

**Report of the
National Institutes of Health
Blue Ribbon Panel on Conflict of Interest Policies**

**A Working Group of the Advisory Committee to the Director
National Institutes of Health**

June 22, 2004



ACKNOWLEDGMENTS

The members of the Committee express their appreciation to the staff of the National Institutes of Health for its administrative support and assistance in fact gathering. The editorial contributions of Dr. Kathi Hanna, an independent consultant, were of major importance in enabling this report to be prepared in the short period of time that was available. All findings and recommendations are entirely those of the Committee.

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FOREWORD

On May 6, 2004, at the 88th meeting of the Advisory Committee to the Director (ACD), the Blue Ribbon Panel on NIH Conflict of Interest Policies, a working group of the ACD, presented its report and recommendations. During the ACD's deliberations, the Panel clarified and amplified several of its points and responded to concerns and questions raised by ACD members. The essence of those deliberations is summarized below. At the conclusion of the session of the ACD meeting devoted to the Panel's report, the ACD voted to accept the Panel's recommendations and transmit them to the Director, NIH.

The definition of "industry" for purposes of the report

The Panel indicated that when the report refers to "industry," the Panel means businesses, such as pharmaceutical and biotechnology companies, and units of other companies that are engaged in similar work.

Positions categorized as "most senior"

The ACD asked for clarification regarding which employees would be considered "most senior" and thereby subject to special restrictions such as the prohibition on consulting. The Panel indicated that they viewed seniority on the basis of the *function* of employees and that the degree of leadership and the breadth of authority held were factors in considering a position "most senior."

Salary ceiling

On the issue of the competitiveness of NIH salaries, the Panel emphasized that only two groups of NIH research staff have salary levels below market rates, the most senior leaders and staff clinicians. The Panel also explained that, because the ceiling on NIH salaries is set through negotiation with the HHS, indexing the top salary to the cost of living is not an option. The current salary ceiling, as determined by the Secretary of HHS, is \$200,000 but retention bonuses and other additions to base pay can bring annual income above that amount.

Time and dollar restrictions on outside activities

The Panel indicated that the report does not address implementation of recommendations. Thus, the report does not cover mechanisms for tracking time spent on approved outside activities in order to apply the recommended 400-hour limit. However, in discussion, the Panel and ACD agreed that, if the recommendation is implemented, tracking outside activity hours will be challenging because these activities take place during an employee's off-time (evenings, weekends, and vacation time). They also agreed that it will be important not to create a "punch-the-time-clock" atmosphere and the Panel noted that the role of supervisors would be important.

The Panel emphasized that the exception to time and dollar restrictions applies specifically to persons providing outside medical care and patient services. The exception would raise the

dollar cap on outside income to 100% of salary, remove the one-source limitation, and provide for a more flexible limitation on time.

Prohibition on compensation in the form of equities

The ACD expressed interest in whether any other federal agency prohibits equities as a form of compensation for outside activities. The Panel was not aware of any agencies that do have such a prohibition and subsequent staff review of materials supplied to the Panel by the Office of Government Ethics did not identify supplemental regulations with such a restriction. The Panel indicated that, in recommending a prohibition on equity compensation, it was aware that such a prohibition could discriminate against small pharmaceutical and biotechnology companies, companies with more promise than cash flow. The Panel reported that it had weighed the potential for such discrimination against the potential damage to NIH's reputation and had decided that the risk to NIH's reputation was the greater danger, and the prohibition on equity compensation is a reasonable tradeoff in order to allow appropriate outside activities to continue. Based on the discussion with the ACD, the Panel agreed that, if the prohibition is implemented, NIH should monitor its impact for deleterious effects.

To further explicate its rationale for the prohibition on equity compensation, the Panel differentiated royalty income from equities. While both can create ongoing income streams, royalties are a stake in an intellectual *property*. The value of intellectual property largely is determined at time of development; later actions make little difference. Equity is a stake in a *company*, so ongoing and future actions can significantly affect the value of the holding. Thus, the conflict of interest concerns associated with equity income are not pertinent to royalties.

Amendments to requests for approval of outside activities

The Panel clarified that its recommendation on requiring annual updates to requests for approval of outside activities does not replace or change the current requirement that employees re-file such requests whenever they have a new outside activity or a substantive change in an ongoing outside activity.

ACD action

Having addressed these issues, the ACD accepted the Blue Ribbon Panel report and voted unanimously to submit the report to the Director, NIH, after it had been updated to reflect the ACD deliberations. This foreword provides the requested revision.

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EXECUTIVE SUMMARY

Recently, concerns have been raised in the media and Congress that some employees at the National Institutes of Health (NIH) have engaged in paid consulting arrangements with, or held shares in, biotechnology companies or other entities that could influence their work as government employees, thereby creating real or perceived conflicts of interest. These concerns have brought new attention to NIH policies regarding approval of such consulting arrangements, the nature of these arrangements (e.g., consulting versus speaking, teaching, or writing), the viability of the NIH system for monitoring outside activities, and the substantial number of high-level NIH employees who are not currently required—by existing laws and regulations—to file public financial disclosure statements.

This report responds to NIH's own inquiry into its conflict of interest policies. Are they sufficient to uphold agency standards and maintain public trust in NIH and its activities? As part of the NIH examination of the consulting activities of NIH investigators, the NIH Director established the Blue Ribbon Panel on Conflict of Interest Policies as a working group of the Advisory Committee to the Director, NIH. This Panel was charged to:

- 1) Review the existing laws, regulations, policies, and procedures under which NIH currently operates regarding:
 - Real and apparent financial conflict of interest of NIH staff where compensation or financial benefit from outside sources is received, including consulting arrangements and outside awards; and
 - Requirements and policies for the reporting of financial interests by NIH staff, including which interests are subject to public disclosure, and what portion of NIH staff file public disclosures;
- 2) Make recommendations for improving existing laws, regulations, policies, and procedures as appropriate;
- 3) Complete the review and development of recommendations within 90 days;¹ and
- 4) Provide recommendations to the Advisory Committee to the Director, NIH, for deliberation and final recommendations to the Director, NIH.

In keeping with this charge, and in making its recommendations, the Panel did not investigate specific allegations or review individual cases under investigation at NIH. Its primary goal was to assess the current status of conflict of interest policies and procedures and make recommendations for improvement, looking to the future.

In its deliberations the Panel found an extremely complex set of rules governing conflicts of interest at NIH. These rules are widely misunderstood by some of the very people to whom they are intended to apply, thereby creating uncertainty as to allowable behavior and adversely affecting morale.

The Panel adhered to one guiding principle in developing its recommendations: NIH employees must avoid conflicts of interest incompatible with the proper exercise of their authority and the

¹ To accommodate NIH and congressional schedules the Panel completed its work in 66 days.

proper performance of their duties. Employees in a position to influence the financial interests of an outside entity such as a current or possible future recipient of an NIH grant or contract should neither receive financial benefits from that organization nor have significant financial interests in it.

The Panel found that relatively few NIH employees engage in consulting agreements with biotechnology or pharmaceutical companies—an activity that currently involves approximately 120 of NIH's 17,526 employees. Yet the high level of reasonable concern expressed by Congress and the media about the potential for conflicts of interest when consulting with industry—itsself a small fraction of the outside activities engaged in by NIH scientists—has had a decidedly negative impact on the morale of a large number of NIH intramural scientists.

In contrast to industry related activities, a substantial number of NIH employees are involved in outside activities with professional societies and with academic and research institutions—primarily in the forms of teaching, speaking, or writing (including editing). In addition, NIH scientists who are recognized for outstanding scientific achievements, leadership, or public service are sometimes the recipients of awards, which may be accompanied by a cash prize. The Panel believes these are important—even essential—activities for NIH scientists, because they are part of the tradition of science and provide evidence of the value and significance of the NIH research community to the larger scientific community.

In its interviews with NIH scientists, the Panel observed that the heightened scrutiny about all ethics issues has further increased the confusion about the existing policies, with a widespread sense that rules are being changed midstream or suddenly overly interpreted out of caution. This has caused heightened concern that NIH scientists will be unable to fully participate in the community of science in the future and has contributed to fears about the impact that possible new policies could have on the recruitment and retention of scientists at NIH. Worse yet, there seems to be widespread fear among NIH employees that they could commit an inadvertent transgression resulting from the difficulties involved in interpreting the sometimes arcane and complex rules.

The Panel believes that the recommendations presented in this report are important for correcting these concerns, and it urges that they be adopted as quickly as possible. This is needed to assure the continued, deserved public confidence in the work of NIH. It should be noted that the Panel did not limit its review to what is possible within existing laws or regulations, but rather focused on those actions that it believes will best serve the NIH mission in the future.

RECOMMENDATIONS

Recommendation 1: NIH senior management and NIH extramural employees who are responsible for program funding decisions and recommendations, and professional staff managing grants and contracts and application review, should not engage in consulting activities with pharmaceutical or biotechnology companies or in paid consulting for academia. The Panel considers speaking for compensation at an industry site as equivalent to consulting for industry. The Panel does not include in this prohibition

time spent in clinical practice by health care practitioners, if approved as an outside activity free of conflicts.

Recommendation 2: The Panel reaffirms current federal law, which states that intramural scientists conducting research with human subjects—for example, investigators and research team members involved in patient selection, the informed consent process, and clinical management of a trial—should not be allowed to have any financial interest in or relationship with any company whose interests could be affected by their research or clinical trial, except in special circumstances, and with an appropriate waiver or authorization.

Recommendation 3: In addition to existing requirements for engaging in outside activities, and the restrictions posed in Recommendations in 1 and 2, the following requirements should be in place for all employees who are involved in the administration or conduct of NIH research programs:

- a. The total amount earned annually from compensated consulting with industry or academia should not exceed an amount equal to 50 percent of the employee's annual salary, and no one source should account for an amount exceeding 25 percent of annual salary.
- b. Employees eligible to engage in compensated outside professional activities should not:
 - i. receive compensation in the form of stock options or other forms of equities for their services
 - ii. spend more than 400 hours per year on these activities (writing excepted).
- c. An exclusion to the above limits should exist for NIH employees who are health care practitioners. For these employees, there should be a more flexible time limitation and the capitation for compensated outside medical care and patient services should be 100 percent of base pay, with the one-source limitation removed.

Recommendation 4: To improve NIH's ability to manage and track approved outside activities:

- a. all requests for outside activities (Form 520) should be updated on an annual basis (with such updates indicating only those changes that have occurred);
- b. supervisors should be held accountable for the evaluation and approval of outside activity requests, and this supervisory function should be a component of a supervisor's performance evaluation; and
- c. NIH should publish an annual agency-wide statistical report on the number and types of outside activities approved for its employees.

Recommendation 5: NIH should seek a change to OGE regulations to allow NIH scientists to receive compensation for teaching, speaking, or writing about their research providing that the information is to be shared in a public forum *and* that it has appeared in the published literature.

Recommendation 6: NIH intramural scientists should continue to be allowed to engage in compensated speaking, teaching, and writing for professional societies and for academic and research institutions as an outside activity providing that all ethics review and approval requirements are met.

Recommendation 7: NIH should seek a change to OGE regulations to permit employees to be identified by their title or position (and institutional affiliation) when engaged in teaching, speaking, or writing as an approved outside activity. Disclaimers should be provided that the activity is not being conducted in the employee's official capacity as an NIH employee and that the views expressed do not necessarily represent the views of NIH.

Recommendation 8: There should be no restrictions on royalties received on works written, edited, or published or on income received from patents licensed by any NIH employee who conducted the work as an approved outside activity.

Recommendation 9: The current OGE rules regarding receipt of bona fide cash awards for meritorious public service or achievement and NIH's interpretations of the rules are reasonable and should apply to all employees. There should be no limit on the amount of money received from a bona fide award. These awards are considered gifts under current law and are not considered outside activities because the employee accepts the award in his or her official capacity.

Recommendation 10: To increase NIH's ability to manage conflicts of interest, it should move immediately to either increase the number of employees required to annually file a confidential disclosure form (Form 450) or find some other means to achieve comparable levels of internal disclosure.

Recommendation 11: NIH should ask OGE to make a regulatory change or seek statutory modifications to provide NIH with greater discretion in determining whether certain Title 42 employees should file a public financial disclosure form (Form 278). This would promote the public interest by increasing transparency and would thereby enhance trust in government. In the meantime, NIH should seek additional equivalency rulings from OGE to increase the number of public filers to include the senior employees specified in Recommendation 1.

Recommendation 12: NIH supervisors should be provided with enhanced training on the criteria to be used for their annual review of financial disclosures so that they can become more effective in managing and avoiding employee conflicts of interest.

Recommendation 13: To preserve public confidence in NIH, the agency should put in place a policy that requires employees to disclose all relevant outside relationships and financial holdings in their work products, such as publications, speeches, and invention disclosures. In addition, where relevant, such disclosures should be made to potential research subjects as part of the informed consent process.

Recommendation 14: NIH employees should be required to submit recusals in writing to immediate supervisors when a potential conflict of interest emerges. The supervisor should then be required to inform those who should be aware of the employee's need to be recused from the official duties for which there is a conflict. As is currently the case, when an employee must be recused from official duties, those duties can be reassigned only to someone at an organizational level above the employee. As such, recused employees or their supervisors will need to inform both superiors and affected subordinates of the recusal.

Recommendation 15: The NIH Ethics Office should prepare a user-friendly document and website that displays the ethics rules in simple language and emphasizes examples of outside activities and financial interests that are permissible, as well as those that are not. Employees seeking approval of outside activities should, as part of their submission of Form 520 and its supplements, indicate in writing that they have reviewed these summary materials and have discussed any questions they have with their relevant ethics official and/or supervisor.

Recommendation 16: The NIH Ethics Advisory Committee should issue a report of its findings, in the form of anonymous case studies and generalizable principles, on a regular basis to provide the NIH community with a clear common body of knowledge by which to understand and interpret ethics rules.

Recommendation 17: NIH management should assure that sufficient resources are provided for the administrative and management functions of its ethics activities to guarantee that the expanded program proposed in this report can be implemented.

Recommendation 18: The NIH Director, working with Congress, should ensure that the agency has authority under Title 42, or some other hiring mechanism, to recruit senior scientific staff in the current highly competitive market. In addition, the NIH Director should ask HHS to review and, if appropriate, raise the current annual salary capitation of \$200,000 for the most senior Title 42 employees at NIH. The Panel is concerned that the present ceiling is limiting the agency's ability to recruit and retain the nation's best scientists as the leaders of NIH.

The Panel believes that the recommendations presented in this report are important for addressing these concerns, and it urges that they be adopted as quickly as possible. This is needed to assure the continued, deserved public confidence in the extraordinary work of NIH, and the quality of its scientific staff. It is also critical for rectifying what the Panel perceives as a growing morale problem among the agency's excellent staff.

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Section I. Introduction

Since the middle of the twentieth century, the American people have invested generously as a nation in biomedical research, believing that such an investment constitutes a public good by improving human health and welfare, directly or indirectly yielding economic dividends, and increasing overall understanding of the human condition. The impact of U.S.-funded medical research has proved to be among one of this country's greatest achievements, saving countless lives and significantly improving the quality of life of people around the world. Each year gains are made in the prevention, diagnosis, and treatment of many diseases, including cardiovascular disease, infectious diseases, stroke, cancer, and depression.

For example, research conducted or sponsored by the National Institutes of Health (NIH), an agency of the Department of Health and Human Services (HHS), has led to a major reduction in mortality related to coronary heart disease and stroke, helping to reduce deaths from coronary heart disease from an expected number of more than 1,300,000 in 2000 to 514,000. Progress has been equally remarkable for hepatitis B and C infections, new cases of which are on the decline, in part because of improved vaccines and the reduced risk of infection from blood transfusion—both outcomes of NIH-funded research. These are but two of hundreds of examples that could be cited to show the benefit of the nation's investment in NIH.

NIH has been the principal steward of this nation's public investment in health research. Through its 17,526 full-time equivalent employees in 27 institutes, centers, and the Office of the Director, NIH conducts and funds biomedical and behavioral research, research training, and related programs for the promotion of health and the dissemination of health information. Its mission is "science in pursuit of fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to extend healthy life and reduce the burdens of illness and disability." More specifically, the NIH mission is to:

- 1) foster fundamental creative discoveries and innovative research strategies and their applications as a basis for advancing significantly the nation's capacity to protect and improve health;
- 2) develop, maintain, and renew scientific human and physical resources that will assure our capability to prevent disease;
- 3) expand the knowledge base in medical and associated sciences in order to enhance the nation's economic well-being and ensure a continued high return on the public investment in research; and
- 4) exemplify and promote the highest level of scientific integrity, public accountability, and social responsibility in the conduct of science.

At the same time that NIH pursues fundamental knowledge related to the prevention, diagnosis, and treatment of a wide variety of common and rare disorders, steady change in the landscape of disease and public health concerns requires that it continuously adopt new approaches and accelerate the pace of its discoveries. For example, NIH has been asked by the public to respond to new challenges posed by an aging population that is experiencing more chronic disease; an

epidemic of obesity, especially among children; AIDS and other emerging infections such as SARS; health disparities; and biodefense.

In addition, the science and technology critical to conducting research is constantly evolving. Powerful and unifying concepts of biology are emerging from the fields of molecular biology, genomics, and proteomics, with the potential to lead to rapid progress. As one example, in the past, cancer research was considered vastly different than heart or brain research. Today, with recent discoveries in molecular and cell biology, we know that biological systems obey common laws and follow similar pathways in both health and disease.

Another critical NIH mandate is to sustain and improve the national clinical research enterprise to ensure that it optimally translates basic discoveries made in the laboratory into clinical application. As a result, the agency supports multidisciplinary clinical research training career paths, innovations in clinical trial design, translational research, and shared clinical resources such as tissue banks and research networks. A phenomenon that extends across the entire scientific enterprise is its need to build, sometimes slowly, on previous work and on a continuum of knowledge and information from disparate fields—an important concept to remember when trying to draw bright lines between one scientific activity and another.

Efforts to fully pursue this wide array of fundamental and clinical lines of inquiry are beyond the reach of any one laboratory, group of investigators, or institution. This has changed the dynamics of today's research teams and will change those of the future as well, for 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. NIH is continually searching for new organizational models for conducting research, including those that encourage risk-taking and novel partnerships, as well as those between the public and private sectors.

The Nature of NIH Research Activities

NIH scientists conduct basic and clinical research at facilities in Bethesda, Maryland, and elsewhere as part of the agency's *intramural research program*. The excellence and success of the intramural research program rests almost entirely on the ability of NIH leadership to attract and retain the best scientists and clinicians. The research that NIH funds at the nation's universities, medical centers, research institutes, and other nonprofit and for-profit organizations through grants, cooperative agreements, and contracts is referred to as the *extramural research program*. The extramural program is administered by NIH employees working on the Bethesda campus and in outlying areas. The intramural and extramural programs are distinct, administratively and through hiring authorities and funding mechanisms. The extramural program currently constitutes approximately 83 percent of total NIH activity, as measured by resource allocations; the intramural program roughly constitutes 10 percent. (These programs are discussed in greater detail in section II of this report.) The remaining 7 percent is allocated for research management and support and other administrative functions.

Both the intramural and extramural programs interact with academia and with pharmaceutical and biotechnology companies in many ways, including funding agreements, formal research agreements, and intellectual property licenses authorized by statutes intended to encourage the commercialization of technologies beneficial to the public health.

Three laws primarily govern this commercialization activity, including the Stevenson-Wydler Technology Innovation Act (P.L. 96-480) in 1980, the Bayh-Dole Act, and the Federal Technology Transfer Act of 1986, as amended. Under these laws, research agencies are encouraged to give licenses to commercial entities for the development of technologies from government-owned patents, and collect royalties for the government (and its employee inventors) as a result of these licenses. Grantees and contractors are also encouraged to retain title to government-funded inventions. Finally, federal agencies are authorized to enter into Cooperative Research and Development Agreements (CRADAs) with non-federal partners to conduct research. Together these three laws have resulted in substantial increases in the transfer of government-funded technologies from government and university laboratories to the private sector in the United States.

In addition to NIH's leading role, industry funding of its own research plays a substantial and growing role in the conduct of medical- and health-related research, with the industrially funded component now far surpassing the annual NIH investment.

These trends, combined with steady encouragement by the public and policymakers to accelerate the translation of basic research into clinical practice, have progressively blurred the once clear lines between academic, government, and commercial research. Moreover, the complexities of science increasingly require that this be a cumulative, interconnected, and competitive enterprise, because now, perhaps more than ever, scientists and their institutions must balance the essential principles of collaboration and collegiality with requirements of competition and secrecy.

Conflict of Interest Practices

In addition to collaborating with academia and industry as part of its mission, NIH employees are also permitted, under strict laws and regulations, to engage in "outside activities," that is, compensated or noncompensated activities that do not constitute their *official duties* or in any way use their public office or public resources for private gain (see Box A). The difficulty of ascertaining the meaning of official duties cannot be overemphasized when assessing whether real or perceived conflicts of interest arise, because this concept is particularly difficult to delineate in dealing with employees who primarily carry out scientific research.

Outside activities might include providing consultative or professional services, including service as an expert witness or consultant; engaging in teaching, speaking, writing, or editing; or providing services to a nonfederal entity as an officer, director, or board member—or as a member of a group, such as a planning commission, an advisory council, an editorial board, or a scientific or technical advisory board or panel. The receipt of bona fide cash awards for meritorious public service or achievement is *not* considered an outside activity. Rather these awards are considered gifts under current law and the employee accepts the award in his or her

official capacity. However, because some particularly prestigious awards can be sizable, they are worth considering when assessing ethics policies. In all cases, employees must receive prior approval before engaging in any of these types of outside activities (see section IV for an extensive discussion of these issues).

Box A: Outside Activities

An employee may not receive compensation for outside activities that relate to his or her official duties. The basis for this rule is the federal criminal statute, 18 USC 209, which prohibits a federal employee from receiving salary or any contribution to or supplementation of salary as compensation for government service from a source other than the U.S. government. According to regulation, an outside activity is considered related to an employee's official duties if the employee was invited primarily because of his official position (this would be a prohibited use of public position for private gain); or if it deals with any matter to which the employee is presently assigned or has been assigned during the previous one-year period; or if it deals with any ongoing or announced policy, program, or operation of NIH.

In addition, federal regulations establish uniform procedures and requirements for certain federal officials to disclose financial interests that could affect their conduct of official duties (e.g., the ownership of certain stocks and other investments). The Ethics in Government Act of 1978 was enacted to preserve and promote public confidence in the integrity of federal officials through, for example, requiring certain officials to disclose their financial interests. This act also established the government's regulatory agency for ethics, the Office of Government Ethics (OGE), to provide overall direction of executive branch policies related to preventing conflicts of interest, including the development of rules and regulations establishing procedures for the filing, review, and, if applicable, the public availability of financial statements, and criteria to guide agencies in determining which employees should submit these reports. NIH requires its employees to meet OGE regulations for financial disclosure and implements these regulations through the processes and procedures required by these regulations, as interpreted by HHS.

These two sets of laws and regulations—those regarding outside activities and those specifying financial disclosure—are intended to prevent conflicts of interest and ensure that public trust and duties are not compromised by inappropriate interests and that citizens can have confidence in the integrity of the federal government.

In the narrower world of biomedical research, conflicts of interest are a set of conditions in which professional judgment concerning a primary interest (e.g., patient welfare or the validity of research) tends to be unduly influenced by a secondary interest (e.g., financial gain from third parties). In the still narrower context of research with human subjects, if professional judgment is swayed by financial or other interests, subjects can be harmed by, for example, implementing study designs that pose unacceptable risks, enrolling subjects inappropriately, or continuing studies that should be modified or stopped. Thus, in some cases conflicts can increase the chances that tangible or even mortal harm could occur.

In the broader world of public service, avoiding conflicts of interest is based on following a set of principles: (1) employees should not engage in financial transactions that conflict with the conscientious performance of duty; (2) employees should not use public office for private gain;

(3) employees should act impartially and not give preferential treatment to any private organization or individual; and (4) employees should not engage in outside employment or activities, including seeking or negotiating for employment, that conflict with official government duties and responsibilities.² As employees of the federal government, NIH employees are subject to federal statutes and regulations that implement these principles of ethical conduct.

Another term, conflict of commitment, is used to describe conflicts in which outside activities, even if not directly in violation of ethics rules, nonetheless distract the employee from one or more of his or her employer's primary interests. For example, an NIH scientist who owns and operates a restaurant nights and weekends might be too tired or distracted to function adequately while at his or her government job.

Although financial interests are typically the main concern when discussing conflicts of interest, they are not the only interests that can cause conflicts. Other interests and activities are inherent to the scientific profession and less tangible than financial compensation and therefore may be more difficult to identify. These include the desire for professional recognition, the need to compete successfully for research resources and promotions, and the desire to disseminate and communicate research findings. Scientists rely on the ability to share information, meet with other scientists regularly, and publish their work. A free exchange of ideas to the extent possible is needed to advance the goal of science, which is to gain new knowledge by building continually on existing knowledge. Over the past 25 years, however, the research environment has increasingly created opportunities for investigators and institutions to profit financially from research, thus intensifying the focus on the potential financial conflicts of interest that are the main focus of this report.

Conflict of Interest Concerns

Tensions are bound to arise between the appropriate drive of individual government scientists to expand their own lines of inquiry through interactions with the private sector and the real or apparent conflicts that might surface between these activities and their public service responsibilities. In addition, issues of disclosure reflect a tension between the need for transparency regarding issues of public importance and the rights of government employees, as citizens, to some measure of privacy. Difficulties also arise from the generally laudable effort to apply one set of rules across the federal government, yet recognize the unique mission and role of NIH as a research organization.

In 2004, NIH's total budget of over \$28 billion is by far the largest public investment in biomedical and behavioral science made by a single nation. In recent years (1999-2003), NIH's budget has doubled, reflecting the generally positive attitude of the public and its representatives toward biomedical science. However, despite nearly universal agreement that NIH is a national treasure, with a level of public support envied the world over, the perception of conflicts of

² These principles of ethical conduct are set forth in Executive Order 12674 (April 12, 1989).

interest among NIH scientists could endanger NIH's mission and reputation and result in diminished public trust. It also could have disastrous consequences for the broader scientific community and NIH itself, as integrity in research is crucial for maintaining scientific excellence and sustaining the public's trust and participation in, and commitment to, scientific research. This requires accountability and transparency in setting priorities, making funding decisions, and conducting the research itself, as well as ensuring that actions are not subject to suspicion or question.

Recently, however, concerns have been raised that some senior NIH scientists have been receiving consulting payments from, or have held shares in, biotechnology companies or other entities that were benefiting from decisions that those scientists could have influenced at least in principle. Concerns also have been expressed regarding the extent of outside consulting engaged in by NIH employees and the potential for conflicts with their official duties. These concerns have brought new attention to the NIH policies that result in approval of such consulting arrangements, the nature of these arrangements (e.g., consulting versus teaching, speaking, or writing), the viability of NIH policies and procedures for monitoring outside activities, and the substantial number of high-level NIH research employees who are not currently required—by existing laws and regulations—to file public financial disclosure statements. They have also led to a series of responses by Congress, federal investigative offices, and NIH itself.

Charge to the NIH Blue Ribbon Panel on Conflict of Interest Policies

This report responds to NIH's own inquiry into its conflict of interest policies and whether they are sufficient to maintain public trust in the agency and its activities. As part of the NIH examination of the consulting activities of NIH investigators, the NIH Director established the Blue Ribbon Panel on Conflict of Interest Policies as a working group of the Advisory Committee to the Director (ACD), NIH. This Panel consists of members of the ACD and outside experts, who are charged to:

- 1) Review the existing laws, regulations, policies, and procedures under which NIH currently operates regarding:
 - Real and apparent financial conflict of interest of NIH staff where compensation or financial benefit from outside sources is received, including consulting arrangements and outside awards.
 - Requirements and policies for the reporting of financial interests by NIH staff, including which interests are subject to public disclosure and what portion of NIH staff file public disclosures.
- 2) Make recommendations for improving existing laws, regulations, policies, and procedures as appropriate.
- 3) Complete the review and development of recommendations within 90 days.³

³ To accommodate NIH and legislative schedules the Panel completed its work in 66 days.

- 4) Provide recommendations to the ACD, NIH, for deliberation and final recommendations to the Director, NIH.

In keeping with this charge, the Panel did not investigate specific allegations or review individual cases under investigation elsewhere. Its primary goal was to assess the current status of conflict of interest policies and procedures and make recommendations for improvement, looking to the future. The Panel met three times in person and once by telephone between March 1, 2004, and April 28, 2004, and heard testimony from over 30 individuals (see appendix C). On the Panel's behalf, a website was established to collect NIH staff views on outside activities, with over 300 responses received (see appendix D). In addition, individual Panel members interviewed, either in person or by telephone, all 27 NIH institute and center directors. At each open meeting of the Panel, time was set aside for public comment, and notices of all meetings were posted in the *Federal Register*.

At the same time the Panel was conducting its work, NIH was also responding to other investigations, including the following:

- HHS Office of Inspector General (OIG): The OIG review is focusing on outside activities and, in addition to writing a descriptive report, it will examine compliance with requirements to provide information on outside activity request forms. OIG held an entrance conference with NIH on March 26, 2004. The final design for the OIG review calls for completing data collection by May 14 and data analysis by June 14. The exit conference will not be held until mid-July 2004 at the earliest.
- OGE program/compliance review: OGE is examining compliance and effectiveness of certain elements of the NIH ethics program (e.g., financial disclosure, outside activities, acceptance of sponsored travel) in selected units of NIH (three institutes or centers and the NIH Ethics Office). OGE has completed its site review, and NIH is awaiting a preliminary report.
- U.S. General Accounting Office (GAO): this review probably will not begin until mid-summer of 2004. GAO's focus will be NIH's implementation of changes in policies and procedures recommended by Advisory Committee to the Director, OGE, and OIG.

Prior to creating the Blue Ribbon Panel, NIH has taken steps to bring greater transparency to employees' reports of financial interests and provide more stringent review of requests for approval of outside activities. On November 20, 2003, the NIH Director announced the establishment of a standing internal committee to strengthen NIH's review of requests for approval of certain outside activities and management of approved outside activities. This review body, the NIH Ethics Advisory Committee (NEAC), is internal to NIH and advisory to the NIH Deputy Ethics Counselor and charged with the review of outside activities for NIH employees in certain positions (e.g., senior NIH officials) and other NIH employees who want to participate in certain types of outside activity (e.g., involving a biotechnology or pharmaceutical company or more than \$10,000 annually in compensation). As of May 1, 2004, NEAC had met 15 times and reviewed 211 cases.

In other events, on February 6, 2004, OGE notified NIH of its approval of the agency's request that 93 high-level positions be considered of "equal classification" to positions subject to the requirement for filing public financial reports. Thus, before and during the Panel's deliberations, events were transpiring to strengthen NIH's system for oversight and management of conflicts of interest.

This report has been organized to directly respond to the Director's charge to the Panel. Following this introduction, section II provides background information on the structure and culture of NIH as a backdrop to the sections that follow. Section III addresses the requirements and policies for reporting by NIH staff of financial interests, including which interests should be subject to public disclosure and who should be required to publicly disclose such information. Section IV addresses the issue of outside activities, focusing on the adequacy of existing laws, regulations, policies, and procedures. Section V provides a summary of the Panel's views and recommendations on these complex issues.

Section II. Background

Understanding some of the key organizational and administrative elements of the National Institutes of Health (NIH) is essential in developing an appreciation of its unique status as a federal agency as well as the difficulties it faces in achieving a uniformly executed ethics policy. These elements include the division of NIH's 27 institutes and centers into intramural and extramural programs, its various hiring authorities and the implications for salary and disclosure of personal financial information, and NIH's mandate to transfer knowledge and technology to the private sector. Each of these elements provides a particular context for implementing conflict of interest ethics rules, which are described in greater detail in subsequent sections of this report.

Overview of the Structure of NIH

NIH is a large, complex, decentralized organization, with headquarters in Bethesda, Maryland. Originally a small set of federal research laboratories supporting the public health mission of the Public Health Service (PHS), NIH has evolved into a group of 27 major institutes and centers and the Office of the Director, each conducting research and related activities on an aspect of human health and disease—mostly through grants to scientists in universities and other nonfederal research institutions.

In the current fiscal year (2004) NIH has a budget of over \$28 billion. Approximately 10 percent of it is dedicated to the intramural research program. Of that amount, roughly \$900 million is spent on clinical research. Other than a percentage dedicated to purely administrative functions, the remainder of the budget (approximately 83 percent) is expended on the extramural research program.

In 2004, the NIH extramural program expects to fund 37,229 research project grants; a number of other research grants, cooperative agreements, and contracts; and 17,566 full-time training positions. These funds are awarded to an extramural research community of an estimated 212,000 research personnel affiliated with approximately 2,800 organizations, including universities, medical schools, hospitals, and other research facilities, both commercial and not-for-profit, in all 50 states as well as the District of Columbia, Puerto Rico, Guam, the Virgin Islands, and international venues. Of the 17,526 full-time equivalent NIH employees, approximately 3,400 provide support for the extramural program. These individuals are responsible for administering the grants and contracts programs—from the development of programs, to peer review, to disbursement of funds, to monitoring of and accounting for ongoing grants and contracts. In general, extramural program employees, many of whom are scientists, do not conduct research as part of their official duties.

In contrast, the intramural research program consists of more than 2,000 research projects conducted by approximately 5,000 government scientists and technical support staff in laboratories and a 250-bed research hospital on the NIH campus. All but six of the 27 institutes and centers have an intramural program. The intramural research program complements and

supplements the extramural program by providing an environment in which long-term, cutting-edge research can be conducted in response to public health needs.

To understand how conflicts might arise from the activities or financial holdings of NIH employees, it is important to appreciate the various roles and functions that might be assigned to an employee as part of his or her official duties. These responsibilities differ markedly depending on whether the employee is in the extramural or intramural program and by role, including leadership rank within the institute or center.

The Extramural Research Program

NIH provides three major types of awards to the extramural community: grants, cooperative agreements, and contracts. *Grants* for health-related research and research training projects or activities make up the largest category of funding. Research project grants are awarded to institutions on behalf of a principal investigator in order to facilitate the pursuit of research on a scientific objective by the investigator's laboratory. The funds to support this research are awarded through a highly competitive peer review process (review by scientists working in the field who are not NIH employees) on the basis of research plans submitted by each investigator. For such grants, NIH itself anticipates no substantial program involvement. In addition, intramural scientists have no influence on decisions made by extramural program staff. These peer reviewers received a modest honorarium. Most disclose all potential conflicts of interest and recuse themselves from decisions that involve a conflict.

Most applications for grant support are unsolicited and originate with the individual investigators, who develop proposed plans for research or research training within an area of interest to NIH. Occasionally, to hasten the development of a program or to stimulate submission of applications in an area of high priority or special concern, an institute will issue a Program Announcement to describe new, continuing, or expanded program interests, or issue a Request for Applications (RFA), inviting grant applications in a well-defined scientific area to accomplish a scientific task.

Cooperative Agreements are similar to grants in that they are awarded to assist and support research and related activities in the extramural community. However, they differ from grants in that the awarding NIH institute or center has a substantial involvement in carrying out the project's activities. The rights, responsibilities, and authorities of the prospective awardee and the NIH institute are developed in advance. To begin the process, the awarding institute typically issues a specific RFA that describes the expected program, functions, and activities, as well as the nature of the shared responsibilities.

As mandated by law, and with few exceptions, the review of grant and cooperative agreement applications involves two sequential levels of review for each application. In this system, the scientific assessment of proposed projects is kept separate from priority-setting decisions about the scientific areas to be supported and the level of resources to be allocated. The first level of review, the evaluation of scientific and technical merit, is conducted by one of many chartered scientific review groups, referred to as SRGs, managed by the NIH Center for Scientific Review, or by the institutes. The group or panel, established according to scientific disciplines or medical

specialties, may consist of as many as 16 to 20 members who are primarily nonfederal scientists with the appropriate range of expertise in the disciplines and areas of research being reviewed.

The second level of review is performed by National Advisory Boards, or Councils, of the NIH institutes and centers. These panels of 12 to 18 members consist of a mixture of scientists and laypersons chosen for their interest in matters related to health and disease. Council members review the applications against a broad background of considerations, including relevance, program goals, and available funds of the institute; they also consider the appropriateness of the scientific review conducted previously by the SRG.

Contracts for research and development (R&D) are awarded to academic institutions and other nonprofit and commercial organizations in order to procure specific activities for scientific inquiries in particular areas of research and development that are needed by NIH. Contract performance is monitored closely by NIH staff to ensure compliance with the specified statement of work.

Contract projects are subject to a multifaceted review process prior to the award. Usually, institute program staff develop the concept for a project, which must be cleared by an outside advisory panel. The concept for a planned project is then translated by NIH program staff into a Request for Proposals (RFP), which clearly specifies the work that must be done by the contractor. Thus, the review process for solicited R&D contracts differs from that for grants in that all offerors are responding to a government-defined, precise statement of work contained in the RFPs.

The proposals responding to the contract solicitation are evaluated against the evaluation criteria specified in the RFP by technical evaluation groups composed typically of nonfederal scientists, who receive a modest honorarium and must disclose all potential conflicts of interest and recuse themselves from decisions that involve a conflict of interest. The recommendations of peer reviewers and the results of separate NIH staff reviews provide the basis for discussions with offerors that are found to be in the competitive range. At the conclusion of these discussions, the viable offerors are asked to submit their best and final offer. The award is then made based on the final offer judged to be most advantageous to the government. An institute may occasionally make an award in response to an unsolicited proposal for a contract if it meets specific NIH program needs and can be adequately justified as a noncompetitive award.

The institute program staff plays an important role in the funding of high-quality extramural research projects. Their responsibilities within an institute are variously allocated according to grant award mechanisms, medical disciplines, or disease areas. These may be determined by the legislation that authorized the institute, by the language of budget authorizations, by specific delegations of authority from the institute directors or the NIH Director, or, within broad limits, by the actions of the appropriate Councils. Thus, the extramural program staff of the institutes is charged with planning and implementing scientific programs and consulting with the Councils about future program developments. They are responsible for keeping up with scientific developments in relevant areas, and they may convene task forces, workshops, or conferences to assess scientific progress in a field or identify new initiatives for an institute. The tasks involved in implementing these program responsibilities range from providing advice to interested

investigators to organizing extensive collaborative projects requiring a multidisciplinary approach by investigators in one or several research institutions.

In summary, the decisions regarding extramural resource allocations are guided, organized, and overseen by a large team composed of some 3,400 NIH employees. However, because of the magnitude, diversity, and complexity of the NIH mission, the agency draws on a large national pool of non-government scientists actively engaged in research for advice on the selection of the most promising research projects for support. Through a process of peer review, these scientists rate applications for grants and proposals for contracts, and they attend review meetings at NIH to discuss and make final recommendations. These recommendations are in turn considered and acted on by National Advisory Boards, or Councils, that are again composed of individuals who are not NIH employees.

This elaborate system of dual review and oversight makes it exceedingly difficult for any one individual to affect or alter the outcome of a funding decision. However, because NIH employees in the extramural program are involved in the allocation of funds to external entities, they are currently held to the same requirements regarding outside activities as intramural employees (even though intramural employees are not involved in funding decisions)(discussed further in section IV). In addition, OGE regulations permit NIH to prohibit or restrict the acquisition or holding of a financial interest or class of financial interests by agency employees and the spouses and minor children of those employees, based on the agency's determination that the acquisition or holding of such financial interests would cause a reasonable person to question the impartiality and objectivity with which agency programs are administered.

The Intramural Research Program

The intramural program consists of basic and clinical research conducted by NIH employees at the Clinical Center in Bethesda or in laboratory facilities on campus or elsewhere. Research programs focus on specific health problems of special concern to a particular institute or sector, including basic research that may not target a specific disease, but that relates to the overall mission of the institute or center. As with extramural research, taking advantage of scientific opportunities requires continuous adjustments to the intramural research programs.

Each institute or center intramural research program is led by a scientific director, who reports to the relevant institute or center director, and along with the institute or center director is responsible for organizing and administering both laboratory and clinical research. The evaluation of NIH intramural research programs, projects, and investigators is performed by Boards of Scientific Counselors, composed of nonfederal scientists with outstanding achievement and expertise in the areas of research pertinent to each of the NIH categorical disease institutes or centers. They assess the research in progress, the proposed research, and the productivity and performance of staff scientists. The boards serve a dual function; they not only provide expert scientific advice to the institute director and scientific director regarding particular projects and employees, they also assess the overall quality of intramural efforts. The intramural programs of the institutes are also reviewed by the National Advisory Councils and sometimes by additional panels of outside experts convened to address specific issues.

The structure and performance of the entire intramural research program (as well as the individual programs of the institutes and centers) has been evaluated many times over the past 25 years by numerous advisory groups, in response to administrative and legislative mandates. Most recently, Dr. Elias Zerhouni, Director of NIH, convened a Blue Ribbon Panel on the Future of Intramural Clinical Research, which focused exclusively on the clinical research programs across NIH. The intramural research program has been highly scrutinized by outside experts for a number of reasons, including its relevance to the extramural program; problems with recruitment and retention of senior scientists; expansions and contractions of its postdoctoral training programs; its sometimes cumbersome administrative requirements and organizational structure; inadequately funded congressional and administrative mandates; and its once deteriorating facility infrastructure, in particular that of the Clinical Center. In response to each of these reviews, NIH leadership has made adjustments to improve the quality and oversight of the program.

Since 1990, the intramural research program's proportion of the total budget decreased steadily from 11 percent of the total budget to about 9.5 percent, although in dollar amounts it has grown with the doubling of the overall NIH budget. Despite these changes, the program retains a distinctive status in the national research enterprise. Its scientists enjoy relatively long-term and stable funding of research programs, which allows them to engage in particularly innovative inquiry, including research with high potential payoff but considerable risk of failure. This stability stands in stark contrast to that found in the extramural scientific community, where investigators spend significant time writing grant applications that might never be funded. In addition, intramural scientists conducting clinical research have access to the NIH Clinical Center, the only hospital in the United States dedicated solely to research. In general, these scientists are not required to teach or serve on the many committees required of their academic colleagues.

Finally, the NIH campus has been an exceptional training ground, especially for clinical investigators. About 3,700 intramural fellows are on campus at any given time working in laboratories and preparing for their research careers. A significant fraction of the senior leadership of the extramural biomedical research community today received its training at NIH in the 1960s and 1970s.

For all of these reasons, the intramural program is an ideal setting to conduct research and has had a long history of attracting excellent scientists. Nonetheless, there are some drawbacks to being an NIH intramural scientist. In general, salaries and laboratory space do not compare favorably with what can be found in the nonfederal sectors, particularly in the case of more senior investigators. In addition, conflict of interest constraints make it more difficult to work with industry, which restricts the flow of technology and information both out of and into NIH.

The rapid growth in the NIH extramural program since the 1970s has enabled biomedical research across the country to expand greatly in size and scope, providing superb opportunities for research and training at academic facilities elsewhere. Thus, it has become increasingly more challenging for NIH to recruit and retain the best scientists, despite progress made in recent years in removing some of the administrative impediments to research and in enhancing the attractiveness of employment through changes in the pay scale and retirement options for senior investigators and the improvement of facilities.

NIH Hiring Authorities⁴

NIH uses a variety of personnel appointment authorities that are applied across the intramural and extramural programs. These are worth briefly mentioning because they have had important implications for salaries and for requirements regarding the disclosure of financial information.

Title 5 USC provides the basic government system for hiring, consisting of the General Schedule (GS) which has 15 grade levels with 10 seniority steps within each level (salary range \$17,152 - \$124,783). More than 13,000 NIH employees are employed under Title 5 authority. Title 5 includes a provision authorizing the payment of up to \$30,000 Physician's Comparability Allowance (PCA) to facilitate recruitment and retention of physicians. At NIH, non-clinical physicians are authorized PCA payments. NIH has separate legal authority under Title 42 USC that authorizes the use of Title 38 USC (Veterans Administration authority) to pay "Physicians Special Pay" (PSP) to physicians and dentists and other special pays to nurses and allied health professionals. HHS policy limits the combination of Title 5 and Title 38 PSP pay for physicians and dentists to \$200,000 total compensation, although the legal limits are higher, and nurses and allied health professionals to Executive Level I.⁵ The special pay authorities were requested to make NIH positions more competitive with those in academe. As of January 2004, there were 97 NIH physicians receiving PSP under Title 38, and their median total compensation was \$178,268.

A second major appointment authority under Title 5 is the Senior Executive Service (SES). This is a government-wide authority, with a pay band of \$131,342⁶ to \$142,500. SES positions typically are managerial or supervisory, having oversight for large organizations, budget authority, and procurement authority. As of January 2004, there were 89 NIH employees in SES positions, and the median pay was \$142,357.

Title 42 USC refers to the Public Health Service (PHS) Act, which contains a number of special hiring authorities under which PHS agencies (e.g., NIH, CDC, FDA) may appoint scientists and "administratively determine" their pay (AD pay plan). Title 42 USC 209(f) and (g) authorities have been established in law for many years (at least since the 1960s). The authority in Title 42 USC 209(g) has been used for many years at NIH to appoint doctoral-level scientists to conduct biomedical research. In 1999, PHS agencies began using the authority in Title 42 USC 209(f) to employ scientists engaged in biomedical research, science policy, administration, and research evaluation. In 2001, NIH established the NIH Title 42 Pay Model to assure appropriate use of the section 209(f) and (g) authorities and provide a flexible and consistent framework for setting pay. Pay under the Model ranges from \$38,000 to \$200,000 (HHS policy limit on pay; there is no legal limit). Compensation committees, both at the institute or center level and at the NIH level, implement the Pay Model under Title 42. The median salary is \$96,589.

The Title 42 CRS (Clinical Research Support) Alternative Personnel System is not a separate authority, but rather refers to the approved usage of Title 42 USC 209(f) authority by the Clinical Center, for a pilot project, which began in 2001. The pilot program was implemented to improve

⁴ All data on numbers of employees, average salaries, and salary ranges is based on what was in NIH pay system databases on January 24, 2004. This means that the salary data do not reflect a recent cost of living adjustment.

⁵ The 2003 rate for Executive Level I was \$171,900, for 2004 it is \$175,700.

⁶ Subsequent to January 24, 2004, legislation *lowered* the bottom of the SES salary range.

recruitment and retention, predominantly in the nursing and allied health personnel fields for patient care. Thus, while Title 42 USC 209(f) is used elsewhere at NIH for doctoral-level scientists, Title 42 CRS is narrower and restricted to the Clinical Center. It has a market rate driven pay model. As of January 2004, there were 484 nursing and allied health employees in this system with a median salary of \$64,473.

Hiring authority also exists under 42 USC sections 282(d)(1), 285a-2(b)(5), and 5b-3(b), which provide for the hiring of special experts. In addition, the Senior Biomedical Research Service is a separate authority under 42 USC, section 237, enacted in law in 1990, as an alternative personnel system for the employment of doctoral level scientists directly engaged in biomedical research or clinical research evaluation. Five hundred positions are authorized across the Public Health Service. NIH's allocation is 337 positions. By law, SBRS pay band runs from Grade 15, Step 1, to Executive Level I, total compensation. As of January 2004, 127 NIH employees held SBRS positions, and the median salary was \$156,042.

An additional hiring authority is the Commissioned Corps of the Public Health Service. It employs a military pay system that had a range of pay for officers in January 2004 of \$43,560 to \$167,316 per year.

In addition to base salary, federal employees can receive recruitment bonuses and retention allowance of up to 25 percent of base pay to attract and retain outstanding personnel. In addition, managers may reward outstanding performers with cash awards up to \$10,000.

Overall, the revamping of the pay bands has made NIH more competitive at the lower and middle career levels, but salaries lag far behind those in the academic and private sectors at the highest levels of management. The differences become especially large for senior-level M.D.s with clinical responsibilities

Significance of Hiring Authorities on Financial Disclosure Requirements

Certain NIH employees are required to disclose their financial interests to NIH staff involved in the ethics program. An employee's responsibility to disclose his or her financial interests depends on position, pay, and/or responsibilities. In some cases, the employee's hiring appointment, described above, also determines whether and how the employee reports his or her financial interests. (See section III for a chart comparing hiring mechanisms and financial disclosure filing requirements.) Similarly, the office(s) or person(s) at NIH (or sometimes at HHS) who is responsible for collecting, reviewing, and certifying such information depends on the filing employee's position, pay, and/or responsibilities. The many hiring authorities used by NIH, combined with different regulatory and statutory requirements regarding financial disclosure, create a patchwork of policies and procedures that could easily lead to misunderstandings.

Commercialization of Government-Owned and Government-Funded Technologies

NIH has a mandate to facilitate the commercialization of its discoveries and inventions, a mandate that has blurred the lines between the public and private sectors and that has fostered an environment in which public-private interactions are encouraged. Although commercialization has merit because of the potential for increased translation of knowledge into clinical application, it is an issue that complicates discussions concerning potential conflicts of interest.

In 1980, in response to concerns about U.S. competitiveness in the global economy, Congress enacted two laws that encourage government-owned and government-funded research laboratories to pursue commercialization of the results of their research. These laws are known as the Stevenson-Wydler Technology Innovation Act (P.L. 96-480) and the Patent and Trademark Amendments of 1980 (P.L. 96-517), the latter also known as the Bayh-Dole Act. Their stated goal is to promote economic development, enhance U.S. competitiveness, and benefit the public by encouraging the commercialization of technologies that would otherwise not be developed into products because of a lack of incentives in the commercial arena.

The Stevenson-Wydler Technology Act established the basic federal technology transfer policies. This legislation enables NIH and other federal agencies to execute license agreements with commercial entities that promote the development of technologies discovered by government scientists. The act also provides a financial return to the public in the form of royalty payments and related fees. In 1986, the directives of this act were augmented by its amendment, the Federal Technology Transfer Act of 1986 (FTTA), which authorizes federal agencies to enter into cooperative research and development agreements with nonfederal partners to conduct research. The FTTA also authorized federal agencies to pay a portion of royalty income to inventors who had assigned their rights to the government, currently a maximum of \$150,000 per inventor per year from all royalty sources. These payments are not considered to be outside income; they are part of the employee's federal compensation.

The Bayh-Dole Act was designed to address barriers to commercial development affecting nongovernment entities, with the aim of moving federally funded inventions toward commercialization. A key provision of the act is that it provides grantees and contractors, both for-profit and not-for-profit, the authority to retain title to government-funded inventions, and it charges them with the responsibility to use the patent system to promote the utilization, commercialization, and public availability of inventions.

If the grantee or contractor institution declines title or elects not to pursue practical application of the technology, the federal agency can elect title to the invention. By law, the funding agency retains a residual interest in all grant- and contract-supported inventions, including a royalty-free, paid-up license to use the technology for government purposes. However, this right does not extend to a licensee's final commercial product, nor does it extend to proprietary information or trade secrets that belong to another party and may be incorporated in the final product.

Recipients of extramural NIH research funds, NIH intramural researchers, other federal agencies, and industry have now had 20 years of experience in technology transfer under Bayh-Dole. To accomplish the transfer of technology, both NIH and NIH-funded extramural institutions typically seek patent protection for inventions arising out of their research and license the rights

to private entities to promote commercialization. In this way, private entities interested in practicing an invention in which they have no ownership may obtain rights to use and commercialize it by entering into a licensing agreement with the patent owner.

A license is a contract with binding commitments on each party, usually involving compensation (i.e., royalties, milestone payments). A license does not grant title, or ownership, to the invention. A license can be exclusive, when only one party is permitted to use or commercialize the technology; co-exclusive, when a limited number of parties have rights to use or commercialize the technology; or nonexclusive, when many parties are allowed to use or commercialize such rights.

Conclusion

Collectively, the organizational configuration, authorities, and mandates of NIH create an environment of competing tensions and interests. First, the unique mission of NIH as a research organization that both funds and conducts research creates two worlds within one agency. The official duties of employees in the extramural program are vastly different from those of employees in the intramural program. Second, the intramural program must compete with the academic and industrial sectors to recruit and retain scientists, who provide the intellectual capital for the agency. This has led to a progressively more competitive pay system that has done much to attract employees at the lower- and mid-career levels but not at the upper levels of management. Third, the various hiring authorities used by NIH have different requirements regarding disclosure of personal financial information by certain employees, creating a complex web of rules and procedures that are not always obvious. Finally, a 25-year-old mandate from Congress to accelerate the transfer of discoveries and inventions to the private sector has created an environment in which the lines once easily drawn between public and private activities are less clear and are at times not congruent with the conflict of interest rules that otherwise limit such interactions.

Against this background, section III will focus on the Panel's findings regarding the appropriate requirements for financial disclosure by NIH employees.

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Section III. Disclosure of Financial Information and Outside Activities

The Ethics in Government Act of 1978 was issued to preserve and promote public confidence in the integrity of government through, for example, requiring certain employees to disclose their personal financial interests. This act also created:

- (1) rules and regulations establishing procedures for the filing, review, and, if applicable, the public availability of financial statements; and
- (2) criteria to guide agencies in determining which employees should submit these reports.

The act also required the Office of Government Ethics (OGE) to issue regulations establishing uniform procedures and requirements for the two types of financial disclosure reporting required of certain employees: public and nonpublic (confidential).⁷ These regulations require high-level officials to report certain financial interests *publicly*, (that is, available to the public through the Freedom of Information Act [FOIA]). In addition, to guarantee the efficient and honest operation of the government, less senior employees, whose government duties involve the exercise of significant discretion in certain sensitive areas, must *confidentially* report their financial interests and outside business activities to their employing agencies. The National Institutes of Health (NIH) holds its employees to these OGE regulations for financial disclosure.

OGE regulations also permit an agency, through supplemental regulations, to prohibit or restrict the acquisition or holding of a financial interest or class of financial interests by agency employees, and the spouses and minor children of those employees, based on the agency's determination that the acquisition or holding of such financial interests would cause a reasonable person to question the impartiality and objectivity with which agency programs are administered. For example, HHS issued regulations that further restrict certain financial interests of financial disclosure report filers in the Food and Drug Administration (FDA).⁸ This is because FDA "is a unique consumer protection and regulatory agency within the [HHS]," and the HHS' standards of conduct needed "further supplementation to reflect this role."⁹ However, these supplemental HHS regulations do not augment the OGE regulations for non-FDA employees who file financial disclosure reports. As such, the supplemental HHS regulations that further restrict financial interests of certain FDA filers do not apply to NIH employees.

Recent media attention has raised several issues about financial disclosure by NIH employees. These include concerns regarding the outside activities that have been allowed for a few highly paid employees and the fact that a large number of highly paid employees are required to file confidentially rather than publicly. Members of Congress have questioned NIH's reliance on an OGE legal opinion that informed the agency that Title 42 employees, including those in senior and/or high-paid positions, could not be classified as public filers. The need to increase the

⁷ Executive Branch Financial Disclosure, Qualified Trusts, and Certificates of Divestiture, at 5 CFR Part 2634.

⁸ See 5 CFR 5501.106(c)(3).

⁹ See 37 *Federal Register* 24347, 24348.

number of NIH employees who file public financial disclosure reports has been a consistent theme of critics. NIH does not have unilateral authority to compel employees to make public disclosure, but it does have the discretion to request that the need for disclosure be determined by OGE through a process of “equal classification determinations,” which recently resulted in the reclassification of 93 NIH employees.

The Panel focused on whether and how financial disclosures by NIH employees should be expanded or otherwise modified to promote public confidence in the integrity of NIH officials. These issues were reviewed in the context of NIH’s implementation of OGE regulations governing confidential and public financial disclosure, as well as the reasoning behind the regulations and interpretations.

To assess the appropriate requirements for maintaining public trust in NIH, it is important to understand the current policies and procedures—specifically, which employees are required to disclose financial interests, and when, how, and to whom? Also relevant is the distinction between the reporting processes themselves and the degree to which such information is publicly accessible, for example readily available (through a website) or accessible only through a FOIA request. For the purpose of clarity in this report, the Panel will refer to the confidential filing of financial information by NIH employees to NIH as “disclosure” and to the public availability of such information as “transparency.”

Financial Disclosure Reporting Requirements

An employee’s responsibility to disclose his or her financial interests generally depends on position, pay, and/or responsibilities. In some cases, the employee’s hiring appointment (e.g., Senior Executive Service [SES]) also determines filing status. Similarly, the office or person responsible for collecting, reviewing, and certifying such information is determined by the filer’s position, pay, and/or responsibilities. For example, financial disclosure reports of deputy ethics counselors are reviewed by the Office of General Counsel, Ethics Division, while the financial disclosure reports of other, nonsenior NIH staff are reviewed by ethics officials in the employee’s institute or center, or in the Office of the Director.

In general, financial disclosure requires the employee to provide information about assets and income, liabilities, outside positions, financial agreements or arrangements, and gifts and travel reimbursements. However, the breadth and depth of information requested in these reports varies with the type of form the employee is required to complete. For example, public reporting Form 278 was developed to collect more specific financial information than the confidential disclosure Form 450. Form 278 requires certain officers and high-level employees in the executive branch to provide information on the actual monetary value of assets and financial transactions. This information is not reported in the confidential financial disclosure Form 450.

*Confidential Financial Disclosure*¹⁰

Some NIH employees must file the standard government-wide OGE form 450 (see appendix E)¹¹, disclosing significant financial information internally to NIH supervisors and ethics officials. These filings are not subject to FOIA requests.

Who Files

Unless subject to public financial disclosure, the following NIH employees are required to file confidential financial disclosure reports:

- In each institute and center: deputy ethics counselors, associate directors, assistant directors, division directors, National Institute of Child Health and Human Development Center directors, executive officers, and deputy executive officers.
- Special Government Employees who are not subject to public disclosure.
- All other employees designated by NIH who perform one or more of the following duties or activities and who have not been excluded from the filing requirements:
 - contracting or procurement;
 - administration, monitoring of grants, licenses, cooperative research and development agreements, or CRADAs, or other federally conferred benefits, regulating or auditing nonfederal entities;
 - other activities that will have a substantial economic effect on the interests of a nonfederal entity; or
 - other activities that have the potential to create real or apparent conflicts of interest.

In reference to the latter category of “all other employees designated by NIH,” OGE permits the agency to require employees in certain positions to file confidential financial disclosure reports. Although hypothetical examples of employees who are required to file confidential financial disclosure reports are provided in the regulation (e.g., a contracting officer who performs certain duties and works with substantial independence), a 1994 memorandum from the Director, OGE,

¹⁰ Confidential financial disclosure reporting requirements are set forth in regulations at 5 CFR 2634, Subpart I. Federal statute requires that these reports and the information that they contain be kept confidential, even in de-identified form. Accordingly, confidential financial disclosure reports are exempt from being released to the public, under exemptions 3 (A) and (B), 4, and 6 of the Freedom of Information Act (FOIA), 5 USC 552(b)(3) (A) and (B), (b)(4), and (b)(6). Agency personnel shall not publicly release the reports or the information that these reports contain, except pursuant to an order issued by a federal court, or as otherwise provided under applicable provisions of the Privacy Act (5 USC 552a), and in the OGE/GOVT-2 government-wide executive branch Privacy Act system of records, as well as any applicable agency records system. FOIA exemption 3 covers information “specifically exempted from disclosure by statute”; exemption 4 protects “trade secrets and commercial or financial information obtained from a person [that is] privileged or confidential”; exemption 6 permits the government to withhold all information about individuals in “personnel and medical files and similar files” when the disclosure of such information “would constitute a clearly unwarranted invasion of personal privacy.”

¹¹ See also ethics.od.nih.gov/forms/forms450.htm for the form. For most NIH employees, the process for preparing, reviewing, and certifying confidential financial disclosure forms involves the employee and the institute or center deputy ethics counselor (or the person with delegated authority).

to the Designated Agency Ethics Officials found, “The most consistent concern which agencies expressed about the system was the process of designating positions in which employees are required to file an [OGE] 450.”¹² There appears to be insufficient uniformity in these determinations.

The responsibility for designating confidential filers generally occurs at the level of the deputy ethics counselor within the institute or center, in many cases with input from an administrative or executive officer or the appropriate office director (e.g., scientific director or deputy director). However, although the institutes and centers use general regulatory criteria to determine which employees must file, each can apply the criteria differently. For example, some institutes and centers require all project officers to file a confidential financial report, while others require only those project officers above a certain pay level (e.g., GS-12 or 13) to file. These determination decisions are presumably due to guidance provided by the 1994 memorandum, which specifies that “designations should be limited to those pay grades where the duties and responsibilities clearly make filing necessary and relevant.”¹³ In 2003, there were 5,533 filers of confidential reports. This number is expected to increase to 5,845 in 2004. The instructions and forms for this report are 6 pages long.

The Process for Confidential Financial Reporting

Most NIH employees who are required to report financial interests use the confidential financial disclosure report (OGE form 450). As an alternative to the OGE 450, an employee may use a different form if he or she has no new financial interests. This form, the OGE 450-A, the Certificate of No New Interests, contains no requests for substantive financial information. As such, the deputy ethics counselor or reviewing official performs only a procedural review of that form to ensure it is properly completed by the employee and tracked by the deputy ethics counselor or reviewing official. However, reviewers may refer to previous OGE 450 forms to ensure the employee does not have any unresolved issues.

What Information Is Disclosed

The confidential reporting system seeks from employees only information that is relevant to the administration and application of criminal conflict of interest laws, administrative standards of

¹² September 14, 1994, available at www.usoge.gov/pages/daeograms/dgr_files/1994/do94031.txt.

¹³ In the 1994 memorandum, OGE continues to add examples of positions or employees who should not be required to file: “In reevaluating which positions require confidential disclosure, consider the following guidance: For those positions involving responsibilities enumerated in 5 CFR 2634.904(a)(1), the regulation compels designation only if the employee will be required to participate personally and substantially through decision or the exercise of significant judgment. For assistance with the terms “personal and substantial,” see the definitions at 5 CFR 2635.402(b)(4) and 2637.201(d). Additionally, the exclusion criteria in § 2634.905 should be considered in conjunction with the designation process, to eliminate designation of positions where, for example, there is a substantial degree of supervision or only a remote possibility of a conflict of interest. Thus, not all employees who must sign a procurement integrity certification under the Office of Federal Procurement Policy Act must also be required to file a confidential financial disclosure report. Agencies may use an appropriate demarcation, such as a position's monetary level of procurement authority, a de facto pay grade floor, or degree of supervision over the position. For positions being designated under the more general criteria in 5 CFR 2634.904(a)(2), designations should be limited to those pay grades where the duties and responsibilities clearly make filing necessary and relevant.

conduct, and agency-specific statutory and program-related restrictions. The basic content of the reports required by the regulations reflects certain information that is generally relevant to all agencies. However, depending on an agency's authorized activities and any special or unique circumstances, additional information may be necessary. In these situations, and subject to the prior written approval of the Director of the OGE, agencies may formulate supplemental reporting requirements.

Public Financial Disclosure

In contrast to confidential filing requirements, as described above, employees who file *public* financial disclosure reports (SF 278 form [see appendix F])¹⁴ currently make the disclosure internally, knowing of the possibility of public access. Before certain financial disclosure reports can be made available to the public, however, two things have to happen. First, the employee must fulfill his or her responsibility to complete the disclosure form and provide it to the appropriate certifying official within the agency (a process that occurs internal to the agency, generally). Second, a member of the public must request access to the information through an application process specified in the Freedom of Information Act (FOIA).¹⁵ To this end, the right of the public to access certain financial disclosure reports is distinguishable from the employee's responsibility for making the required disclosure.

Who Files

Public filers are defined by regulation to include the following positions:

- Members of the SES and the Senior Scientific Service (SSS).
- Employees whose positions are classified above GS-15, generally described as “senior level” (SL) or “scientific and technical” (ST).
- Commissioned Corps at O-7 pay levels.
- Non-GS employees whose annual rate of basic pay¹⁶ is equal to or greater than 120 percent of GS-15, Step 1,¹⁷ not inclusive of locality adjustments, with the exception of Title 42, Career GS/GM-15 level employees and Commissioned Corps Officers at the O-6 level and below.
- Experts, consultants, or advisory committee members appointed as Special Government Employees (SGEs), who are reasonably expected to serve more than 60 calendar days in any calendar year, and whose annualized salary is equal to or greater than 120 percent of pay for a GS-15, Step 1.

¹⁴ See ethics.od.nih.gov/forms/forms278.htm for the SF 278.

¹⁵ Specified at 5 CFR 2634.603.

¹⁶ Per a February 11, 1998, OGE legal opinion, "rate of basic pay" in 5 USC app., § 101(f)(3) means the lowest step or entry level pay authorized for a particular pay grade or range. See www.usoge.gov/pages/advisory_opinions/advop_files/1998/98x2.txt.

¹⁷ As of January 2004, 120 percent of GS-15, Step 1 is \$104,927 (based on the base GS-15, Step 1 salary of \$87,439, at www.opm.gov/oca/04tables/pdf/gs.pdf). This base amount excludes locality adjustments and “additional” pay (such as bonuses, awards, and allowances), but includes annual or periodic pay adjustments (such as cost-of-living raises). The base amount is used in calculating the 120 percent of GS-15, Step 1.

Section III. Disclosure of Financial Information

- As of February 6, 2004, through an “equal classification” determination¹⁸ from OGE (as requested by NIH), institute and center directors,¹⁹ deputy directors, scientific directors, and clinical directors are also required to file public financial disclosure reports.

Unless holding one of the positions listed above, career GS/GM-15 level employees, Commissioned Officers at the O-6 level and below, and employees under the Title 42 appointment mechanism are exempt from the public financial disclosure requirement, even though their salaries may exceed 120 percent of the GS-15, Step 1 pay level. For example, the Title 42 mechanism can be used to support *specific* public disclosure by individuals in positions (e.g., doctoral-level scientists and certain allied health personnel for patient care) at pay ranges from \$38,000 to \$200,000. However, the appointments made under Title 42 are not *required* to file public financial disclosure reports because the regulations require employees to file only if they are in a pay *category* which has a “basic rate of pay” that is equal to or greater than 120 percent of the minimum rate of basic pay for GS-15, Step 1, or \$104,927. The Title 42 appointment mechanism has no basic rate of pay (i.e., Title 42s have no minimum pay), and because of this, such employees do not meet the public financial disclosure filing criteria.

Although members of the SES do file public financial disclosure reports, shifting higher-paid Title 42 employees to the SES does not provide a general solution for several reasons:

- Many Title 42 employees do not meet the SES qualifications. The SES is for senior managerial, supervisory, and program policy personnel; while Title 42 is for doctoral-level scientists and physicians, nurses, and allied health personnel engaged in biomedical research, clinical care, and/or scientific management/leadership activities.
- The ceiling placed on the number of SES positions at NIH cannot accommodate the expansion that would be entailed in such a shift.
- The top SES pay level is well below the top pay provided under Title 42, and mechanisms to supplement salary (e.g., bonuses and allowances for recruitment and retention) cannot be guaranteed because they are not part of base pay.

In February 1998, OGE wrote the following in response to queries about exclusions from the public financial disclosure:

...some [division] employees who receive relatively high amounts of pay would not be required to file. We agree that this may occur, but that is also the case with a number of other pay systems. It would be up to Congress to amend the financial disclosure statute, if they intended a different result. As an alternative, [division] employees may be required

¹⁸ Under the authority under 5 CFR 2634.202(c), the OGE (not NIH) may require any other officer or employee in any other position determined to file a public financial disclosure report if that individual occupies a position that is equivalent to a position that is already specifically designated in the statute by category or salary level. This determination is called “equal classification.”

¹⁹ The “equal classification” determination for institute and center directors was previously requested by NIH on June 6, 1994, in a memorandum to OGE; however, OGE ruled that such determination at that time could not be provided “without additional details concerning these positions.” NIH at the time did not seek to provide additional information. Note, however, that prior to the 2004 OGE “equal classification” determination, institute and center directors voluntarily filed the public financial disclosure report.

by [the Department] to file confidential financial disclosure reports, under subpart I of 5 CFR part 2634, if the criteria therein for defining confidential filers are met. While less intrusive of filers' privacy, the confidential system serves the same goal as the public system, which is primarily to prevent conflicts of interest.²⁰

The Process for Public Financial Disclosure Reporting

Public financial disclosure reporting requirements are described in the regulations,²¹ and the information is filed on the SF 278 form. For most NIH employees, the process for preparing, reviewing, and certifying public financial disclosure forms involves the employee and the institute's or center's deputy ethics counselor.

What Information Is Disclosed?

The public financial disclosure reporting system seeks the following information from employees: a brief description of any interest in property held by the filer or his or her immediate family; origin and total investment and noninvestment income; purchases, sales, and exchanges above a certain amount; certain gifts and reimbursements; liabilities and categorization of amount; agreements and arrangement for future employment; and outside positions, including income above a certain amount. The instructions and forms for this report are 18 pages long.

Table 1 at the end of this section compares the requirements for qualification as a public versus a confidential filer.

Discussion

Current requirements for reporting income from outside activities, or from investments that might have relevance to one's official duties, do not always capture the information needed to manage conflicts of interest. The only employees who must currently *publicly* disclose all outside activities as well as financial interests are those required to file an OGE Form 278 annually.

The most obvious problem that needs to be corrected is the accident of legislative and regulatory history that exempts even highly paid Title 42 employees from this disclosure. NIH has been eliminating this problem by securing equivalency determination from OGE with respect to its most senior employees, so that these employees are now required to file Form 278. This is an effective first step to ensuring that potential conflicts of interest at the highest level of NIH are properly managed. In addition, the complexity of Form 278 weakens its intent and it is therefore the Panel's opinion that OGE should seek simplification of reporting, a change requiring legislation and that would be applied government-wide.

²⁰ Letter to a Designated Agency Ethics Official from Stephen P. Potts, dated February 11, 1998. Available at http://www.usoge.gov/pages/advisory_opinions/advop_files/1998/98x2.html

²¹ 5 CFR Part 2634, Subpart F.

Section III. Disclosure of Financial Information

As specified by OGE, the filing of an annual confidential disclosure of financial interests (OGE Form 450) is limited to “those pay grades where the duties and responsibilities clearly make filing necessary and relevant.” At present, more than 5,000 of the more than 17,000 NIH employees are required to disclose in this manner. Individuals who file this relatively brief confidential form need to disclose outside activities with industry and academia, and if the income from these activities exceeds \$200. However, there is no way of knowing the exact amounts of compensation involved. Form 450 is a government-wide form established by OGE, and therefore not easily changed. Further, if an individual is not required to file either a public or confidential financial disclosure form, and does not have an outside activity approved through the HHS Form 520—as can be the case—NIH might have no way of knowing whether a potential conflict of interest exists.

Conclusion

It is critical to maintain public confidence that NIH’s ethics standards and practices ensure that all potential conflicts of interest are managed or eliminated. There are three key considerations in determining whether and what type of disclosure should be required: 1) does NIH know enough to prevent and manage conflicts of interest? 2) do those who would be directly affected by such interests (e.g., subjects of research) have the information necessary to make informed choices? and 3) does the public have access to sufficient information to maintain public confidence in the integrity of NIH? In answering these questions the Panel attempted to balance the needs of NIH, as well as those of research subjects and the public, with the rights of NIH employees as U.S. citizens to an appropriate and reasonable degree of privacy.

Recommendations are made in Section V of this report to improve financial reporting policies and practices.

Table 1: Financial Filing Requirements by Appointment Mechanism

	Presidential Appointee, Presidential Appointee-Senate Confirmed	Title 42 ¹		SES, Senior Level (SL), Senior Technical (ST)	Special Government Employees	Commissioned Corps	Title 5 ² (including employees that receive Title 38 ³ Physician Special Pay)
		NIH Deputy Directors, Institute and Center (IC) Directors, IC Deputy Directors, Scientific Directors, Clinical Directors	All Others				
Public Financial Disclosure	Yes.	Yes.	No.	Yes.	Yes, if expected to serve >60 days in one year and pay is equal to or over \$104,927.	Yes, if O-7.	No, unless designated by OGE as requiring public financial disclosure (See **)
Confidential Financial Disclosure	No.	No.	Yes, if position or responsibilities meet requirements. (See *)	No.	Yes, if not subject to public disclosure.	Yes, if below O-7 and if position or responsibilities meet requirements (See *)	Yes, if position or responsibilities meet requirements (See *)

* Required for associate director, assistant director, division director, NICHD center directors, executive officers, deputy executive officers and all other employees designated by the deputy ethics counselor who meet one or more of the following criteria and who have not been excluded from the filing requirements: contracting or procurement; administration, monitoring of grants, licenses, CRADAs, or other federally conferred benefits; regulating or auditing nonfederal entities; other activities that will have a substantial economic effect on the interests of a nonfederal entity; or other activities that have the potential to create a real or apparent conflict of interest.

** Under the authority under 5 CFR 2634.202(c), the OGE (not NIH) may require any other officer or employee in any other position determined to file a public financial disclosure report if that individual occupies a position that is equivalent to a position that is already specifically designated in the statute by category or salary level. This determination is called "equal classification."

1 Unique to PHS agencies. Used to hire scientists in both the intramural and extramural programs who are engaged in biomedical research, science management, science administration, science policy, and research administration. Includes those employees in the Senior Biomedical Research Service (SBRS) and Administratively Determined (AD) pay plan.

2 This mechanism is used to fill most positions within the federal government at GS-1 through GS-15 and positions in the wage grade trades and labor occupations. Pay is based on the qualifications of the appointee and is limited by Office of Personnel Management pay regulations.

3 Authorizes the NIH Director to pay physicians and dentists appointed in the civil service (Title 5) additional pay subject to the provisions of Chapter 74 Title 38 USC, a Department of Veterans Affairs authority.

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Section IV. Outside Activities

National Institutes of Health (NIH) employees, like other government employees, can legally choose to engage in outside activities (paid or unpaid) under certain conditions, with the primary stipulation that the activity must not pose a conflict of interest for the individual as a government employee. Thus, the activity can in no way interfere with the ability of the employee to conduct his or her official duties, provide the individual or institution engaging the federal employee with an advantage regarding policy and resource decisions, or allow the employee to use public resources for personal gain.

Many outside activities have no relationship at all to the employee's official duties, such as, for example, playing the violin in an orchestra, while others are so closely related that it is exceedingly difficult to draw the line between a scientist performing official duties and a scientist using his or her personal, intellectual, and creative capital in outside activities. This is especially challenging when the proposed activity draws on the expertise and knowledge of the employee, of which only a portion could be rightly attributed to his or her career as an NIH scientist.

Scientists typically complete extensive postgraduate programs, often with multiple postdoctoral fellowships at different institutions. In many cases, scientists are recruited to NIH after several years, possibly decades, of conducting research and teaching at an academic institution or working for industry. Thus, the value of the scientist becomes his or her accumulated knowledge, which is manifest in that individual's accomplishments, discoveries, writings, and considered opinions. Deciding at what point knowledge and expertise become elements of a federal employee's "official duties," particularly in complex fields, is a major challenge facing those determining the policies that govern conflicts of interest at NIH.

Despite the potential for conflicts of interest to arise when a government scientist engages in outside activities, a number of arguments can be made in favor of a policy that allows some NIH employees to engage in outside activities—albeit within strict guidelines, subject to thorough oversight, and with a high level of transparency. First, absent good reasons otherwise, Americans, including federal employees, are free to work beyond their primary employment and to be paid for that work. Second, for NIH to compete with the other likely employers, it must not unduly restrict opportunities for interesting and remunerative outside activities. In order to achieve excellence and pursue its mission most effectively, NIH must be able to compete for the very best scientists. Finally, Congress and every recent administration has embraced technology transfer as one of the missions of NIH. Allowing individual outside activities, including those that involve consulting with industry, is an important aspect of technology transfer, both to and from NIH. This interaction facilitates the transfer of research advances at NIH to those entities that are most likely to bring the benefits of these results to the public, namely commercial firms.

It is unrealistic to assume that an optimal level of interactions with scientists in academia and industry for achieving the mission of NIH can be reached if all NIH scientists are prohibited from accepting compensation for such activities, which are traditional in much of the scientific community and often require a level of effort well beyond one's official duties. Moreover, the

interactions with industry sometimes will require confidentiality agreements concerning the commercial information provided by industry that are forbidden in any official duty activity. These outside activities complement, but do not duplicate more formal relationships between NIH scientists and industry, such as cooperative research and development agreements (CRADAs).

The proportion of NIH employees engaged in compensated outside activities with industry is relatively small. Of the 17,526 full-time equivalent employees at NIH as of March 2004, 118 employees were involved in 196 consulting arrangements with pharmaceutical or biotechnology companies. Of the 196 activities, all but 5 involve compensation: 173 involve cash payments, and 49 involve owning stock in the company (these compensation elements are not mutually exclusive).

No argument in favor of allowing outside compensated activities for NIH employees precludes strict limits or prohibitions on certain employees (for example, those in position of authority or with control over allocation of resources). There clearly is a need to consider the official duties of the employee with respect to each type of compensated activity being proposed (e.g., consulting, speaking, writing, teaching, receiving awards) and to the specific circumstances surrounding such activity. Thus, determining whether an outside activity poses a real or perceived conflict of interest should be decided on a case-by-case basis, as is currently done at NIH. Nevertheless, the system of making such determinations must be guided by clear principles, provide reasonable consistency, and have transparent procedures.

This section describes the Panel's findings concerning the current policies and procedures used by NIH to oversee compensated outside activities, discusses the implications of these policies in the context of different classes of outside activities and of NIH personnel, and makes recommendations for improvement.

Current Policies and Procedures Governing Outside Professional Activities

Consistent with the government's Principles of Ethical Conduct, regulations are in place at NIH to mitigate against actual or apparent conflicts of interests, which can result from financial interests and outside professional activities, whether compensated or non-compensated. A conflict of interest arises under two circumstances. The first can occur when an employee is involved in a particular matter as part of his or her official duties with an outside organization with which he or she also has a financial interest, or one that is imputed²² to him or her. The second occurs when an employee is involved with a specific party in a matter and has a covered relationship²³ with the outside organization. In either case, the conflict can be real²⁴ or

²² Imputed interests include financial interests of the employee's (1) spouse; (2) minor child; (3) general partner; (4) an organization in which the employee serves as an officer, director, trustee, general partner, or employee; or (5) a person or organization with which the employee is negotiating or has an arrangement for prospective employment.

²³ An employee has a covered relationship with (1) a person, other than a prospective employer described in 5 CFR 2635.603(c), with whom the employee has or seeks a business, contractual or other financial relationship that involves other than a routine consumer transaction; (2) a person who is a member of the employee's household, or who is a relative with whom the employee has a close personal relationship; (3) a person for whom the employee's spouse, parent or dependent child is, to the employee's knowledge, serving or seeking to serve as an officer, director, trustee, general partner, agent, attorney, consultant, contractor or employee; (4) any person for whom the employee

apparent,²⁵ and in limited circumstances, it may be waived²⁶ or the employee's participation may be authorized²⁷ in order to allow him or her to be involved in the matter.

Conflicts, or the appearance of them, may arise either as a result of an employee's outside activities or because of his or her personal financial interests. Although many outside activities and financial interests do not constitute a conflict of interest, or the appearance of one, federal agencies such as NIH review many of the activities and interests of its employees to ensure adherence to the Principles of Ethical Conduct, as well as to other relevant federal statutes and regulations. NIH holds its employees to the federal ethics regulations as well as to HHS supplemental regulations, as described below.

NIH and all other federal agencies and employees must comply with generally applicable statutes and Office of Government Ethics (OGE) regulations²⁸ that state that an employee shall not engage in any outside activity that:

- Is prohibited by statute or by an agency supplemental regulation;
- Would, because of a financial conflict of interest or an appearance of such a conflict, require the employee's disqualification from matters so central or critical to the performance of his or her official duties that the employee's ability to perform those duties would be materially impaired.
- Would involve compensated or uncompensated service as an expert witness, other than on behalf of the United States, in any proceeding before a federal court or agency in which the United States is a party or has a direct and substantial interest, unless, as provided in the OGE regulations, the employee's participation is authorized by the agency in which he or she serves; or
- Would involve compensation from any source other than the Federal Government for teaching, speaking, or writing that relates to the employee's official duties.

HHS has issued a supplemental regulation²⁹ that prohibits for all HHS employees:

- Compensated outside work preparing or assisting in the preparation of any grant application, contract proposal, report, or other document intended for submission to HHS; and

has, within the last year, served as officer, director, trustee, general partner, agent, attorney, consultant, contractor or employee; or (5) an organization, other than a political party described in 26 USC 527(e), in which the employee is an active participant.

²⁴ A real conflict exists when an employee participates personally and substantially in particular matters that have a direct and predictable effect on a financial interest of the employee, or one of the five "others" listed above. In this case, participation in the official matter is in violation of the criminal statute 18 USC 208.

²⁵ An appearance of a conflict exists when an employee is involved in a particular matter involving specific outside parties (including individual or corporate entities), and the employee knows that the matter will have a direct and predictable effect on the financial interests of a member of his or her household or knows that a person with whom he or she has a covered relationship is, or represents, a party to the matter.

²⁶ Waiver issued pursuant to 18 USC 208(b)(1) by the person responsible for the employee's appointment to his or her position is used to resolve a real conflict of interest.

²⁷ Authorization given pursuant to 5 CFR 2635.502(d) by agency designee is used to resolve an apparent conflict of interest.

²⁸ Title 5 CFR Part 2635, entitled *Standards of Ethical Conduct for Employees of the Executive Branch*.

²⁹ 5 CFR Part 5501.

- Compensated outside work in an activity funded by an HHS grant, contract, cooperative agreement, cooperative research and development agreement (CRADA), or other funding mechanism authorized by statute.

OGE regulations state that, when required by an agency supplemental regulation, an employee will obtain prior approval before engaging in outside employment or other outside activities. The standard for approval of an outside activity request is that it “shall be granted unless it is determined that the outside employment or other outside activity is expected to involve conduct prohibited by statute or federal regulation, including 5 CFR Part 2635 and [the HHS supplemental regulation].”

If it wishes to impose additional restrictions, an agency must issue a regulation that supplements the OGE regulation. However, an agency may explain how federal statutes and the OGE regulations apply to employees of that agency, as NIH has done in its Policy Manual, in which the rules applicable to the outside activities of NIH employees are as follows:

Activities Must Not Be Related to Official Duties. An employee may not receive compensation for outside activities that relate to his or her official duties.³⁰ An outside activity is considered related if the employee was invited primarily because of his or her official position (this would be a prohibited use of public position for private gain), or if it deals with any matter to which the employee is presently assigned or has been assigned during the previous one-year period, or if it deals with any ongoing or announced policy, program, or operation of NIH. Exception: An employee may teach a course, with or without compensation, on topics related to his or her official duties when that course involves at least two presentations and is offered as part of a regularly scheduled curriculum at an accredited institution of higher education.

Prohibited Activities. An employee may not accept compensation for service of any kind that is funded by an HHS contract, grant, cooperative agreement, or other funding mechanism. Compensation is also prohibited for assisting in the preparation of or preparing a grant application or other document intended for submission to HHS.³¹

Restrictions on Outside Medical or Similar Professional Practice. In order to obtain approval for outside professional practice involving patient care, an employee must agree and assure that (1) the employee will not have outside patient contact, including telephone calls during official working hours, and patient support, including emergency services, must be provided by someone other than the employee during those hours; (2) NIH patients may not be referred to the private practice of an NIH employee, or from such practice to NIH, and the patients must be informed in advance of this policy; (3) the employee will never knowingly establish a physician-patient relationship in outside practice with any current or recently discharged NIH patient; (4) no employee with final responsibility for the admission of patients to the Clinical Center may

³⁰ The basis for this rule is the federal criminal statute, 18 USC 208, which prohibits a federal employee from participating personally and substantially, as part of his official duties, in any matter that would have a direct and predictable effect upon the financial interest of the employee, the employee’s spouse, minor child, general partner, an organization in which the employee serves as an officer, director, trustee, general partner, or employee, or an organization with which the employee is negotiating or has an arrangement for prospective employment.

³¹ This prohibition is imposed by 5 CFR 5501.106(c), the HHS regulation that supplements the OGE ethics regulation.

receive a fee for service as consultant to another physician where the patient's condition would appear to make him or her eligible for Clinical Center admission in an area currently supervised by that employee; and (5) an employee will not accept primary responsibility for the care of an outside patient except in circumstances where it will clearly not impose on, or interfere with, his or her responsibilities as a federal employee.

Participation in the Business Affairs of Outside Organizations. Under some circumstances, an employee may participate in the internal and external business operation of an outside organization as an outside activity, including involvement in the human resources, financial, and fund-raising activities of the organization. Such involvement usually occurs when an employee serves as an officer or member of the board of directors of an outside organization. Such service requires that the employee be disqualified (recused) from any involvement with the organization in the course of carrying out his or her duties for NIH.

Unlimited Use of Personal Time. An employee must conduct all outside activities on personal time. If outside work is to be performed during normal NIH working hours, the employee must be on approved annual leave, leave without pay, credit hours, or compensatory time and not be present at his or her duty station. There is no limit on the amount of personal time an employee may spend on outside activities as long as it does not affect his or her ability to carry out official duties.

No Use of Government Resources. An employee may not use government resources (e.g., equipment, services, stationery, or other supplies or staff) in the performance of outside activities. Only information that is in the public domain may be used, and that information must not derive from work the employee has done within the last year. An employee may provide information on work performed prior to the last year which has been publicly disclosed, provided the information is not the subject of ongoing research, programs, or policies. The employee may also provide information that is based on his or her general scientific or professional knowledge and expertise and not derived specifically from employment at NIH.

With certain exceptions, both the employee and an outside organization are prohibited from referencing the title and place of work of an employee in connection with any outside activity or employment, including speaking or writing.

Any Form of Compensation Is Acceptable. An employee may receive compensation for his or her outside work in the form of money, stocks, or any other financial instruments that have monetary value.

Advance Written Approval Required. Under the HHS supplemental regulation, the following outside activities require advance approval whether or not they are compensated: (1) consultative or professional services, including service as an expert witness; (2) teaching, speaking, writing, or editing that relates to an employee's official duties, or that would be undertaken as a result of an invitation extended by a person who is a prohibited source³² within the meaning of the OGE

³² The OGE regulation defines a covered relationship as any person who: (1) is seeking official action by the employee's agency; (2) does business or seeks to do business with the employee's agency; (3) conducts activities regulated by the employee's agency; (4) has interests that may be substantially affected by performance or

regulation; and (3) services to a nonfederal entity as an officer, director, or board member, or as a member of a group, such as an editorial board, or scientific or technical advisory board or panel, that requires the provision of advice, counsel, or consultation—unless the service is provided without compensation to a political, religious, social, fraternal, or recreational organization and the position held does not require the provision of professional services.

The NIH policy on outside activities and on avoiding conflicts of interest states that an “apparent conflict of interest” arises when an employee is involved in a particular matter involving specific outside parties (including individuals and corporations) and the circumstances are such that a reasonable person with knowledge of the relevant facts would question the impartiality of the employee in the matter.

The NIH policy is interpreting the OGE regulation³³ that refers to a loss of impartiality as a situation in which an employee knows that a particular matter involving specific parties is likely to have a direct and predictable effect on the financial interest of a member of his or her household, or knows that a person with whom the employee has a covered relationship is or represents a party to such matter and that the circumstances would cause a reasonable person with knowledge of the relevant facts to question the employee’s impartiality.

In a general sense, an appearance of a conflict of interest is something less than a real or actual conflict or what is sometimes referred to as a direct conflict. Prior to 1995 (see below) NIH restricted an employee from engaging in an outside activity with a company that has business dealings not directly involving the employee but falling within the laboratory or branch in which the employee works. That restriction was addressing an *appearance* of a conflict of interest. The appearance of a conflict would be reduced if the company had business dealings only with the institute or center in which the employee works or only with NIH, HHS, or the federal government rather than his or her laboratory or branch. In thinking about these degrees of appearance or the line between a real and an apparent conflict, it is helpful to consider the degree to which an employee with an outside consulting agreement can influence or appear to influence official interactions with his or her outside employer. The degree of real or apparent influence would thus be greater for a high-level employee than it would be for a lower-level employee. The degree of the appearance also may depend on the scope and potential impact of the interaction of the employee’s agency or agency component with the company or industry with which the employee has an outside activity.

Other Terminology and Concepts

Preferential Treatment. Conflicts can be created if an outside party is given preferential treatment by an NIH employee conducting official duties, for example, the employee provides a lecture at only one industrial firm and refuses invitations to conduct similar activities at other firms.

nonperformance of the employee’s official duties; or (5) is an organization a majority of whose members are described in clauses (1) through (4) of this sentence.

³³ 5 CFR § 2635. 501.

Conflict of Commitment. This term refers to the potential adverse effect on an employee's ability to carry out the duties of his or her primary job when engaging in an outside activity. A conflict of commitment might arise because of time constraints or because of competing loyalties or responsibilities. The current restrictions on the outside activities of NIH employees do not use this term, but they do state that an employee's outside activities cannot interfere with the performance of his or her official duties.

Prior to 1995 (see below), the NIH limit on the total number of hours that could be devoted to outside activities (all of which had to be conducted on "personal" time) was a way of ensuring that there was no interference based on the amount of time devoted to the outside activities. Similarly, the previous NIH limitations on the amount of compensation from a single outside source and on compensation in the form of stock or stock options could be seen as addressing a potential conflict of commitment. The greater an employee's involvement with a single company, either through time or compensation, the more that company could be seen as competing with the employee's commitment and loyalty to NIH, his or her primary employer.

Institutional Conflict of Interest. This term is not used in federal ethics statutes or regulations or in past or present NIH policies. However, it is a concept that has been of interest to HHS and NIH in the context of institutions that conduct research involving human subjects. In a 2001 report to Congress, the General Accounting Office (GAO)³⁴ concluded that a research institution's equity ownership or other financial interest in a company sponsoring research at the institution may affect the institution's review, approval, or monitoring of research conducted by the institution or the allocation of equipment, facilities, and staff for research. Although GAO's recommendation regarding institutional conflicts of interest was not limited to a particular type of research, the agency noted that recent interest in the issue had been prompted by reports that financial conflicts of interest may have been associated with harm to research subjects. The GAO report called on HHS to develop specific guidance or regulations addressing institutional conflicts of interest.

On March 31, 2003,³⁵ HHS requested public comment on draft guidelines entitled *Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection*. The draft guidelines recommend that institutions engaged in federally conducted or supported human subjects research should consider the following actions regarding institutional financial conflicts of interest:

- Establish criteria to determine what constitutes an institutional conflict of interest, including identifying leadership positions for which the individual's financial interests are such that they may need to be treated as institutional financial interests.³⁶

³⁴ U.S. GAO, *Biomedical Research: HHS Direction Needed to Address Financial Conflicts of Interest* (GAO-02-89) (November 2001), 7.

³⁵ 68 *Federal Register* 15456.

³⁶ The October 2002 report of the Association of American Medical Colleges Task Force on Financial Conflicts of Interest in Clinical Research, entitled *Protecting Subjects, Preserving Trust, Promoting Progress II: Principles and Recommendations for Oversight of an Institution's Financial Interests in Human Subjects Research*, concludes that an institutional official's position may convey an authority that is so pervasive or a responsibility for administration of research programs that is so direct that a conflict between that individual's financial interests and the institution's human subjects research should also be considered an institutional conflict of interest. The report does not address

- Establish a conflict of interest committee (COIC), to address both individual and institutional financial interests, or establish a separate COIC to address institutional financial interests.
- Establish procedures for the disclosure of institutional financial relationships to COICs.
- Use independent organizations to hold or administer the institution's financial interest.

The draft guidance applies to “federally conducted or supported” human subjects research and thus would apply to elements of the NIH intramural research program. NIH’s intramural research program has drafted a policy that is directed toward the disclosure and management of financial conflicts of interest. The draft policy would apply to individuals who substantially participate in the development, conduct, or analysis of clinical research protocols or in the oversight of human subjects research at NIH.

As a federal agency, NIH cannot have any equity or ownership interest in a company, but it can and does have financial interests in companies through receipt of royalties from the licensing of NIH inventions, from the receipt of monetary and other support from companies under CRADAs, through gifts, or through formal or informal collaborative research arrangements. The definition of a financial conflict of interest in the draft intramural research program policy includes obtaining royalties or being an inventor of products being evaluated in human subjects research or of products that could benefit from the human subjects research.

Authorization. An appearance of a loss of impartiality in performing official duties can be waived under the OGE regulation.³⁷ Where an employee’s participation in a particular matter involving specific parties does not violate laws or regulations, but would raise a question in the mind of a reasonable person about the employee’s impartiality, the agency designee may authorize the employee to participate in the matter, based on a determination that the interest of the government in the employee’s participation outweighs the concern that a reasonable person may question the integrity of the agency’s programs and operations. Factors that may be taken into consideration include (1) the nature of the relationship involved; (2) the effect that resolution of the matter would have on the financial interests of the person involved in the relationship; (3) the nature and importance of the employee’s role in the matter, including the extent to which the employee is called upon to exercise discretion in the matter; (4) the sensitivity of the matter; (5) the difficulty of reassigning the matter to another employee; and (6) adjustments that may be made in the employee’s duties that would reduce or eliminate the likelihood that a reasonable person would question the employee’s impartiality.

The NIH policy states that an employee who has served as a consultant, employee, or board member of an outside organization within the last year may not participate in official matters involving that organization for one year after the termination of the relationship. The deputy ethics counselor may determine that a shorter period of disqualification would be appropriate based on an evaluation of the facts of the case and on the application of the factors listed above.

the effect of an institutional financial interest in a company on an employee’s proposed outside work for that company.

³⁷ 5 CFR § 2635.502(d).

Disqualification or Recusal. An employee with an outside activity that creates a real or apparent conflict with his or her official duties can remove the conflict by disqualifying or recusing him- or herself from the performance of the duties that would create the conflict. This occurs at the time the outside activity is approved if the conflict is foreseeable. Under the HHS regulation, if the disqualification that would be necessary to permit the outside activity is so central or critical to the performance of the employee's official duties that his or her ability to perform the duties of the position would be materially impaired, the outside activity cannot be approved, or if previously approved, the outside activity must be discontinued. Even if a disqualification does not meet this standard of interference with an employee's official duties, it could be seen as creating a conflict of commitment, because NIH is agreeing to give up the services of the employee in certain areas so that he or she can pursue an interest in serving an outside employer.

For a high-level employee, a disqualification could pose both administrative and appearance issues. If an employee is the head of a division, institute, or center, it could appear that the official is responsible for all activities within that component, even though a recusal has been in place. Because high-level officials may not assign their responsibility for official duties that would conflict with outside activities to employees that they supervise, the responsibility must be assigned to a higher-level employee. For institute and center directors this would require assigning the duties at least to the Deputy Director of NIH, whose responsibilities are normally NIH wide, rather than being limited to a single institute or center.

Approval Process for Outside Activities

Responsibility for implementing the NIH ethics program is coordinated within the 27 institutes and centers and the Office of the Director, NIH. Some of those involved include staff in the central NIH Ethics Office, NIH deputy ethics counselors and ethics officers in each of the 27 institutes and centers, and staff in OGE and the HHS Office of General Counsel. The NIH Ethics Office serves as the main NIH ethics contact. Its responsibilities include providing assistance to the deputy ethics counselors and ethics officers in each institute and center and to other managers and supervisors on all aspects of the NIH Ethics Program, including activities with outside organizations. This office advises the Director, NIH, and other top management officials of new developments, trends, and practices associated with the participation of NIH employees in outside organizations. It also provides assistance on informal or formal training for officials as needed, disseminates ethics information to those who need to know, and conducts post-audit reviews.

The HHS supplemental regulation requires that advance written approval must be obtained by all employees for certain outside activities, whether or not they involve compensation. Supervisors review and approve or deny outside activity requests by performing two functions: 1) a supervisory management review to consider whether the outside activity could be performed more appropriately as an official duty activity and to consider the amount of time that will be involved in the activity; and 2) a supervisory ethics review to identify conflicts of interest and determine whether a conflict will require the employee to recuse (disqualify) him- or herself from critical official duties.

The process for review and approval of outside activities for NIH employees in certain positions (e.g., senior NIH officials) and other NIH employees who desire a certain type of outside activity (e.g., involving a biotechnology or pharmaceutical company or more than \$10,000 in compensation) recently changed, involving a new NIH Ethics Advisory Committee [NEAC]; described below). Activities outside NEAC jurisdiction are reviewed and approved by institute and center ethics staff. However, it is important to note that the requirement to submit outside activity requests has not changed for the employee, even though NIH's processes and procedures for reviewing outside activity requests have changed to bring certain types of cases under central NEAC oversight.

Where the outside activity creates a real conflict of interest, it is not likely to be approved. However, as described above, it is possible that a waiver or authorization could be granted, in limited circumstances, to allow the employee to have both the outside activity and participate in an official duty matter that involves the outside entity. NIH anticipates that waivers or authorizations rarely would be approved. A waiver or authorization may be granted in certain circumstances, for example, to a new NIH employee who wishes to complete a short-term research project with a previous employer while beginning to work on matters involving that previous employer as part of the employee's official duties. However, it is unlikely that NIH would issue a waiver or authorization for employees who are first assigned to a matter involving an outside organization and then wish to engage in an outside activity with that same organization. In this circumstance, the requested new activity creates the conflict and it would not be approved.

To request to participate in an outside activity, the NIH employee has to complete an Outside Activity Packet. Although there is no annual reporting requirement, any substantive change in the scope of the approved activity would constitute a new activity requiring submission of another Outside Activity Packet. This packet includes the following forms:

- HHS 520: This form is used within HHS to request approval of proposed outside activities (activities that are totally outside regular official duties and with outside organizations). The HHS 520 is required for all outside activities as described above.
- Unnumbered NIH Supplement to the HHS 520: This form provides additional information about the outside activity so that the deputy ethics counselor can make an informed decision regarding the appropriateness and permissibility of the activity. The Unnumbered NIH Supplement to the HHS 520 is required for all compensated outside activities.
- NIH 2657: This NIH form is used to provide additional information for certain outside activities. The NIH 2657 is required for consulting for industry, legal consulting/testimony, and professional practice for physicians, nurses, and allied health care professionals (e.g., respiratory technicians, social workers, phlebotomists).

The approval process for outside activities involves one of the following four processes:

No Approval Required

Some activities are exempt from the outside activities restrictions. These include activities that do not involve an employee's work-related professional skills and abilities. Examples of outside activities that are not work related include playing an instrument in an orchestra, appraising antiques, or teaching aerobic classes. Employees may engage in these types of activities without prior approval by a supervisor or deputy ethics counselor. Also not covered by the NIH outside activity definition are religious or community service (serving as an officer of a religious organization or as PTA president), or other activities that do not readily identify the employee with NIH (retail clerk or similar positions). However, if such outside activities involve a pharmaceutical or biotechnology company, they must undergo review by NEAC and receive approval from the NIH deputy ethics counselor.

Recommendation by Supervisor and Approval by an Institute or Center Deputy Ethics Counselor

An employee's request for approval of an outside activity can be granted by a deputy ethics counselor after recommendation by the supervisor, as long as the outside activity does not fall under NEAC jurisdiction.³⁸

Recommendation by Supervisor and Approval by a Deputy Ethics Counselor: Waiver or Authorization Required

Although 18 USC 208 prohibits a federal employee from taking part as a government official in any matter in which he or she has a financial interest, other provisions of the statute allow the use of a waiver to allow an employee with a real conflict of interest to continue performing official duties despite the actual conflicting interests. For example, an agency may determine that a disqualifying financial interest in a particular matter is not substantial enough to likely affect the integrity of the employee's services to the government. On making that determination, the agency can waive the employee's disqualification notwithstanding the financial interest and permit the employee to participate in the matter. To obtain a waiver, an employee using a waiver form must disclose the situation to the person responsible for his or her appointment (e.g., institute or center director or designee).

Separate from a waiver, an authorization can permit an employee to participate in a specific matter in the employee's official capacity with an outside organization in which the employee is engaged in a personal capacity, despite the appearance of a conflict of interest with the outside organization. An appearance of a conflict arises when an employee is involved in an official matter involving specific outside parties and circumstances are present that would cause a reasonable person with knowledge of the relevant facts to question the employee's impartiality in the official matter. The institute or center deputy ethics counselor determines whether such an authorization should be granted.

³⁸ NEAC reviews requests that involve (1) awards from nongovernmental sources that include a cash payment (including travel reimbursement) equal to or more than \$2,500; (2) any outside activity request involving a biotechnology or pharmaceutical company; (3) any outside activity request that involves anticipated compensation of more than \$10,000, or which is expressed as a future income stream; or (4) any outside activity for which payment will be entirely, or in part, in the form of stock, stock options, or any other equity position.

Recommendation by the Supervisor and a Deputy Ethics Counselor, Review and Recommendation by NEAC, Approval by the NIH Deputy Ethics Counselor: No Waiver or Authorization Required

Effective January 12, 2004, the approval processes and procedures were modified for certain activities and employees.

- For outside activity and cash award requests from institute and center directors, employees in the Office of the Director, NIH, and senior staff (NIH deputy, associate, and office directors), the review process involves NEAC and the NIH deputy ethics counselor.
- For outside activity and cash award requests from institute and center deputy directors, scientific directors, clinical directors, and extramural directors, the review process involves the institute or center director, NEAC, and the NIH deputy ethics counselor.
- For all other NIH employees, where the conditions for NEAC review apply, the process involves the employee's supervisor in the institute or center, the appropriate deputy ethics counselor, NEAC, and the NIH deputy ethics counselor, if the conditions for NEAC review apply.

After NEAC has reviewed the outside activity request and has made a recommendation to the NIH deputy ethics counselor, the NIH deputy ethics counselor either approves or disapproves the activity.

Changes in NIH Outside Activity Rules Over Time

The current NIH Policy Manual chapter governing the outside activities of NIH employees was adopted in 1998. It is based on the outside activity provisions of the 1993 OGE government-wide regulation setting forth standards of ethical conduct and the 1996 HHS regulation supplementing the OGE standards. The NIH manual explains how those provisions apply to NIH employees. More stringent restrictions can be imposed only through NIH-requested amendments to the HHS supplemental regulation, which would need to be approved by OGE.

From 1988 to 1995, NIH had more stringent limits on the outside activities of its employees than it does today. In a 1995 audit of the NIH ethics program, OGE identified several restrictions on outside activities that went beyond the restrictions in the 1993 OGE government-wide regulation. OGE pointed out that under its regulation the more stringent limits could not be applied to employees unless they were employed by an agency to which the supplemental regulation applies. Subsequently, on November 3, 1995, the Director of NIH notified institute and center directors and Office of the Director staff that NIH's outside activity policy was being changed to conform to the less restrictive government-wide standards of conduct.

The following restrictions on outside activities based on the 1993 NIH policy thereby became ineffective in 1995 because they were not issued through a supplemental regulation:

Prohibited Sources for Outside Activities. Intramural employees could engage in an outside activity only if the outside entity had no involvement with the employee's laboratory or branch. Extramural employees could engage in an outside activity only if the entity had no involvement with the employee's institute, center, or division.

Compensation Limitations. Limit of \$25,000 from any one outside source (exceptions could be approved by NIH of up to \$50,000), except compensation for books and royalty income. (From 1988 to 1993 the limit on total compensation from consulting for industry and law firms was \$25,000 per year; with no more than \$12,500 from any one company or law firm. The limits on lecturing for industry were the same, with an additional \$2,000 per activity limit.)

Service Limitations. Time for all compensated outside activities was limited to 500 hours. (From 1988 to 1993, the only service limitation was for outside clinical practice: 400 hours per year and a weekly tour of duty that did not interfere with the employee's ability to perform NIH duties.)

Stock Holdings. Employees and their spouses and minor children could not receive stock or stock options as compensation for outside work

Limits on Type of Outside Activity. Service in a management position or on boards of directors of a related activity was not permitted for any NIH employee.

Stringent Limits on High-Level Officials. High-level officials, defined as the NIH Director, NIH deputy directors, NIH associate directors, and institute and center directors and deputy directors, were limited to writing and editing, outside professional practice (patient care), and participation as members of committees or associations involved in selecting recipients of prizes, preparing professional examinations, or other similar activities.

The pre-1995 limitations on outside activities prohibiting compensation in the form of stock or stock options and on receiving more than \$25,000 from a single company addressed both conflict of commitments and the appearance of a conflict of interest.

Holding stock or stock options, particularly in a start-up company, greatly increases the potential amount of compensation and can provide the individual with an ownership interest that gives this activity a dominant role in the individual's priorities over a longer period of time.

Discussion

The Panel considered the broad classes of outside activities that could pose a potential conflict of interest, or the appearance of one, including consulting or professional practice; teaching speaking, and writing; and awards. Each of these three broad categories will be discussed separately below.

Consulting and Professional Practice

Scientific consulting currently is allowed when the “primary purpose is to render scientific or professional advice based on the scientist’s personal expertise.” This type of consulting can take a number of forms, including serving on scientific or advisory boards for biotechnology or pharmaceutical companies, serving as an expert witness in a trial, or serving as a scientific consultant to a company. Payment can be in the form of cash, stock, or stock options, according to current NIH policy.

If serving on a scientific advisory or review board for a private entity involves decisional authority, then the employee must conduct that activity outside of his or her official duties, whether compensated or not. In fact, a private entity would be unlikely to engage the employee in the activity without pay as part of his or her official government duty because doing so would expose confidential and discrete business information (the NIH employee would not be allowed to sign a confidentiality agreement under current government regulations).

Under the current system of approval, enacted in January 2004, any outside activity involving a biotechnology or pharmaceutical company must be reviewed by NEAC, in addition to all other relevant levels of review, and it must be approved by the NIH Deputy Ethics Counselor. In addition, compensation from such outside activities must be disclosed through the HHS 520 Form (see section III).

Other professional activities might include medical or allied health professional practice; for example, a physician at the Clinical Center might have a practice in which he or she sees patients on the weekend or serves as an attending physician at a community emergency room at night. The NIH employees who spoke to the Panel gave many reasons for valuing opportunities for outside activities, including the educational and professional opportunities offered by serving in an advisory capacity to an organization working in related but distinct areas of research, the ability to remain competitive with academic counterparts in the same field, the ability to apply broadened thought and expertise to their own work at NIH, and the ability to supplement income.

The difficulty, however, is determining whether the consulting activity involves matters directly related to the employee’s official duties. It is the responsibility of the employee, of his or her supervisor, and of ethics officials at NIH to determine whether such a conflict exists; if it does, the activity would be prohibited.

Teaching, Speaking, and Writing

In its 1994 report, *On Being a Scientist*, the National Academy of Sciences wrote the following:

...science is inherently a social enterprise—in sharp contrast to a popular stereotype of science as a lonely, isolated search for the truth. With few exceptions, scientific research cannot be done without drawing on the work of others or collaborating with others....The object of research is to extend human knowledge of the physical, biological, or social world beyond what is already known. But an individual's knowledge properly enters the

domain of science only after it is presented to others in such a fashion that they can independently judge its validity. This process occurs in many different ways. Researchers talk to their colleagues and supervisors in laboratories, in hallways, and over the telephone. They trade data and speculations over computer networks. They give presentations at seminars and conferences. They write up their results and send them to scientific journals, which in turn send the papers to be scrutinized by reviewers. After a paper is published or a finding is presented, it is judged by other scientists in the context of what they already know from other sources. Throughout this continuum of discussion and deliberation the ideas of individuals are collectively judged, sorted, and selectively incorporated into the consensual but ever evolving scientific worldview. In the process, individual knowledge is gradually converted into generally accepted knowledge....The social mechanisms of science do more than validate what comes to be known as scientific knowledge. They also help generate and sustain the body of experimental techniques, social conventions, and other “methods” that scientists use in doing and reporting research....Because they reflect socially accepted standards in science, their application is a key element of responsible scientific practice.³⁹

The sharing of information is critical to the success of science. Not only do scientists publish the results of specific research projects, many also write review articles or book chapters, or serve as textbook or monograph editors for an entire area of endeavor. Science is a knowledge-based enterprise in which scientists with significant expertise are strongly encouraged, even obligated, to share that expertise with scientists-in-training and with the broader scientific community.

NIH intramural scientists routinely teach, speak, and write as part of their official duties. However, opportunities frequently arise to conduct these activities on a broader basis than is required or expected of a government employee. For example, a laboratory chief is expected to supervise the research program of his or her laboratory and to endeavor to have the research results emanating from that laboratory published. These are part of the laboratory chief’s official duties. However, asking this scientist to edit or write a textbook about his or her area of research, teach a course at a local university, or give a series of lectures would likely impinge on his or her regular work week, unless personal time was used, including evenings, weekends, or annual leave time.

Although research scientists in the NIH environment enjoy distinct advantages, they also forego participating in significant activities to work at NIH instead of at a university campus or medical school. In trying to attract and retain the best intellectual talent at NIH, particularly given the lack of comparability of government compensation to that in the private sector, it is especially important to look critically at NIH as a “campus” and to determine ways to strengthen and enliven NIH’s academic atmosphere to make it more attractive to the most talented scientists.

Three attributes characterize the academic environment: (1) multiple and diverse colleagues working in a broad interdisciplinary context; (2) a culture of scholarship that includes the opportunity for open and vigorous exchange of ideas and freedom of inquiry and discourse; and (3) a rich environment devoted to research and to educating and training the leaders of tomorrow.

³⁹ National Academy of Sciences. 1994. *On Being a Scientist*. Washington, D.C.: National Academy Press.

The breadth and diversity of the academic community can in principle be mimicked by the large number of scientists working within NIH. It would be enhanced, however, by opportunities for this community of scientists to interact with other scientists more freely. NIH, as large as it is, does not represent the universe of scholarly inquiry in the biomedical sciences. NIH scientists must be allowed to travel, to attend conferences with their colleagues, and to visit professors at other institutions. The biomedical research community is also an international network. To the degree that the ability of NIH scientists to interact with this network is stifled, we risk making it more difficult to recruit and retain the finest scientists, and we limit the ideas and the connections that inform their work. To treat NIH as an island into itself would severely detract from its ability to serve as an effective generator of new research and knowledge.

The culture of scholarship and open discourse go hand in hand. The culture of scholarship, although intangible on many levels, characterizes the finest universities in the world, where intellectual activity is valued in and of itself and scholars are encouraged to cross disciplines, to challenge one another, to ask open questions, and to express radical, unusual, and innovative ideas. This openness of scholarly discourse helps us move toward the important paradigm shifts that lead to breakthroughs in our understanding of the biology of disease and its treatment.

Although NIH does not see itself primarily as an educational institution, the ability of scientists to attract highly qualified graduate students is key to infusing new ideas into the enterprise. Also, because NIH does not have a medical school or graduate school, it is essential that NIH scientists are encouraged to teach both in NIH graduate programs and also on a consultant basis as they visit medical schools throughout the country and the world. It is certainly possible to make teaching and mentoring activities more available to NIH scientists. In addition to the salutary effect it will have on the quality of the science, it also will help the best NIH researchers have an influence on the education of many of the young scientists who will become tomorrow's leaders.

As important as this atmosphere of academic freedom is to scholarly pursuit, the fact nonetheless remains that when working as an employee of the public one must assume certain additional restraints due to the special fiduciary responsibilities imposed. Thus, an employee must request permission to conduct teaching, speaking, or writing as an outside activity. Problems arise when the teaching, speaking, or writing is related to the employee's official duties—that is, when it relates to ongoing assignments or those given within the last year—or when it relates to an ongoing program, policy, or operation of the agency. However, because science is a cumulative endeavor, this requirement can give the appearance of allowing employees to teach, speak, or write only on topics about which they know little.

There are some relatively obscure exceptions to this limitation. For example, writing or editing a scientific book as a compensated outside activity may be allowed if the publication deals only in small part with information gained through official responsibilities. The OGE regulations provide some examples of such exceptions: An NCI scientist, for example, who specializes in the molecular biology of cancer may not be compensated for a book that focuses on research that he or she performs at NIH. However, it is acceptable to edit a textbook on the treatment of all cancers that conveys “scientific knowledge gleaned from the scientific community as a whole” and that includes a chapter on the molecular biology of cancer. In addition, editing a scientific or professional journal is allowed as an official duty only if it does not involve making final

judgments about what is to be published. Yet the alternative of teaching, speaking, and writing for compensation is also restricted and is allowed “on a subject within the employee’s discipline or inherent area of expertise based on his educational background or experience even though the teaching, speaking, or writing deals generally with a subject within the agency’s areas of responsibility.”

Teaching for compensation is allowed as an outside activity if it involves multiple presentations, involves a course that is part of an established curriculum, or involves elementary or secondary schools or institutions of higher learning. If a scientist seeks permission to speak for compensation as an outside activity, he or she must do so as a private citizen, not as an employee of NIH. This leads to that individual’s name appearing on the program with no institutional affiliation (e.g., Dr. Joan Smith, Bethesda, Maryland).

In the Panel’s discussion with NIH scientists, it learned that the above set of complex and difficult to interpret regulations gives rise to many ambiguities and creates a real conflict with the scientific culture outside of the NIH. This in turn casts a shadow over the full participation of NIH scientists with the rest of the scientific community that harms both the morale and productivity of NIH scientists.

Awards

Scientists who make significant contributions to their field, serve as leaders, or excel as communicators and educators are frequently given awards by philanthropic foundations, professional societies, industry, or federal or state governments. Most scientists consider the most prestigious of these awards to be the Nobel Prizes, but many other significant awards are made annually or periodically, involving in some cases considerable cash awards. In addition to the better known and larger awards, family funds are often granted to universities to establish career achievement or leadership awards in science. The growth in the number of these awards has been attributed to many factors, including the wish to honor worthy scientists in new and emerging fields and the goal of individuals and charitable organizations to boost their scientific credentials by identifying themselves with and rewarding first-class scientists. Scientists who receive these awards are frequently required to prepare a lecture as an “acceptance speech.” The cash prizes for these awards can range from a few hundred to thousands of dollars.

Recognition is a critical incentive for motivating scientists. Awards resulting from the critical evaluation and assessment of an individual’s or group’s work or career by peers, including distinguished scientists, hold considerable value to the recipients. Awards not only raise the visibility of the scientist, but also enhance the reputation of his or her institution and research area.

In a June 2003 letter to the Director of NIH, the House Committee on Energy and Commerce announced that it was investigating whether NIH is properly implementing ethics statutes and regulations relating to “lecture awards,” which are cash awards that recognize public service and scientific leadership that are given to NIH officials by an organization in connection with the presentation of a scientific lecture sponsored by that organization. The letter stated that committee staff had identified instances of the organization making the award having applied for

or having received funds from the official's agency, doing business with or seeking to do business with the agency, or having interests that could be substantially affected by performance or nonperformance of the official's duties.

OGE has determined that bona fide awards, including the cash incident to those awards, are to be treated as gifts in recognition of meritorious public service or achievement rather than as compensation or earned income for delivering the speech that is routinely expected of an honoree at an award presentation.

The OGE government-wide ethics regulation⁴⁰ states that an employee may accept a gift that is a bona fide award for meritorious public service or is incident to such an award, subject to the following conditions:

(1) a gift of cash or investment interest in any amount and other gifts with an aggregate market value in excess of \$200 may be accepted only upon a written determination by an agency ethics official that the award is made as part of an established program of recognition under which awards are made on a regular basis, or which is funded to ensure its continuation on a regular basis, and selection of award recipients is made under written standards; and (2) an honorary degree from an institution of higher education may be accepted upon a written determination by an agency ethics official that the timing of the presentation would not cause a reasonable person to question the employee's impartiality in a matter affecting the institution; and (3) an employee who may accept an award or honorary degree under condition (1) or (2) may also accept meals and entertainment given to him or her and to members of his or her family at the presentation of the degree or award.

The OGE regulation provides the following example of a permissible award: Based on a determination by an agency ethics official regarding the requisite award program and the application of written criteria for the award, an NIH employee may accept the Nobel Prize for Medicine, including the cash award that accompanies the prize, even though the prize is conferred on the basis of laboratory work performed at NIH and requires a speech based on the employee's official duty work as a scientist.

NIH implements the OGE requirements as follows:⁴¹

- Official Duty Activity. Although acceptance of most awards must be approved, they need not be approved as an outside activity. The employee accepts the award as part of his official duties or in his personal capacity while on approved annual leave.
- Prohibited Awards. An employee may not accept an award from an organization whose interests may be substantially affected by the performance or nonperformance of the employee's official duties or from an association, the majority of whose members would be substantially affected by the performance or nonperformance of the employee's official duties.

⁴⁰ 5 CFR 2635.204(d)(1).

⁴¹ Appendix 10 of NIH *Policy Manual*, chapter 2300-735-4, Outside Work and Related Activities with Outside Organizations.

- Permissible Awards. A bona fide award for meritorious public service that is not from an organization or association described above; is not cash or an investment interest; and that has a market value of \$200 or less may be accepted. No written approval is required in that instance.
- Other Awards. An employee may accept other awards if approved as set forth below.
- Approval of a Deputy Ethics Counselor. Except for permissible awards, all awards from outside organizations must be approved in advance by a deputy ethics counselor. In order to approve an award of cash or investment interest of any value or another type of award (e.g., tangible personal property) with a market value in excess of \$200, the deputy ethics counselor must certify that the award has been made on a regular basis or, in the case of a newly created award program, is funded in such a way that continuation is ensured; and the selection of the awardee(s) is made on the basis of written standards or by an established selection committee.

In reviewing the request for approval, the deputy ethics counselor should consider:

- (1) an award may be accepted for work performed at NIH and an employee may accept any money associated with the award, upon approval; and
- (2) an award may be accepted from most sources, including those meeting the definition of prohibited sources, unless the source is an organization that has interests that may be substantially affected by the performance or nonperformance of the employee's official duties.

The first example of the application of this rule states that an intramural employee who works in a laboratory that has a CRADA and a contract with a drug company may accept an award from that drug company where the employee has no personal involvement in or responsibility for either mechanism. The second example states that an extramural NIH employee could receive an award from a university as long as the employee does not currently administer grants or contracts from that university. If an application for NIH funding is received from the university within one year of the employee's receipt of the award, the employee should be disqualified in order to avoid the appearance of a conflict of interest.

- Disqualification. If the deputy ethics counselor decides that acceptance of the award will create the appearance of a conflict of interest, the employee will be disqualified or recused from all matters involving the awarding institution. At a minimum, the disqualification will extend from the date of the decision to accept the award until the date of the award ceremony or final receipt of all monetary items associated with the award (e.g., travel expenses), whichever is later.

Conclusion

Because NIH employees have a wide variety of official duties, it is not possible to recommend one set of rules that would appropriately apply across all categories of personnel. As such, one can view the restrictions that should be placed on employees in terms of position in the organization, with the range of allowable outside activities, investments, and interests

diminishing as one's official responsibilities increase. In its deliberations the Panel found an extremely complex set of rules governing conflicts of interest at NIH, and in fact, across the federal government. In the context of NIH, with its unique mission to conduct and support research on its own campus, across the country, and internationally, these rules are widely misunderstood by the very people to whom they are intended to apply. This has created uncertainty about allowable behavior and engendered fear of inadvertent transgressions—thereby significantly damaging morale.

The Panel found that most of NIH's policies and procedures for managing conflicts of interest are fundamentally reasonable and appropriate, albeit confusing, and it believes that the agency has been responsive to direction provided to it in this area by HHS, OGE, and Congress. However, improvements can be made to impose greater restrictions on some types of activities, relax some restrictions that are inappropriate and counterproductive, and improve the overall management of these issues at NIH through better training, education, and resource management.

The Panel makes recommendations about improving policies and practices with regard to review, oversight, and disclosure of outside activities in the next section of this report.

Section V. Recommendations

Overview of Recommendations

The National Institutes of Health (NIH) is a national and global treasure. Its principal asset is its employees, including the truly remarkable scientists and practitioners who choose to serve as its employees. In many ways the future health of our nation depends on a robust and productive NIH. However, if care is not taken, unresolved concerns about conflict of interest could severely damage the ability of NIH to continue to serve the public's health. Appropriate and effective conflict of interest policies help maintain a balance by, on the one hand, ensuring that the science NIH conducts and its funding decisions are not, and do not appear to be biased or corrupted, causing the public, the broader scientific community, and the government's funding officials to lose faith in the institution's credibility, and, on the other hand, avoiding a level of restriction on activities that would drive talented individuals away from NIH as an employer and discourage the dissemination of knowledge. This could happen, for example, if a new set of rules was enacted that was highly inconsistent with the established practices of the scientific community.

Developing sound policies for managing and preventing conflicts of interest requires the balancing of several sometimes competing values and considerations. First, government employees, like all other citizens, are entitled to a life of their own with reasonable privacy. But at the same time, the public has a right to complete assurance that outside activities will not inappropriately influence an employee's judgment or commitment to public service. Second, although sound arguments can be made for the enactment of consistent and uniform conflict of interest rules across the federal government, each agency, including NIH, has unique circumstances and needs. Third, a government employee should not receive personal financial gain for outside activities by exploiting knowledge gained through his or her government position. Yet much of the accumulated knowledge and value of a scientist might well have resulted from efforts made and accomplishments achieved outside of government service. The Panel has sought diligently to balance these sometimes conflicting considerations as it developed its recommendations.

In its deliberations the Panel found an extremely complex set of rules governing conflicts of interest at NIH and, in fact, across the federal government. In the context of NIH, with its unique mission to conduct and support biomedical and health-related research on its own campus, across the country, and internationally, these rules are widely misunderstood by some of the very people to whom they are intended to apply. This has created uncertainty about allowable behavior and has engendered fear that inadvertent transgressions could occur—significantly damaging morale.

The Panel found that most of NIH's policies and procedures for managing conflicts of interest are reasonable and appropriate, and it believes that the agency has been responsive to direction provided to it in this area by the Department of Health and Human Services (HHS), the Office of Government Ethics (OGE), and Congress. However, improvements can be made to impose greater restrictions on some types of activities, relax some restrictions that are inappropriate and counterproductive, enhance disclosure and transparency, and improve the overall management of these issues at NIH through better training, education, and resource management.

Foremost among these recommended improvements is the necessity to either severely restrict or prohibit altogether compensated consulting with industry by three categories of employees: 1) senior NIH officials, 2) NIH extramural employees who are responsible for program funding decisions and managing grants and contracts and application review, and 3) scientists conducting research with human subjects.

Further, equity payments in all forms should be (prospectively) eliminated for those employees who are permitted to consult with industry. All outside consulting should, as is currently the case, be conducted on the employee's own time (e.g., vacation, annual leave, weekends). In addition, to avoid conflicts of commitment, outside professional activities should be further limited to an annual aggregate of 400 hours per year. For the same reason, the compensation for such activities should be limited to 50 percent of NIH salary (exclusive of bonuses), with no more than 25 percent of base salary being derived from any one source. Any exceptions to these limits must be reviewed by the NIH Ethics Advisory Committee (NEAC) and approved by the NIH Ethics Official.

Recusal as a means of avoiding conflicts of interest should be used sparingly. NIH should continue to disallow its employees to enter into outside consulting situations that would require them to systematically recuse themselves from official duty matters, except under exceptional circumstances and with careful NIH oversight.

All outside activities *related to NIH's mission* should be disclosed to NIH ethics officials, as is currently required, and disclosed publicly where required by statute. Similarly, all significant investments by NIH employees or their immediate families in biotechnology or pharmaceutical companies should be disclosed to NIH, as should any other significant investments that relate to, or the value of which could affect or be affected by, the employee's work, whether or not the employee is involved in outside activities. In addition, all work products related to NIH's mission that result from such activities (e.g., written material, speeches, and informed consent documents) should include a disclosure of such activities or financial interests.

Finally, employees should be *encouraged* to participate in the customary pursuits of the scientific community—even with some appropriate level of compensation—including teaching, speaking, writing, editing, and receiving awards. There should be no limit on the amount of money an employee is allowed to receive from bona fide awards for meritorious public service or achievement, from royalties generated from inventions, or from work written or edited as an outside activity (as compared to the limits proposed above for consulting). Moreover, where the activities could reasonably be considered an official duty, the reimbursement of reasonable travel expenses for NIH scientists by outside organizations should be more broadly and uniformly allowed where this facilitates *public* scientific communication and interaction. NIH employees can and should make better use of rules that allow them to accept travel and other expenses for outside activities. The Panel also recommends that federal rules be changed to allow employees engaged in such outside activities to publicly be identified as being affiliated with NIH. The current practice that denies this ability is unduly restrictive.

Framework for the Panel's Recommendations

The Panel's recommendations are presented in a manner that recognizes the hierarchy and diverse roles and responsibilities of NIH employees. Because NIH employees have a wide variety of official duties, it is not possible to recommend one set of rules that would appropriately apply across all categories of personnel. As such, one can classify the restrictions that should be placed on employees in terms of their position in the organization, with the range of allowable outside activities, investments, and interests diminishing as the level and scope of official responsibilities increase.

The most senior NIH employees include the NIH Director and his or her other senior staff (those who report directly to the NIH Director); and the institute and center directors and their senior staff (deputy, scientific director, clinical director, and other senior staff who report directly to the IC directors). These individuals provide leadership for the priorities, programs, policies, and procedures of their respective institutes or centers or for NIH in its entirety and have the potential to exert considerable influence over funding and policy decisions and the allocation of resources. Moreover, because of the broad reach of their authorities, it would be difficult for many of these individuals to recuse themselves from decisions or activities posing a real or perceived conflict without unduly compromising their responsibilities to their official duties.

Two other groups of employees should be subject to special restrictions to avoid conflicts of interest: NIH extramural staff responsible for program funding decisions, managing grants and contracts, and application review; and intramural scientists conducting studies with human subjects.

An additional important category of employees is those who perform intramural scientific and medical research in NIH laboratories with no special role in decisions regarding the allocation of government resources and no involvement with human subjects. Restrictions for these employees should not be as stringent as those applied to the three categories of employees described above.

Accordingly, the Panel focused its recommendations on those employees directly involved in either overseeing or executing the research programs of NIH. Although all employees support that mission, and some also might be engaged in outside activities that are subject to government ethics rules, the Panel did not examine non-research-related categories of employees.

Senior Leadership, Employees with Direct Responsibility for Extramural Grants and Contracts, and Researchers Conducting Human Subjects Research

Based on discussions with a large number of witnesses, the Panel believes that—with careful review and monitoring—it is advantageous for NIH and for the scientific enterprise to allow many NIH employees (especially intramural investigators) to engage in limited, remunerated outside activities, including those with biotechnology and pharmaceutical companies. However, the Panel recommends that other employees, specifically those in senior management positions

across the institutes and centers and designated NIH extramural staff should not be allowed to engage in consulting activities with biotechnology and pharmaceutical companies under any circumstances.

There are two primary reasons for this restriction. First, the potential for real or perceived conflicts of interest increases with rising authority, decisionmaking capacity, and proximity to the allocation of public resources. Second, because of the public and national leadership roles played by senior NIH officials, financial relationships with industry may have the appearance of giving preference to certain private interests over the public's interests or of giving preference to one private interest over another.

In addition to consulting for industry, scientists are sometimes asked to serve as consultants to academic institutions, for example, as members of a scientific advisory board or as site visitors for inspections, accreditation decisions, or funding decisions (from either public or private sources), sometimes for pay. A large majority of NIH grants and contracts are awarded to academic institutions around the country. Thus, senior NIH employees and those NIH employees in the extramural research program responsible for funding strategies and decisions should **not** be allowed to engage in such outside activities with academia for compensation. This is already prohibited by HHS supplemental regulations for all NIH employees if the program at the university is funded by an HHS mechanism. It would be exceedingly difficult for a high-level NIH official or a grants or contracts administrator to avoid real or perceived conflicts of interest if he or she were receiving compensation from a grantee institution or contractor. Except when the conflict is waived, involvement in outside activities requires individuals to recuse themselves when matters related to the sources of their outside activities come before the employee in his or her official capacity. Employees at the highest levels of an institute or a center or those directly involved in programmatic and funding decisions should do their utmost to avoid being in a position of having to recuse themselves from matters that are central to their official responsibilities. NIH would otherwise suffer from the absence of these individuals during times of critical decisionmaking.

Recommendation 1: NIH senior management and NIH extramural employees who are responsible for program funding decisions and recommendations, and professional staff managing grants and contracts and application review, should not engage in consulting activities with pharmaceutical or biotechnology companies or in paid consulting for academia. The Panel considers speaking for compensation at an industry site as equivalent to consulting for industry. The Panel does not include in this prohibition time spent in clinical practice by health care practitioners, if approved as an outside activity free of conflicts.

As a separate category of employees, clinical researchers have a special responsibility for ensuring the safety and ethical care of human subjects. Conflicts of interest have the potential to threaten the safety of research subjects, and, therefore, these employees should also be subjected to a very high level of scrutiny. NIH clinical researchers conducting clinical trials are currently not allowed to have consulting arrangements with or financial interests in companies involved in the trials they are conducting, such as drug companies providing or directly affected by the provision of the agent being tested. The Panel endorses this policy. The Panel also noted with

approval the guidelines developed by the Association of American Medical Colleges (AAMC) for research with human subjects conducted by scientists working in academia. The AAMC guidelines acknowledge that “research with human subjects is a privilege that imposes unique obligations.” The guidelines assert that financial interests in research with human subjects are “potentially problematic” and require “close scrutiny.” They urge institutions to set up policies that require “full *prior* reporting of...significant financial interests that would reasonably appear to be affected by the individual’s research....” The guidelines also promote *transparency*, described as “full and ongoing internal reporting and external disclosure of significant financial interests that would reasonably appear to affect the welfare of subjects or the conduct or communication of research.”

In simplest terms the AAMC guidelines recommend that there should be a rebuttable presumption against certain financial interests in human subjects research. The Panel concurs with this approach but also believes that there might be some circumstances in which such interests do not pose a conflict or could improve or enhance the safety of a research study. NEAC should review such exceptions and recommend to the NIH Ethics Officer an effective conflict of management plan.

Recommendation 2: The Panel reaffirms current federal law, which states that intramural scientists conducting research with human subjects—for example, investigators and research team members involved in patient selection, the informed consent process, and clinical management of a trial—should not be allowed to have any financial interest in or relationship with any company whose interests could be affected by their research or clinical trial, except in special circumstances, and with an appropriate waiver or authorization.

Compensated Outside Activities for Other Research-Related NIH Employees

Most NIH intramural scientists play no role in the allocation of NIH resources to outside entities. The Panel recommends that for these scientists a wider range of outside activities should be allowed than for the three groups or activities just described. Persuasive arguments can be made in favor of a policy that allows these NIH employees to engage in outside activities—albeit within clear guidelines, subject to thorough oversight, and with a high level of transparency.

First, absent good reasons otherwise, and in the interest of promoting the freedom of individuals, as well as academic and scientific freedom, restrictions should not be imposed beyond those that are needed to protect the interests of the primary employer, the U.S. government. Second, for NIH to compete successfully with other potential employers of NIH scientists, the agency must not prevent its employees from taking the opportunity to engage in interesting and remunerative outside activities. Third, Congress and every recent administration have embraced technology transfer as one of the basic missions of NIH. Although fundamental research is of great importance, it will in general affect the health of the American public only when it is translated through the actions of industry. Engaging in outside activities, including those with industry, is essential to accomplishing the goal of technology transfer, both to and from NIH. This type of

activity supplements and does not duplicate or overlap with the formal and public arrangements negotiated through Cooperative Research and Development Agreements (CRADAs).

In addition to consulting with industry, an NIH intramural scientist who has nothing to do with the awarding of extramural grants and contracts might be invited to perform an important service as a paid consultant to an academic institution or professional society—for example, to conduct a site visit or help prepare an academic program in his or her field for accreditation. Such activities are mutually beneficial—if not prohibited by HHS supplemental regulations because the activity is funded by HHS—as the NIH scientist can learn as much from the process as the institution gains from the scientist’s expertise. These activities are not part of the scientist’s official duties and would have to be conducted, if at all, on his or her own time.

If all NIH scientists described above were to be prohibited from accepting appropriate compensation for outside activities, it would be unrealistic to expect that their level of interaction with scientists in academia and industry would be sufficient to allow NIH to fully achieve its mission. The Panel believes that with careful oversight and monitoring, potential conflicts of interest can be effectively avoided in a way that respects the rights of individuals to pursue their personal and scientific interests while simultaneously maintaining public trust in NIH.

Restrictions on Compensation and Time

To avoid conflicts of commitment in outside activities, the Panel recommends that, for all NIH employees except those engaged in outside medical practice, both a time and an income limit be applied with respect to the outside professional activities that are permitted in any given year, similar to those specified in requirements at the agency prior to 1995. The total time spent on outside professional activities should not exceed 400 hours a year to ensure that every employee’s overriding concern is his or her NIH duties. For the same reason, total outside compensation should not exceed an amount equal to 50 percent of the employee’s annual salary (exclusive of bonuses), except in very special circumstances, and no more than an amount equal to 25 percent of annual salary should be derived from a single outside source. (Exceptions to these limits include the receipt of royalties from patents or written work attributed to approved outside activities, as well as bona fide awards, as described below, and outside medical practices, as discussed below.)

In addition, to further ensure that an employee retains a primary obligation to his or her government duties, compensation for outside activities should be limited to cash, with payment in any form of equities, including stock options, prohibited. The latter forms of payment in essence make the NIH employee an owner of the company, in addition to coupling reward with outcomes, with consequences that could cause a conflict of commitment as well as interest.

The Panel believes that there should be a special accommodation made with respect to the compensated outside activities of those NIH employees who are health care practitioners (e.g., physicians, nurses, social workers). Except where special personnel systems have been designed to more closely match salaries in the nonfederal market, this group of employees at NIH is particularly underpaid in comparison to their colleagues elsewhere. Moreover, as health care providers, this group should be encouraged to engage in a more extensive clinical practice than

that experienced at NIH. This will help them continuously hone and maintain skills derived from providing care to a wider array of patient populations than might be seen on a regular basis at the NIH Clinical Center or as part of their official duties. Providing medical care and patient services in outside settings does not pose any conflict of interest, as long as those patients are not also enrolled in NIH clinical studies with which the NIH employee is involved, a limitation imposed by existing NIH policies.

Recommendation 3: In addition to existing requirements for engaging in outside activities, and the restrictions posed in Recommendations in 1 and 2, the following requirements should be in place for all employees who are involved in the administration or conduct of NIH research programs:

- a. The total amount earned annually from compensated consulting with industry or academia should not exceed an amount equal to 50 percent of the employee's annual salary, and no one source should account for an amount exceeding 25 percent of annual salary.**
- b. Employees eligible to engage in compensated outside professional activities should not:**
 - i. receive compensation in the form of stock options or other forms of equities for their services**
 - ii. spend more than 400 hours per year on these activities (writing excepted).**
- c. An exclusion to the above limits should exist for NIH employees who are health care practitioners. For these employees, there should be a more flexible time limitation and the capitation for compensated outside medical care and patient services should be 100 percent of base pay, with the one-source limitation removed.**

In general, the Panel finds the discussions in the now-superseded 1985 NIH policy on "Outside Work and Activities" to be useful for defining the types of potential conflicts that must be avoided in permitting such activities. Thus, for example, a researcher clearly should not consult with a company that has applied for or received a research contract from the employee's own laboratory or branch. But applying this principle more widely to exclude companies involved with the employee's institute, as specified in 1985, would be too expansive a restriction. It would often eliminate scientists from interactions with industry where, due to the lack of control on the part of the employee over some far off activity in a different area of work, no conflict is possible. Exactly where the line needs to be drawn will depend on individual circumstances and thus should be decided through consultation with the appropriate NIH ethics officials.

Likewise, an employee should not consult for a company whose products are leased or purchased by NIH where the employee has a role in such transaction, or for a company where the official position of the employee is likely to be used to promote a product or service. Again, determining whether an outside activity poses a real or perceived conflict of interest must be decided on a case-by-case basis, as is currently done at NIH.

Monitoring and Tracking of Outside Activities

Currently, to request to participate in an outside activity, an NIH employee has to complete an outside activity application, which includes HHS Form 520 and supplemental forms if compensation is involved, or if certain activities will be conducted, such as consulting for industry, legal consulting or testimony, and professional practice for physicians, nurses, and allied health care professionals.

Current regulations require that advance written approval must be obtained by all employees for certain outside activities, whether or not they involve compensation. In addition, the process for review and approval of outside activities for NIH employees in certain positions (e.g., senior NIH officials) and other NIH employees who desire a certain type of outside activity (e.g., involving a biotechnology or pharmaceutical company or more than \$10,000 in compensation) has recently changed, involving the newly created NEAC. These mechanisms, if properly implemented, appear to be effective means for monitoring outside activities, although the Panel believes that such approvals should be revisited on an annual basis.

Recommendation 4: To improve NIH's ability to manage and track approved outside activities:

- a. all requests for outside activities (Form 520) should be updated on an annual basis (with such updates indicating only those changes that have occurred);**
- b. supervisors should be held accountable for the evaluation and approval of outside activity requests, and this supervisory function should be a component of a supervisor's performance evaluation; and**
- c. NIH should publish an annual agency-wide statistical report on the number and types of outside activities approved for its employees.**

Compensation for Teaching, Speaking, or Writing and Awards

As described in section III of this report, only a relatively small number of NIH employees are engaged in consulting arrangements with industry. In contrast, a substantial number of NIH employees are involved in outside activities with professional societies and with academic and research institutions—primarily in the forms of teaching, speaking, or writing (including editing). In addition, NIH scientists who are recognized for outstanding scientific achievements, leadership, or public service are sometimes the recipients of awards, which may be accompanied by a cash prize. The Panel believes these are important—even essential—activities for NIH scientists, since they are part of the tradition of science and provide evidence of the value and significance of the NIH research community to the larger scientific community. For example, speaking at academic institutions or other similar public fora is a critical part of being a productive and contributing scientist. It provides an important avenue for the exchange of scientific ideas, and both the speakers and the audiences benefit.

Some of the current restrictions placed on intramural scientists invited to speak at a public forum have been counterproductive to the dissemination and exchange of scientific knowledge, as well as to the retention and recruitment of the most outstanding individuals by NIH. Among the most

troubling requirements the Panel reviewed is that, under the current rules, employees may not be compensated for speaking or writing about their scientific work unless it has been both *completed* and published for at least a year. Here the term “completed” has been interpreted by NIH to mean that the researcher is no longer concerned with the issue. However, because of the iterative nature of scientific inquiry, most scientific work is never completed. For example, a scientist might spend an entire career (at NIH and elsewhere) pursuing one narrow area of research. Moreover, new employees may have decades of past research accomplishments in the same area prior to coming to NIH, and under current rules they could be restricted in speaking and writing as an outside activity for an extended period of time, if not indefinitely.

The need to prevent scientists, as well as other government employees, from being paid twice to conduct the same work is appropriate. Accordingly, it is reasonable to require that scientists who engage in teaching, speaking, and writing about *current, unpublished* work do so only as an *official* duty. This type of official duty communication should be encouraged and supported by NIH as promoting the free exchange of information.

However, once a research project has been concluded to the point of publication, it seems unnecessarily punitive to forbid an NIH scientist from receiving a reasonable honorarium for a lecture on that *published* work at an academic institution or elsewhere, as would any other scientist. These customary but generally modest amounts recognize the extra effort required to prepare for and attend such an activity on the employee’s own time and can be monitored with appropriate oversight through the NIH ethics process. In general, the Panel believes that such compensation does not represent a conflict. Furthermore, it allows the NIH scientist to be treated in the same manner as nearly all other scientists, which is in the best interest of NIH, the public, and the scientific community at large.

In addition, it is crucial that these employees continue to be allowed to have reasonable transportation and related expenses paid for by the sponsors of seminars and colloquia delivered at universities and in other public settings where much scientific information is exchanged. Equally important, these scientists should be able to acknowledge their NIH affiliation on such occasions. In the interest of full disclosure, it is counterproductive for employees to “hide” their institutional affiliation, in accordance with current ethics rules. Any reference to one’s role as an NIH employee to suggest NIH endorsement when none is intended is, of course, inappropriate, but this issue is readily resolved through disclaimers.

Regarding royalties or disbursements obtained through the outside activities of textbook writing or editing, the Panel could find no compelling reason to limit the amount of money that an employee can receive, as long as the activity received prior approval and was deemed to pose no conflict of interest, which generally should be the case.

Recommendation 5: NIH should seek a change to OGE regulations to allow NIH scientists to receive compensation for teaching, speaking, or writing about their research providing that the information is to be shared in a public forum *and* that it has appeared in the published literature.

Recommendation 6: NIH intramural scientists should continue to be allowed to engage in compensated speaking, teaching, and writing for professional societies and for academic and research institutions as an outside activity providing that all ethics review and approval requirements are met.

Recommendation 7: NIH should seek a change to OGE regulations to permit employees to be identified by their title or position (and institutional affiliation) when engaged in teaching, speaking, or writing as an approved outside activity. Disclaimers should be provided that the activity is not being conducted in the employee's official capacity as an NIH employee and that the views expressed do not necessarily represent the views of NIH.

Recommendation 8: There should be no restrictions on royalties received on works written, edited, or published or on income received from patents licensed by any NIH employee who conducted the work as an approved outside activity.

Recommendation 9: The current OGE rules regarding receipt of bona fide cash awards for meritorious public service or achievement and NIH's interpretations of the rules are reasonable and should apply to all employees. There should be no limit on the amount of money received from a bona fide award. These awards are considered gifts under current law and are not considered outside activities because the employee accepts the award in his or her official capacity.

Disclosure and Transparency

Current requirements for reporting income from outside activities, or from investments that might have relevance to one's official duties, do not always capture the information needed to manage conflicts of interest. The only employees who must currently *publicly* disclose all outside activities as well as financial interests are those required to annually file a Form 278 (see section III of this report). The most obvious problem that needs to be corrected is the accident of legislative and regulatory history that exempts even highly paid Title 42 employees from this disclosure. NIH has ameliorated this problem by securing equivalency determinations from OGE with respect to its most senior employees, so that these employees are now required to file Form 278. This is an effective first step toward ensuring that potential conflicts of interest at the highest level of NIH are properly managed. In addition, the Panel recognizes the complexity of Form 278 and encourages OGE to seek simplification of reporting, a change that will require legislation and would become government wide.

As specified by OGE, the filing of an annual confidential financial report (OGE Form 450) is limited to "those pay grades where the duties and responsibilities clearly make filing necessary and relevant." Currently, more than 5,000 of the more than 17,000 NIH employees are required to disclose in this manner. Individuals who file this relatively brief confidential form need to disclose outside activities with industry and academia if the income from these activities is greater than \$200. However, the 450 form does not capture the precise amount of compensation, and because it is a government-wide form established by OGE, it is not easily changed. Further,

if an individual is not required to file either a public or confidential financial disclosure form, as can be the case, NIH has *no* way of knowing whether a potential conflict of interest exists, unless he or she has submitted an outside activity request using HHS Form 520.

The Panel differentiates between public disclosure and internal disclosure within NIH for purposes of managing conflicts. Although public disclosure may be seen as a potential tool for managing conflicts by exposing them, it has its limitations (i.e., the desired outcome might be to eliminate or avoid the conflicted activity rather than merely expose it). Moreover, it is severely limited by government-wide statutes and regulations that govern the rules for public disclosure of private information collected and maintained by government agencies (including the Privacy Act). The Panel applauds the actions taken by NIH thus far in appealing to OGE to expand the number of officials required to file public disclosures and recommends further expansion of that approach for upper management. The Panel recognizes, however, that any expansion of the number of public filers will be limited by law, and that the heavy burden of detailed disclosure entailed by the complex form now in use makes it undesirable for general use even if permitted. Thus, the principal tool for conflict management for many employees will continue to be confidential filing within NIH, using OGE Form 450.

It is critical to maintain public confidence that NIH's ethics standards and practices ensure that all potential conflicts of interest are being managed or eliminated. There are three key considerations in determining whether and what type of disclosure should be required: 1) does NIH know enough to prevent and manage conflicts of interest? 2) do those who would be directly affected by such interests (e.g., subjects of research) have the information necessary to make informed choices? and 3) does the public have access to sufficient information to maintain public confidence in the integrity of NIH and its research? In answering these questions the Panel attempted to balance the needs of NIH, as well as those of research subjects and the public with the rights of NIH employees under law to an appropriate and reasonable degree of privacy.

Recommendation 10: To increase NIH's ability to manage conflicts of interest, it should move immediately to either increase the number of employees required to annually file a confidential disclosure form (Form 450) or find some other means to achieve comparable levels of internal disclosure.

Recommendation 11: NIH should ask OGE to make a regulatory change or seek statutory modifications to provide NIH with greater discretion in determining whether certain Title 42 employees should file a public financial disclosure form (Form 278). This would promote the public interest by increasing transparency and would thereby enhance trust in government. In the meantime, NIH should seek additional equivalency rulings from OGE to increase the number of public filers to include the senior employees specified in Recommendation 1.

Recommendation 12: NIH supervisors should be provided with enhanced training on the criteria to be used for their annual review of financial disclosures so that they can become more effective in managing and avoiding employee conflicts of interest.

Recommendation 13: To preserve public confidence in NIH, the agency should put in place a policy that requires employees to disclose all relevant outside relationships and financial holdings in their work products, such as publications, speeches, and invention disclosures. In addition, where relevant, such disclosures should be made to potential research subjects as part of the informed consent process.

Finally, NIH employees are required to recuse themselves from official duties when a conflict or potential conflict of interest arises and no waiver has been granted. For example, an employee might have a spouse who is an employee of an academic institution applying for a grant or might have financial holdings (that exceed the de minimis threshold) in a company competing to be a vendor for services provided to NIH. In some cases, an employee assigned to participate in either that grant or contract might be asked to divest those interests. In other cases, a waiver might be granted, or conversely, the employee may have to recuse him- or herself from certain matters. However, there is no current requirement that recusals be put in writing, which limits the effectiveness of this method for managing and avoiding conflicts of interest.

Recommendation 14: NIH employees should be required to submit recusals in writing to immediate supervisors when a potential conflict of interest emerges. The supervisor should then be required to inform those who should be aware of the employee's need to be recused from the official duties for which there is a conflict. As is currently the case, when an employee must be recused from official duties, those duties can be reassigned only to someone at an organizational level above the employee. As such, recused employees or their supervisors will need to inform both superiors and affected subordinates of the recusal.

Ethics Training and Administration

By any measure, the ethics rules of the federal government, enforced through law and by OGE rulings—but with additional layers of policies and procedures invoked by HHS and NIH—have created a complex set of regulations that are not readily understood. Confusion caused by vague and overly broad language in the regulations themselves has accentuated the need for many cases to be decided with appropriate attention to context and the specific facts of the situation. Add to this the complexity of 27 separate units at NIH, each interpreting the rules in a slightly different way, and what emerges is what appears to many employees to be a Conflicts of Interest Tower of Babel. This can be remedied in two ways: 1) increase uniformity and consistency in interpreting and applying the rules across NIH, and 2) provide an enhanced program of training and information dissemination for both supervisors and the employee populations in general.

Although some employees currently must complete an ethics training course, confusion about what is allowed and what is not allowed seems to be rampant. Simplified and clear information is needed to ensure that all employees understand their ethics obligations. The creation of NEAC has provided an opportunity to develop a common body of knowledge or best practices—analogue to case law—based on that committee's review of individual cases. This information should be used to instruct the NIH community on issues of particular concern, sensitivity, or confusion, using concise and thoughtful forms of communications that have been pretested using a focus group of the intended recipients and revised with its input.

Recommendation 15: The NIH Ethics Office should prepare a user-friendly document and website that displays the ethics rules in simple language and emphasizes examples of outside activities and financial interests that are permissible, as well as those that are not. Employees seeking approval of outside activities should, as part of their submission of Form 520 and its supplements, indicate in writing that they have reviewed these summary materials and have discussed any questions they have with their relevant ethics official and/or supervisor.

Recommendation 16: The NIH Ethics Advisory Committee should issue a report of its findings, in the form of anonymous case studies and generalizable principles, on a regular basis to provide the NIH community with a clear common body of knowledge by which to understand and interpret ethics rules.

Recommendation 17: NIH management should assure that sufficient resources are provided for the administrative and management functions of its ethics activities to guarantee that the expanded program proposed in this report can be implemented.

Other Observations

Strategies for Retaining the Most Senior Employees at NIH

One issue that continued to arise throughout the Panel’s deliberations—related to but beyond the specific charge of the Panel—is the adequacy of government compensation for NIH employees. Although financial remuneration did not appear to be the primary or even an important consideration for many scientists engaged in outside activities, the Panel did consider whether the potential for NIH scientists to participate in compensated outside activities as a supplement to basic government pay is necessary to recruit and retain the world’s best scientists. Many of these scientists have tens of years invested in higher education, and many have multiple degrees, with additional years spent in postdoctoral fellowships and completing residency requirements.

The Panel found that for lower and midlevel scientists, NIH salaries were reasonably comparable to those in academia. It heard from intramural scientists that the ability to engage in teaching, speaking, and writing as other scientists do was generally more critical than salaries in their decision to come to or stay at NIH. However, as scientists became more senior and more experienced, NIH salaries become less competitive when compared to the nongovernmental sectors: This is especially true at the highest levels of the agency and for staff clinicians, for whom compensation, in financial terms, is far from competitive.

Title 42 authority provides a special hiring mechanism through what is known as “administratively determined” pay. Title 42 addresses the authority of the agency to appoint doctoral-level scientists in biomedical research, science policy, administration, and research evaluation. Thus, it has a very specific scope and it is currently used as the authority to pay employees salaries in the range from \$38,000 to \$200,000, with the possibility of bonuses—recruitment, retention, or performance—calculated on a percentage of the employee’s base pay.

The current cap of \$200,000 has been in place since 2000, contributing to severe salary compression at this level.

Because the Panel is recommending that the most senior NIH leaders be prohibited from engaging in nearly all compensated outside activities, it is especially critical that the agency consult with HHS to consider whether the current limit of \$200,000 for the nation's senior government scientists is hindering NIH's efforts to recruit and retain the preeminent scientific leaders it needs. The Panel believes that for such individuals this ceiling should be raised.

Recommendation 18: The NIH Director, working with Congress, should ensure that the agency has authority under Title 42, or some other hiring mechanism, to recruit senior scientific staff in the current highly competitive market. In addition, the NIH Director should ask HHS to review and, if appropriate, raise the current annual salary capitation of \$200,000 for the most senior Title 42 employees at NIH. The Panel is concerned that the present ceiling is limiting the agency's ability to recruit and retain the nation's best scientists as the leaders of NIH.

The Current Morale of NIH Scientists

The Panel was surprised to learn that relatively few NIH employees are in fact engaged in consulting agreements with biotechnology or pharmaceutical companies—an activity that currently involves only about 120 of NIH's 17,500 employees. Yet the high level of reasonable concern expressed by Congress and the media about the potential for conflicts of interest when consulting with industry—itsself a small fraction of the outside activities engaged in by NIH scientists—has had a decidedly negative impact on the morale of a large number of NIH intramural scientists.

In its interviews with NIH scientists, the Panel observed that a heightened scrutiny with regard to ethics issues has increased the confusion about the existing policies. There is a widespread sense that rules on all outside activities are being changed midstream or suddenly overly interpreted out of caution. NIH scientists are concerned that they might be unable to fully participate in the community of science in the future, and senior management worries about the impact that possible new policies could have on the recruitment and retention of scientists at NIH. Worse yet, there seems to be widespread fear of committing an inadvertent transgression in this complex of sometimes arcane rules and interpretations. In short, many NIH scientists sense that they are unfairly being forced to live under a cloud of suspicion.

The Panel believes that the recommendations presented in this report are important for addressing these concerns, and it urges that they be adopted as quickly as possible. This is needed to assure the continued, deserved public confidence in the extraordinary work of NIH, to continue to enhance the quality of the scientific staff at NIH, and to rectify what the Panel perceives as a critical and growing morale problem among the agency's excellent staff.

**Appendix A:
NIH Blue Ribbon Panel on Conflict of Interest Policies
A Working Group of the Advisory Committee to the Director, NIH**

Roster

Bruce Alberts, Ph.D. (Co-Chair)

President
National Academy of Sciences
Washington, DC

Norman R. Augustine (Co-Chair)

Chairman, Executive Committee
Lockheed Martin Corporation
Bethesda, Maryland

Christine Cassel, M.D.

President
American Board of Internal Medicine
Philadelphia, Pennsylvania

Thomas H. Murray, Ph.D.

President
The Hastings Center
Garrison, New York

Phillip Pizzo, M.D.

Dean, School of Medicine
Stanford University
Stanford, California

The Honorable Stephen D. Potts

Chairman, ERC Fellows Program
Ethics Resource Center
Washington, D.C.

Dorothy Robinson, Esq.

Vice President and General Counsel
Yale University
New Haven, Connecticut

Lawrence Sadwin

President
Lifestyle Security, L.L.C.
Warren, Rhode Island

James Siedow, Ph.D.

Vice Provost for Research
and Professor of Biology
Duke University
Durham, North Carolina

Reed V. Tuckson, M.D.

Senior Vice President
Consumer Health & Medical Care
Advancement
UnitedHealth Group
Minnetonka, Minnesota

Appendix B: Panel Biographies

BRUCE ALBERTS, PH.D. has served in the full-time position of President of the National Academy of Sciences, a private and independent non-governmental organization in Washington D.C. since July 1, 1993. In that position he also chairs the National Research Council, the operating arm of the National Academies (which also includes the National Academy of Engineering and the Institute of Medicine, two other important honorary societies). Prior to moving to Washington, Dr. Alberts was a full-time faculty member who carried out research in cell and molecular biology while teaching undergraduates, graduate students and medical students. After graduating *summa cum laude* from Harvard College in 1960, he received his Ph.D. in Biophysics from Harvard in 1965. After a year of postdoctoral research in Geneva, Switzerland, he joined the faculty at Princeton University as an Assistant Professor of Chemistry in 1966. Ten years later, he left Princeton to become a professor at the Medical School at the University of California, San Francisco (UCSF). At UCSF for 17 years, he was awarded a Lifetime Professorship by the American Cancer Society, and he served as the Chair of the Department of Biochemistry and Biophysics. Much of the scientific work that was carried out in the laboratory of Dr. Alberts focused on dissecting the detailed molecular mechanisms, involving the miniature protein machines that all cells use to make new copies of their chromosomes through a process called DNA replication. This research was funded by a series of grants from the NIH as well as by several other research agencies. The National Academies are frequently asked to study hard problems by the National Institutes of Health and many other government agencies. Recent examples include the report *Enhancing the Vitality of the National Institutes of Health: Organizational Changes to Meet New Challenges*, published in July 2003, and a report on the *Discovery of Antivirals against Smallpox* to be released in May 2004.

NORMAN R. AUGUSTINE joined the Douglas Aircraft Company in 1958 as Program Manager and Chief Engineer. Beginning in 1965, he served in the Office of the Secretary of Defense as an Assistant Director of Defense Research and Engineering. Joining the LTV Missiles and Space Company in 1970, he served as Vice President, Advanced Programs and Marketing. In 1973 he returned to government where he served as Assistant Secretary for R&D and subsequently as Under Secretary and for four months as Acting Secretary of the Army. Joining Martin Marietta Corporation in 1977 as Vice President of Technical Operations, he later served as Chairman and CEO, having previously been President and Chief Operating Officer. He served as President of Lockheed Martin Corporation upon the formation of that company in 1995, and became Chief Executive Officer and later Chairman. He currently serves as Chairman of the Executive Committee of Lockheed Martin. Mr. Augustine served as Chairman and Principal Officer of the American Red Cross for nine years and is a former Chairman of the Education Task Force of the Business Roundtable, and a member of that organization's Policy Council. He is a former Chairman of the National Academy of Engineering and a former President of the Boy Scouts of America. He has been on advisory boards to the White House, U.S. Senate, NASA, FAA, and the Departments of Defense, Army, Navy, Air Force, Energy, Transportation, and Homeland Security, the General Accounting Office, and NATO. He has been presented the National Medal of Technology, has five times been awarded the Department of Defense's highest civilian decoration, the Distinguished Service Medal, and has received the Joint Chiefs of Staff Distinguished Public Service Medal among numerous other government

service medals. Mr. Augustine received both his bachelor's and master's degrees in aeronautical engineering from Princeton University.

CHRISTINE K. CASSEL, MD, MACP, became President and CEO of the American Board of Internal Medicine and ABIM Foundation in Philadelphia, in July 2003, after recently serving as Dean of the School of Medicine and Vice President for Medical Affairs at Oregon Health & Science University in Portland, Oregon. Dr. Cassel is a leading expert in geriatric medicine, medical ethics and quality of care. Among her many professional associations, Dr. Cassel is immediate Past-Chair of the ABIM Foundation Board of Trustees and is currently Chair of the Board of the Greenwall Foundation, which supports work in bioethics; President of the American Federation for Aging Research; member of the Advisory Committee to the Director at the National Institutes of Health. Dr. Cassel was recently elected to the Institute of Medicine Governing Council. She served on previous IOM committees responsible for influential reports on quality of care and medical errors, chaired a recent report on end-of-life care, and co-chaired a report on public health. Earlier, Dr. Cassel served on the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry (1997-98). An active scholar and lecturer, Dr. Cassel publishes extensively in professional journals, books, editorials and special reports. She is currently concerned with quality improvement in health care, health-professional education, biomedical ethics, geriatric medicine, palliative care, healthcare policy, and healthy aging. Nationally prominent as chief editor of a seminal textbook, *Geriatric Medicine* (Fourth Edition), Dr. Cassel also edited *A Practical Guide to Aging* (1997), co-authored *Ethical Dimensions in the Health Professions* (1993), and co-edited *Ethical Patient Care* (2000), *Approaching Death* (1997), *Encyclopedia of Bioethics* (1995), and *Nuclear Weapons and Nuclear War* (1984). Her new book, *Medicare Matters: Older Americans and the Future of Medicare*, is currently in press. Dr. Cassel was formerly Chair of the Department of Geriatrics and Adult Development and Professor of Geriatrics and Medicine at Mount Sinai School of Medicine in New York City. During ten years at the University of Chicago, Pritzker School of Medicine, Dr. Cassel was Chief of the Section of General Internal Medicine, Professor of Geriatrics and Medicine, Founding Director of the Robert Wood Johnson Clinical Scholars Program, and Founding Director of the Center for Health Policy Research. Dr. Cassel received her medical degree from the University of Massachusetts and completed her residency in internal medicine at Children's Hospital and the University of California at San Francisco, with subsequent fellowships in bioethics and geriatrics at San Francisco and Portland, Oregon.

THOMAS H. MURRAY, PH.D. is President of The Hastings Center, an independent non-profit, non-partisan research institute devoted to ethical issues in health and medicine and the life sciences. Dr. Murray was formerly the Director of the Center for Biomedical Ethics in the School of Medicine at Case Western Reserve University in Cleveland, Ohio, where he was also the Susan E. Watson Professor of Bioethics. Dr. Murray's research interests cover a wide range of ethical issues in medicine and science, including genetics, children, organ donation, and health policy. Among Dr. Murray's current activities, he directs a research project on conflicts of interest in biomedical research. He is a founding editor of the journal *Medical Humanities Review*, and is on the editorial boards of *Human Gene Therapy*, *Politics and the Life Sciences*, *Cloning, Science, and Policy*, *Medscape General Medicine*, *Teaching Ethics* and the *Journal of Law, Medicine & Ethics*. He is also editor, with Maxwell J. Mehlman, of the Encyclopedia of Ethical, Legal and Policy Issues in Biotechnology, (John Wiley & Sons, 2000). He served as a

presidential appointee to the National Bioethics Advisory Commission from 1996 – 2001 where he served as chair of the subcommittee on genetics. He served as a member of the Committee on Ethics of the American College of Obstetrics and Gynecology and is former Chair of the Social Issues Committee of the American Society for Human Genetics. He is currently a member of the Ethics Committee of the Human Genome Organization. He is a past member and founder of the Working Group on Ethical, Legal and Social Issues to the National Institutes of Health Center for Human Genome Research, and chaired its Task Force on Genetics and Insurance. He is Past President of the Society for Health and Human Values. From 1999 to 2000 he served as the President of the American Society for Bioethics and Humanities. Dr. Murray also served as a member of the AAMC Task Force on Conflicts of Interest from 2001-2002 and is currently a member of the Center for Strategic & International Studies' Council on Biotechnology Research, Innovation and Public Policy. He also serves on the Advisory Committee for the Genomics Institute at the Wadsworth Center, is an Affiliated Scholar of the Institute for Bioethics, Health Policy and Law at the University of Louisville and is a member of the Food and Drug Administration's Biological Response Modifiers Advisory Committee. He is the author of more than 200 publications. His most recent books are *The Worth of a Child*, published by the University of California Press, and *Healthcare Ethics and Human Values: An Introductory Text with Readings and Case Studies*, Blackwell Publishers, which he edited with Bill Fulford and Donna Dickenson.

PHILIP A. PIZZO, M.D. became Dean of the School of Medicine at Stanford University in April, 2001 leaving his previous position as the Physician-in-Chief and Chair of the Department of Medicine at Children's Hospital, Boston and the Thomas Morgan Rotch Professor and Chair of Pediatrics at Harvard Medical School. Prior to that, Dr. Pizzo served sequentially as a Senior Investigator, Chief of the Infectious Disease Section, and Chief of Pediatrics, at the National Cancer Institute. He received his B.A. from Fordham College, graduating Phi Beta Kappa and cum laude in 1966. He received his M.D. degree with Honors and Distinction in Research in 1970 from the University of Rochester School of Medicine. After completing his residency in Pediatrics at Children's Hospital, Boston, in 1973, Dr. Pizzo joined the Pediatric Oncology Branch of the National Cancer Institute (NCI) as a clinical associate, and then served as a pediatric oncology investigator at the National Institutes of Health (NIH), where he trained in both pediatric oncology and infectious diseases. In 1981 Dr. Pizzo was appointed chief of Pediatrics at NCI, and in 1995 was named Acting Scientific Director of NCI's Division of Clinical Sciences. He was also the director of the Infectious Disease Section at NCI. Dr. Pizzo also was professor of Pediatrics at the Uniformed Services University of the Health Sciences in Bethesda, MD. Dr. Pizzo's research efforts have focused on the treatment of childhood cancers and on the diagnosis, management, and prevention of infectious complications in immunocompromised hosts. He and his colleagues also developed new treatments for children with symptomatic HIV infection. The author of over 500 articles and editor of 13 books, Dr. Pizzo also serves on numerous national and international advisory and editorial boards and has received many honors and awards for his scientific work. He is a member of numerous distinguished societies, including the Institute of Medicine of the National Academy of Sciences.

STEPHEN D. POTTS, J.D. is Chairman of the Fellows Program of the Ethics Resource Center (ERC), a non-profit organization focused on organizational ethics, a position he has held since September 2000. He will become Chairman of the Board of ERC on June 15, 2004. Prior to joining ERC, Mr. Potts served for 10 years (1990-2000), under two Presidents, as Director of the U.S. Office of Government Ethics. Prior to that time, Mr. Potts was a Partner at Shaw, Pittman, Potts & Trowbridge from 1961 until 1990. He also held the position of Vice President of Cherokee Life Insurance Company from 1959 to 1961, and was an Associate Attorney at Farris, Evans & Evans in Nashville, Tennessee from 1957 to 1959. In addition, Mr. Potts served as a 1st Lieutenant in the U.S. Army, Judge Advocate General's Corps. Mr. Potts served as Interim President of the Ethics Resource Center until February 2002. He also serves on the organization's Board of Directors. Other business activities include serving as a Member, Board of Directors, Fairways Corporation, 1972 – 1990; Member, Board of Directors, Wood River Capital Corporation, 1985 – 1988; Member, Board of Directors, Marline Oil Corporation, 1978 – 1985; Agency Vice President, Cherokee Life Insurance Company, 1959-1961; American Bar Association; District of Columbia Bar Association; and Tennessee Bar Association. Other civic activities he has been affiliated with include the Board of Advisors, University of Kentucky. Mr. Potts earned his bachelors degree in Political Science from Vanderbilt University, and an L.L.B. from Vanderbilt Law School.

DOROTHY K. ROBINSON, J.D. is Vice President and General Counsel of Yale University, where she has served as chief legal counsel for nineteen years, and as an officer of the University for almost as long. Previously, she held positions as Deputy General Counsel, Director of Federal Relations and Associate General Counsel of Yale University. Before coming to Yale in 1978, she practiced law with the firm of Hughes Hubbard & Reed in New York City. She received her B.A. from Swarthmore College, with Honors, and Phi Beta Kappa in 1972. She received her J. D. in 1975 from the University of California School of Law (Boalt Hall), where she served on the California Law Review. She is a member of the bar of the states of Connecticut, New York and California, and of various federal courts. Ms. Robinson has served as a director of the National Association of College and University Attorneys, and on committees, task forces and advisory boards of numerous other national organizations concerned with higher education. Among these, she served on the Association of American Universities Task Force on Research Accountability, and on the Association of American Medical Colleges Task Force on Financial Conflicts of Interest in Biomedical Research. She has also served on boards of trustees for a variety of other educational, charitable and community organizations.

LAWRENCE B. SADWIN is a business and community leader. He is a strong advocate for health education, conducting effective community service programs to encourage personal behavior change, and increasing funding for biomedical research. Sadwin's 20-year commitment to non-profit leadership at the local, regional, and national levels is rooted in his personal victory over heart disease, coupled with an extensive family history of cardiovascular disease. He was the 2001-2002 Chairman of the Board of the American Heart Association, the chief volunteer executive officer responsible for the overall administration of the association's business affairs, public relations and development. He is committed to furthering the cause of illness prevention and cure by putting a face to heart disease. This was demonstrated most uniquely when Sadwin was the model for an interpretive sculpture called "A Fine Line Between Hope and Despair", by the internationally known artist, Christianne Corbat, whose work

explores the relationship between art, medicine, and healing. Sadwin is also a member of the National Leadership Council of Research!America, an organization dedicated to increasing funding for medical research. His business career began as a senior in college, when he took over his family's textile manufacturing business after the untimely death of his father to heart disease. Sadwin served as the company's CEO for the next 30 years. As a local community leader, Sadwin has assisted in the development of more than \$25 million in urban renewal projects and has raised millions of dollars for local and national philanthropic and religious organizations. He currently serves as Chairman of the Board of Landmark Medical Center, Woonsocket, Rhode Island and is a member of the Public Advisory Board of the Joint Commission on Accreditation of Health Care Organizations. Sadwin also holds an Honorable Discharge as a First Lieutenant in the United States Army Reserve. Sadwin and his wife, Joan, are the proud parents of two wonderful children and four extraordinary grandchildren.

JAMES N. SIEDOW, PH.D. received his BA from the University of Texas at Austin in 1969 and completed his Ph.D. in plant biochemistry from Indiana University in 1972. He did postdoctoral research at the University of Michigan and Rice University before joining the Duke University faculty as an Assistant Professor of Botany in 1976. He became a Full Professor of Botany in 1987 and a Professor of Biology in 2000. He was a recipient of the Trinity College Distinguished Teaching Award in 1984. Past service at Duke includes election to the Executive Committee of the Academic Council (1992-93) and as Chair of the Academic Council (1994-96). He also served as the Dean of Faculty Development in Arts and Sciences from 1997-99. He became Vice Provost for Research in January, 2001. Professionally, Siedow has held numerous positions in the American Society of Plant Physiologists, including President, Chair of the Board of Trustees, Secretary, and Chair of the Public Affairs Committee. He spent a year as a Program Director of the Cellular Biochemistry Program at the National Science Foundation in 1998-99. He has served as an Associate Editor of the journal *Plant Physiology* and Editor of *Plant Science* and is currently an Associate Editor of *Plant Molecular Biology* and on the Editorial Boards of the *Journal of Biological Chemistry*, *Current Opinion in Plant Biology* and *Genome Biology*. Siedow's research has involved the study of oxidative processes in higher plants with an emphasis on those processes related to plant respiration. A long-term project in his laboratory has involved characterizing the structural and regulatory features of the unusual cyanide-resistant oxidase found in all plant mitochondria. A second, long-term collaboration with a group at North Carolina State University led to elucidation of the molecular mode of action of a toxin associated with the fungus responsible for the Southern Corn Leaf Blight.

REED V. TUCKSON, M.D. currently serves as the Senior Vice President for Consumer Health and Medical Care Advancement at UnitedHealth Group, a for profit health care company that encompasses several related companies that are engaged in a broad range of health related activities. A graduate of Howard University and Georgetown University School of Medicine, he has served as Senior Vice President, Professional Standards, for the American Medical Association, and is former President of the Charles R. Drew University of Medicine and Science in Los Angeles. Dr. Tuckson has served as Senior Vice President for Programs of the March of Dimes Birth Defects Foundation and as Commissioner of Public Health for the District of Columbia. In his position at UnitedHealth Group, Dr. Tuckson is interested in basic and clinical research, involved in the translation of new knowledge into clinical practice, and is an active user of health and preventive services research. His work necessarily involves him in pharmaceutical

industry issues, the conduct of clinical trials, technology assessment, evaluation of clinical care, data and information systems, and advocacy for a robust research enterprise among other activities. He is a former member of the Baxter Board of Directors. Dr. Tuckson is a member of the Institute of Medicine and serves as member of the Secretary of Health and Human Services' Advisory Committee on Genetics, Health and Society. He has held a number of other federal appointments, including cabinet level advisory committees on health reform, infant mortality, children's health, violence, and radiation testing.

Appendix C: Meetings and Speakers

March 1-2, 2004

Jordan J. Cohen, M.D., President, Association of American Medical Colleges

Ned Feder, Ph.D., Scientific Review Administrator, National Institute of Diabetes and Digestive and Kidney Diseases

Merrill Goozner, Director of Integrity in Science, Center for Science in the Public Interest Robert Hosenfeld, Director, NIH Office of Human Resources

Holli Beckerman Jaffe, J.D., NIH Ethics Officer and OD Ethics Coordinator, NIH Ethics Office, Office of the Director, NIH

Raynard Kington, M.D., Ph.D., Deputy Director, NIH

Marek J. Maryanski, Ph.D., President and Director of R&D, MGS Research, Inc., Madison, CT and Adjunct Associate Professor of Radiation Oncology, Columbia University, New York, NY

Barbara McGarey, J.D., NIH Legal Advisor, NIH Branch, Public Health Division, Office of the General Counsel, HHS

Stuart D. Rick, J.D., Deputy General Counsel, Office of General Counsel & Legal Policy, Office of Government Ethics

LaVerne Stringfield, Director, Office of Federal Advisory Committee Policy, Office of the Director, NIH

Edgar M. Swindell, J.D., Associate General Counsel and Designated Agency Ethics Official, Office of the General Counsel, HHS

Elias A. Zerhouni, M.D., Director, National Institutes of Health (NIH)

Diana Zuckerman, Ph.D., President, National Center for Policy Research for Women and Families

March 12, 2004

Duane Alexander, M.D., Director, National Institute on Child Health and Human Development, NIH

Jack Bennink, Ph.D., Senior Investigator, Viral Immunology Section, National Institute of Allergy and Infectious Diseases, NIH

Jeremy Berg, Ph.D., Director, National Institute of General Medical Sciences, NIH

Ned Feder, Ph.D., Scientific Review Administrator, National Institute of Diabetes and Digestive and Kidney Diseases

Michael Gottesman, M.D., Deputy Director for Intramural Research, Office of the Director, NIH

Lee Helman, M.D., Chief, Pediatric Oncology Branch; Deputy Director, Center for Cancer Research, National Cancer Institute, NIH

Holli Beckerman Jaffe, J.D., NIH Ethics Officer and OD Ethics Coordinator, NIH Ethics Office, Office of the Director, NIH

Raynard S. Kington, M.D., Ph.D., Deputy Director, NIH

Allan Kirk, M.D., Ph.D., Chief, Transplant Surgery Section, Transplantation and Autoimmunity Branch, National Institute of Diabetes, Digestive, and Kidney Diseases, NIH

Lance Liotta, M.D., Ph.D., Chief, Laboratory of Pathology, National Cancer Institute, NIH

Mitchell Max, M.D., Chief, Clinical Trials Unit, Pain and Sensory Mechanisms Branch, National Institute of Dental and Craniofacial Research, NIH

Connie Noguchi, Ph.D., Chief, Molecular Cell Biology Section, Laboratory of Chemical Biology, National Institute of Diabetes and Digestive and Kidney Diseases, NIH

Robert Nussbaum, M.D., Chief of the Genetics Disease Research Branch, National Human Genome Research Institute, NIH

Harold Varmus, M.D., President and Chief Executive Officer, Sloan-Kettering Memorial Cancer Center

Danny Weinberger, M.D., Director, Genes, Cognition, and Psychosis Program, Clinical Brain Disorders Branch, National Institute on Mental Health, NIH

April 2, 2004

Andrea Abati, M.D., Staff Clinician, Laboratory of Pathology, National Cancer Institute, NIH

Duane Alexander, M.D., Director, National Institute on Child Health and Human Development, NIH

William Fitzsimmons, Executive Officer, National Institute of Mental Health

Marilyn L. Glynn, J.D., Acting Director, U.S. Office of Government Ethics

Merrill Goozner, Director of Integrity in Science, Center for Science in the Public Interest

Richard Hodes, M.D., Director, National Institute on Aging, NIH

Joseph Mindell, M.D., Ph.D., Investigator, Membrane Transport Biophysics Unit, National Institute of Neurological Disorders and Stroke, NIH

John Park, M.D., Ph.D., Investigator, Surgical and Molecular Neuro-Oncology Unit, National Institute of Neurological Disorders and Stroke, NIH

Appendix D

Questions to NIH Staff About Outside Activities and Conflict of Interest

As part of the National Institutes' of Health (NIH) ongoing efforts to examine the guidelines governing consulting activities of its scientists, the NIH established a Web site to collect NIH staff views on outside activities. This effort was launched as part of the NIH's Blue Ribbon Panel on Conflict of Interest Policies, a working group of the Advisory Committee to the Director, NIH.

The charge of the Blue Ribbon Panel is to review the existing laws, regulations, policies, and procedures under which NIH currently operates regarding: (1) real and apparent financial conflict of interest of NIH staff where compensation or financial benefit from outside sources is received, including consulting arrangements and outside awards, and (2) requirements and policies for the reporting of NIH staff's financial interests, including which interests are subject to public disclosure, and what portion of NIH staff file public disclosures. The Panel is also charged with making recommendations for improving existing laws, regulations, policies, and procedures, as appropriate.

To accomplish these goals, the Blue Ribbon Panel posed the following questions to NIH staff:

- Should NIH staff be allowed to consult for compensation and/or engage in other compensated outside activities? If so,
 - What compensated activities should they be allowed to engage in and why?
 - What limits should be put in place?
 - Which compensated activities or types of compensation should they be prohibited and why?
- What would be the impact on the NIH mission if NIH prohibited all compensated outside activities for its employees? What data or other information do you have to support your views?
- What information concerning compensated outside activities do you think should be disclosed to the public? Who should be required to disclose in this way?
- What other advice would you give to the Blue Ribbon Panel as they address their charge?

NIH staff members were invited to submit responses to the questions from March 4 by April 15, 2004.

Appendix E
OGE Form 450

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**INSTRUCTIONS FOR
OGE FORM 450,
CONFIDENTIAL FINANCIAL
DISCLOSURE REPORT**

A. Why You Must File

This report is a safeguard for you as well as the Government. It provides a mechanism for determining actual or potential conflicts between your public responsibilities and your private interests and activities. This allows you and your agency to fashion appropriate protections against such conflicts.

B. Who Must File

Agencies are required to designate positions at or below GS-15, O-6, or comparable pay rates, in which the nature of duties may involve a potential conflict of interest. Examples include contracting, procurement, administering grants and licenses, regulating/auditing non-Federal entities, other activities having a substantial economic effect on non-Federal entities, or law enforcement.

All special Government employees (SGEs) must file, unless exempted by their agency or subject to the public reporting system. Agencies may also require certain employees in positions above GS-15, O-6, or a comparable pay rate to file.

C. When To File

New entrant reports: Due within 30 days of assuming a position designated for filing, unless your agency requests the report earlier. No report is required if you left another filing position within 30 days prior to assuming the new position. (SGEs must file new reports upon each reappointment or redesignation, at the time specified by the agency.)

Annual reports: Due not later than October 31, unless extended by your agency.

D. Reporting Periods

New entrant reports: The reporting period is the preceding twelve months from the date of filing.

Annual reports: The reporting period covers October 1 through September 30 (or that portion not covered by a new entrant report). However, no report is required if you performed the duties of your position for less than 61 days during that twelve-month period. (All reappointed or redesignated SGEs file reports, regardless of the number of days worked.)

E. Where To File

With ethics officials at the agency in which you serve or will serve, or in accordance with their procedures.

F. Definitions

Dependent Child - means your son, daughter, stepson, or stepdaughter if such person is either:

- (1) unmarried, under age 21, and living in your household; or
- (2) a “dependent” of yours for Federal income tax purposes. See 26 U.S.C. 152.

Honoraria - means payments (direct or indirect) of money or anything of value to you or your spouse for an appearance, speech or article, excluding necessary travel expenses. Also included are payments to charities in lieu of honoraria.

Special Government Employee (SGE) - is defined in 18 U.S.C. 202(a) as: an officer or employee of an agency who performs temporary duties, with or without compensation, for not more than 130 days in a period of 365 days, either on a full-time or intermittent basis.

G. General Instructions

1. Filers must provide sufficient information about outside interests and activities so that ethics officials can

make an informed judgment as to compliance with applicable conflict of interest laws and standards of conduct regulations.

2. This form consists of five parts, which require identification of certain specific financial interests and activities. **NO DISCLOSURE OF AMOUNTS OR VALUES IS REQUIRED.** You must complete each part (except as indicated for Part V) and sign the report. If you have no information to report in any part or do not meet the threshold values for reporting, check the “None” box. New entrants and SGEs are not required to complete Part V.

3. You must include information applicable to yourself, your spouse, and dependent children on Parts I, II and V. This is required because their financial interests are attributed to you under ethics rules in determining conflicts of interest. Information about your spouse is not required in the case of divorce, permanent separation, or temporary separation with the intention of terminating the marriage or permanently separating. Parts III and IV require disclosures about yourself only.

4. You may distinguish any entry for a family member by preceding it with **S** for spouse, **DC** for dependent child, or **J** for jointly held.

Part I: Assets & Income

Assets:

1. Report all assets held for investment or for the production of income by **you, your spouse, and dependent children**, with a value greater than \$1,000 at the end of the reporting period or which produced more than \$200 in income during the reporting period.

Salary and Earned Income:

1. **For yourself:** report all sources of salary and earned income greater than \$200 during the reporting period.
2. **For your spouse:** report all sources of salary and earned income if greater than \$1,000 (for honoraria, if greater than \$200).

3. **For dependent children:** no earned income needs to be reported.

Examples of Assets:

- | | |
|-----------------------------|------------------------------------|
| - Stocks | - Bonds |
| - Tax Shelters | - Investment Real Estate |
| - Mutual Funds | - Pensions |
| - Annuities | - IRA/401(k) Holdings |
| - Trust Holdings | - Commodity Futures |
| - Trades & Businesses | - Partnership Interests |
| - Investment Life Insurance | - Collectibles held for Investment |

Examples of Income:

- | | |
|--------------------------|----------------------------|
| <u>Investment Income</u> | <u>Earned/Other Income</u> |
| - Dividends | - Fees |
| - Rents and Royalties | - Salaries |
| - Interest | - Commissions |
| - Capital Gains | - Retirement Benefits |
| | - Honoraria |

Notes:

1. For **pensions**, you will ordinarily just need to indicate the name of the sponsoring employer. However, if you have control over the specific investment assets held in your pension account (it is not independently managed), you must also list those underlying investments or attach an account statement that lists them.
2. For publicly available **mutual funds**, you are only required to indicate the name of the fund, not the investments that the mutual fund holds in its portfolio. You must, however, always indicate the full name of the specific mutual fund in which you hold shares, not just the general family fund name.
3. For other publicly available investment funds, such as publicly offered units of **limited partnerships**, the disclosure requirements are the same as for mutual funds -- list the full name of the limited partnership, but not its underlying portfolio investments.
4. For a **privately held trade or business**, report its name, location, and description of activity.

Do Not Report:

1. Your personal residence, unless you rent it out;
2. Federal Government salary or retirement benefits such as the Thrift Savings Plan;
3. Social Security benefits;
4. Money owed to you, your spouse, or dependent child by a spouse, parent, sibling or child;
5. Accounts including certificates of deposit, savings accounts, interest-bearing checking accounts, or any other forms of deposit in a bank, savings and loan association, credit union or similar financial institution;
6. Money market mutual funds and money market accounts;
7. U.S. Government obligations (including Treasury bonds, bills, notes and savings bonds);
8. Government securities issued by U.S. Government agencies or Government-sponsored corporations, such as TVA, GNMA, FNMA; and
9. The underlying holdings of a trust that: 1) was not created by you, your spouse, or dependent children, **and** 2) the holdings or sources of income of which you, your spouse, and dependent children have no past or present knowledge. An example is a trust created by a relative, from which you receive periodic income but have no knowledge about its assets. Just identify the trust by name and date of creation.

Part II: Liabilities

Report for Yourself, Spouse, and Dependent Children:

1. Liabilities over \$10,000 owed to any creditor at any time during the reporting period.

Do Not Report:

1. Mortgages on your personal residence unless you rent it out;
2. Personal liabilities owed to a spouse, or the parent, sibling, or child of you, your spouse, or dependent child;
3. Loans for personal automobiles, household furnishings, or appliances, where the loan does not exceed the purchase price; and
4. Revolving charge accounts where the outstanding liability does not exceed \$10,000 at the end of the reporting period.

Part III: Outside Positions

Report for Yourself:

1. All positions outside the U.S. Government held at any time during the reporting period (including positions no longer held), whether or not paid.

Positions include an officer, director, trustee, general partner, proprietor, representative, executor, employee, or consultant of any of the following:

1. A corporation, company, firm, partnership, trust, or other business enterprise;
2. A non-profit organization;
3. A labor organization; and
4. An educational or other institution outside the Federal Government.

Do Not Report:

1. Positions held in any religious, social, fraternal, or political entity;
2. Positions solely of an honorary nature; and
3. Positions held by a spouse or dependent child.

Part IV: Agreements or Arrangements

Report Your Agreements or Arrangements for:

1. Current or future employment;
2. A leave of absence from private or other non-Federal employment;
3. Continuation of payment by a former employer other than the Federal Government (including severance payments); and
4. Continuing participation in an employee pension or benefit plan maintained by a former employer other than the Federal Government.

Do Not Report:

1. A spouse or dependent child's agreements or arrangements.

Part V: Gifts and Travel Reimbursements

Note: Part V is not applicable to new entrants and SGEs.

Report for You, Your Spouse, and Dependent Children:

1. Travel-related cash reimbursements received from one source during the reporting period totaling more than \$285.
2. Any other gifts totaling more than \$285 from any one source. A "gift" is defined as anything of value, unless you give something of equal or greater value to the donor. This includes tangible items and in-kind transportation, food, lodging, and entertainment.

Note: Gifts or reimbursements valued at \$114 or less need not be included in determining the over \$285 reporting threshold.

Do Not Report:

1. Anything received from relatives, the U.S. Government, D.C., State, or local governments;
2. Bequests and other forms of inheritance;
3. Gifts and travel reimbursements given to your agency in connection with your official travel;
4. Gifts of hospitality (food, lodging, entertainment) at the donor's residence or personal premises; and
5. Gifts or reimbursements received by a spouse or dependent child totally independent of the relationship to the filer (*Example: a spouse's reimbursement in connection with private employment*).

Privacy Act Statement

Title I of the Ethics in Government Act of 1978 (5 U.S.C. App.), Executive Order 12674, and 5 CFR Part 2634, Subpart I, of the Office of Government Ethics regulations require the reporting of this information. The primary use of the information on this form is for review by Government officials of your agency, to determine compliance with applicable Federal conflict of interest laws and regulations. Additional disclosures of the information on this report may be made: (1) to a Federal, State or local law enforcement agency if the disclosing agency becomes aware of a violation or potential violation of law or regulation; (2) to a court or party in a court or Federal administrative proceeding if the Government is a party or in order to comply with a judge-issued subpoena; (3) to a source when necessary to obtain information relevant to a conflict of interest investigation or decision; (4) to the National Archives and Records Administration or the General Services Administration in records management inspections; (5) to the Office of Management and Budget during legislative coordination on private relief legislation; and (6) in response to a request for discovery or for the appearance of a witness in a judicial or administrative proceeding, if the information is relevant to the subject matter. This confidential report will not be disclosed to any requesting person unless authorized by law. See also the OGE/GOVT-2 executive branchwide Privacy Act system of records.

Penalties

Falsification of information or failure to file or report information required to be reported may subject you to disciplinary action by your employing agency or other authority. Knowing and willful falsification of information required to be reported may also subject you to criminal prosecution.

Public Burden Information

This collection of information is estimated to take an average of one and a half hours per response, including time for reviewing the instructions, gathering the data needed, and completing the form. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Deputy Director for Administration and Information Management, U.S. Office of Government Ethics, Suite 500, 1201 New York Avenue NW., Washington, DC 20005-3917. Do not send your completed OGE Form 450 to this address. See Section E for where to file.

Pursuant to the Paperwork Reduction Act, as amended, an agency may not conduct or sponsor, and no person is required to respond to, a collection of information unless it displays a currently valid OMB control number (that number, 3209-0006, is displayed here and in the upper right-hand corner of the first page of this OGE Form 450).

Mere disclosure of the required information does not authorize holdings, income, liabilities, affiliations, positions, gifts or reimbursements which are otherwise prohibited by law, Executive order, or regulation.

If you need assistance in completing this form, contact the ethics officials in the agency in which you serve or will serve.

Executive Branch CONFIDENTIAL FINANCIAL DISCLOSURE REPORT

Page Number

Employee's Name <i>(Last, first, middle initial)</i>		Position/Title		Grade	Reporting Status: <input type="checkbox"/> New entrant <input type="checkbox"/> Annual
Agency		Branch/Unit and Address		Work Phone	If New Entrant, Date of Appointment
Check box if special Government employee (SGE) <input type="checkbox"/>		If an SGE, Home Address <i>(Number, Street, City, State and ZIP Code)</i>			
I certify that the statements I have made on this form and all attached statements are true, complete, and correct to the best of my knowledge.				Signature of Employee	Date

Date Received by Agency	On the basis of information contained in this report, I conclude that the filer is in compliance with applicable laws and regulations (except as noted in "comments" box below).	Signature and Title of Supervisor/Other Intermediate Reviewer <i>(If agency requires)</i>	Date
Signature of Agency's Final Reviewing Official and Title		Date	Comments of Reviewing Officials
			(Check box if continued on reverse) <input type="checkbox"/>

Part I: Assets and Income

None

Identify for you, your spouse, and dependent children: 1) assets with a fair market value greater than \$1,000 at the close of the reporting period or producing income over \$200; and 2) sources of earned income such as salaries, fees, honoraria (other than U.S. Government salary or retirement benefits, such as the Thrift Savings Plan) which generated over \$200 in income during the reporting period. Earned income sources of your spouse must be reported if greater than \$1,000 (greater than \$200 for honoraria). No earned income needs to be reported for dependent children.

Assets include (but are not limited to): stocks, bonds, tax shelters, real estate, mutual funds, pensions, annuities, IRAs, trusts, commodity futures, trades and businesses, and partnership interests.

Exclude your personal residence, unless you rent it out, and deposit accounts in financial institutions. See instructions for additional exclusions.

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	Assets and Income Sources <i>(Identify specific employer, business, stock, bond, mutual fund, type/location of real estate, etc.)</i>	(X) if no longer held	Nature of Income over \$200 <i>(Rent, interest, dividends, capital gains, salary, etc.)</i>	Date <i>(Only for honoraria)</i>
Examples	Rental Condo, Anchorage, Alaska		Rent	
	Dee, Jones & Smith, Hometown, USA	X	Salary	
	(S) Alexandria Medical Clinic, Alexandria, VA		Salary	
	Franklin Equity Mutual Fund		Dividends/Capital Gains	
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				

Executive Branch CONFIDENTIAL FINANCIAL DISCLOSURE REPORT

Page Number

Employee's Name *(Last, first, middle initial)*

Part I: Assets and Income

<i>Assets and Income Sources (Identify specific employer, business, stock, bond, mutual fund, type/location of real estate, etc.)</i>	<i>(x) if no longer held</i>	<i>Nature of Income over \$200 (Rent, interest, dividends, capital gains, salary, etc.)</i>	<i>Date (Only for honoraria)</i>
11			
12			
13			
14			
15			
16			
17			
18			
19			
20			
21			
22			
23			
24			
25			
26			
27			

Employee's Name <i>(Last, first, middle initial)</i>
--

Work Phone

Part II: Liabilities None

Report for you, your spouse, and dependent children. liabilities over \$10,000 owed at any time during the reporting period (over \$10,000 at the end of the period if revolving charge accounts). **Exclude** a mortgage on your personal residence unless it is rented out; loans for autos, household furniture or appliances; and liabilities owed to certain family members (see instructions).

Creditors <i>(Name and address)</i>		Type of Liability <i>(Mortgage, promissory note, etc.)</i>
Example	First Alaska Bank, Anchorage, Alaska	Mortgage on rental property in Anchorage, AK
1		
2		
3		

Part III: Outside Positions None

Report any positions, whether or not compensated, which you held outside the U.S. Government during the reporting period. Positions include (but are not limited to) an employee, officer, director, trustee, general partner, proprietor, representative, executor, or consultant for a business, non-profit or labor organization, or educational institution. **Exclude** positions with religious, social, fraternal, or political entities or those solely of an honorary nature. You need not report any positions of your spouse or dependent children.

Organization <i>(Name and address)</i>	Type of Organization	Position	(X) <small>If no longer held</small>	
Example	Dee, Jones & Smith, Hometown, USA	Law Firm	Associate	X
1				
2				
3				
4				

Part IV: Agreements or Arrangements None

Report your agreements or arrangements for current or future employment, leaves of absence, continuation of payment by a former employer (including severance payments), or continuing participation in an employee benefit plan. You need not report agreements or arrangements of your spouse or dependent children.

Terms of Any Agreement or Arrangement		Parties	Date
Example	Will receive retained pension benefits (independently managed, fully funded, defined contribution plan)	Dee, Jones & Smith, Hometown, USA	2/99
1			
2			
3			

Part V: Gifts and Travel Reimbursements None

Do not complete this part if you are a new entrant or special Government employee.

Report for you, your spouse, and dependent children. gifts or travel reimbursements you have received from one source totaling more than \$285. **Exclude** anything valued at \$114 or less; anything received by your spouse or dependent child totally independent of their relationship to you; anything from a relative or from the U.S. Government; anything given to your agency in connection with your official travel; and food, lodging, or entertainment received as personal hospitality at the donor's residence or premises.

Source	Description <i>(For travel-related items, include itinerary)</i>	Date	
Example	Dee, Jones & Smith, Hometown, USA	Leather briefcase as a departing gift	2/99
1			
2			
3			
4			

Appendix F
Standard Form (SF) 278

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**Standard Form 278
Executive Branch Personnel
PUBLIC FINANCIAL
DISCLOSURE REPORT**

Instructions for Completing SF 278

I. Introduction

Reporting Periods

Incumbents: Complete Schedules A, B, C, and Part I of D. The reporting period is the preceding calendar year, except Part II of Schedule C and Part I of Schedule D where you must also include any positions held and agreements or arrangements made from the beginning of the filing year until the date you file. Schedule B need not include transactions made, or gifts or reimbursements received, during a period when the filer was not a Federal employee.

Termination Filers: Complete Schedules A, B, C, and Part I of D. The reporting period begins at the end of the period covered by your previous filing and ends at the date of termination of Government employment in the position.

Nominees, New Entrants and Candidates for President and Vice President: Complete Schedules A, C, and D (candidates do not file Part II of Schedule D), as follows:

- **Schedule A** - The reporting period for income (BLOCK C) is the preceding calendar year and the current calendar year up to the date of filing. Value assets in BLOCK B as of any date you choose that is less than 31 days before the date of filing.

- **Schedule C, Part I** (Liabilities) - The reporting period is the preceding calendar year and the current calendar year up to any date you choose that is less than 31 days before the date of filing.

- **Schedule C, Part II** (Agreements or Arrangements) - Show any agreements or arrangements as of the date of filing.

- **Schedule D** - The reporting period is the preceding two calendar years and the current calendar year up to the date of filing.

Scope of Disclosure

The extent of the reporting requirement is noted in each schedule. The various schedules of this form require reporting of your financial interests and activities, both in the U.S. and abroad, except as otherwise noted. In addition to your individual financial information, you are required to report information concerning your spouse and dependent children in several schedules of the form. However, no report is required with respect to your spouse if he or she is living separate and apart from you with the intention of terminating the marriage or providing for permanent separation. In addition, no report is required with respect to any income or obligations of an individual arising from the dissolution of marriage or permanent separation from a spouse. There are other exceptions to the reporting of assets and income, transactions, and liabilities of a spouse or dependent child which are discussed in the instructions applicable to those subjects.

A basic premise of the statutory financial disclosure requirements is that those having responsibility for review of reports filed pursuant to the Ethics in Government Act or permitted public access to reports must be given sufficient information by reporting individuals concerning the nature of their outside interests and activities so that an informed judgment can be made with respect to compliance with applicable conflict of interest laws and standards of conduct regulations. Therefore, it is important that you carefully complete the attached form. This report is a safeguard for you as well as the Government, in that it provides a mechanism for determining actual or potential conflicts between your public responsibilities and your private interests and activities and allows you and your agency to fashion appropriate protections against such conflicts when they first appear.

A Presidential nominee to a position requiring the advice and consent of the Senate shall file with the Senate committee considering the nomination an amendment to the initial report, which shall update all items of earned income and honoraria through the period ending no earlier than 5 days before the scheduled date of the Senate committee hearing on the nomination. This update shall be provided in the manner requested by the Senate committee considering the nomination. Copies shall be provided to OGE and your agency ethics official.

Definition of Terms

- **Category of Amount**

Reportable financial interests are disclosed either by actual amount or by category of amount, depending on the interest, as specified by the form. You may, but you are not required to, indicate an actual amount where the form provides for a category of amount or value.

- **Dependent Child**

The term “dependent child” means your son, daughter, stepson, or stepdaughter if such person is either: (1) unmarried, under age 21, and living in your household, or (2) a “dependent” of yours within the meaning of section 152 of the Internal Revenue Code of 1986.

- **Excepted Investment Fund**

An excepted investment fund is a mutual fund, common trust fund of a bank, pension or deferred compensation plan, or any other investment fund, which is widely held; publicly traded (or available) or widely diversified; and under circumstances where you neither exercise control over nor have the ability to exercise control over the financial interests held by the fund. A fund is widely diversified when it holds no more than 5% of the value of its portfolio in the securities of any one issuer (other than the U.S. Government) and no more than 20% in any particular economic or geographic sector.

- **Gifts**

See instructions for Schedule B, Part II.B.

- **Honoraria**

The term “honoraria” means payments of money or anything of value to you or your spouse for an appearance, speech, or article, excluding necessary travel expenses. See 5 U.S.C. app. § 505(3).

- **Personal Savings Account**

The term “personal savings account” includes a certificate of deposit, a money market account, or any other form of deposit in a bank, savings and loan association, credit union, or similar financial institution.

- **Trusts (“Qualified” and “Excepted”)**

See instructions for Schedule A, Part II.B., and 5 C.F.R. Part 2634, Subpart D.

- **Value**

You may use any one of the methods described below, in determining fair market value:

Option 1 - any good faith estimate of the value of the property if the exact value is unknown or not easily obtainable;

Option 2 - value based upon a recent appraisal of the property interest;

Option 3 - the purchase price of your property interest, or estimated retail price of a gift;

Option 4 - the assessed value of the property for tax purposes, adjusted to reflect current market value if the tax assessment is computed at less than 100% of current value;

Option 5 - the year-end book value of non-publicly traded stock, or the year-end exchange value of corporate stocks, or the face value of corporate bonds or comparable securities;

Option 6 - the net worth of your interest (as in a business partnership or other jointly held business interest);

Option 7 - the equity value of your interest (as in a solely owned business or commercial enterprise); or

Option 8 - exact value (e.g., personal savings accounts) or any other recognized indication of value (such as last sale on a stock exchange).

II. Who Must File

a. Candidates for nomination or election to the office of President or Vice President.

b. Presidential nominees to positions requiring the advice and consent of the Senate, other than those nominated for judicial office or as a Foreign Service Officer or for appointment to a rank in the uniformed services at a pay grade of O-6, or below.

c. The following newly elected or appointed officials:

- The President;

- The Vice President;

- Officers and employees (including special Government employees, as defined in 18 U.S.C. § 202) whose positions are classified above GS-15 of the General Schedule, or the rate of basic pay for which is fixed, other than under the General Schedule, at a rate equal to or greater than 120% of the minimum rate of basic pay for GS-15 of the General Schedule.

- Members of the uniformed services in pay grade O-7 or above;

- Officers or employees in any other positions determined by the Director of the Office of Government Ethics to be of equal classification to above GS-15;

- Administrative law judges;

- Employees in the excepted service in positions which are of a confidential or policy-making character, unless by regulation their positions have been excluded by the Director of the Office of Government Ethics;

- The Postmaster General, the Deputy Postmaster General, each Governor of the Board of Governors of the U.S. Postal Service and officers or employees of the U.S. Postal Service or Postal Rate Commission in positions for which the rate of basic pay is equal to or greater than 120% of the minimum rate of basic pay for GS-15 of the General Schedule;

- The Director of the Office of Government Ethics and each designated agency ethics official; and

- Civilian employees in the Executive Office of the President (other than special Government employees) who hold commissions of appointment from the President.

d. Incumbent officials holding positions referred to in section II.c. of these instructions if they have served 61 days or more in the position during the preceding calendar year.

e. Officials who have terminated employment after having served 61 days or more in a calendar year in a position referred to in section II.c. and have not accepted another such position within 30 days thereafter.

III. When to File

a. Within 30 days after becoming a candidate for nomination or election to the office of President or Vice

President, or by May 15 of that calendar year, whichever is later, but at least 30 days before the election, and on or before May 15 of each succeeding year an individual continues to be a candidate.

b. At any time after the President or President-elect has publicly announced an intention to nominate an individual referred to in section II.b. of these instructions, but no later than 5 days after the President transmits the nomination to the Senate.

c. Within 30 days after assuming a position described in section II.c. unless such an individual has left another such position within 30 days prior to assuming the new position, or has already filed a report with respect to nomination for the new position (section II.b.) or as a candidate for the position (section II.a.).

d. No later than May 15th annually, in the case of those in a position described in section II.d.

e. In the event an individual terminates employment in the position and does not accept another position described in section II.c. within 30 days, the report must be filed no later than the 30th day after termination.

f. Extensions. An employing agency may grant an extension of time of up to 45 days to a filer to file any report under sections III. c.-e. above (the FEC for any report under section III. a. above). OGE may grant an additional extension of time up to 45 days to file any such report.

g. Fee for Late Filing. Any individual who is required to file this report and does so more than 30 days after the date the report is required to be filed, or, if an extension is granted, more than 30 days after the last day of the filing extension period, shall be subject to a \$200 late filing fee. A report is considered to be filed when it is received by the agency. Unless waived by OGE, such fee will be collected by the filer's agency, for deposit with the U.S. Treasury.

IV. Where to File

a. Candidates for President and Vice President, with the Federal Election Commission.

b. The President and Vice President, with the Office of Government Ethics.

c. Members of a uniformed service, with the Service Secretary concerned.

d. All others, with the designated agency ethics official, or that official's delegate, at the agency in which the individual serves, will serve or has served.

e. In the case of individuals nominated by or to be nominated by the President to positions requiring confirmation of the Senate, see 5 C.F.R. Part 2634 for expedited procedures and filing location.

V. General Instructions

a. This form consists of the front page and four Schedules. If possible, use a black ink pen or typewriter to fill out your report. You must complete each Part of all Schedules as required. If you have no information to report in any Part of a Schedule, you should indicate "None." If you are not required to complete Schedule B or Part II of Schedule D, you should leave it blank. Schedule A combines a report of income items with the disclosure of certain property interests. Schedule B deals with transactions in real property or certain other assets, as well as gifts and reimbursements. Schedules C and D relate to liabilities and employment relationships. After completing the first page and each Part of the Schedules (including extra sheets of any Schedule where continuation pages are required for any Part), consecutively number all pages.

b. The information to be disclosed is only that which the Ethics in Government Act of 1978, as amended (the Act) and 5 C.F.R. Part 2634 specifically require. You may, however, include any additional information, beyond those requirements, that you wish to disclose for purposes of clarification. Disclosure of information does not authorize any holdings, income, honoraria, liabilities, transactions, gifts, reimbursements, affiliations or positions otherwise prohibited by law, Executive order, rule or regulation.

c. Combine on one form the information applicable to yourself, your spouse and dependent children; or if more convenient, use separate schedules to report the required information applicable to family members. You may, if you desire, distinguish any entry for a family member by preceding the entry with an (S) if it is for a spouse or a (DC) if it pertains to a dependent child. Joint assets may be indicated by a (J). See 5 C.F.R. Part 2634, Subpart C, for exclusions in the case of separation or divorce.

d. Definitions of the various terms used in these instructions and detailed information as to what is required to be disclosed are contained in 5 C.F.R. Part 2634.

e. In the case of references to entities which are operating trades or businesses which do not have listed securities, you must provide sufficient information about these private entities to give the reviewers of your disclosure report an adequate basis for the conflicts analysis required by the Act. Thus, you must disclose the location and primary trade or business of private entities, as well as attributed interests and activities not solely incidental to such a primary trade or business. For instance, if your family swimming pool services corporation incurs a liability to purchase an apartment house for investment in addition to its pool services business, you will have to report the apartment house investment as part of the nature of the business of the family corporation.

f. In the case of references to entities which are investment funds such as mutual or pension funds (whether public or private), you must disclose the portfolio holdings and all other items such as transactions and liabilities to the extent otherwise required for reportable interests, unless the entity is an “excepted investment fund.” See Definition of Terms above.

g. If you need assistance in completing this form, contact the designated agency ethics official of the agency in which you serve, will serve, or have served.

Schedule A

I. General Instructions

Two of the general disclosure requirements of the Act concern certain interests in property (generally referred to here as assets) and items of income. Schedule A is designed to enable you to meet both of these reporting requirements. Generally a description of your, your spouse's, and your dependent child's assets and sources of income is required to be listed in BLOCK A of the Schedule. Reading from left to right across the page from each description of the asset or income source, you will be able to report in BLOCK B the value of each asset, and in BLOCK C the type and amount of income generated by that asset or received from the non-asset source.

On Schedule A are four examples which are representative of the reporting scheme of this Schedule. The first example represents the proper method of reporting stock of Central Airlines Company held at the end of the reporting period which then had a value of \$75,000. The individual had also received dividends of \$1,500, reported in BLOCK C. If the Central Airlines stock had been sold, there would be a check in the “None (or less than \$1,001)” column in BLOCK B if the individual no longer owned any of the stock at the end of the reporting period, and there would be an entry for capital gains as well as dividends in BLOCK C if they were realized

during the period. The second example represents the proper method of reporting the source of \$130,000 of earned income from private law practice, as well as \$18,500 the reporting individual maintained in the capital account in the law firm at the end of the reporting period.

The third example represents acceptable reporting of an investment fund which is widely held, widely diversified (or publicly traded) and independently managed. Because it meets these requirements, no individual assets of the fund need to be reported, and the type of income does not need to be broken into dividends, interest, or capital gains as long as the column for “excepted investment fund” is marked. The fourth example reports a mutual fund held in an IRA from which the filer has accrued dividends of \$10,000.

Normally you will have to list an item only once in BLOCK A with all other value and income information associated with that item shown on the same line to the right. However, when you have a number of different kinds of financial arrangements and income involving one entity, a full disclosure of all the required information for that entity may require more than one line. You may always use more than one line for clarification if you choose.

II. Property Interests and Assets

(BLOCKS A and B)

A. Items to Report

Report the identity and category of valuation of any interest in property (real or personal) held by **you, your spouse or dependent child** in a trade or business, or for investment or the production of income which has a fair market value which **exceeds \$1,000** as of the close of the reporting period. These interests include, but are not limited to, stocks, bonds, pension interests and annuities, futures contracts, mutual funds, IRA assets, tax shelters, beneficial interests in trusts, personal savings or other

bank accounts, real estate, commercial crops, livestock, accounts or other funds receivable, and collectible items held for resale or investment. **Exceptions:** Exclude your personal residence (unless rented out) and any personal liability owed to you, your spouse or dependent child by a spouse or dependent child, or by a parent, brother, sister or child of you, your spouse, or dependent child. Exclude any retirement benefits (including the Thrift Savings Plan) from Federal Government employment and any social security benefits. Exclude also any deposits aggregating \$5,000 or less in personal savings accounts in a single financial institution.

With respect to assets of a spouse or a dependent child, do not report items:

- (1) which represent your spouse's or dependent child's sole financial interest or responsibility and of which you have no knowledge;
- (2) which are not in any way, past or present, derived from your income, assets, or activities; and
- (3) from which you neither derive, nor expect to derive, any financial or economic benefit.

Note: It is very difficult for most individuals to meet all three parts of this test, especially (3). For instance, if you file a joint tax return with your spouse, you derive a financial or economic benefit from the items involved and you are charged with knowledge of those items. A trust for the education of your minor child would also convey a financial benefit to you. Therefore, those asset and income items do not fit the test.

A personal residence held for investment or production of income, such as a summer home rented during parts of the year, must be reported.

Intermittent sales from personal property such as collections of antiques or art holdings demonstrate that the items are held for investment or the production of income and should therefore be reported.

B. What to Show on the Form

Enter the identity of the asset in BLOCK A and then show the value in BLOCK B. **Only the category of value, rather than the actual value of the property interest or asset,** must be shown. You need not disclose which valuation methods you used.

For assets such as stocks, bonds, and securities, report any holdings directly held or attributable to **you, your spouse or dependent child** from one source totaling more than \$1,000 in value. **Identify the holding and show the category of value.** If you hold different types of securities of the same corporation (e.g., bonds and stocks of “X” Corporation), these holdings should be considered as being from the same source for purposes of determining whether the aggregate value of the interest is below or above the \$1,000 threshold value. Report personal savings accounts only if they aggregate more than \$5,000 in a single financial institution.

If you have an interest in an investment fund or pool which is an “excepted investment fund” (see Definition of Terms above), you need only identify the interest by giving the complete name of the fund, rather than identifying the underlying assets as well.

To report interests of you, your spouse, or dependent child in a business, a partnership, or joint venture, or the ownership of property held for investment or the production of income, identify the character of the ownership interest, and the nature and location of the business or interest, unless it is a publicly traded security. For example, the entry for a holding of farm land might show, under BLOCK A... “sole ownership of 100 acres of unimproved dairy farmland on Rural Route #1 at Pine Bluff, Madison County, Wisconsin.”

You must disclose the primary trade or business of non-public entities, as well as interests and activities not solely incidental to such a trade or business. For

example, if your family is involved in a private real estate investment business but as a side interest buys stock through the business in a bank, you must disclose that in addition to real estate (by type and general location), the family business holds an interest in a bank.

For an IRA (Individual Retirement Account), indicate the value of each underlying asset, as well as the income derived therefrom (even though deferred for Federal tax purposes) in accordance with section IV below, to enable the reviewer to evaluate compliance with applicable laws and regulations. If the IRA were invested solely in a mutual fund such as “Templeton World Fund, Inc.” and the investment properly disclosed in Schedule A, that would be sufficient identification of the asset, since for most reporting individuals that fund would be an “excepted investment fund.” If, however, the IRA had an individual or privately managed portfolio, detailed disclosure of the portfolio would be required on Schedule A in the same amount of detail as if each investment were directly held.

With respect to trusts in which a vested beneficial interest in principal or income is held, or as to which you serve as trustee, report trust interests and trust assets which had a value in excess of \$1,000. See 5 C.F.R. Part 2634 for more information about vested interests.

You need not report the identity of assets of a trust of which you, your spouse or dependent children are the beneficiaries if the interest is:

1. a “qualified blind trust” or “qualified diversified trust,” which has been certified by the Office of Government Ethics, in accordance with 5 C.F.R. Part 2634, Subpart D, or

2. an “excepted trust,” that is, one which:

A. was not created by you or your spouse or dependent children, and

B. has holdings or sources of income of which you, your spouse and dependent children have no knowledge.

In the case of these special types of trusts, you should show in BLOCK A the identity of the trust, including the date of creation, and next to BLOCK C, the classification of the trust as a “qualified trust” or an “excepted trust.” You should also report in BLOCK B the category of the total cash value of the interest in a qualified blind or qualified diversified trust, unless the trust instrument was executed prior to July 24, 1995, and precludes the beneficiary from receiving information on the total cash value of any interest therein. (The category of amount of the trust income, if it exceeded \$200, must also be reported in BLOCK C, in accordance with section IV below.)

Note: You are not permitted by the statute to “create” an excepted trust by instructing a trustee not to divulge information or otherwise avoiding previous sources of knowledge upon entering Government service.

Do not report a trust of which your spouse or dependent child is a beneficiary that meets the three part test set forth in the second paragraph under II.A. A trust that does not fit that exception may still be an excepted trust under this section; in such case, it must be reported, but the assets need not be identified.

Except for the special trusts or funds referred to above, you must identify each individual investment held by a trust or fund, which had a value in excess of \$1,000. For example, in BLOCK A an entry such as “trust held by First National Bank (Boston, MA) consisting of ITT stock, U.S. Treasury certificates, and Dallas Municipal Bonds” might be made. In BLOCK B the applicable value of each trust asset would be entered. (As described under IV.B.6. Trust Income, below, the income from each asset would be entered in BLOCK C as well as income from assets of the trust sold during the reporting period.)

III. Earned and Other Non-Investment Income

(BLOCKS A and C)

A. Items to Report

For yourself, report the identity of the source in BLOCK A and the type and **actual** amount in BLOCK C of non-investment income **exceeding \$200** from any one source. Such income includes fees, salaries, commissions, compensation for personal services, retirement benefits, and honoraria. Report these items on the same line as related interests in property, if any.

For your spouse, report the source, but not the amount, of non-investment income exceeding \$1,000 and the source, amount and date of honoraria exceeding \$200 from any one source. **No report of the earned or other non-investment income of your dependent children is required.**

Exclude for yourself and spouse income from employment by the United States Government and from any retirement system of the United States (including the Thrift Savings Plan) or from social security.

B. What to Show on the Form

1. HONORARIA - For **you or your spouse**, show honoraria aggregating more than \$200 from any one source. Report the **identity of the source** in BLOCK A, and the **date** of the services performed and **actual amount** in BLOCK C. List each honorarium separately. For example, if, prior to your Government service, you received \$1,500 for a speech before the Chicago Civic Club on March 19, 1999 of which \$200 was actually spent for round-trip travel, and \$200 went to the agent who made the speaking arrangement, on your new entrant report you would enter in BLOCK A... "Chicago Civic Club, 18 Lakeshore Dr., Chicago, IL"; in BLOCK C under OTHER (specify type)... "Honorarium"; for

ACTUAL AMOUNT... "\$1,100," and under DATE... "3/19/99." Honoraria received and donated to charity must be reported, but a notation explaining that fact may be included in reporting such items. The source, date and amount of payments made or to be made directly to a charitable organization in lieu of honoraria must also be disclosed.

2. EARNED AND OTHER NON-INVESTMENT INCOME - Include all income, exclusive of honoraria, from non-investment sources including fees, commissions, salaries, and income from personal services or retirement. Report the **identity of the source and give the actual amount of such income** exceeding \$200 from any one source. For example, if you earned \$450 teaching at a law school, enter in BLOCK A... "John Jones Law School, Rockville, MD"; in BLOCK C under OTHER... "Salary"; and under ACTUAL AMOUNT... "\$450." If you earned \$75 for teaching in one law school and \$250 from teaching at another school, report only the \$250 amount. Report employee benefits and severance payments which meet the reporting requirements separately from salary.

If **your spouse** has earned income in excess of \$1,000 (other than honoraria) from any one source, **identify the source but show nothing under amount.** If your spouse is self-employed in a business or profession, for example as a practicing psychologist who earned \$10,500 during the year, you need only show under BLOCK A... "practicing psychologist."

IV. Investment Income

(BLOCKS A and C)

Report items of investment income on the same line of Schedule A as the related property interest or other asset from which income is derived. Note that some property interests or other assets will not have a related item of income. In such a case, check "None (or less than \$201)" in BLOCK C under category of amount.

A. Items to Report

Report the identity in BLOCK A and the type and value in BLOCK C of any investment income over \$200 from any one source received by or accrued to the benefit of **you, your spouse or dependent child** during the reporting period. For purposes of determining whether you meet the over \$200 threshold from any one source, you must aggregate all types of investment income from that same source. For your spouse or dependent child such income is only required to be reported if the asset source meets the reporting threshold in section II above.

Investment income includes, but is not limited to: income derived from dealings in property, interest, rents, royalties, dividends, capital gains; income from annuities, the investment portion of life insurance contracts, or endowment contracts; your distributive share of partnership or joint venture income, gross business income, and income from an interest in an estate or trust. You need not show the actual dollar amount of dividends, rents and royalties, interest, capital gains, or income from qualified trusts, excepted trusts, or excepted investment funds. For these specific types of income, you need only check the category of amount of the item reported. For all "other investment income" as described in item 7 below, you will have to report the actual dollar amount of income from each source, and indicate the type in the space marked "Other Income (Specify Type & Actual Amount)" in BLOCK C.

B. What to Show on the Form

Check all applicable classifications of income and corresponding categories of amounts. If more than one type of income is derived from the same asset, check all relevant types (unless an excepted investment fund) and categories of amount. Categories of amount may be distinguished by using the abbreviations D, R, I and CG in the boxes, in lieu of checks, to represent dividends, rents/royalties, interest or capital gains.

1. DIVIDENDS - Show in BLOCK C the amount **you, your spouse or dependent child** accrued or received as dividends from investment sources including common and preferred securities and underlying assets of pensions and mutual funds (unless an excepted investment fund). **Identify the source of such income and check the category of amount.** For example, if cash dividends of \$950 were received for shares of common stock of IBM, enter in BLOCK A... “IBM common” and in BLOCK C check that dividend income was received and check the appropriate category of amount.

2. RENTS AND ROYALTIES - Show income accrued or received by **you, your spouse or dependent child** as rental or lease payments for occupancy or use of personal or real property in which any one of you has an interest. In addition, show payments accrued or received from such interests as copyrights, royalties, inventions, patents, and mineral leases or other interests. **Identify the source of such income and check the category of amount.** For example, if you received \$2,000 as rental income from an apartment building in Miami, Florida, enter in BLOCK A... “apartment building at 5802 Biscayne Blvd., Miami, FL,” and in BLOCK C check that rental income was received and check the appropriate category of amount.

3. INTEREST - **Identify the source and the category of amount** of any interest accrued or received by **you, your spouse or dependent child** as income from investment holdings including: bills and notes, loans, personal savings accounts, annuity funds, bonds, and other securities. For example, if you earned \$300 in interest during the calendar year on a Savings Certificate with Federal Savings and Loan, enter in BLOCK A... “Federal Savings and Loan (Baltimore, MD)-Savings Certificate,” and in BLOCK C check that interest income was received and check the appropriate category of amount.

4. CAPITAL GAINS - Report income from capital gains realized by **you, your spouse or dependent child** from sales or exchanges of property, business interests, partnership interests or securities. **Identify the source**

and check the category of amount of the gain. An example of an entry in BLOCK A might be “sale of one-third interest in 100-acre farm in Hamilton County, Iowa” and in BLOCK C check that capital gains were received and check the appropriate category of amount.

5. INVESTMENT FUND INCOME - **Identify the fund and the category of amount and the type(s) of income** from investment funds such as mutual or pension funds for **you, your spouse or dependent child.** This may include dividends, capital gains and interest for a single fund or income from an excepted investment fund. Income from each individual asset of the fund must also be listed, unless it is an excepted investment fund, in which case income from individual assets is not required to be listed. See Definition of Terms above for discussion of excepted investment funds.

6. TRUST INCOME - Report the **category of amount and the type of income** accrued or received from any trust. Whenever you are required to identify the source of trust income, either for **yourself or for a spouse or dependent child**, it is not enough simply to say “John Jones Trust.” Generally, the investment holdings of the trust, discussed above under “Property Interests and Assets,” and the income derived from each holding must be identified to the same extent as if held directly. However, if the trust is a qualified trust or an excepted trust, in BLOCK A show only the identity of the trust including the date of creation, in BLOCK B the category of the total cash value of your interest (if a qualified trust), next to BLOCK C check the classification of the trust interest as a “qualified trust” or “excepted trust,” and in BLOCK C show the category of amount of income attributable to you, your spouse or dependent child.

7. OTHER INVESTMENT INCOME - Report any other items of investment income exceeding \$200 and not described above, along with the specific type and **actual amount**, such as gross income from business interests, endowment or annuity contract payments, estate income, or a distributive share of a partnership or joint business venture income. To identify the sources of

other investment income, either for **you, your spouse, or a dependent child**, briefly characterize in BLOCK A the nature of the business or investment interest and, when applicable, the location: for example... “one-third ownership in a retail furniture store at 1010 Grand Ave., Chicago, IL.” In BLOCK C under OTHER, specify the applicable type of income, for example... “distributive share” from a partnership or “gross income” from a proprietorship, and under ACTUAL AMOUNT the actual amount of such income which was received during the reporting period. Where the asset is listed because of a value of greater than \$1,000 in BLOCK B, but it does not produce more than \$200 in income for the reporting period, check “None (or less than \$201)” instead of listing the actual amount.

Schedule B

I. Part I - Transactions

A. General Instructions and Items to Report

This part is to be completed by incumbents and termination filers only. Give a description, the date, and the category of amount of any purchase, sale, or exchange of any real property, stocks, bonds, commodity futures, excepted investment fund shares, and other securities by **you, your spouse or dependent child** when the amount involved in the transaction exceeded \$1,000. Also, indicate whether sales were made pursuant to a certificate of divestiture previously issued by OGE to permit delayed recognition of capital gain. (For more information on certificates of divestiture, see 5 C.F.R. Part 2634, Subpart J.) This includes reporting any sale or exchange of an asset involving an amount exceeding \$1,000 when the sold or exchanged asset did not yield income of more than \$200 (and therefore was not reported on Schedule A), or reporting the purchase of an asset involving an amount exceeding \$1,000 but at the end of the reporting period having a value of \$1,000 or less and earning income of \$200 or less during the reporting period (and therefore not appearing on

Schedule A). The example on the form shows the proper way to disclose Central Airlines common stock the reporting individual purchased for \$75,000 on 2/1/99. Note that on Schedule A there is an entry for the stock as well since it was still held at the end of the reporting period.

You need not report a transaction involving (1) your personal residence (unless rented out); (2) a money market account or personal savings account; (3) an asset of your spouse or dependent child if the asset meets the three-part test set forth under the instructions for Schedule A, at II.A.; (4) a holding of a “qualified blind trust,” a “qualified diversified trust,” or an “excepted trust”; (5) U.S. Treasury bills, notes, and bonds; (6) transactions which occurred prior to your Federal Government employment; or (7) transactions solely by and between the reporting individual, spouse, or dependent child.

You will need to report any transactions made by a non-public business or commercial enterprise, investment pool, or other entity in which you, your spouse or dependent child have a direct proprietary, general partnership or other interest unless (1) the entity is an “excepted investment fund,” or (2) the transaction is incidental to the primary trade or business of the entity as indicated by you on Schedule A. (See also sections V.e. and f. of the General Instructions preceding those for Schedule A.)

B. What to Show on the Form

Under identification of assets, identify the property or securities involved in the purchase, sale or exchange, and give the date of the transaction. For example, under IDENTIFICATION OF ASSETS... “GMC common stock”; under TYPE OF TRANSACTION... check type; under DATE... enter date transaction occurred; under AMOUNT OF TRANSACTION... check the category of value of the sale price, purchase price, or exchange value of the property involved in the transaction. You must also indicate whether an item was sold pursuant

to a certificate of divestiture issued by the Office of Government Ethics under 5 C.F.R. Part 2634, Subpart J, to permit delayed recognition of capital gain.

Where multiple transactions have occurred which involve the same asset, you may list the item once, check purchase and/or sale, and indicate... “biweekly,” “throughout year,” or other appropriate frequency, and the aggregate amount of the sales and purchases. Reporting an exchange generally requires reporting two items since one item is exchanged for another.

II. Part II - Gifts, Reimbursements, and Travel Expenses

A. General Instructions

This Part is to be completed by incumbents and termination filers only. The Act requires you to disclose the receipt of certain gifts, in-kind travel expenses, and travel-related cash reimbursements **by you, your spouse or dependent child** from any one source other than the U.S. Government. This reporting requirement applies to gifts and reimbursements received by your spouse or dependent child to the extent the gift was not given to him or her totally independent of the relationship to you.

B. Items to Report

Report gifts received by **you, your spouse or dependent child** from any one source during the reporting period **aggregating more than \$260**, such as tangible items, or food, lodging, transportation, or entertainment; and travel-related cash reimbursements **aggregating more than \$260** from any one source. A “gift” means any payment, forbearance, advance, rendering or deposit of money, or anything of value, unless consideration of equal or greater value is received by the donor. In determining which gifts and reimbursements must be reported or aggregated, **exclude** these items:

1. Anything having a value of \$104 or less;

2. Anything received from “relatives.” The term “relatives” means an individual who is your father, mother, son, daughter, brother, sister, uncle, aunt, great uncle, great aunt, first cousin, nephew, niece, husband, wife, grandfather, grandmother, grandson, granddaughter, father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, sister-in-law, stepfather, stepmother, stepson, stepdaughter, stepbrother, stepsister, half brother, half sister, your spouse's grandfather or grandmother, or your fiance or fiancée;

3. Bequests and other forms of inheritance;

4. Suitable mementos of a function honoring the reporting individual;

5. Food, lodging, transportation, and entertainment or reimbursements provided by a foreign government within a foreign country or by the United States Government, or D.C., State or local governments;

6. Food and beverages not consumed in connection with a gift of overnight lodging;

7. Anything given to a spouse or dependent child totally independent of the relationship to you;

8. Gift items in the nature of communications to your office, such as subscriptions to newspapers and periodicals;

9. Gifts of hospitality (food, lodging, entertainment) on the donor's personal or family premises, as defined in 5 C.F.R. Part 2634;

10. Gifts and reimbursements received during non-Federal employment periods; and

11. Reimbursements you received for political trips which were required to be reported under section 304 of the Federal Election Campaign Act of 1971 (2 U.S.C. § 434).

C. What to Show on the Form

1. GIFTS - Report the identity of the source, a brief description, and the value of gifts aggregating more than \$260 from any one source which were received by **you, your spouse or dependent child** and which do not fall within any of the categories of exclusions enumerated above.

a. Food, Lodging, Transportation, Entertainment. Include travel itinerary, dates, and nature of expenses provided. To reach a more than \$260 aggregation, you determine whether any one or combination of the components within this gift category received from one source amounts to more than \$260 in value. For example, if you spent a weekend at a hunting lodge owned by AmCoal Corporation, and you received lodging fairly valued at \$150, food valued at \$115, and entertainment valued at \$125, the aggregate value of the gift is \$390. A gift of this nature - hospitality at a lodge owned by a corporation rather than an individual - would not qualify as a "personal hospitality" exclusion. To report this gift you would show, under SOURCE ... "AmCoal Corp., 1210 North St., Chicago, IL"; under BRIEF DESCRIPTION... "lodging, food, and entertainment as a guest at hunting lodge owned by AmCoal, 1/25-27/99"; and under VALUE... "\$390."

b. Other Gifts - If you and your spouse each receive a \$175 figurine from the same donor (source), the gifts have a value of more than \$260 and must be reported. To report a gift, identify the source, briefly describe the item(s), and show the value. In the case of the figurines, report on the form under SOURCE... "Artifact Co., 153 Utah St., Omaha, NE"; and under BRIEF DESCRIPTION... "two porcelain figurines." Under VALUE... "\$350" would be shown.

2. REIMBURSEMENTS - Report the source, a brief description (including a travel itinerary, dates, and the nature of expenses provided), and the value of any cash reimbursements (except those from the United States Government or otherwise excluded) aggregating more than \$260 which **you, your spouse or dependent**

child received from any one source. For example, if you were reimbursed \$400 for travel and lodging expenses in connection with a speech you made for the Denver Realtors Association, you would report this item on the form by showing under SOURCE... "Denver Realtors Assoc., 45 Bridge St., Denver, CO"; under BRIEF DESCRIPTION... "travel expenses for speech made in Denver: United Airlines round trip from Washington, D.C. 1/22-23/00, \$275; Denver Airport Marriott, \$125"; and under VALUE... "\$400" would be shown. If your spouse made this speech and received the reimbursement totally independent of his or her relationship to you, no information for this item need be reported.

Note: If you receive food, transportation, lodging, and entertainment or a reimbursement of official travel expenses from a non-profit tax-exempt institution categorized by the IRS as one falling within the terms of 26 U.S.C. § 501(c)(3), you must report the name of the organization, a brief description of the in-kind services or the reimbursement and the value. If known, you may also wish to note the date you received the required written approval from your agency to accept such items. See 5 U.S.C. § 4111 and 5 C.F.R. Part 410, Subpart E. You do **not** have to report an official reimbursement received **by the agency** since it will not be received by you in your personal capacity (nor by your spouse or dependent child). See 31 U.S.C. § 1353 (or other agency statute) and 41 C.F.R. Chapter 304.

Schedule C

I. Part I - Liabilities

A. General Instructions

The Act requires you to disclose certain of your financial liabilities. The examples on the form show how to report a mortgage on real estate the reporting individual held for the production of income and a promissory note. Note that you will need to disclose the date, interest rate and term (if applicable) of each liability. Also note you must disclose the highest amount owed on

any liability held during the reporting period, not just at the end of the period. If the liability was completely paid during the period, you may also note that on the form if you wish.

B. Items to Report

Identify and give the category of amount of the liabilities which **you, your spouse or dependent child** owed to any creditor which exceeded \$10,000 at any time during the reporting period, **except:**

1. a personal liability owed to a spouse or dependent child, or to a parent, brother, sister, or child of you, your spouse or dependent child;
 2. a mortgage or home equity loan secured by real property which is the personal residence (or a second residence not used for producing income) of you or your spouse;
 3. a loan secured by a personal motor vehicle, household furniture, or appliances, where the loan does not exceed the purchase price of the item;
 4. a revolving charge account where the outstanding liability did not exceed \$10,000 as of the close of the reporting period; and
 5. any liability of your spouse or dependent child which represents the sole financial interest or responsibility of the spouse or child, and about which you have no knowledge, and which is not derived from your income, assets, or activities, and concerning which you neither derive nor expect to derive any financial or economic benefit.
- You are required to report any liability of any non-public company, investment pool, or other entity, in which you, your spouse or dependent child have an interest, unless (1) the liability is incidental to the primary trade or business of the entity as indicated by you on Schedule A, or (2) the entity is an excepted investment fund. (See also

sections V.e. and f. of the General Instructions preceding those for Schedule A.)

C. What to Show on the Form

Under CREDITORS (NAME AND ADDRESS), show the name and address of the actual creditor unless the reporting individual is only able to identify a fiduciary and certifies in the report that he has made a good faith effort to determine who the actual creditor is and was unable to do so, or upon his certification that such determination is otherwise impracticable. Under TYPE OF LIABILITY, briefly indicate the nature of the liability. Under DATE, enter date loan incurred; under INTEREST RATE, note the set rate or, if a variable one, the formula used to vary the rate, i.e. prime +2%; and under TERM, show the duration of the loan. Check the category of value for the highest amount owed during the reporting period.

II. Part II - Agreements or Arrangements

A. General Instructions and Items to Report

Provide information regarding any agreements or arrangements you have concerning (1) future employment; (2) a leave of absence during your period of Government service; (3) continuation of payments by a former employer other than the United States Government; and (4) continuing participation in an employee welfare or benefit plan maintained by a former employer other than United States Government retirement benefits. This includes any agreements or arrangements with a future employer entered into by a termination filer. The example on the form shows the severance agreement under which the reporting individual expects to receive a lump sum payment from the law firm he has left in order to enter the Government. (Also note the related asset and income reported in the second example on Schedule A of the form.)

For purposes of public disclosure, you must disclose any negotiations for future employment from the point you and a potential non-Federal employer have agreed to your future employment by that employer whether or not you have settled all of the terms, such as salary, title, benefits, and date employment is to begin. Your agency may require internal disclosure of negotiations much earlier and you should seek guidance before conducting any negotiations with persons with whom you do business. A criminal statute, 18 U.S.C. § 208, applies to official actions you may take while negotiating future employment.

B. What to Show on the Form

Under STATUS AND TERMS, describe the agreement or arrangement with appropriate specificity. Under PARTIES, show the name of the organization, or entity, and (if applicable) the name and title of the official, corporate officer, or principal person responsible for carrying out the terms of the agreement or arrangement. Under DATE, show the date of any such arrangement. **No report is required regarding any agreement or arrangement entered into by a spouse or dependent child.**

Schedule D

I. Part I - Outside Positions

A. Items to Report

Report all outside positions held at any time during the reporting period, as well as those positions you currently hold as an officer, director, trustee, general partner, proprietor, representative, employee or consultant of (1) any corporation, company, firm, partnership, trust, or other business enterprise; (2) any non-profit organization; (3) any labor organization; (4) any educational institution; or (5) any organization other than the United States Government. **Exclude** positions held in any

religious, social, fraternal, or political entity, and any positions solely of an honorary nature. Be sure to report on Schedule A any income over \$200 that you received from acting in any of these positions. **No report is required regarding any positions held by your spouse or dependent child.**

B. What to Show on the Form

Give the name, address and brief description (type) of the organization, the title or other brief functional description of the position, and the dates you held the position. If you currently hold the position, in the entry block under TO, note "Present."

II. Part II - Compensation in Excess of \$5,000 Paid by One Source

A. General Instructions

This Part is to be completed by nominees and new entrants only. You must disclose your sources of compensation in excess of \$5,000 and the nature of the duties you provided. This includes not only the source of your salary or other fees, but the disclosure of clients for whom you personally provided more than \$5,000 in services even though the clients' payments were made to your employer, firm or other business affiliation. The examples on the form show the proper way to disclose the business affiliation which paid the reporting individual's compensation, in this case a law firm, and a client of the firm for which the reporting individual personally provided over \$5,000 worth of services. This Part does not require you to disclose the value of the compensation for these services; it does require a brief description of the services you provided. When a source has paid you directly, you should have a corresponding entry on Schedule A if the payment was within the reporting period for Schedule A. A client who paid your business affiliation more than \$5,000 for your services will appear only in this Part.

B. Items to Report

Report the nature of the duties performed or services rendered for any person (other than the United States Government) from which compensation in excess of \$5,000 in either of the two preceding calendar years or the present calendar year was received by you or an entity which billed for your services (business affiliation). **Exclude:** (1) information to the extent that it is considered confidential as a result of a privileged relationship established by law, or (2) information about persons for whom services were provided by a business affiliation of which you were a member, partner or employee unless you were directly involved in the provision of the services. The name of a client of a law firm is not generally considered confidential. **No report is required regarding compensation paid to your spouse or a dependent child.**

C. What to Show on the Form

Under SOURCE, give the name and address of the person to whom services were provided, for example, "Newark Real Estate Co. (Newark, NJ)"; and under BRIEF DESCRIPTION, the title or other brief functional description of the services rendered, for example: "tax matters researched for above firm while an associate with Quinn and Ouspensky."

Privacy Act Statement

Title I of the Ethics in Government Act of 1978, as amended (the Act), 5 U.S.C. app. § 101 et seq., and 5 C.F.R. Part 2634 of the Office of Government Ethics regulations require the reporting of this information. The primary use of the information on this report is for review by Government officials to determine compliance with applicable Federal laws and regulations. This report may

also be disclosed upon request to any requesting person pursuant to section 105 of the Act or as otherwise authorized by law. You may inspect applications for public access of your own form upon request. Additional disclosures of the information on this report may be made: (1) to a Federal, State, or local law enforcement agency if the disclosing agency becomes aware of a violation or potential violation of law or regulation; (2) to a court or party in a court or Federal administrative proceeding if the Government is a party or in order to comply with a judge-issued subpoena; (3) to a source when necessary to obtain information relevant to a conflict of interest investigation or decision; (4) to the National Archives and Records Administration or the General Services Administration in records management inspections; (5) to the Office of Management and Budget (OMB) during legislative coordination on private relief legislation; and (6) in response to a request for discovery or for the appearance of a witness in a pending judicial or administrative proceeding, if the information is relevant to the subject matter. See also the OGE/GOVT-1 executive branchwide Privacy Act system of records. Knowing and willful falsification of information, or failure to file or report information required to be reported by section 102 of the Act, may subject you to a civil monetary penalty and to disciplinary action by your employing agency or other appropriate authority under section 104 of the Act. Knowing and willful falsification of information required to be filed by section 102 of the Act may also subject you to criminal prosecution.

Public Burden Information

This collection of information is estimated to take an average of three hours per response, including time for reviewing the instructions, gathering the data needed, and completing the form. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Associate Director for Administration,

U.S. Office of Government Ethics (OGE), Suite 500, 1201 New York Avenue, NW., Washington, DC 20005-3917. **Do not** file financial disclosure reports at this address; submit them as indicated in "Where to File" on page 3.

Pursuant to the Paperwork Reduction Act, as amended, an agency may not conduct or sponsor, and no person is required to respond to, a collection of information unless it displays a currently valid OMB control number (that number, 3209-0001, is displayed here and in the upper right-hand corner of the first page of this Standard Form 278).

Important Note on Reporting of Higher-Value Category Items on Schedules A, B and C of the SF 278:

For assets, income, transactions and liabilities of over \$1,000,000 in value that are held solely by your spouse or dependent children, just mark the over \$1,000,000 column. For such items which you as the filer hold, either singly or jointly with your spouse or dependent children, you must mark the other higher categories of value, as appropriate. For assets, transactions and liabilities, the higher categories are \$1,000,001 to \$5,000,000; \$5,000,001 to \$25,000,000; \$25,000,001 to \$50,000,000; and over \$50,000,000. For income, the higher categories are \$1,000,001 to \$5,000,000; and over \$5,000,000. Asterisked notes on Schedules A, B, and C explain these higher-value category reporting requirements.

Executive Branch Personnel PUBLIC FINANCIAL DISCLOSURE REPORT

Date of Appointment, Candidacy, Election, or Nomination (Month, Day, Year)	Reporting Status (Check Appropriate Boxes)	Incumbent <input type="checkbox"/>	Calendar Year Covered by Report <input type="text"/>	New Entrant, Nominee, or Candidate <input type="checkbox"/>	Termination Filer <input type="checkbox"/>	Termination Date (If Applicable) (Month, Day, Year) <input type="text"/>	Fee for Late Filing Any individual who is required to file this report and does so more than 30 days after the date the report is required to be filed, or, if an extension is granted, more than 30 days after the last day of the filing extension period, shall be subject to a \$200 fee.
Reporting Individual's Name	Last Name			First Name and Middle Initial			
Position for Which Filing	Title of Position			Department or Agency (If Applicable)			Reporting Periods Incumbents: The reporting period is the preceding calendar year except Part II of Schedule C and Part I of Schedule D where you must also include the filing year up to the date you file. Part II of Schedule D is not applicable. Termination Filers: The reporting period begins at the end of the period covered by your previous filing and ends at the date of termination. Part II of Schedule D is not applicable. Nominees, New Entrants and Candidates for President and Vice President: Schedule A --The reporting period for income (BLOCK C) is the preceding calendar year and the current calendar year up to the date of filing. Value assets as of any date you choose that is within 31 days of the date of filing. Schedule B --Not applicable. Schedule C, Part I (Liabilities) --The reporting period is the preceding calendar year and the current calendar year up to any date you choose that is within 31 days of the date of filing. Schedule C, Part II (Agreements or Arrangements) --Show any agreements or arrangements as of the date of filing. Schedule D --The reporting period is the preceding two calendar years and the current calendar year up to the date of filing.
Location of Present Office (or forwarding address)	Address (Number, Street, City, State, and ZIP Code)			Telephone No. (Include Area Code)			
Position(s) Held with the Federal Government During the Preceding 12 Months (If Not Same as Above)	Title of Position(s) and Date(s) Held						
Presidential Nominees Subject to Senate Confirmation	Name of Congressional Committee Considering Nomination			Do You Intend to Create a Qualified Diversified Trust? <input type="checkbox"/> Yes <input type="checkbox"/> No			
Certification	Signature of Reporting Individual				Date (Month, Day, Year)		
I CERTIFY that the statements I have made on this form and all attached schedules are true, complete and correct to the best of my knowledge.							
Other Review (If desired by agency)	Signature of Other Reviewer				Date (Month, Day, Year)		
Agency Ethics Official's Opinion	Signature of Designated Agency Ethics Official/Reviewing Official				Date (Month, Day, Year)		
On the basis of information contained in this report, I conclude that the filer is in compliance with applicable laws and regulations (subject to any comments in the box below).							
Office of Government Ethics Use Only	Signature				Date (Month, Day, Year)		
Comments of Reviewing Officials (If additional space is required, use the reverse side of this sheet)							
(Check box if filing extension granted & indicate number of days _____) <input type="checkbox"/>							
(Check box if comments are continued on the reverse side) <input type="checkbox"/>							
Agency Use Only							
OGE Use Only							

Do not complete Schedule B if you are a new entrant, nominee, or Vice Presidential or Presidential Candidate

Reporting Individual's Name	SCHEDULE B	Page Number
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Part I: Transactions

Report any purchase, sale, or exchange by you, your spouse, or dependent children during the reporting period of any real property, stocks, bonds, commodity futures, and other securities when the amount of the transaction exceeded \$1,000. Include transactions that resulted in a loss.

Do not report a transaction involving property used solely as your personal residence, or a transaction solely between you, your spouse, or dependent child. Check the "Certificate of divestiture" block to indicate sales made pursuant to a certificate of divestiture from OGE.

None

	Identification of Assets		Transaction Type (x)			Date (Mo., Day, Yr.)	Amount of Transaction (x)													
			Purchase	Sale	Exchange		\$1,001 - \$15,000	\$15,001 - \$50,000	\$50,001 - \$100,000	\$100,001 - \$250,000	\$250,001 - \$500,000	\$500,001 - \$1,000,000	Over \$1,000,000*	\$1,000,001 - \$5,000,000	\$5,000,001 - \$25,000,000	\$25,000,001 - \$50,000,000	Over \$50,000,000	Certificate of divestiture		
Example	Central Airlines Common		x			2/1/99				x										
1																				
2																				
3																				
4																				
5																				

*This category applies only if the underlying asset is solely that of the filer's spouse or dependent children. If the underlying asset is either held by the filer or jointly held by the filer with the spouse or dependent children, use the other higher categories of value, as appropriate.

Part II: Gifts, Reimbursements, and Travel Expenses

For you, your spouse and dependent children, report the source, a brief description, and the value of: (1) gifts (such as tangible items, transportation, lodging, food, or entertainment) received from one source totaling more than \$260, and (2) travel-related cash reimbursements received from one source totaling more than \$260. For conflicts analysis, it is helpful to indicate a basis for receipt, such as personal friend, agency approval under 5 U.S.C. § 4111 or other statutory authority, etc. For travel-related gifts and reimbursements, include travel itinerary, dates, and the nature of expenses provided. **Exclude** anything given to you by

the U.S. Government; given to your agency in connection with official travel; received from relatives; received by your spouse or dependent child totally independent of their relationship to you; or provided as personal hospitality at the donor's residence. Also, for purposes of aggregating gifts to determine the total value from one source, exclude items worth \$104 or less. See instructions for other exclusions.

None

	Source (Name and Address)		Brief Description	Value
Examples	Nat'l Assn. of Rock Collectors, NY, NY		Airline ticket, hotel room & meals incident to national conference 6/15/99 (personal activity unrelated to duty)	\$500
	Frank Jones, San Francisco, CA		Leather briefcase (personal friend)	\$300
1				
2				
3				
4				
5				

Do not complete Schedule B if you are a new entrant, nominee, or Vice Presidential or Presidential Candidate

SCHEDULE B continued
 (Use only if needed)

Reporting Individual's Name

Page Number

Part I: Transactions

	Identification of Assets	Transaction Type (x)			Date (Mo., Day, Yr.)	Amount of Transaction (x)												
		Purchase	Sale	Exchange		\$1,001 - \$15,000	\$15,001 - \$50,000	\$50,001 - \$100,000	\$100,001 - \$250,000	\$250,001 - \$500,000	\$500,001 - \$1,000,000	Over \$1,000,000*	\$1,000,001 - \$5,000,000	\$5,000,001 - \$25,000,000	\$25,000,001 - \$50,000,000	Over \$50,000,000	Certificate of divestiture	
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*This category applies only if the underlying asset is solely that of the filer's spouse or dependent children. If the underlying asset is either held by the filer or jointly held by the filer with the spouse or dependent children, use the other higher categories of value, as appropriate.

SCHEDULE C

Page Number

Part I: Liabilities

Report liabilities over \$10,000 owed to any one creditor at **any time** during the reporting period by you, your spouse, or dependent children. Check the highest amount owed during the reporting period. **Exclude**

a mortgage on your personal residence unless it is rented out; loans secured by automobiles, household furniture or appliances; and liabilities owed to certain relatives listed in instructions. See instructions for revolving charge accounts.

None

Creditors (Name and Address)		Type of Liability	Date Incurred	Interest Rate	Term if applicable	Category of Amount or Value (x)													
						\$10,001 - \$15,000	\$15,001 - \$50,000	\$50,001 - \$100,000	\$100,001 - \$250,000	\$250,001 - \$500,000	\$500,001 - \$1,000,000	Over \$1,000,000*	\$1,000,001 - \$5,000,000	\$5,000,001 - \$25,000,000	\$25,000,001 - \$50,000,000	Over \$50,000,000			
Examples	First District Bank, Washington, DC	Mortgage on rental property, Delaware	1991	8%	25 yrs.														
	John Jones, 123 JSt., Washington, DC	Promissory note	1999	10%	on demand			x			x								
1																			
2																			
3																			
4																			
5																			

*This category applies only if the liability is solely that of the filer's spouse or dependent children. If the liability is that of the filer or a joint liability of the filer with the spouse or dependent children, mark the other higher categories, as appropriate.

Part II: Agreements or Arrangements

Report your agreements or arrangements for: (1) continuing participation in an employee benefit plan (e.g. pension, 401k, deferred compensation); (2) continuation of payment by a former employer (including severance payments); (3) leaves

of absence; and (4) future employment. See instructions regarding the reporting of negotiations for any of these arrangements or benefits.

None

Status and Terms of any Agreement or Arrangement		Parties	Date
Example	Pursuant to partnership agreement, will receive lump sum payment of capital account & partnership share calculated on service performed through 1/00.	Doe Jones & Smith, Hometown, State	7/85
1			
2			
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6			

Reporting Individual's Name	SCHEDULE D	Page Number
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Part I: Positions Held Outside U.S. Government

Report any positions held during the applicable reporting period, whether compensated or not. Positions include but are not limited to those of an officer, director, trustee, general partner, proprietor, representative, employee, or consultant of any corporation, firm, partnership, or other business enterprise or any non-profit organization or educational institution. **Exclude** positions with religious, social, fraternal, or political entities and those solely of an honorary nature. None

	Organization (Name and Address)	Type of Organization	Position Held	From (Mo., Yr.)	To (Mo., Yr.)
Examples	Nat'l Assn. of Rock Collectors, NY, NY ----- Doe Jones & Smith, Hometown, State	Non-profit education ----- Law firm	President ----- Partner	6/92 ----- 7/85	Present ----- 1/00
1					
2					
3					
4					
5					
6					

Part II: Compensation in Excess of \$5,000 Paid by One Source

Report sources of more than \$5,000 compensation received by you or your business affiliation for services provided directly by you during any one year of the reporting period. This includes the names of clients and customers of any corporation, firm, partnership, or other business enterprise, or any other non-profit organization when you directly provided the services generating a fee or payment of more than \$5,000. You need not report the U.S. Government as a source. None

Do not complete this part if you are an Incumbent, Termination Filer, or Vice Presidential or Presidential Candidate.

	Source (Name and Address)	Brief Description of Duties
Examples	Doe Jones & Smith, Hometown, State ----- Metro University (client of Doe Jones & Smith), Moneytown, State	Legalservices ----- Legal services in connection with university construction
1		
2		
3		
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