absurd that taxpayers have been footing the bill for nearly two years for Dr. Sunderland, even though he wants to leave and the NIH wants him out.

We are going to reauthorize the NIH and help make it a stronger scientific agency that delivers for the American people. But NIH needs the public trust to make it happen. That is only going to happen if there is meaningful enforcement. Sensible and decisive leadership on such enforcement is a needed first step.

MR. WHITFIELD. Thank you, Chairman Barton. At this time we will recognize Mr. Agwunobi for his opening statement.

TESTIMONY OF THE HONORABLE JOHN AGWUNOBI, ASSISTANT SECRETARY FOR HEALTH, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; DR.

RAYNARD KINGTON, DEPUTY DIRECTOR, NATIONAL INSTITUTES OF HEALTH, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; DR. JOHN NIEDERHUBER, DIRECTOR, NATIONAL CANCER INSTITUTE, NATIONAL INSTITUTES OF HEALTH, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; DR. THOMAS R. INSEL, DIRECTOR, NATIONAL INSTITUTE OF MENTAL HEALTH, NATIONAL INSTITUTES OF HEALTH, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; AND WILLIAM FITZSIMMONS, EXECUTIVE OFFICER, NATIONAL INSTITUTE OF MENTAL HEALTH, NATIONAL INSTITUTES OF HEALTH, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

DR. AGWUNOBI. Thank you, Chairman Whitfield, Chairman Barton, and members of the subcommittee. Thank you for inviting me to testify at today's hearing on management and disciplinary procedures of the Public Health Service Commissioned Corps.

My name is John Agwunobi and I am the Assistant Secretary for Health with the U.S. Department of Health and Human Services. As the Assistant Secretary for health, I serve as the Secretary's primary advisor on matters involving the Nation's public health and I oversee the U.S. Public Health Service Commissioned Corps.

The Corps is one of seven uniformed services of the United States. It is composed of more than 6,000 active-duty health professionals who serve at HHS and at other Federal agencies including the Bureau of Prisons, the Department of Homeland Security, the U.S. Coast Guard, and a number of others. The origins of the Corps may be traced back to the passage of an act in 1798 that provided for the care and relief of sick and injured merchant seaman. In the 1870s, the loose network of locally controlled hospitals was subsequently reorganized into the Marine Hospital Service. This name was changed in 1912 to the Public Health Service because it was noted that this force of dedicated individuals were taking on broader and broader responsibilities in pursuit of the public health of our Nation.

As America's uniformed service of public health professionals, the Corps achieves its mission to protect, promote, and advance the health and safety of the Nation through rapid and effective response to the public health needs, leadership and excellence in public health practice, and the advancement of public health science. Now, the Corps today has a specialized career system. It is designed to attract, develop, and retain health professionals who may be assigned to Federal, State, or local agencies and indeed to some international agencies and organizations.

The Corps has grown into one of the most significant public health assets in the world. In doing so, a tradition has evolved of a long and successful partnership with agencies where officers are employed. Corps members have served honorably and have been at the forefront of many of the advances in public health over this Nation's history. Indeed, the Commissioned Corps was there at the beginning, the inception of the National Institutes of Health. Corps officers are expected to uphold the highest standards of ethical behavior both in their official roles and in their personal conduct. The Corps takes seriously any allegations of illegal infractions or other wrongdoings that bring discredit and dishonor to the Corps and to the Department of Health and Human Services.

Now, I have been invited to discuss with the subcommittee the subject of disciplinary and administrative actions that may be taken against Corps officers and the requirement and procedures applicable to the termination of an officer's commission for misconduct. Misconduct by a Corps officer includes violation of any HHS standards of conduct regulations or of any other Federal regulation, law, or official government policy. The Corps has a variety of administrative and disciplinary actions that can be initiated to address officers who engage in misconduct. The decision as to which type of action to be applied is based upon the nature of infraction and the status of an officer. Generally, lesser offenses may be dealt with by the officer's line supervisor in the agency of employment through letters of reproval or reprimand. When a potential offense is serious enough for a disciplinary action that affects the officer's pay, rank, or employment, the matter is referred to the Corps for one of several possible board review processes. These included temporary promotion review boards, involuntary retirement boards, and boards of inquiry. A board of inquiry may be convened when an officer is charged by his or her supervisor with conduct constituting grounds for disciplinary action. Upon a finding of misconduct, a board may recommend the following action: termination of commission, which may include loss of retirement benefits and a reduction in rank or grade. All testimony before the board is given under oath or affirmation, and when the board has completed its deliberations, its recommendations are forwarded to me, the ASH, for final decision-making.

I will just conclude by saying that, sir, as you are aware, Secretary Leavitt is currently directing a major transformation of the Commissioned Corps. It is designed in part to allow us an opportunity to examine all of our policies and administrative systems and to ensure that they are robust, rigorous, and efficient in their implementation. I fully understand the gravity of the issues being explored by the subcommittee and I want to thank you again for inviting me to testify. I am ready to

answer questions. I stand at your convenience to answer any questions you might have.

[The prepared statement of Hon. John Agwunobi follows:]

PREPARED STATEMENT OF THE HON. JOHN AGWUNOBI, ASSISTANT SECRETARY FOR HEALTH, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Introduction

Chairman Whitfield and Members of the Subcommittee, thank you for inviting me to testify at today's hearing on management and disciplinary procedures of the Public Health Service Commissioned Corps.

My name is John Agwunobi, and I am the Assistant Secretary for Health with the U.S. Department of Health and Human Services (HHS). As the Assistant Secretary for Health (ASH), I serve as the Secretary's primary advisor on matters involving the nation's public health and oversee the U.S. Public Health Service (PHS) for the Secretary. The PHS is comprised of agency divisions of HHS and the Commissioned Corps, a uniformed service of more than 6,000 active duty health professionals who serve at HHS and other federal agencies, including the Bureau of Prisons, the Department of Homeland Security, and the U.S. Coast Guard. The mission of the Commissioned Corps is: "Protect, promote, and advance the health and safety of the Nation." I am the highest ranking member of the Commissioned Corps; I am a Regular Corps officer and hold the rank of Admiral.

The Public Health Service

The origins of the Public Health Service (PHS), one of the seven uniformed services of the United States, may be traced to the passage of an act in 1798 that provided for the care and relief of sick and injured merchant seamen. In the 1870s, the loose network of locally controlled hospitals was reorganized into a centrally controlled Marine Hospital Service and the position of Supervising Surgeon, later becoming the Surgeon General of the United States, was created to administer the Service. The first Supervising Surgeon, Dr. John Maynard Woodworth, adopted a military model for his medical staff and created a cadre of mobile, career service physicians who could be assigned to areas of need. The uniformed services component of the Marine Hospital Service was formalized as the Commissioned Corps by legislation enacted by Congress in 1889. At first open only to physicians, over the course of the twentieth century, the Corps expanded to include dentists, dieticians, engineers, environmental health officers, health service officers, nurses, pharmacists, scientists, therapists, and veterinarians.

The scope of activities of the Marine Hospital Service also began to expand well beyond the care of merchant seamen in the closing decades of the nineteenth century, beginning with the control of infectious disease. As immigration increased dramatically in the late nineteenth century, the Marine Hospital Service was assigned the responsibility for the medical inspection of arriving immigrants at sites such as Ellis Island in New York. Because of the broadening responsibilities of the Service, its name was changed in 1912 to the Public Health Service. The Service continued to expand its public health activities as the Nation entered the twentieth century, with the Commissioned Corps leading the way. As the century progressed, PHS Commissioned Corps officers served their country by controlling the spread of contagious diseases such as yellow fever and smallpox (eventually assisting in the eradication of this disease from the world), conducting important biomedical research, regulating the food and drug supply, providing health care to underserved populations, supplying medical assistance in the aftermath of disasters, and in numerous other ways.

As America's uniformed service of public health professionals, the Commissioned Corps achieves its mission to, "Protect, promote, and advance the health and safety of the Nation," through rapid and effective response to public health needs, leadership and excellence in public health practices, and the advancement of public health science. The Corps today is a specialized career system designed to attract, develop, and retain health professionals who may be assigned to Federal, State or local agencies or international organizations. The PHS, with the Commissioned Corps at its center, has grown from a small collection of marine hospitals to one of the most significant public health programs in the world. In doing so, the tradition of a long and successful partnership has evolved with the agencies where officers are employed. Corps members have served honorably and been at the forefront of many of the advances in public health over this nation's history.

Disciplinary and Administrative Actions

I have been invited to discuss with the Subcommittee the subject of disciplinary and administrative actions that may be taken against Corps officers; and the requirements and procedures applicable to the termination of an officer's commission for misconduct.

Corps officers are expected to uphold the highest standards of ethical behavior, both in their official roles and in their personal conduct. Commissioned Corps officers are on duty 24 hours a day, seven days a week, similar to our sister Services. The Corps takes seriously allegations of illegal infractions or other wrongdoing that brings discredit and dishonor to the Corps and the Department. We believe the Corps should strive for excellence of character and excellence in performance of duty, and we expect nothing less. When a determination is made that an officer has engaged in misconduct, he/she is subject to disciplinary action.

As a preliminary matter, I note that Commissioned Officers in the PHS and the National Oceanic and Atmospheric Administration (NOAA) are not generally under the purview of the Uniformed Code of Military Justice (UCMJ). Under the UCMJ jurisdictional statute, 10 U.S.C § 802, PHS and NOAA officers are subject to the UCMJ only when they are assigned to and serving with the armed forces.

If this jurisdictional prerequisite is not satisfied, cases of alleged misconduct involving individual Corps officers are solely handled in accordance with Commissioned Corps policies, as set forth in published Corps issuances. If there are potential criminal issues involved, these must be referred to the HHS Office of the Inspector General (OIG), which will coordinate with the Department of Justice for purposes of law enforcement investigation and prosecution. Non-criminal misconduct may be investigated by the agency operating division or by the Corps, depending on the situation.

Generally speaking, under Corps policy issuances, there are two broad categories of disciplinary administrative action available for uses in cases involving PHS Commissioned Corps officers: those actions not requiring a hearing – which include only a Letter of Reproval and a Letter of Reprimand – and those actions requiring a hearing – that is, all other administrative disciplinary actions up to and including termination of an officer's commission. The nature of the hearing requirement may differ depending on the officer's status (probationary vs. non-probationary, Reserve Corps vs. Regular Corps, etc.), as I will more fully describe in a moment. Moreover, involuntary termination of an officer's commission results in the loss of all benefits otherwise associated with the officer's uniformed services status.

How does the Corps define officer misconduct? Misconduct by a Regular or Reserve Corps officer includes violation of the HHS Standards of Conduct Regulations or of any other Federal regulation, law, or official Government policy. Such misconduct by an officer constitutes grounds for disciplinary or administrative action.

Some examples of officer misconduct include, but are not necessarily limited to:

- Disobedience or negligence in obeying lawful orders of an official superior;

- Absence from his/her assigned place of duty without authorized leave;
- Unauthorized use or consumption of controlled substances or alcohol while on duty, being under the influence of such substances or alcohol while on duty, or illegally possessing, transferring, or ingesting controlled substances at any time;
- Abusive treatment of subordinate officers, employees, patients or program beneficiaries, or of members of the public in their dealings with the Government;
- Engaging in action or behavior of a dishonorable nature which reflects discredit upon the officer and/or PHS;
- Submission of false information in an application for appointment or in any other official document;
- Failure to observe generally accepted rules of conduct and the specific provisions of law and Standards of Conduct regulations;
- Failure to comply with the Office of Government Ethics (OGE) regulations, Departmental supplemental and any other applicable standards of ethical conduct or regulations;
- Failure to exercise informed judgment to avoid misconduct or conflict of interest;
- Failure to consult supervisors or the Agency or Program's Ethics Officer, when in doubt about any provision of regulations; or
- Conviction of a felony.

Typically, administrative and disciplinary cases occurring within the Corps involve marginal or substandard performance, periods of being Absent Without Leave (AWOL), and cases of minor misconduct. The actual number of disciplinary cases is less than 1 percent of the Corps' active duty strength. In the past two years, there were approximately 100 disciplinary actions or pending actions that involved a total of 82 officers.

The Corps has a variety of administrative and disciplinary actions that can be initiated to address officers who engage in misconduct. The decision as to which type of administrative or disciplinary action to be applied is based upon the nature of the infraction and the status of the officer. Lesser offenses may result in a Letter of Reproval, an administrative action generally taken by a supervisor, which does not become part of an officer's personnel folder. More serious offenses can lead to the termination of an officer's commission based on the recommendation of a Board of Inquiry or an Involuntary Termination Board. If a determination is made that an officer's commission should be terminated, then the status of the officer determines what mechanism to be used and the level of due process that must be afforded to the officer in carrying out the action. For example, an officer who is on probation during their first three years on active duty may be summarily terminated upon 30 days notice with an opportunity to provide a written statement to the Director, Office of Commissioned Corps Operations. However, a Regular Corps officer or an officer who is eligible for retirement is afforded an opportunity to appear at a Board and present witnesses.

As a practical matter, disciplinary and administrative actions are enacted or recommended at the lowest level of the supervisory and administrative chain. Through delegation, the HHS Operating and Staff Division Heads, regional offices, the Surgeon General and Deputy Surgeon General, or the Director, Office of Commissioned Corps Operations (OCCO) have the authority to issue a letter of reproval or a letter of reprimand and to make recommendations to the Commissioned Corps regarding more serious disciplinary actions.

To summarize, the disciplinary and administrative actions that may be taken against an officer may be grouped into two classifications, those actions not requiring Board review and recommendation and those disciplinary actions that require board review and recommendation. It is important to note, however, that even in cases that do not require Board review, the agency to which the officer is assigned works in consultation with the Commissioned Corps in developing a reasonable plan of disciplinary action.

Actions not requiring board review and recommendation are the following:

- A Letter of Reproval, which is generally issued by the officer's line supervisor. The letter is retained in the officer's duty station personnel file and does not become part of the officer's official personnel folder (OPF).
- A Letter of Reprimand, which is generally issued by the line supervisor with the concurrence of the officer's administrative chain of command. This letter becomes part of the officer's OPF for a period of two years. While a Letter of Reprimand is within the officer's OPF, he/she is not eligible for promotion, deployment, or to receive a PHS award.
- Suspension from Duty is an administrative action recommended by the line supervisor with concurrence of the administrative chain of command. An officer may be placed in a non-duty with pay status pending resolution of disciplinary or administrative matters if such action is believed to be in the best interest of the Government.
- Summary Termination is an action where the Corps terminates an officer's commission without the review and recommendation of a board. Such action can be taken for officers who are AWOL for 30 or more consecutive days or those officers found guilty by a civil authority of one or more criminal offenses and having been sentenced to confinement for a period in excess of 30 days with or without suspension of probation. In addition, the commission of a Reserve Corps officer may be terminated during the first three years of his/her current tour of active duty – normally for substandard performance or misconduct.

The Commissioned Corps also has disciplinary actions that require board review and recommendation; they are the following:

- Temporary Promotion Review Board (TPRB). This Board is appointed and convened by the Surgeon General to make recommendations about whether an officer should retain a temporary promotion based upon evidence that: an officer's performance has deteriorated to an unsatisfactory level; an officer has engaged in misconduct; an officer is functioning at more than one grade below his/her temporary grade; an officer has failed to respond to progressive discipline; or an officer has failed to meet or maintain readiness standards, licensure requirements, and/or any other requirements set by the PHS Commissioned Corps. The ASH has the authority to revoke the temporary promotion of Regular and Reserve Corps officers based on a Board recommendation.
- Involuntary Termination Board for Reserve Corps Officers (ITB). Except in the case of summary terminations, requests for involuntary termination of Reserve Corps officers are reviewed by an Involuntary Termination Board (ITB). An ITB may be convened for misconduct, substandard performance, and/or no suitable assignment. The ASH has the authority to terminate a Reserve Corps officer's commission without the consent of the officer based on the recommendation of the Board.
- Involuntary Retirement Board (IRB). An officer may be referred to an IRB after 19 years of creditable service by the Director, OCCO, based upon the

recommendation of the OPDIV/StaffDIV, Program Head or his/her designee to which the officer is assigned. The grounds to refer an officer to an IRB include, but are not limited to, substandard performance, conduct issues, falsification of official documents, or no suitable assignment. The IRB's findings and recommendations, along with all documentation, are forwarded to the Surgeon General for approval or disapproval. The decision of the Surgeon General is based upon the IRB's findings and recommendations, and any other relevant information in the record. A commissioned officer may be retired without the officer's consent following the completion of 20 years of active service.

- A Board of Inquiry (BOI) may be convened when an officer is charged by his/her superior or by any responsible person or persons with conduct constituting grounds for disciplinary action. Upon a finding of misconduct, a BOI may recommend the following actions: termination of commission and/or reduction in rank/grade. When a BOI recommends that an officer's commission be terminated and the ASH concurs, the ASH will then make a final decision as to the characterization of service based on the board's recommendation, e.g., honorable, general (under honorable conditions), or other than honorable.

To explain a little more fully, a Board of Inquiry consists of at least three PHS commissioned officers, who are Commander or Captain in rank. A PHS representative(s), one or more PHS commissioned officers, is appointed to prepare the statement of charges and specifications against the officer and to act in the interest of the Government before the Board. The hearing is conducted by a Presiding Officer and the proceedings are not limited by formal rules of evidence, but do require reasonable standards of competency, relevancy, and materiality. All testimony before the BOI is given under oath or affirmation. When the BOI has completed its deliberations, its recommendations are forwarded to the ASH for final decision making.

The officer who is being charged does have the right to 30 days advance written notice, the opportunity to appear in person, with or without counsel, before the Board, and the opportunity to present witnesses before the BOI.

Particularly for the Board of Inquiry, when allegations brought forward against an officer include possible violations of the United States criminal code, the law requires the matter to be referred to the OIG. In such cases, we do not conduct any further proceedings, including any investigations, without the prior express concurrence of an authorized representative of OIG. We proceed only when it is determined that the Board of Inquiry will not pose any risk to criminal proceedings.

These are the disciplinary actions that can be taken by the Commissioned Corps in cases of misconduct by an officer. They are based in the policies and procedures that currently govern our Service. As you are aware, HHS Secretary Leavitt is directing a major transformation of the Corps. As part of this transformation, we are examining our policies and administrative systems to ensure they are robust and rigorous. We seek to ensure that our disciplinary approaches and procedures match those serious ethical questions that face us today and in the future.

In conclusion, I fully understand the gravity of the issues being explored by the Subcommittee and want to thank you again for inviting me to testify. I am ready to answer questions posed by the Subcommittee.

MR. WHITFIELD. Thank you, Mr. Secretary.

Dr. Kington, you are recognized for 5 minutes for your opening statement.

DR. KINGSTON. Thank you, Chairman Whitfield, Ranking Member Stupak, and members of the subcommittee. I am Raynard Kington. I am the Principal Deputy Director of the National Institutes of Health. I appear at your request today to testify about enforcement of ethics rules at the agency.

The mission of NIH is to advance biomedical and behavioral science to promote the health of the public. Part of achieving our mission requires working collaboratively with many parts of the private sector including colleges, universities, and research institutions across the country as well as private industry. Especially in our dealings with private industry, we always keep in mind the unique role we play in being guided always first by the requirement that we support science of the highest quality that will lead to improvements of health without consideration of personal or institutional profit. As the biomedical research enterprise of this country has grown in size and complexity over recent decades, the need for NIH to be seen both by the public at large and the scientific community as an unbiased source of scientific information has grown as well. We must be vigilant and adaptive in response to the evolution of the biomedical research enterprise so that that goal remains at the top of our priorities.

We were reminded of this responsibility in 2004 largely through the investigative work of this subcommittee when we learned that a small percentage of NIH scientists had taken undue advantage of or ignored Federal ethics rules that allowed them to engage in paid outside consulting with industry. As a result of these cases, the NIH and the Department of Health and Human Services working with the Office of the Government Ethics completely banned any paid consulting by NIH employees for the pharmaceutical and biotech industries. We took this action because even the suggestion of ethical lapses, apparent or real, in NIH programs would undermine public confidence in federally supported medical research and we could not allow this to happen.

In addition to these necessary ethics reforms, we disciplined 34 NIH intramural scientists who had violated ethics rules by failing to seek approval for or report consulting relationships with industry, failing to take annual leave while consulting, or consulting in areas that overlap with their official duties. These actions resulted from information provided through the subcommittee's earlier investigation that identified 81 NIH scientists who had allegedly consulted with industry but had not reported their consulting relationships to NIH as required. NIH investigated those individuals as well as 22 others either featured in the media or discovered when we asked our scientists to report any additional consulting that had not been reported to their supervisors. When violations were found, NIH implemented sanctions ranging from

oral admonishment to suspension. In all cases where individual scientists failed to take leave to conduct outside activities, we ordered that the leave be paid back to the Government. In some cases, scientists returned honoraria that were inappropriately received, and in two serious cases, the NIH recommended that the employees be terminated. Every disciplinary action taken was guided by Federal personnel regulations and policies governing such matters which guarantee all employees access to due process, require the Government to consider several factors when recommending a particular discipline, and encourage the use of alternative forms of discipline.

The review of the 103 cases involves multiple components of the agency. The NIH Office of Management Assessment, NIH's official liaison to the Office of the Inspector General, conducted reviews of all the cases, determining the facts and identifying the violations of our rules. The NIH ethics office was brought in to help assess whether specific ethics rules had been violated, particularly in matters involving potential overlap between official duties and private consulting. Under my direction, an expert panel of NIH Institute directors comprised of an objective group of Institute and Center directors, whose institutes did not have any cases, were convened to determine in each case where the employee had not received prior approval to engage in activity, whether the scientists' outside activities overlapped with official duties. This step was taken because determining whether activities that had not received prior approval would have been approvable had procedures been followed was one relevant piece of information to be considered in determining penalties. Ten cases were referred to the Office of Inspector General for potential violations of criminal law. Upon completion of the reviews, the Office of Human Resources used existing policies to recommend appropriate penalties for those found to have violated the rules.

Two of the cases remain in the aftermath of our reviews. They involve NIH scientists who are also members of the Public Health Service's Commissioned Corps. In each of these cases, we concluded that violations of Federal ethics rules were so egregious that they would have warranted proposed dismissal had the employee been part of the Civil Service. The cases were referred to the Corps because NIH cannot terminate the employment of Commissioned Corps officers. As Admiral Agwunobi noted, only the Corps itself after conducting a formal board of inquiry can dismiss officers in this circumstance. While these unique cases were pending before the Commissioned Corps and recognizing that each had not been formally adjudicated, NIH had to determine appropriate continuing duties for the scientists, each of whom remains an NIH employee.

It is important to note that neither the agency nor the Commissioned Corps anticipated at the outset that it would take as long as it has taken to resolve these cases. The employees involved are clinical investigators with responsibilities involving hundreds of patients and are leading researchers in important areas of public health concern. Their supervisors decided that the proper course of action should be determined by the needs of patients and the research while final decisions regarding employment were being determined. To the extent possible and under certain restrictions, we attempted to facilitate the needs of the patients and those important areas and research but only after it was clear that their continued involvement in no way harmed patients. Indeed, there was considerable concern about abruptly stopping their continued involvement as leaders of large clinical studies. In one of the studies where the employee's actions continued to raise concern about his case, one of our institutes took further action, restricting his activities pending the outcome of the Commissioned Corps inquiry.

We also continue to address issues raised in the course of the committee's investigation of the particular cases under discussion today. First, as NIH witnesses testified at the June 14 hearing, we are in the process of clarifying guidelines for NIH investigators so that they know which formal mechanisms are to be used to transfer human tissue samples to outside collaborators. In cases involving the transfer of material derived from human subjects, all written agreements must be accompanied by rigorous checks and balances including the review and approval by senior leadership at the relevant institute. Second, human subjects' protection oversight at the NIH requires that use of all human subject samples be under continuing review of an institutional review board or overseen by the NIH Office of Human Subject Research and we are strengthening the system of oversight for continued review. Third, NIH is clarifying our policies regarding the presentation of scientific information to FDA advisory committees. NIH scientists may not appear at FDA committee meetings as representatives of outside companies. There may be, however, circumstances where it would be appropriate and beneficial to the public for a particular NIH scientist to appear at an FDA advisory committee meeting as part of his or her official duties. NIH is preparing a specific policy which will describe the circumstances in which such appearances are permissible. We will keep the subcommittee apprised of our progress as we implement these changes.

As a result of these investigations and reforms implemented by NIH, we believe that these cases are remnants of past policies. With new restrictions in place and a more efficient and rigorous ethics program underway, we are confident that the problems previously identified by this subcommittee are behind us.

Thank you for this opportunity to testify. I would be pleased to answer any questions members might have. Thank you.

[The prepared statement of Dr. Kington follows:]

PREPARED STATEMENT OF DR. RAYNARD KINGSTON, DEPUTY DIRECTOR, NATIONAL INSTITUTES OF HEALTH, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Chairman Whitfield, Ranking Member Stupak and Members of the Subcommittee. I am Dr. Raynard Kington, Principal Deputy Director of the National Institutes of Health (NIH). I appear today at your request to testify about the enforcement of the Agency's ethics rules.

NIH's mission is to conduct research that will lead to better methods of diagnosing, treating, preventing, and curing disease. The research that we support has resulted in improvements in detecting disease, better therapies, and more effective vaccines.

The United States leads the world in biomedical research. We have achieved and maintained our preeminent status by balancing a massive public and private sector partnership. The programs of NIH are supported by appropriated funds, whereas the pharmaceutical and biotechnology industries finance their research from revenues or the promise of profits. Nevertheless, the translation of research from the bench to the bedside cannot occur without collaborations between publicly-supported researchers and industry scientists. While some work in government and others operate in industry facilities, they undergo similar training, and their methods are often indistinguishable.

Most biomedical research, whether funded by the public or private sector, is conducted at non-government facilities. An exception to that is the NIH intramural program, where research is conducted in federal facilities by government scientists, although this intramural research represents only ten percent of NIH's overall budget.

It is expected that those at NIH entrusted with Federal funds are faithful stewards of the public trust. This clearly means that NIH-funded research must be free of bias and the influence of profit incentives. To this end, NIH and the Department of Health and Human Services (HHS), working with the Office of Government Ethics, banned any paid-consulting for NIH employees with the pharmaceutical and biotechnology industries.

We took this action because even the suggestion of ethical lapses, apparent or real, in NIH programs would undermine public confidence in federally-supported medical research. We could not allow this to happen.

In addition to these ethics reforms, we disciplined 34 NIH intramural scientists who had violated the previous ethics rules by failing to seek approval for -- or even report -- consulting relationships with industry, by failing to take annual leave while consulting, or by consulting in areas that overlapped with their official duties. These actions were taken because information provided through the Subcommittee's earlier investigation had identified NIH scientists who consulted for industry but had not reported their consulting relationships to NIH. NIH investigated these individuals, as well as other individuals whose cases were discovered when we asked our scientists to report any undisclosed consulting to their supervisors. When violations were found, NIH implemented sanctions ranging from oral admonishments to letters of reprimand to suspensions. In all cases where individual scientists failed to take leave to conduct outside activities, they were directed to pay back that leave to the government. In many cases, scientists returned honoraria that were inappropriately received.

The review of these cases involved multiple components of NIH. The Office of Management Assessment (OMA), NIH's official liaison to the HHS Office of the Inspector General (OIG), conducted reviews of all the cases, determining the facts and identifying violations of rules. My office convened an expert panel of NIH Institute

Directors, whose Institutes did not have any cases, to determine whether the scientists' outside activities overlapped with official duties. The NIH ethics office gave technical advice and administrative support to this panel. Ten cases were referred to the OIG due to potential violations of criminal law. Upon completion of the reviews, the Office of Human Resources used existing policies to identify appropriate penalties for those found in violation of the rules.

Two of the cases identified in the internal review are still active. They involve NIH scientists who are also members of the Public Health Service Commissioned Corps (Corps). In each of the cases, NIH concluded that the facts were sufficiently egregious to warrant referral to the Corps, which has independent authority to investigate the facts and the latitude to determine the most appropriate level of discipline for its commissioned officers through the Board of Inquiry process.

We also continue to address issues raised in the course of the Committee's investigation of the particular cases under discussion today. First, as NIH witnesses testified at this Subcommittee's June 14, 2006, hearing, we are in the process of clarifying guidelines for NIH investigators to inform them which formal mechanisms are to be used to transfer human tissue samples to outside collaborators. In cases involving the transfer of material derived from human subjects, all written agreements must be accompanied by rigorous checks and balances, including the review and approval by senior leadership at the relevant Institute. Second, the use of samples or data of human subjects, as HHS regulations prescribe, is overseen by an Institutional Review Board or by the NIH Office of Human Subjects of Research. Third, NIH is clarifying its policies regarding the presentation of scientific information to Advisory Committees at the Food and Drug Administration (FDA). NIH scientists may not appear at FDA Advisory Committee meetings as representatives of outside companies. There may, however, be circumstances where it would be both appropriate and beneficial for a particular NIH scientist to appear at an FDA Advisory Committee meeting as part of his or her official duties. NIH is preparing a specific policy which will describe the circumstances in which such appearances are permissible. We will keep the Subcommittee apprised of our progress as we implement these changes.

As a result of these investigations and reforms implemented by NIH, cases such as those being discussed today are hopefully remnants of past policies. With new restrictions in place and a more efficient and rigorous ethics program underway, we are confident that the problems previously identified by this Subcommittee are behind us.

Thank you for the opportunity to testify. I will be pleased to answer any questions Members of the Subcommittee may have.

MR. WHITFIELD. Thank you, Dr. Kington.

Now, it is my understanding that Dr. Niederhuber, Dr. Insel, and Mr. Fitzsimmons do not have any opening statement but are here simply to answer questions. Is that correct?

DR. NIEDERHUBER. That is correct.

MR. WHITFIELD. All right. We have three votes on the House floor. We have about 4 minutes left in the first vote and then there will be two 5-minute votes. So we will recess the hearing until we go cast these votes, and I would expect we will be back here before 2:00. So you all relax and we will be back in a few minutes. Thank you.

[Recess]

MR. WHITFIELD. The hearing will reconvene, and Chairman Barton has another hearing that he is going to be involved in so I am going to

recognize him for the first round of questions. Chairman Barton is recognized for 10 minutes.

CHAIRMAN BARTON. Thank you, Mr. Chairman, and I thank Ranking Member Stupak for allowing me to go out of turn. I am not real sure exactly who these questions should be referred to, whether they should be Mr. Agwunobi or Mr. Kington or Dr. Insel, so I am going to ask the question and then whichever person appears appropriate should answer it.

My concern, the thrust of my question is going to be, we have an employee, Dr. Sunderland, who has been recommended for termination, who offered to resign subject to certain conditions, and that resignation was not accepted, who testified before this subcommittee and took his constitutional privilege against self-incrimination under the Fifth Amendment and yet he is still on the payroll, going to work and doing things that would appear to be inappropriate. Let me give you an example. He was recommended for termination by Dr. Insel. The following week was approved apparently for a travel request to go to Denmark. Now, that was revoked after the committee staff questioned that. All in all, he has apparently though been approved for travel five times since he was recommended that he be terminated and one of those was a trip to Hawaii. In addition, he has been approved for somewhere between $20,000 and $95,000 in compensation and various expenses since his recommendation for termination. There has yet to be a court of inquiry so we have an individual here who everybody appears to acknowledge at least appears to have repeatedly violated some of the ethical rules at NIH and yet he is still on active duty, fully funded, and the NIH is even helping to pay to move some of his equipment and personal belongings to New York. Why in the world is that going on? Who wants to take an attempt to answer that?

DR. AGWUNOBI. Thank you, Mr. Chairman. If I may, I will try to talk to the active-duty part of this and then I will defer to my NIH colleagues to speak to the NIH-specific aspects of your question.

In situations where a Commissioned Corps officer is alleged to have had or to have participated in serious misconduct, the rules and requirements of the Commissioned Corps require that that individual, in the situation, the facts and the premise be inquired into and investigated by a board of inquiry. That board of inquiry makes a determination as to whether or not the facts, the evidence, statements from witnesses, whether or not in their minds this board of typically three to five Commissioned Corps officers and others, they make a determination as to whether or not they believe a recommendation needs to be made that the individual be terminated. Now, I would add that a similar circumstance would happen if--

CHAIRMAN BARTON. But you have not conducted that board yet.

DR. AGWUNOBI. That is correct, sir.

CHAIRMAN BARTON. And it is not even scheduled.

DR. AGWUNOBI. Sir, the board of inquiry was actually ordered by the Surgeon General at the time, Richard Carmona. This was done shortly after the allegation was formally brought to the Corps. That board of inquiry was subsequently suspended by the Surgeon General, that order was suspended because of a request that we received from the Department of Justice. They informed us that a criminal inquiry was underway and that they required us to stand down, stand to one side, suspend our activities so that they could pursue the criminal investigation.

CHAIRMAN BARTON. What if that takes 15 years? How long are you going to--I mean, look, I respect the Department of Justice but that shouldn't preclude the Commissioned Corps from doing its duty. You have got an individual in our service that has been accused and there appears to be more than adequate evidence, it is evidence enough that it has been recommended he be terminated, and yet he is going on trips to Hawaii. We are paying to move his personal effects to New York.

DR. AGWUNOBI. Yes, Mr. Chairman.

CHAIRMAN BARTON. I do not understand that.

DR. AGWUNOBI. As it relates to the board of inquiry, that is a process that will determine what kind of discipline needs to occur, and there is only one reason why that board of inquiry hasn't finished its work. The only reason is because at the request of the Department of Justice and in pursuit of justice--

CHAIRMAN BARTON. Well, where are you going to conduct this court of inquiry?

DR. AGWUNOBI. It is a standing policy within our organization, it is long adhered to within the uniformed service, the Commissioned Corps, and I would add--

CHAIRMAN BARTON. Why would it not be appropriate to go ahead and conduct the court of inquiry? Let us assume you exonerate the man. Then that helps him with the DOI and Department of Justice investigation. On the other hand, let us assume that you convict him or find him--I don't know what the correct legal term is, but find that he is actually guilty of the allegations. Then that would be a plus in the investigation of DOJ.

DR. AGWUNOBI. My understanding--

CHAIRMAN BARTON. I don't understand why you--I can't think of a good analogy in the Congress that would apply but in any event, why in the world is he being approved for travel? Why in the world is he going on travel? Why in the world is he having the NIH staff help him package

and send NIH materials and his personal effects to his next place of employment?

DR. KINGSTON. Sir, let me respond initially and then Dr. Insel can respond as well. The decisions regarding his day-to-day work assignments by practice was handled by his immediate supervisors at the Institute but it is important to remember a couple points here. First of all, none of us, neither the Commissioned Corps nor the agency ever anticipated it would take this long to resolve the matter, and the expectation was that it would be resolved more quickly. In the interim, there was a balancing decision made about how much he should be allowed to do because we did not have the authority without this board of inquiry to terminate him, and a decision was made--

CHAIRMAN BARTON. Why is that?

DR. KINGSTON. Because those are the rules, the way the--

CHAIRMAN BARTON. The only way you can terminate an individual is if they have been convicted of some gross crime or something?

DR. KINGSTON. For commissioned officers, there is the policy that Admiral Agwunobi just described and this is the way the policies are set up, that we may not terminate an officer in that position independently.

CHAIRMAN BARTON. So as long as he can drag this out, he is a free agent? He can do whatever he wants to do and the NIH management is just going to make sure that his pay voucher is there?

DR. KINGSTON. We can take actions in terms of supervising but we can't terminate, and maybe Dr. Insel could comment on the--

CHAIRMAN BARTON. What if he just stopped coming to work? What if he just said the hell with it, I am not--then could you terminate him?

DR. AGWUNOBI. Sir, our rules say that if you are away without leave, AWOL, for more than 30 consecutive days, that is reason for summary termination, even without a board. We have pretty clear rules on when is an individual referred to a board and when can they be summarily terminated. In that situation, that would apply.

CHAIRMAN BARTON. What if he came one day a month, every 25th day?

DR. AGWUNOBI. Sir, if there was a--

CHAIRMAN BARTON. I mean, he is not doing--let us be a little bit positive. He is showing up. Apparently he is trying to work, so I guess he should be commended for that, but--

DR. AGWUNOBI. Sir, in any circumstance where his supervisor believes that there is misconduct that requires action that could affect the person's commission, rank, retirement, these are all situations that would require us to use a board of inquiry to inquire into the facts, make a determination and a--

CHAIRMAN BARTON. That would be nice if you had held a board of inquiry. Now, Dr. Insel, my briefing says that you recommended that he be terminated. Is that correct?

DR. INSEL. That is correct. I think it was November 21, 2005.

CHAIRMAN BARTON. Okay. Now, do you think it is appropriate since you recommended his termination that he still be allowed to basically continue his activities as he sees fit?

DR. INSEL. Well, the first point in your opening statement, you said that you thought it was absurd that he is still working for us, and I think that may have been kind. I think this is, as I told you in June, well beyond the time that any of us would have liked to have seen this resolved, and it is not clear, as you are pointing out, that the end is in sight even now.

CHAIRMAN BARTON. If he were not in the Commissioned Corps, would you have more ability to terminate him?

DR. INSEL. Yes.

CHAIRMAN BARTON. So the fact that he is part of the Commissioned Corps makes it more difficult?

DR. INSEL. It takes--

CHAIRMAN BARTON. Does it make it impossible?

DR. INSEL. It takes it out of my hands. Were he in the Civil Service, I believe he would have been gone before the end of 2005.

CHAIRMAN BARTON. But why has he not been restricted? I mean, it is bad enough that he hasn't been terminated but why hasn't he been restricted in his activities and prevented from having access to apparently all of his equipment and office materials and things like that?

DR. INSEL. So he has been restricted in a number of ways but that has been iterative, and in retrospect, we should have some of that earlier. Had we known this was going to take so long and had we known the extent of violations, some of which we are only finding out about how, we would have done more much earlier. What we were doing throughout though was, we recognized that there was a difference between the outside activities which were the source of the violations and all of the concerns about his ethical behavior and his official duty activities. Official duty had to do with what the studies were that he was involved with, how he behaved while he was at work. We don't have here a record of him harming patients. We don't have here a record of an integrity, a research problem. This is about outside activities and those were greatly restricted very early on. In terms of the official-duty piece, you asked before about why would he be allowed to go to a meeting. Well, this was part of his job. He represented the Institute in terms of work that he did.

CHAIRMAN BARTON. Well, if he has been recommended for termination, I would think if you can't fire the man, you could at least put him on leave without pay, and if you can't put him on leave without pay, you could at least restrict him to showing up at the office and doing some routine work that doesn't impact the outside world in any way.

DR. INSEL. So let us go through the options because we have talked about this right along. It has been a concern about what we actually could do in this situation, and I must say, to some extent this is frontier territory. We haven't been in this situation before. Leave without pay we were told was not an option.

CHAIRMAN BARTON. Why is that?

DR. INSEL. I might refer that to--

CHAIRMAN BARTON. I apologize for my time expiring. But if we could just finish this before I have to turn it back over.

DR. AGWUNOBI. Mr. Chairman, I would just start by restating, there is only one reason why a board of inquiry hasn't sat and met on the individual that you identified and that is because the Department of Justice has asked us to hold while they conduct a criminal investigation. Leave without pay is a disciplinary intervention. It would require that this individual go before a board of inquiry and that that board of inquiry determine what the intervention needed to be before it could be recommended. That process would have occurred once again if it weren't for the fact that the Department of Justice is conducting an ongoing criminal investigation and has asked us to hold--

CHAIRMAN BARTON. Well, I predict, if you don't do the board of inquiry, the Department of Justice will take at least another 2 years, and he is still going to be on the payroll. If you hang your hat on waiting for the Department of Justice, and I am not down on the Department of Justice but, they do not operate on the same timetable. You have got somebody that has been recommended for termination. Since then he has gone on at least one trip to Hawaii and yet you are still sitting here telling us you don't even have a time for it. You don't even have a time for it. I mean, I understand due process and I respect the rights of the accused to have the ability to face their peers and all this but that doesn't mean they can hide under bureaucracy for years and years and years, and that is what is happening. Now, the Department of Justice can request that you do something, but that does not prevent you from doing your duty and your duty is not to let this individual continue to operate apparently without any penalty for what appears to be serious violations of the ethical rules of the NIH.

Mr. Chairman, I have abused the privilege. I apologize for that, and I yield back.

MR. WHITFIELD. At this time I recognize Mr. Stupak of Michigan for 10 minutes.

MR. STUPAK. Thank you, Mr. Chairman. Dr. Insel, let me just follow up where the Chairman left off. If he is an employee of NIH but really a Corps employee, why not just send him back to the Corps and not even have him at NIH anymore? Doesn't it really cause the other people at NIH who are trying to do their jobs, doesn't it look sort of odd to them to have this person who is under this cloud of suspicion for so long who you recommended for termination to still be there doing functions? Why not just send him back? You can send him back, can't you?

DR. INSEL. Well, that is a good question and one that I am not sure I have the full answer for. We have looked at a lot of options and there have been meetings with senior NIH management and--

MR. STUPAK. Well, can't you send him back?

DR. INSEL. So since he is effectively detailed to us, the question had been raised about--

MR. STUPAK. Well, is there an end date of this detail? Does he have to be there for so many years? Isn't it really at your discretion?

DR. INSEL. No, I think it is at the Corps' discretion as to where the detail takes place as far as--

MR. STUPAK. So as director of NIH, you don't have any say on who gets detailed to you?

DR. INSEL. Well, not when someone has been there for a while. I can ask my colleagues to the right. I actually don't know that there has been an instance of changing the detail in this kind of a case but--

DR. KINGSTON. That was--we had lengthy discussions with the various specialists in actions we could take and in numerous discussions, that was never raised as something that we were allowed to do.

MR. STUPAK. Okay. I am raising it now. Can you send him back?

DR. KINGSTON. Well, we would have to ask the authorities to see whether we could.

MR. STUPAK. I mean, I find it rather appalling. You are sitting there saying he is going to these meetings representing NIH under this dark cloud that everybody knows about. What the heck kind of signal does that send everybody else? I mean, I would think someone would go out and take the bull by the horns and do something here. It has been 4 years since we brought this your attention. Four years. We are still going round and round. He represents the NIH, is under a cloud of suspicion. He has got criminal investigations going on. Gentlemen, someone has got to accept some responsibility and do something here.

DR. AGWUNOBI. Sir, the particular case that you described, it is my understanding it was first referred to the Commissioned Corps in

December of 2005 for action. We have been in dialog with the leadership of NIH since then as partners--

MR. STUPAK. Eleven months, haven't been able to make a decision.

DR. AGWUNOBI. Well, actually a decision was made within 60 days. A decision was made to hold a board of inquiry. We--

MR. STUPAK. But my question was, why not just send him back to the Corps?

DR. AGWUNOBI. As I say, sir, the conversation, the partnership between us and the agency decided that the best approach to handling this circumstance was a board of inquiry. Once again, the only reason why that board of inquiry--

MR. STUPAK. Right. I understand. Okay. I don't want to use up my whole time going over--how about Mr. Walsh? There is no board of inquiry on him, is there?

DR. AGWUNOBI. I believe there is. A board of inquiry has been ordered.

MR. STUPAK. As of like a couple days ago you just started it?

DR. AGWUNOBI. Within the last week, sir.

MR. STUPAK. Yeah, so he sat in limbo for 9 months from January of 2005 until September 7, so for 9 months he wasn't under a board of inquiry once again and he is not a Corps person, right?

DR. AGWUNOBI. No--

MR. STUPAK. Oh, he is?

DR. AGWUNOBI. Yes, sir.

MR. STUPAK. So why was no decision made on him then, Mr. Walsh?

DR. AGWUNOBI. A decision was made when the board of inquiry was ordered for Dr. Sunderland that we would hold the board of inquiry for Walsh upon completion of the board for Sunderland.

MR. STUPAK. So he sat for 9 months not knowing whether or not there would be one?

DR. AGWUNOBI. A board of inquiry hasn't sat on him yet, sir.

MR. STUPAK. Okay. Mr. Kington, if I may--Dr. Kington. Go to Exhibit #3 because I was looking at this spreadsheet produced by the Office of Management Assessment and it is entitled Results of 103 Individuals' Reviews by NIH Human Capital Group, Exhibit #3. Some of these findings and subsequent actions are simply astounding. An investigator named J. Gade, if I am saying that right, was found to have received almost half a million dollars, $500,000 without prior approval and was given a 45-day suspension. So Mr. Gade is an investigator. How much money would he make a day?

DR. KINGSTON. Actually, I am not--I don't know what his salary is.

MR. STUPAK. Well, with a 45-day suspension, that comes out to $11,000 per day. Did he have to pay back the half-million dollars?

DR. KINGSTON. I am not aware that he returned the payments.

MR. STUPAK. So therefore if I am making maybe $1,000 a day and I am sure that is more than generous of what he makes, I am $10,000 ahead because I don't have to pay anything back, so where is the deterrent in this kind of activity?

DR. KINGSTON. First of all, it was unprecedented for us to suspend without pay an NIH scientist. No one in the entire administration of the agency had ever had a case even remotely close to suspending an employee for 9 weeks of pay, especially for a senior scientist, so it was a significant penalty and all of--every step of the way, every step of the way we obeyed Federal personnel rules and regulations that--

MR. STUPAK. Come on. You can't tell me Federal rules say you can accept improper $500,000--

DR. KINGSTON. You are right, and--

MR. STUPAK. --and you can keep your job, you get a 45-day suspension, you don't have to pay it back and everybody is happy.

DR. KINGSTON. This was a significant penalty. We--

MR. STUPAK. Forty-five days? Come on. This is a half-million dollars.

DR. KINGSTON. Nine weeks of leave without pay, it is unprecedented for an NIH scientist to have received--

MR. STUPAK. So then what does it take for an NIH person to be terminated? If a half a million dollars won't do it, what does it take?

DR. INSEL. Can I add to that?

MR. STUPAK. Sure.

DR. INSEL. I think the answer to your question is conflict. This was a case in which it was determined as far as I can understand, and Dr. Kington can give you more information about this, but there was no inherent conflict of interest. All the activities, though they were highly paid, were considered to have been approvable, but they were not disclosed.

MR. STUPAK. So if it would have been approved, he could have kept the half-million dollars?

DR. INSEL. Had they been approved, had they been disclosed, we wouldn't be talking about this.

MR. STUPAK. Do you have scientists who receive half a million dollars in outside activities that is approved?

DR. INSEL. In 2006, that is no longer possible, but--

MR. STUPAK. No, back then, before this, 2005--

DR. INSEL. Not even in 2005.

MR. STUPAK. Okay. Explain this one to me. How about Steven Katz, director of NIAMS, received about $275,000 but no action was taken because the employee, and I quote now from Title III, "remedied the violation." What does that mean? How do you remedy a violation?

DR. KINGSTON. First of all, let me respond. These reviews were handled centrally by the NIH Office of Management Assessment. We followed standard GAO rules and regulations and it was determined--

MR. STUPAK. Excuse me, Doctor. I only have a limited time.

DR. KINGSTON. It was determined that--

MR. STUPAK. So what does "remedied the violation" mean?

DR. KINGSTON. It was determined that it was not a significant violation, and I was intentionally, as were all of the senior leadership, kept away from specifics because we might be appeal officials later on and if we had been involved--

MR. STUPAK. That is fine, but just--

DR. KINGSTON. --it would have been prejudice.

MR. STUPAK. Well, what does "remedied the violation," what does it mean? He paid it back?

DR. KINGSTON. There was some type of compensation and that it was determined that it was not severe enough to warrant any type of significant intervention, and that was true. That case was reviewed at length, and Dr. Katz was not found to have--

MR. STUPAK. Well, there are others here, between $40,000 and $60,000, and you have things like oral admonishment.

DR. KINGSTON. There were a number of factors taken into consideration. Those factors are guided by law, and we--

MR. STUPAK. You know, every one of us Members up here, I bet you, receive at least once a year a letter in the mail and there is always a dollar bill stapled at the top of it and it is like I am paying you a dollar to answer my letter. Okay. We send the dollar back. You know what would happen if any one of us took a dollar for answering a piece of mail? We would all be out the door. And why? Because of ethics and integrity and no blemish on it. You are blemishing the Corps. You are blemishing the NIH. And these are just, oh, give him an oral admonishment. That doesn't fly.

DR. KINGSTON. There is a system that determines the factors that are taken into consideration for any type of penalty. Every step of the way we assure that any action that we took fit within the Federal rules and regulations about what penalties were taken and every step of the way we followed Federal rules and regulations and laws that determine what factors are considered when taking disciplinary action against an employee.

MR. STUPAK. I will bet you there is no Federal rule or regulation that says half a million dollars, you get 45 days off, $275--

DR. KINGSTON. That is correct, because the rules are more complex than that.

MR. STUPAK. And it is your interpretation and it is your application of those rules and regulations?

DR. KINGSTON. We believe that we applied those rules rigorously and consistently across the cases and consistent with how any other disciplinary action was--

MR. STUPAK. Consistent with what? What did you review it with? You said you never had these problems before. So where is your consistency? Where is your parallel? How did you make that determination?

DR. KINGSTON. That is a fair question.

MR. STUPAK. What is your baseline?

DR. KINGSTON. That is a fair question. What we did is, in the process of determining what range of interventions were appropriate for any specific case, we consulted the specialists who handle employee disciplinary action at the agency for any type of disciplinary action and we in each case had that specialist determine the range that the violation fit into in terms of disciplinary action compared to all the other disciplinary actions that the agency has taken, and in every case, we have complied with the recommendations of those specialists who specifically asked that question. We asked that question.

MR. STUPAK. Are the specialists within the Federal government or private?

DR. KINGSTON. No, the specialists are Federal employees who specialize in determining what are the appropriate disciplinary actions for any specific case, and in every single case we followed Federal rules to the letter.

MR. STUPAK. I am glad those guys aren't on the sentencing guidelines, let me tell you.

Dr. Insel, is it true that the Alzheimer's study that we spent so much time on that Dr. Sunderland did, has that been discarded now? Is anyone going to further try to look for biomarkers to try for early detection? Has that study been abandoned?

DR. INSEL. The study isn't abandoned. There is a--what I think you are referring to is called the BIOCARD study, biomarkers in elder controls at risk for dementia. That study is an NIH study. It still has an ongoing and continuing protocol, but it is closed at NIH for new accrual of patients.

MR. STUPAK. But the study is still going on?

DR. INSEL. The study is not going on currently. It is a longitudinal study and so we are in a suspended state here.

MR. STUPAK. So in other words, there is no funding going into it?

DR. INSEL. There is no funding going into it.

MR. STUPAK. Why don't you get back all the money these people took for consulting, put it back in there and fund the study, because it is a program that Congress feels very strongly about. So now you have bad apples, now we suspend the study because we can't fund it, so why don't we just take these fines and costs--not fines and costs, I am sorry--these consulting fees and put it back in?

DR. INSEL. So can I clarify what we mean by suspension?

MR. STUPAK. Sure.

DR. INSEL. This is a longitudinal study. The hope would be that it would go for 20 to 30 years. We are in I think the 11th year of this study.

MR. STUPAK. Right.

DR. INSEL. Right now there have been no new patients entered in I believe since January of 2005 at NIH. The NIMH itself is not likely to want to continue to bring in new patients for the study because we are shifting and going in other directions.

MR. STUPAK. But you still have the research and things like this on this study, right, on the subjects you already have entered into the study?

DR. INSEL. Will there be additional research?

MR. STUPAK. Yes.

DR. INSEL. The hope would be that we will find a way to keep this going but it doesn't mean that necessarily NIMH has to--

MR. STUPAK. Well, why can't you keep it going? Is it money or you don't want to have further studies or persons come into it?

DR. INSEL. Well, it is a combination of things. I think the study is meritorious. I think it is worth doing. It is outside of our core mission. We would like to use our funds for--

MR. STUPAK. Well, why did you start it if it is outside your core mission and after spending millions of dollars for almost 2 decades?

DR. INSEL. That is a good question.

MR. STUPAK. Or 11 years.

DR. INSEL. The intramural program, which is the part of our agency here in Bethesda where we have got lots of exciting things going on occasionally does do projects such as this one that aren't that closely connected to the Corps. I came in and decided that I wanted us to be much more mission-focused and so as the leader of the agency decided that this was--

MR. STUPAK. Who is going to do the research then on Alzheimer's if you are not doing it?

DR. INSEL. Well, we have two other agencies within NIH, the National Institute of Aging and the National Institute of Neurological Diseases. They spend collectively about $656 million on Alzheimer's. So this study is a very, very small piece, but it is the clinical research on Alzheimer's in Bethesda in the intramural program.

MR. STUPAK. Sure, trying to determine the biomarkers. Thank you.

MR. WHITFIELD. Thank you, Mr. Stupak.

I think all of us recognize the NIH is the national leader and the premier obviously government agency in research and development looking for cures of all sorts of diseases and maladies. I think all of us also recognize the importance as Dr. Insel said the last time he was here of setting the high standards, and in your testimony, Dr. Kington, you talked about how after you all started looking into this, you had 52 violations. You disciplined 34 scientists. You referred 10 cases to appropriate officials for possible violations of criminal laws. That is for an institution that has the reputation that NIH has and how that sort of all-encompassing disclosure of ethical violations and--it is sort of disturbing. Are any of you disturbed about it or concerned about it or are we making more of it than should be made of it?

DR. KINGSTON. Not at all. We were all deeply concerned about the reputation of the agency and our ability to accomplish our mission, which is why we aggressively responded. We worked closely with the department and the Office of Government Ethics to pass regulations that now preclude any outside consulting with industry. We aggressively pursued the cases. We have greatly expanded our ethics program so that we feel confident that we are building a program that will be the best in the Federal government. We have responded quite aggressively because we were appalled that we had a system that didn't appear to be working as well as it could have.

MR. WHITFIELD. Now, had you ever had anything at this scale before of violations of NIH ethics rules--

DR. KINGSTON. I asked that question, and I was told no.

MR. WHITFIELD. So the largest scandal, if we can call it that, in NIH's existence then?

DR. KINGSTON. And we certainly hope it will be the last.

MR. WHITFIELD. Now, I think--

DR. INSEL. I am sorry, if I could add to that. I think when you see a list like this though, one way to understand it is, that it is not as if we suddenly collected a number of people who had ethical dilemmas. What was happening here was that there was a systemic problem to some extent. We weren't doing the job we needed to do to make the rules clear and to make sure people could follow them, and so the scandal came about as a way of forcing all of that to change.

MR. WHITFIELD. Now, I am not going to be an apologist for NIH, but you are dealing with some particularly skilled people here. These scientists are involved in very important research and I am assuming that salaries paid by the Commissioned Corps and NIH generally may not be as high as in the private sector. I am also assuming that they allowed these consulting agreements on the side as a way of subsidizing salaries. Would that be correct?

DR. KINGSTON. It was an allowable way, but it is also important to remember that a relatively small minority of all of the thousands of scientists at NIH actually engaged in consulting activities with pharmaceutical and biotech. It actually was a small number.

MR. WHITFIELD. But now that is banned completely. Is that correct?

DR. KINGSTON. Yes, it is banned completely.

MR. WHITFIELD. Are you going to lose a lot of scientists as a result of that?

DR. KINGSTON. It is a concern. We have begun--even when we announced in the Federal Register the new regulations prohibiting outside consulting, we made a commitment to the public that we would reassess the impact of those regulations on the agency. There have been anecdotal cases of scientists who attributed part of the reason why they left the agency recently to these rules. We are in the process of having a more formal evaluation of the impact, and if we determine that it is harming the agency, we will come to the appropriate decider to decide how we can correct it, but we won't do anything that will allow the agency to be vulnerable to the allegation of being not perfectly unbiased in our decision-making, and anything that might harm the reputation of the agency, we take very seriously.

MR. WHITFIELD. So this did send some tremors through the entire agency out there. Would that be correct?

DR. KINGSTON. I think the tremors were deep.

MR. WHITFIELD. Now, the commissioned officers of the Corps, I think in your testimony you said they are not under the Uniform Code of Military Justice. Is that correct?

DR. AGWUNOBI. That is correct.

MR. WHITFIELD. And Chairman Barton and Mr. Stupak both talked about how the board of inquiry had been delayed because of a request from the Justice Department. The Corps is not required by any law to delay the board of inquiry, is it?

DR. AGWUNOBI. Sir, I should clarify just a little on the UCMJ. There are certain circumstances under which the Commissioned Corps does subject itself to the Uniform Code of Military Justice, the first being our officers were posted to the U.S. Coast Guard. As you know, sir, we

provide healthcare services to the members of the U.S. Coast Guard, our sister service. The other is when we are militarized by the President by executive order. Now, having said that, I would urge the Chair and members to recognize that it is a longstanding practice, indeed there is policy that reflects this notion of deferring to criminal investigations when we have a civil proceeding underway, and it doesn't just apply to the Commissioned Corps. Indeed, if a civilian working in one of HHS's agencies was referred for criminal investigation and the Department of Justice asked the civilian authorities to delay their civil investigation because they were worried that it might impinge upon the criminal investigation, there are many circumstances in which I imagine even civilians would defer to that situation.

MR. WHITFIELD. Well, I just may point out that in Oversight and Investigations, this subcommittee particularly is involved in a lot of oversight and investigation regarding issues in which crime is involved, and the Department of Justice comes to us frequently and asks us to delay anything and everything we are doing and we seldom do it.

DR. AGWUNOBI. Sir, the pursuit of justice is tantamount in our minds and in our thoughts. We would be loathe to have a situation where our board of inquiry, our investigation into the allegations of any Commissioned Corps officer in some way jeopardized or hampered the pursuit of a criminal investigation.

MR. WHITFIELD. But what about Mr. Walsh? There was no criminal investigation with Mr. Walsh, was there?

DR. AGWUNOBI. No, sir. My understanding--I don't know the details of either of the cases. I serve in the appellate process in this, in our system and I don't know the details of either case, but I do know that the board of inquiry for Mr. Walsh was not delayed because of a request by the Department of Justice specifically to that case.

MR. WHITFIELD. It was delayed why?

DR. AGWUNOBI. We use an office in the Commissioned Corps to perform these investigations, to staff and manage these investigations. A decision was made when the two cases were presented to us to do the most egregious at the time, this was their determination at the time, Dr. Sunderland, and to then--potentially egregious, I should correct and say--and then follow with Walsh. A series of events transpired in which the Department of Justice asked us for a 30-day delay, subsequently continued to extend their requests for a delay and unfortunately that led to a delay in the implementation of the board of inquiry for Dr. Walsh until fairly recently.

MR. WHITFIELD. And why couldn't you have done both?

DR. AGWUNOBI. It was determined that in order to provide the best service, the most efficient service and to ensure that all the procedures

and rules that are a part of the Commissioned Corps were followed, it was to be--an operational determination was made that it was better to do one after the other.

MR. WHITFIELD. But after all of this investigation has been completed now, Dr. Kington, I want to make sure I understand, 10 cases have been referred to the appropriate officials for criminal investigation. Is that correct?

DR. KINGSTON. Yes. Following standard policies, we referred--when there was sufficient concern about a criminal violation, we referred I believe a total of 10 to the Inspector General.

MR. WHITFIELD. And I acknowledge your commitment to maintaining the highest standards for NIH, the institution that is involved in such important research for the whole country, for the whole world. Are all you really confident that the changes that you have made are sufficient and that things can work very well moving forward?

DR. KINGSTON. Now I function as the senior ethics official for the agency so I have oversight responsibility for all of the personnel-related ethics actions, and I can say without any hesitation that we have committed an extraordinary amount of thought and resources to actually making sure that we have a system that works, and I am confident that when the transformation is completed--we are still in the process of doing it--we will have an exemplary system and we will be able to prevent many potential problems.

MR. WHITFIELD. You have so many different institutes out there. The fact that you are the chief ethical officer, how do you get it out to all the institutes so that they are all on board?

DR. KINGSTON. And that is an important question that we asked ourselves, how do we have that work. The way it works is that the authorities related to the ethics and government act come from the Office of Government Ethics. Then there is a senior person who is the designated agency ethics official, in this case, Mr. Ed Swindell. I report to him for this part of my job, and in a similar way, we are restructuring so each of the senior ethics officials at 27 individual institutes and centers in turn reports to me. It is in their performance plans. I have an opportunity to respond when they are reviewed every year and we are setting up a system of random audits that will assess at multiple levels of the agency whether or not the ethics rules are being applied rigorously, and we have committed the people and the resources and the infrastructure to having this work.

MR. WHITFIELD. And Dr. Trey Sunderland is still an employee at NIH and is involved in certain restricted activities. Is that correct?

DR. KINGSTON. Yes.

MR. WHITFIELD. Is he at the mental health institute, Dr. Insel?

DR. INSEL. Yes. If I can respond, there have been a number of restrictions of his activities, but again the options we had seemed to us were limited. As you may recall at the last hearing, we had a discussion about leave with pay, which was one option that I think the subcommittee was interested in. We felt that was not appropriate here. We have changed his duties so that he is working in a different part of the institute. He does not have access to clinical samples that the subcommittee was so concerned about before, and there are a number of other restrictions in terms of his outside activities and official duties.

MR. WHITFIELD. And a lot of those samples have been returned also, correct?

DR. INSEL. The samples that the previous hearing was about, Pfizer samples, have all been returned.

MR. WHITFIELD. At this time I recognize the gentleman from Texas, Mr. Burgess, for 10 minutes.

MR. BURGESS. Thank you, Mr. Chairman, and I appreciate this ongoing hearing.

Now, the comment was made that Dr. Sunderland was hiding under the bureaucracy of the Department of Justice, but I guess I would just like to know, would Dr. Sunderland leave if he were free to do so today?

DR. INSEL. If I can answer, he asked to leave in November of 2004 so it is almost the second anniversary of when he asked to be allowed to leave the NIH.

MR. BURGESS. So his continued presence there is not necessarily voluntary at this point?

DR. INSEL. By no means.

MR. BURGESS. Now, does Dr. Sunderland--let me make sure I understand this correctly. Is he purely involved in research or does he have clinical duties as well?

DR. INSEL. His role has been until recently as the Chief of the geriatric psychiatry branch which is a clinical research branch, so he was seeing patients, seeing subjects in research studies.

MR. BURGESS. So he does have responsibilities that involve direct patient care?

DR. INSEL. He did. At this point he is no longer involved with direct patient care.

MR. BURGESS. And when did those stop?

DR. INSEL. Oh, I think that goes back to sometime early in 2005. I believe it was perhaps either January or February of 2005.

MR. BURGESS. You know, without speculating about the guilt or innocence or rightness or wrongness of the situation, there are some things that come up certainly with your own investigations and with our testimony that we have heard here that would call into question

someone's judgment, and in the clinical practice of medicine, I mean, you are only as good as your judgment. I just wonder the wisdom of leaving someone whose judgment was called into question and continuing to deliver clinical care and be involved clinically with patients. In a private or a regular hospital setting, that would be cause for summary suspension and a convening of a fair hearing and all of the things that you normally would associate with loss of hospital privileges. Either Dr. Insel or Dr. Kington.

DR. INSEL. If I may respond, it is important to separate out his official duty for which there has never been a question about his competence or integrity. The issues of patient care, we have certainly never gotten a complaint about patient harm or an issue that is related to his ability as a geriatric psychiatrist and I think it is probably fair to say that he is one of the most highly sought after and highly respected geriatric psychiatrists in the country. Part of what I think got him into this situation was making bad judgments about taking lots of the invitations and being used as a sort of opinion leader in the field. It now appears for personal gain as well as for whatever effect he was having on the field as well.

MR. BURGESS. Right, and that error in judgment, whether it be your hand in the till or inappropriately taking invitations, it does beg the question, is that judgment impairment that is now evident, is that going to spill over into the clinical setting and are patients going to be harmed as a direct result? Our responsibility is to the safety of our patients.

DR. INSEL. Right. If the question is whether those outside duty activities in some ways have contaminated his official duty, what he was doing in the hospital, in the clinic, we haven't seen any evidence of that.

MR. BURGESS. Just for recapping for my benefit, the BIOCARD study, quickly, what was that again?

DR. INSEL. This is a long-term longitudinal study of controls of healthy people who are at risk for Alzheimer's disease because they had a first-degree relative with the disease.

MR. BURGESS. Dr. Kington, in response to some questions that were asked by this committee in June of 2005, the question comes up whether the committee was given misleading information from the National Institute of Mental Health in response to the committee's questions on its request letter concerning spinal fluid samples that were collected in the National Institute of Mental Health lithium study in early Alzheimer's disease patients. The question I believe was were all the records relating to tissue samples regarding Dr. Molchan's lithium study turned over. Did we get a misleading answer in our request for that answer of a question?

DR. KINGSTON. I think in retrospect, there probably was--it was clear that there was incomplete information that was conveyed to the committee but it is also important to recognize that the way that these requests were handled were essentially they came into--were largely coordinated through the office of the director and then delegated to the Director of NIMH to answer the questions. He in turn relied on information that was given to him, and the answer could only be as accurate as that information that was given to him, and Dr. Insel may want to respond as well.

MR. BURGESS. If I could, let me just pursue that for a second. Now, the samples that have been testified to here today, Pfizer has returned those samples?

DR. KINGSTON. Pfizer has returned all remaining samples in its control.

MR. BURGESS. And that was at what? A fifth, an eighth, a half? Any rough estimate of how much--

DR. KINGSTON. Actually I don't know the exact amount.

MR. BURGESS. So in addition, the National Institute of Mental Health has five storage freezers of samples recovered that Dr. Sunderland shipped to New York without proper approval. What will the NIH do with the unused and recovered samples from Dr. Sunderland's shipments to advance Alzheimer's research? In other words, will these samples indeed be used in an ongoing study?

DR. KINGSTON. And that is under consideration now by NIMH and I will let Dr. Insel respond.

MR. BURGESS. You testified earlier that that study was not stopped. Is that correct?

DR. INSEL. There is some confusion here so let us break it down a little bit. There are five freezers. Not all of those involve samples that were returned from Pfizer. That is actually a relatively small part of the entire collection. The five freezers do involve samples that have been collected by the geriatric psychiatry branch over many, many years. Most of them are cerebrospinal fluid but there are other kinds of samples as well. Those aren't going anywhere. The question remains how they will be handled in the future. There needs to be IRB approval and an IRB-approved protocol for them to be used in any sort of ongoing or collaborative research. The options include such things as maintaining a repository--because I do believe these are valuable samples and apparently other people believe that as well--that could be used by a number of collaborators and at this point we do have an IRB-approved protocol with a new principal investigator. If he deems it worthwhile, he could find collaborators anywhere who may be interested. In terms of this BIOCARD study, the one that you bring up, its value really will

have to be determined at some point in the future. Three hundred and fifty subjects, only 14 of them have developed any signs of Alzheimer's disease. It is another 10 years before we can begin to see the 50 or 60 subjects that will then make this such a valuable study. So we are talking long term, and there will be plenty of time to figure out how that will be planned out. It will remain though as something that we can hold within--this is government property. These are NIH samples.

MR. BURGESS. So the delay really hasn't damaged the value of the study?

DR. INSEL. Well, the question remains whether those 350 subjects are still on board or not. If someone comes back to them 3 years from now, are they still going to want to participate or have we lost the very critical window when changes are taking place.

MR. BURGESS. So at this point, is the BIOCARD study going on at NIH or an extramural program anywhere else or in a private institution anywhere else?

DR. INSEL. There was a BIOCARD, called BIOCARD 2.0 that was begun at North Shore Hospital which was Dr. Sunderland's prospective future employee.

MR. BURGESS. Should that make any of us up here suspicious?

DR. INSEL. It makes me very worried that he would have anything to do at this point with that study. That study is actually also terminated and the employer has no longer offered him the position that was on the table for the last 2 years.

MR. BURGESS. Well, maybe sitting on this committee for the last year has made me cynical, but I would be very suspicious about that activity at North Shore Hospital in regards to what we have learned in this committee. Would there have been any way to protect the patients from the inconvenience and the disruption in the study and anxiety from a move by keeping the study at NIH under the leadership of someone else in Dr. Sunderland's group? Presumably he wasn't the only one involved in that, so did we have other scientists at NIH who could have just simply picked this up without inconveniencing and aggravating families?

DR. INSEL. So there will still be samples there so that is not going anywhere, but if we are taking about new accrual of information so additional people coming in and additional samples collected toward the future, who would do that? When Dr. Sunderland announced he was leaving, his deputy, Dr. Robert Cohen, took over. He became the principal investigator on this study. Dr. Cohen then decided to leave, I believe in September of 2005, and in the effort to find someone else could take this over as a principal investigator, Dr. Joel Kleinman stepped forward and he had been involved with this study already but he

is not someone who would be able to do the clinical support and the clinical evaluations of patients with Alzheimer's so we have no one in place who is able to do that at this time in the intramural program at NIMH.

MR. BURGESS. Have the rules on outside consulting--and this is a question for anyone on the panel. Have the rules on outside consulting caused the loss of scientists at NIH? Are the rules overly restrictive at this point?

DR. KINGSTON. We believe the rules are appropriate for this current situation but we are in the process of evaluating its impact. As I said earlier, there are individual scientists who have said that the rules played a role in their decision to leave the agency.

MR. BURGESS. How many scientists have left?

DR. KINGSTON. We are just beginning to collect the information on that, but it is anecdotal information only up to this point.

MR. BURGESS. Is there--I mean, you are the NIH so you are all smart people. Is there a way to construct a program that would allow with transparency and full disclosure would allow scientists to participate in outside consulting to prevent us from losing valuable members of the scientific community?

DR. KINGSTON. And that is a question we plan to ask ourselves in the future but we thought that we shouldn't even ask that question until we have in place comprehensive, well-managed, thorough system of oversight of the rules that we have now which are significant. So at some point as we stated when the rules were changed, we plan to go back and ask that very question, is there some way to allow more outside activities, but at this point we do not anticipate considering that question.

MR. BURGESS. I hope you are not waiting for the Department of Justice. Mr. Chairman, I will yield back.

MR. WHITFIELD. Thank you, Dr. Burgess. At this time I recognize Mr. Stupak for some additional questions.

MR. STUPAK. Thank you, Mr. Chairman. Mr. Chairman, first of al, I would like the statement of the Honorable John Dingell be entered into the record, please.

MR. WHITFIELD. Without objection, so ordered.

[The prepared statement of Hon. John D. Dingell follows:]

PREPARED STATEMENT OF THE HON. JOHN D. DINGELL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Thank you, Mr. Chairman, for holding this hearing and for proceeding in such a bipartisan manner. The witnesses who are here today should provide much useful information. But I note that the Inspector General (IG) of the Department of Health and Human Services (HHS) is not present and apparently has little to say on these matters. Congress created the IGs to protect the integrity of the Departments in their charge.

President Reagan called the IGs his "junkyard dogs." It appears in this case that this IG had its teeth pulled.

The sad fact is that this Inspector General has returned the responsibility for policing the Food and Drug Administration (FDA) and the National Institutes of Health (NIH) back to those entities. For example, when this Committee asked the IG on a bipartisan basis to determine if the employees at the FDA were accepting drug company money and other favors such as those we uncovered at NIH (including at least one instance where an FDA official had received permission to engage in 14 separate activities at drug company expense), the IG declined. We were informed the IG would merely analyze the FDA conflict-of-interest policies for us.

A fundamental purpose of the Inspector General is to investigate possible instances of criminal misconduct by HHS employees. Without that independent checking, or at least the possibility of that review, the laxity and coziness that led to the current problems will continue. I hope the result of this current investigation will encourage the Administration to reexamine the role of the HHS Inspector General and to determine how best to utilize that office.

MR. STUPAK. Let me ask this question. It seems like now we take this issue very seriously but I have to stop and wonder what was going on before this subcommittee staff and probably the L.A. Times really pushed you into doing something here. It has been 4 years I think when we first brought this to your attention, and when I look at Exhibit #3 that I asked about earlier and it says on here, for so many of them, it says infraction, failure to adhere to procedures before engaging in outside activities which tells me failure to adhere means they didn't get permission before they engaged in outside activities. Either they were never asked, they never asked to engage in outside activity for a drug company or whatever it is or they were never told. So do you have to fill out--even before this investigation, do you have to fill out a yearly financial disclosure form about your outside activities?

DR. KINGSTON. It depends upon the specific position that a person is in. There are approximately 6,000 individuals who every year are required to report a confidential disclosure of financial status and then there is another 600 or so who every year are required to report one that is publicly disclosed and much more detailed.

MR. STUPAK. Well, I would take it a medical officer would have to disclose, correct?

DR. KINGSTON. Probably. It depends upon the specific--

MR. STUPAK. A senior investigator?

DR. KINGSTON. Again, probably.

MR. STUPAK. Well, actually every one of these that you put down on this three or four page document that have failure to adhere to procedures before engaged in outside activities. They should have put forth this disclosure form before they engaged in outside activities, correct?

DR. KINGSTON. They should have requested permission and then having received permission and completed the activity, they should have reported the income.

MR. STUPAK. But if they didn't receive the permission, then as a backup they should have at least reported the income that they received, right?

DR. KINGSTON. Right. It didn't negate the failure to receive prior approval--

MR. STUPAK. So they failed to disclose or would it be considered making false statements when they signed the form then, perjury when they signed the form?

DR. KINGSTON. I am not sure of the legal term but it is considered a significant violation when the employee reports and signs that they are disclosing everything when they haven't.

MR. STUPAK. If it is a significant violation, then why are most of these a letter of caution, the action taken against them?

DR. KINGSTON. For each case we considered a range of factors, again guided by Federal rules, the severity of the action in question, the amount of the activity, whether or not the activity was approvable, and there was a continuum of severity. For those at the most extreme end, we recommended termination. Everything else is dependent upon the specifics of the individual case.

MR. STUPAK. Sure. Convince me that I am wrong, but here is what I see. I spent 12 years in law enforcement. If we even did anything a shade like this, we were fired on the spot, okay? And if we wanted a board of inquiry, we had to appeal it ourselves. The department sure didn't give us a board of inquiry. We had to do it ourselves. Here is what it tells me. I look at this list and all these people, it tells me one of a couple things going on here. The agency was so reluctant to investigate, it tells me this has been going on for a long, long, long time. The soft pedaling is because people who would have been severely penalized for which they did, which we believe they should be, probably would have started to talk to the press then and said this has been going on X amount of years which then leads to the question, what is the tentacles of the drug companies in the NIH? As Chairman Whitfield says, you do all of our research, all the maybe world's best research, but is it all tainted because of payments made and the influence of drug companies and others on the research being done by NIH? Is that--am I wrong on that?

DR. KINGSTON. We recognize that there was a problem, and we responded aggressively. We asked for and received permission to ban this type of activity completely at the agency. We did that. With regard to soft penalties, I would say that we responded in a way that complied

with every single Federal rule, regulation, and policy which guides the penalties and a range of factors are taken into consideration. I would not characterize what we did as soft pedaling. Quite the contrary. We did exactly what was appropriate and we considered all of the factors that we are required by law to consider when we make penalty decisions.

MR. STUPAK. Here is the problem. You didn't even know what was going on until this committee and the L.A. Times put it in front of you and insisted you do it. The response we initially got--I have been on this committee now for 10 years--was sweep it under the rug, forget it, it is not going to happen, but because of this staff up here, and the subcommittee staff did a great job here, and some L.A. Times articles, you never would have done it. So you wouldn't know to ban it if you don't know it exists. How can you ban something if you don't realize there is a problem? It has been a problem for a long time, and you were so reluctant to do it so your comments about we are aggressive doing this and that, you can't ban something you didn't know was going on. You had a financial disclosure form that these people all violated. Every one of them had to do it. They all violated it. So I am really concerned that the research may not be of the quality and the integrity we hope it would be and we rely upon it to be for the American people.

DR. KINGSTON. I would disagree strongly with the characterization that the industry has tentacles that call into question the validity of our research. This was a very small number of individuals. Many people on the list that you are holding now were found not to have violated rules. The numbers that were found to have violated with penalties was 34. We have 18,000 employees. We have a history of remarkable accomplishments. When we were informed, I agree, with the information that the committee provided to us and other investigations provided to us, we did a much more detailed review of the system. Perhaps we should have done that sooner. As soon as we had information, we aggressively investigated, and as soon as we could, we obtained permission to ban this activity entirely. I strongly disagree with the characterization that there are fundamental questions about the validity of our science. NIH has an extraordinary reputation. That doesn't mean that we can't improve things. We took your allegations and questions very seriously and we acted aggressively, and NIH is a different agency now as a result of your bringing this problem to our attention.

MR. STUPAK. At least for me, I don't see it as a different agency. Four years, you still can't make a decision on some of these people. You soft-sold these people. You should have got them for falsifying records if nothing else, if you couldn't get them for the money, and--

DR. KINGSTON. If it was a question of criminal violations, even a question of a criminal violation, we referred it to the appropriate authorities. We do not have the authority--

MR. STUPAK. Every one of these who have failure to disclose, you submitted those failure-to-disclose forms to the Department of Justice for criminal investigation? Is that what you are telling me?

DR. KINGSTON. I am not a lawyer. I know which specific--

MR. STUPAK. You don't have to be--

DR. KINGSTON. --criminal code--

MR. STUPAK. --a lawyer to refer it. I am just asking you, did you refer all these then?

DR. KINGSTON. We referred all of the allegations that considered that we thought were in consultation with the Office of the Inspector General might involve criminal violations. We referred every one that reached that threshold to the Inspector General following standard policies that we use to decide how to refer every day when there are questions about various activities at the agency.

MR. STUPAK. But when you look at this whole thing, you still can't for us tie together requests for outside activities, leave to do work, or financial disclosures. It seems like you are still grappling with those issues and how to address it at NIH and how you are going to deal with it in the future. You have proposals--

DR. KINGSTON. We are--

MR. STUPAK. You have proposals 4 years later.

DR. KINGSTON. No, we are grappling with it. In fact--

MR. STUPAK. You are grappling with it?

DR. KINGSTON. In fact now, NIH employees cannot receive permission to conduct outside consultation with pharmaceutical or biotech.

MR. STUPAK. I thought you said before an IBR or something like that, you said, right?

DR. KINGSTON. No, it is unequivocal. NIH--

MR. STUPAK. Let me--

DR. KINGSTON. --employees may not consult--

MR. STUPAK. As of when?

DR. KINGSTON. As of promulgation of the rules about a year ago. September of 2005 I believe were the final supplemental regulations under the Ethics in Government Act.

MR. STUPAK. What happens if I fail to disclose my outside activities now under these new rules that you have? What happens?

DR. KINGSTON. As before, when an employee is found to have failed to disclose and comply with the Federal rules, we open a review of the case, usually managed by the Office of Management Assessment in

consultation with the ethics officials involved, and then that turns on the whole case of--

MR. STUPAK. So in these new rules, if I violate these new rules, you don't spell out what the penalties are?

DR. KINGSTON. The penalties are determined by Federal regulations and--

MR. STUPAK. So we are right back to where we are here today.

DR. KINGSTON. Actually, no.

MR. STUPAK. Because every one of these people had to fill out the form, they didn't do it properly, they did not get permission or they failed to disclose and there is no discipline other than a letter of caution. Even under your new rules, if I fail to disclose or I don't get permission, it is going to go back to the same board that is going to take a look at the Federal rules and regulations and say hmm, well, I guess we give them a letter of caution again because that is what you did already. You set the precedent. I would think--

DR. KINGSTON. No, we followed--

MR. STUPAK. --you would have some new rules--

DR. KINGSTON. --Federal law.

MR. STUPAK. I would think you would have some new rules and those new rules say if you fail to disclose, you will get a minimum 3 to 7 days off, depending on the amount of money, it may be higher. It could even result in termination. I would think that is what you would want to do to keep the integrity, but to go back into this and say well, we will look at the Federal law and see what Federal law says and maybe a couple years later we will make a decision. I don't have any confidence in what you are going to do. I see us right back to where we are right here, and maybe in 6 years if we are still up here, all of us who have been here for a while, we will come back and say oh, I guess we are back at hearing number eight on this NIH research and the influence and fail to disclose, failure to give financial disclosures and all that and we are going to be right back where we are.

DR. KINGSTON. NIH is not where we are. Unequivocally we are not where we were. The rules prohibit consultation as an outside activity with industry. It is not allowed. Anyone who does it is violating Federal regulations. We are not the agency that we were before. We have a greatly expanded, more comprehensive ethics review system. I have no question that if anyone actually comes and actually drills down and looks at how we are actually implementing rules, you will see that we are rigorously reviewing and enforcing the regulations. We are a different agency in this dimension as a result of this review.

MR. STUPAK. Without some affirmative statement, they will look at the past precedent, and based upon past precedent, every lawyer will

argue that is what you have to do because that is what you did in 2006 and that is what you are going to have to do in 2010 and 2014. I will stand by my statement which I basically mean, this has been going on for a long time, long before this committee brought it before, and I believe the tentacles of the drug companies influence the research of the NIH, much to the dismay of the American people.

DR. KINGSTON. We disagree with that characterization.

MR. BURGESS. The gentleman's time has expired. Do you have any objection if I have a second round of questions? Thank you. Dr. Kington, I can't believe that with that last thought, I mean clearly there is a benefit for having a relationship between a pure research structure which is the National Institutes of Health and the private companies, the pharmaceutical companies and the biotech companies on the outside. There is no question that there are great things happening at the NIH but in order to deliver those great things into the treatment rooms and into the operating rooms and into the hands of the American people, it does require a collaboration between NIH and the private sector. Would you agree with that statement?

DR. KINGSTON. Yes.

MR. BURGESS. And I guess I am also a little troubled because I haven't been here for 10 years and when I came in, it was roughly around the time that you promulgated the new rules that were very restrictive as far as allowing researchers at NIH to collaborate or to work in consultation with outside sources, and again, I am concerned about a young person who shows great promise and a great mind not availing themselves of a career at the NIH because after all, it is a dead-end job. You can't go anywhere. Your earnings are capped and you will do far better if you work for someone in one of the pharmaceutical houses or one of the biotech companies. Is that a concern of the NIH?

DR. KINGSTON. It is a concern. We believe that we offer a really extraordinary and unique place to conduct scientific research. It is also important to note that we can still and do engage in collaborative research with industry. We do it using many different mechanisms including what is called a CRADA, a cooperative research and development agreement, which is done in a very transparent, open, competitive way in which we actually have an explicit agreement to work together with industry to develop an area of science. So there are opportunities for our scientists to work collaboratively in their official capacity and we are concerned about, that we have to provide the type of environment that allows us to continue to recruit and retain the very best researchers and we will be monitoring that on a continuing basis.

MR. BURGESS. And in general, has Congress been helpful to you toward that goal or hurtful?

DR. KINGSTON. This has been a painful process for us but we think that we are a better agency as a result.

MR. BURGESS. Let me--and I will just say, I have made several trips out to the NIH and I am always just absolutely astounded by the way your researchers have the ability to look over the horizon and see things that are coming that the rest of us would never even consider.

But Dr. Niederhuber, let me just ask you a couple of questions. We have had you here and I came in late and I don't know whether anyone has bothered you or not on this panel. Dr. Thomas Walsh, that name has come up. You are familiar with Dr. Walsh?

DR. NIEDERHUBER. Yes.

MR. BURGESS. Now, as I understand it, Dr. Walsh was involved in some of the same types of activities that Dr. Sunderland was, but perhaps not nearly to the degree that Dr. Sunderland was involved. Is that a fair characterization?

DR. NIEDERHUBER. Yes, I think that is fair.

MR. BURGESS. In your--and by the way, welcome and congratulations on being the new head of the NCI. I think that is tremendous. Andy Esenbach was always a good friend. I look forward to him doing good things over at FDA. But have you exercised your supervisory authority to restrict Dr. Walsh's workplace activities and some of his outside activities given the nature of the allegations?

DR. NIEDERHUBER. Yes. We have certainly restricted his outside activities as Dr. Kington has indicated. Dr. Walsh, as you may know, is probably the world's expert on antifungal agents and a very distinguished and compassionate physician. He still is a very valuable part of the clinical team in terms of the patient work that we do at NCI because of that expertise.

MR. BURGESS. Would you regard the infractions alleged to have been committed, were they serious violations?

DR. NIEDERHUBER. We certainly agree that these were serious. These were in many ways acts of omission in terms of reporting, shouldn't have taken place, certainly violated the code of conduct for the NCI and the NIH.

MR. BURGESS. Was there consideration given to terminating the relationship with this individual?

DR. NIEDERHUBER. Yes.

MR. BURGESS. And what was the decision there?

DR. NIEDERHUBER. We in November of 2005 made that recommendation.

MR. BURGESS. That his service would be terminated?

DR. NIEDERHUBER. Yes.

MR. BURGESS. And what is the status of that currently?

DR. NIEDERHUBER. That is--as Dr. Agwunobi has said, the Admiral has said, it is under current review.

MR. BURGESS. So that--Admiral, that is under the same status that we were informed for Dr. Sunderland?

DR. AGWUNOBI. No, sir. A board of inquiry has been ordered by the Acting Surgeon General.

MR. BURGESS. Can a scientist at the National Cancer Institute accept gift donations specifically to support his lab or her lab from a drug company in exchange for services performed for the drug company, Dr. Niederhuber?

DR. NIEDERHUBER. Not at this time.

MR. BURGESS. At any time in the past has that been--

DR. NIEDERHUBER. I am not sure I know the answer to that. I defer that to Dr. Kington. He would probably know the history better than I do.

DR. KINGSTON. I don't believe it was ever explicitly approved to have a quid pro quo, but again, this is a sort of special area of law that I am not specifically familiar with.

MR. BURGESS. Well, Dr. Niederhuber, currently does the NCI conduct any conflict-of-interest review over gifts such as these, gifts that would be given to a specific researcher in return for specific work?

DR. NIEDERHUBER. Gifts can--at this time, we have a system, and Dr. Kington can also comment on this, but we have a system through the foundation of NIH in which we keep our science and our scientists really at arm's length so it is a way of continuing to work with the private sector, but it is done through a process and a foundation that keeps our scientists directly away from the source of those gifts and the company. Is that a fair--do you want to comment further--

DR. KINGSTON. And we would be happy to sort of comment for the record in more detail about this specific question if there are specific questions you had about how the policy was implemented for accepting gifts.

MR. BURGESS. Very well. Well, under what conditions would a scientist at the National Cancer Institute be able to assist a drug company with advisory meetings with the FDA?

DR. NIEDERHUBER. Well, we have--we are working on putting a very specific policy in place. That is not quite completed yet. Dr. Kington can comment again on that. But the only way at this time that I am aware that one of our distinguished scientists with specific expertise that could be helpful to the American people, helpful to the specific committee of the FDA reviewing a particular question would be in the official line of duty as an expert, more or less an expert witness to that, not as a representative of any outside agency.

DR. KINGSTON. It is important to note that NIH employees may not under Federal law appear before the Food and Drug Administration as a representative of a private company. It is a violation of Federal law to do that. There may be circumstances in which the expertise of an NIH scientist is appropriately brought to bear to aid the sister agency in assessing the science and that can and does happen. As Dr. Niederhuber pointed out, we are in the midst of developing clearer guidelines so that everyone understands what the criteria are for deciding when it is appropriate to do that.

MR. BURGESS. Well, again, I want to thank everyone for--oh, I beg your pardon. The Chairman is back. The Chairman is recognized for--

CHAIRMAN BARTON. I just have a few wrap-up questions. I want to go back to try to tie this thing down on this court of inquiry with the Assistant Secretary for Health and I mispronounced your name, Agwunobi. Is that close?

DR. AGWUNOBI. Thank you, sir. That is perfect.

CHAIRMAN BARTON. I at least want to try to get your name right. When do you expect the court of inquiry to be convened on Dr. Sunderland?

DR. AGWUNOBI. As per our policy, sir, when we receive clearance from the Office of Inspector General, we will proceed. The orders have been written and the board is currently suspended pending receipt of that clearance.

CHAIRMAN BARTON. When do you expect to get that?

DR. AGWUNOBI. Sir, I would be reluctant to guess.

CHAIRMAN BARTON. Well, guess.

DR. AGWUNOBI. Sir, not knowing the ongoing details of the criminal investigation, not knowing what the allegations are specifically and where and what--

CHAIRMAN BARTON. Are you going to do anything as a consequence of today's hearing to try to expedite the convening of that board of inquiry?

DR. AGWUNOBI. Sir, I can assure you that as soon as we receive clearance to proceed, we will proceed immediately.

CHAIRMAN BARTON. But you are not going to do anything to get clearance to proceed?

DR. AGWUNOBI. Sir, we are going to continue to seek to avoid any intervention that would hamper the pursuit of justice in a criminal investigation.

CHAIRMAN BARTON. So you are not going to do anything?

DR. AGWUNOBI. Sir, we are following all our policies and we stand ready to--

CHAIRMAN BARTON. No, you are not. You are sitting on your bottom and you are not doing anything. Be honest about it.

DR. AGWUNOBI. No, sir.

CHAIRMAN BARTON. How long has it been since Dr. Insel recommended Dr. Sunderland be terminated?

DR. AGWUNOBI. I am not sure when Dr. Insel made the recommendation.

CHAIRMAN BARTON. How long has it been, Dr. Insel?

DR. AGWUNOBI. I can tell you that the NIH first responded--first indicated to us in December of 2005, I think that is correct, they would like for us to pull together a board of inquiry. The order was written pretty much within 60 days and suspended quickly upon the receipt of a request to do so.

CHAIRMAN BARTON. Dr. Insel, how long has it been? Is he correct? Is that November of 2005?

DR. INSEL. I think the letter was November 21, 2005.

CHAIRMAN BARTON. Are your hands tied until this court of inquiry is convened?

DR. INSEL. Well, as far as I can tell, we are using up our options. We can restrict activities but he is still with us until we have a decision from the Commissioned Corps.

CHAIRMAN BARTON. And Dr. Kington, is it NIH policy that when another agency requests your agency to do something, you stop everything you are doing and don't take any further action until that agency is satisfied with its action?

DR. KINGSTON. I don't think as a rule there is an explicit policy but in general--

CHAIRMAN BARTON. Well, is it a rule that if the Department of Justice--that there is going to be no pressure exerted on the Commissioned Corps to do this court of inquiry until the Department of Justice says it can? Is that your rule?

DR. KINGSTON. No, but the practice has--

CHAIRMAN BARTON. Do you have the ability to do the court of inquiry without the permission of the Department of Justice?

DR. KINGSTON. We don't conduct the board of inquiry. The--

CHAIRMAN BARTON. I know that.

DR. KINGSTON. --Commissioned Corps does, so we can't--so the answer is, we cannot.

CHAIRMAN BARTON. But the Inspector General is part of Dr. Zerhouni's management team.

DR. KINGSTON. Well, actually, the Inspector General is an office of the Secretary of the Department. They are the official liaison with the

Department of Justice for us so--but in any case, the board of inquiry--we can't conduct a board of inquiry.

CHAIRMAN BARTON. I understand that. I am not asking you to conduct it. I am asking you to help expedite it. The Commissioned Corps is not going to do anything. They will be sitting here 3 years from now saying they can't do anything if the Department of Justice has an ongoing investigation.

DR. AGWUNOBI. Sir, we are in constant communication with the Department of Justice. We are working closely with--

CHAIRMAN BARTON. As far as I am aware, it is not a law of the United States that one agency cannot conduct its own disciplinary action subsequent to a criminal investigation at another agency. Now, that may be the practice and that may be a gentleman's agreement but it is not the law.

DR. AGWUNOBI. Sir, it is a policy within the Commissioned Corps that we--

CHAIRMAN BARTON. Well, I am going to formally recommend that you make an exception to that policy. You have somebody thumbing his nose at the entire NIH code of ethics and you folks don't seem to care. This committee cares. And I am going to call Dr. Zerhouni and I will talk to the Inspector General and we are going to get in touch with the Department of Justice, but it is a farce of what the American people think is right and wrong to not be able to go forward because the Department of Justice has a pending investigation. I have worked with the Department of Justice for 20 years and they have some investigations that go on for 20 years. So if you wait for them to finish their investigation, you may be waiting. In fact, you may retire without it happening, and my guess is, if I have the staff call over to DOJ or I call the Attorney General, they're going to say we haven't told the Commissioned Corps they can't do their board of inquiry; we just let them know that we have a pending investigation. I mean, I have been down that road before. So, you know, this is not a good day for truth and justice in the American system because you have at least one individual who appears to have really committed some egregious violations and he is not being held accountable, and I think that is wrong. And with that, I yield back, Mr. Chairman.

MR. BURGESS. I thank the Chairman of the full committee. With that, not seeing any other Members who wish to speak, I want to thank the panel of witnesses for their attendance today and their testimony. We certainly appreciate their participation in this hearing.

This hearing will stand adjourned. The record will remain open for the requisite 30 days.

MR. STUPAK. And Mr. Chairman, just one more. Written questions will be included in for the hearing?

MR. BURGESS. Correct.

MR. STUPAK. Thank you.

[Whereupon, at 3:31 p.m., the subcommittee was adjourned.]

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