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Jordan J. Cohen, M.D., President

October 2, 2003

Dr. Michael Holland
Office of Science and Technology Policy
Executive Office of the President
1650 Pennsylvania Ave NW
Washington, DC 20502

By email: mholland@ostp.eop.gov

Re: Request for Information for Research Business Models Subcommittee of the NSTC Science Committee, 68 FR 46631-2

Dear Dr. Holland:

The Association of American Medical Colleges (AAMC) appreciates this opportunity to submit comments to the National Science and Technology Council on its review of "business models" supporting research between federal agencies and academic and other non-governmental institutions.

The AAMC represents the nation's 126 accredited medical schools, over 400 affiliated teaching hospitals, and 94 academic medical societies representing nearly 105,000 faculty members. Our constituent institutions perform more than half of the extramural research sponsored by the National Institutes of Health. Given that biomedical and health research accounts for nearly 51% of the federal budget allocated to basic research1, our member organizations are clearly significant partners in the nation's research enterprise. Moreover, many of these academic medical centers are part of larger universities or state systems of higher education that directly interact with the entire panoply of federal science agencies as well as other federal, state and local organizations. Respecting this fact, we join and endorse the insightful comments responding to this notice of the Council on Governmental Relations (COGR), which analyzes the benefits, costs and burdens of federal regulations on behalf of the nation's major research universities. Our comments here are intended to add our perspective to these and other views from the academic community.

In general, the AAMC views the federal-academic-industrial partnership in research as an

1 *NSF Science Indicators 2002*, reporting $10.4 billion in budget authority for health research out of $20.3 billion total in basic research in FY 2001. Table 4-20.

immense achievement of American science policy, and the continuation of this partnership will be no less—and arguably even more—vital to ensuring the nation's welfare, security, and prosperity in the new century. As with any partnership, stability, transparency, and a reasonable level of predictability in expectations and behaviors are necessary for success, as the AAMC commented several years ago on the *Presidential Review Directive #4*.2 At that time, we expressed concern that progressive, incremental changes in grants policy, regulations, and other federal actions had increasingly moved the federal-academic partnership away from an "investment model" and closer to a "procurement model" of government funding for science that, while perhaps more comforting to and protective of some federal administrators and auditors, nevertheless threatened to impede scientific creativity and productivity and ultimately diminish the long-term financial stability of academic research institutions.3 We called for a reaffirmation of the fundamental principles and assumptions underlying the federal sponsorship of university research, stabilizing the terms of the partnership, and strengthening mechanisms for collegial consultation and dialogue.

In large part, key councils and legislation have reaffirmed the assumptions underlying the federal-academic partnership (and its mutual interaction with industry),4 and the government's and the public's appreciation and support for biomedical and other scientific research has grown. Nevertheless, the AAMC continues to have concerns that a mostly piecemeal accumulation of directives, restrictions, mandates, and alterations in policy and budgeting seriously threaten the partnership. These actions are typically taken unilaterally within agencies, and seemingly without due regard for the sustainability of scientific institutions or the federal-academic partnership itself, core values that lie at the heart of the cost-reimbursement model for academic research.

In consideration of business models for federal support of research, we agree with COGR in seeking models that correctly identify the real "products" of academic research (e.g., new knowledge, a cadre of trained personnel), the requirements and challenges of this research (e.g., adequate facilities, instrumentation, and cross-disciplinary support), and above all that "strive to return to a costing and regulatory system that is equitable, effective and that appropriately reflects the diversity and needs of the individual research providers."5 *The AAMC strongly supports COGR's view of the NSTC subcommittee's request for comments as an initial invitation to participate in a constructive and ongoing dialogue, and with this expectation, we focus here*

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2 AAMC letter to Cliff Gabriel on the Presidential Review Directive, "Review of the Government University Partnership", dated 1997.
3 As the AAMC then noted, "….[C]ost accounting strategy has replaced science policy as the philosophical driver of the [federal-academic] relationship."
4 Notably, the Executive Order of Dec. 29, 2000 and NSTC's subsequent report, *Implementation of the NSTC Presidential Review Directive-4: Renewing the Federal Government-University Research.* Also, the NSF Reauthorization Bill, H.R. 4664 (P.L. 107-368).
5 COGR comment letter to Dr. Michael Holland, September 2003.

on an initial, exemplary, but by no means exhaustive, enumeration of issues and potential data sources:

Inconsistency of federal policies and objectives: Recent decades are replete with examples of the federal government's unilateral shifting of the terms of the government-university relationship, often under the guise of cost accounting. The most notable of many changes has been OMB's ex cathedra revision to Circular A-21 establishing an arbitrary 26-percent cap on the recovery of administrative expenses for academic institutions (but not for independent research institutions, which are subject to Circular A-122). At the same time, universities labor under a steadily increasing administrative burden of meeting ever expanding and ever more demanding regulatory and reporting requirements.

Other chafing federal actions include a legislated cap on salary levels reimbursable by NIH grants that is below actual salaries paid to investigators, and especially, to physician investigators who have been deemed for more than three decades an "endangered species"6; caps on stipends for pre- and post-doctoral fellowships and training grants that are below the competitive levels many institutions must provide; limitations on recovery from federal grants of graduate student tuition costs at levels below that charged by many institutions, a restriction that is particularly punitive to private universities; and eliminating funding for the NIH's Biomedical Research Support Grant mechanism, which was created specifically to provide flexible support of institutional research capacity. The net effect of these actions has been the cumulative transfer of legitimate costs of federal research to awardee institutions.

The AAMC believes that the cap on the reimbursement of administrative costs and related cost-shifting actions are central issues that must be addressed in any contemporary discussion of federal-academic business models. COGR, the Association of American Universities, and their member organizations have monitored the cost-reimbursement issues closely7 and we urge the NSTC to engage in dialogue with the academic community on this urgent topic. We also cite RAND's excellent study, *Paying for University Research Facilities and Administration*, which provides further data.8

Accountability: The doubling of the NIH budget has heightened the obligations of the NIH and the biomedical research community to demonstrate their accountability in the use of federal funds in discovery-oriented research.9 The AAMC believes that NIH

6 Wyngaarden JB. The clinical investigator as an endangered species. *New England Journal of Medicine*. 1979; 301;23:1254-9.
7 COGR, *Cost of Doing Business*, forthcoming.
8 Goldman CA, Williams T. RAND; Santa Monica, CA, 2000.
9 Korn, D. et al. The NIH budget in the post-doubling era. *Science*. 2002;296(5572):1401-2.

responded with exemplary competence to the strict requirements of the 1993 Government Performance and Results Act (GPRA, P.L. 103-62). We urge the NSTC to examine the NIH's most recent GPRA report.10 The AAMC was disappointed to learn that the Office of Management and Budget opted not to accept NIH's "GPRA goals" in implementing its own management performance tool, but has sought to mandate yet a new set of performance measures.

Regulatory Requirements: The health information privacy provisions of HIPAA are perhaps the most portentous example conceivable of a regulatory regime fundamentally altering the research environment. Unless modified, the privacy rule threatens major impedance of biomedical and health sciences research that is already subject to significant oversight. In the view of the AAMC, the privacy rule excessively intrudes upon the established Institutional Review Board (IRB) system of human research oversight, burdening biomedical and behavioral researchers, their institutions, and research participants with onerous procedural requirements, ambiguous regulatory standards, and extensive new liability concerns destined to breed cautionary behavior and vexing delays. The rule imposes new *civil and criminal liability* upon hospitals, health plans, and providers for their use or disclosure of medical information for research purposes, even when such uses and disclosures are approved by an IRB. The new liability under the rule is above and beyond the legal consequences that flow from an entity's failure to observe federal research regulations or applicable state laws. Increased liability, when coupled with the compliance burden imposed by the rule's procedural requirements, creates a substantial disincentive for covered entities to accommodate the needs of biomedical and health researchers. The threat is most severe to population-based research requiring access to large numbers of archival medical records, such as public health and epidemiological studies, health services research, post-marketing assessment of the safety and effectiveness of drugs and medical devices, and retrospective studies required to understand and eliminate the systemic causes of medical errors.

The AAMC, joined over time by many other academic and health advocacy organizations11, warned of the hazard that such regulations would pose for medical and health research.12 The Association has initiated a web-based survey to try to document the extent of the rule's impact on research and research institutions, and intends to make the findings of this study available. Most recently (according to *Washington Fax*,

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10 See http://www1.od.nih.gov/gpra/gpra_nih_c.htm, accessed Sept. 24, 2003.
11 Coalition letter to Sec. Thompson, Nov. 20, 2001.
http://www.aamc.org/advocacy/library/hipaa/corres/2001/112001.htm, accessed Sept. 24, 2003.
12 Kulynych J, Korn D. The new federal medical-privacy rule. *New England Journal of Medicine,* . 2002;347(15):1133-4. Also, Kulynych J., Korn D. Use and disclosure of health information in genetic research: weighing the impact of the new federal medical privacy rule. *Am J Law Med*. 2002;28(2-3):309-24.

September 24) a subcommittee of the National Cancer Advisory Board delivered its report of "adverse effects" of HIPAA on cancer research.13 We expect more such reports will be forthcoming from the several medical specialty organizations.

In other regulatory matters, the NIH, at the request of Congress, has examined approaches to reduce regulatory burden in biomedical research. NIH's report, though now several years old, provides some examples of these approaches.14 The AAMC itself has joined the Federation of American Societies for Experimental Biology (FASEB) in calling for rationalization of hazardous waste regulations as they apply to university research, and we endorse FASEB's insightful comments to the NSTC in this regard.15 The Environmental Protection Agency has expressed willingness to reconsider provisions of the Resource Conservation and Recovery Act (RCRA) that while arguably appropriate for industry often apply inappropriately to academic institutions. Rationalization of RCRA regulations should allow universities to meet tailored, performance-based standards developed in cooperation with state and local authorities that often also regulate waste disposal.

Research infrastructure: AAMC's constituents indicate that facilities and research space remain a significant constraint for new research, and academic institutions have assumed the predominant burden for construction of new facilities.16 The Association and other organizations have asked that support for renovation and construction of research facilities in general, and for research facilities for non-human primates, recombinant rodents, and other animals in particular, be a priority of the NIH and its National Center for Research Resources.17 An NIH advisory group, the Working Group on Research Facilities, has innovatively proposed to create a federal loan guarantee program for new facility construction.18 Such a program would, with minimal cost to federal partners, improve opportunities for financing new facilities at PHS grantee institutions. Creation of this program would, of course, require federal legislation.

A major impediment in biomedical research—incredibly, in spite of the growth of the NIH budget—has been limited access to commercially available, state-of-art instrumentation, and particularly so-called high-end instruments, such as high-field

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13 Hawkins, Andrew. "HIPAA privacy regs unintended consequences hinder oncology research, NCI panel reports.", Sept. 24, 2003. www.washingtonfax.com.
14 http://grants2.nih.gov/grants/policy/regulatoryburden/index.htm#toc
15 FASEB comment letter to Dr. Michael Holland, 2003.
16 See for example, National Science Foundation, Division of Science Resources Statistics, *Scientific and Engineering Research Facilities: 2001,* NSF 02-307, Project Officer, Leslie Christovich (Arlington, VA 2002).
17 Comment letter to NIH/NCRR by Presidents of AAU, AAMC, and NASULGC, May 9, 2003. http://www.aamc.org/advocacy/library/research/corres/2003/050903.pdf, accessed Sept. 24, 2003.
18 See http://www.nih.gov/about/director/061901.htm, accessed Sept. 24, 2001.

MRIs, PET scanners, or certain types of mass spectrometers. NIH's central program for shared instrumentation (i.e., used by three or more investigators) has received relatively little increased funding, adjusted for inflation, from the early 1990s. A new program to support purchase of high-end instrumentation has been implemented at NIH, though it has been grossly insufficient to address a significant share of the meritorious applications submitted. There may be opportunities for creating programs that establish especially expensive and complicated instruments, which require dedicated full-time staff, as regional resources, to be shared among institutions.

Cross-disciplinary models: Much biomedical research infrastructure is supported by separate NIH institutes and centers to further their respective research missions. The growth of multi-disciplinary research across the biomedical sciences underscores the opportunity for further efforts to coordinate support of infrastructure across NIH and with other federal agencies. NIH's use of DOE-funded synchrotron radiation facilities to support biological investigations is a successful and instructive model. Clearly, identification of appropriate mechanisms for review and support of infrastructure across agencies is a challenging task, but pilot projects might be used to test the feasibility of alternative approaches. Efforts should be made to develop proposals or options to strengthen coordination of investment in merit-reviewed, cross-disciplinary research infrastructure. NIH could initiate such efforts, and should also encourage academic institutions to identify opportunities for regional research resources that can be shared among multiple institutions.

Information technology: The need for a national, uniform, inter-operative clinical information system to support patient-centered clinical research has become an urgent priority in the age of human genomics. The AAMC, with support from the National Science Foundation, has completed a study of clinical informatics, recommending, among other initiatives, that academic health centers take the lead in developing and adopting a common set of specifications, while allowing commercial vendors to focus on systems development.19 The fact is that medical information systems in academic medical centers have been designed largely to support the finance and administrative operations of hospitals and clinics, or, more recently, to provide bioinformatics capability in support of research in structural and functional genomics. The development and implementation of clinical information systems *designed for support of clinical research* is a daunting undertaking of national scope that AAMC believes will only be accomplished through a public-private partnership catalyzed by federal leadership and challenge funding.

In conclusion, the AAMC welcomes the NSTC's review of these issues and looks forward to

19 AAMC. *Information Technology Enabling Clinical Research.* Washington, DC, 2003 (available on request.)

assisting the Council in its deliberations. We hope that this is the beginning of a continuing dialogue with the university and academic medical center communities that can refresh and reinvigorate the federal-academic research partnership. Questions or requests for further information should be directed to Dr. David Korn, AAMC's Senior Vice President for Biomedical and Health Sciences Research (202-828-0509, dkorn@aamc.org).

Sincerely,

Jordan J. Cohen, M.D.

cc: David Korn, M.D.