

THIS IS PART TWO OF A TWO PART ISSUE

VARMUS AND ANDERSON TO LEAVE NIH *MS, AS*

NIH Director Harold Varmus announced on October 7, that he will be leaving his post at the end of the year to head the Memorial Sloan-Kettering Cancer Center in New York City.

Head of the federal government's biomedical and behavioral research agency for six years, Varmus has been the beneficiary of tremendous support from the Congress, which has put his agency on track for a doubling of its budget within five years. In her released statement, Health and Human Services Secretary Donna Shalala emphasized that "[h]istory will judge him as the leader who brought new energy, vision and excitement to the world's greatest scientific institution . . . The solid, generous, bipartisan support NIH now enjoys is due in large part to his leadership."

For the social and behavioral sciences, Varmus has been educated by the Office of Behavioral and Social Science Research about the importance of the social, behavioral, and cultural factors that influence health. This had led to a number of initiatives on prevention, social-cultural factors in health, and pressure to examine health disparities. However, as the Senate report language indicates (See page 3 of Part One of this issue), progress has been slow and funding has been limited.

Doing a lot of the educating of Varmus, was the head of the OBSSR, Norman Anderson. After more than four years, Anderson has also announced that he will be leaving NIH in mid-January. Anderson has accepted a position as Professor of Health and Social Behavior at the Harvard School of Public Health. He will also become a Vice President for Research and Development of and a Principal of Behavioral Sciences Unlimited, a new startup company that will be part of the Abacus Group.

Anderson, the OBSSR's first director, officially opened the OBSSR on July 1, 1995. He has worked tirelessly ever since to integrate the social and

behavioral sciences throughout the NIH health research enterprise. For the very small budget under which it operates, Anderson's contributions to the social and behavioral sciences at NIH are many and lasting. While we are disappointed that he is leaving the OBSSR, we are pleased that he will continue as a leader and spokesperson for the social and behavioral sciences while at Harvard. NIH will form a search committee to find a replacement for Anderson. In the interim, it is expected that an acting director will be named.

OMB COMPLETES WORK ON A-110 DATA SHARING AND FOIA *MS*

The Office of Management and Budget (OMB) has published its final rule (See *Federal Register*, October 8, 1999, Pages 54926-30) regarding the Shelby provision to last year's omnibus appropriations bill. The provision required that all recipients of federal grants must provide their research data to anyone who requests it under the Freedom of Information Act (FOIA). The OMB had the task of interpreting the legislation and applying it to Circular A-110 which governs grants to non-profit institutions, including universities (for earlier stories see *UPDATE*, August 9, 1999, May 17, 1999, February 8, 1999, December 14, 1998).

On February 4, OMB published its first attempt at interpreting the Shelby language. It elicited 9,000 comments from the scientific community, the business community, and the public. OMB went

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back to the drawing board and on August 11 it published version two. This elicited 3,000 responses during the 30-day comment period. Among the comments was a six page letter from Senators Richard Shelby (R-AL), Trent Lott (R-MS), Ben Nighthorse Campbell (R-CO), and Phil Gramm (R-TX) complaining strongly that OMB had eviscerated their intent to allow the public access to information produced with federal funds.

The final rule closely resembles the August 11th version with some changes to accommodate some of the Senators' complaints. Throughout the process OMB has made it clear, as they do in the explanation to the final rule, that they tried hard to balance the public's right to know with the "traditional scientific process" and to produce procedures that would work in practice. The preamble to the final version contains strong language about the importance of science and technology — "the principal agents of change and progress" — to the nation's health and prosperity. Thus, OMB ensures that "we have not construed the statute as requiring scientists to make research data publicly available while the research is still ongoing."

OMB also notes that the "issuance of this final revision meets the statutory requirement imposed by OMB's appropriation for FY 1999 within the time in which it has legal effect." Some are interpreting this to mean that OMB believes that the Shelby

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provision expired with the end of Fiscal Year 1999 on September 30. This is an argument some in the scientific community have posited. The courts will probably have to resolve the issue.

In explaining the final revision, OMB notes that: "we have always understood that it would be the recipient, not Federal agency staff, who would identify the research data in the recipient's files which are responsive to a FOIA request." However, the Federal awarding agency would have the right to seek additional information from the recipient. The final revision also substitutes "similar information which is protected under the law" for "information which may be copyrighted or patented" under the definition of data. OMB also replaced the word "files" with "information" with regard to the protection of confidentiality, since some examples of research data such as video or audio tapes of research projects would not necessarily be in files. They also made consistent the language in the "data" definition and "published" definition.

To accommodate Shelby, et.al.'s objection to limiting the rule to regulations, OMB has changed the language to refer to "an agency action that has the force and effect of law." They refused to go as far as the Senators wanted and did not include guidelines and other agency notices that do not have the force of law. OMB did not include an impact threshold of \$100 million, as they suggested in the second version. Shelby, et. al, strongly opposed such a limitation. Most people expressed satisfaction with the definition of "published" and the only change was one of consistency noted earlier.

The Cost Reimbursement issue was not settled. OMB suggested a possible agreement between the agency and the researcher that would allow the grant recipient to keep an accounting for the associated costs of responding to the FOIA request. The awarding agency would then seek reimbursement from the FOIA requester and then reimburse the grant recipient.

The new rules will take effect on November 8, 1999, and effects grants made after that date or renewed after that date. The current Circular A-110 requires recipients to retain records pertaining to the grant for three years after the final report. It also states that if the recipient chooses to keep these records longer than three years, "the recipient must

make them available for review in response to requests from a federal agency." Nothing has changed here. Finally, the new rules apply only to grants, not contracts, and they apply to a research project supported by both non-Federal and Federal funds.

OMB usually reviews all new rules after three years. Whether these new rules survive anticipated court challenges in the next three years will be interesting given the amount of heat they have generated this past year.

The New Rules

(c) The Federal Government has the right to:

(1) obtain, reproduce, publish or otherwise use the data first produced under an award; and

(2) authorize others to receive, reproduce, publish or otherwise use such data for Federal purposes.

(d) (1) In addition, in response to a Freedom of Information Act (FOIA) request for research data relating to published research findings produced under an award that were used by the Federal Government in developing an agency actions that has the force and effect of law, the Federal awarding agency shall request, and the recipient shall provide, within a reasonable time, the research data so that they can be made available to the public through the procedures established under the FOIA. If the Federal Awarding agency obtains the research data solely in response to a FOIA request, the agency may charge the requester a reasonable fee equaling the full incremental cost of obtaining the research data. This fee should reflect costs incurred by the agency, the recipient, and applicable subrecipient. This fee is in addition to any fees the agency may assess under the FOIA.

(2) The following definitions apply for the purposes of paragraph (d) of this section:

(i) *Research Data* is defined as the recorded factual material commonly accepted in the scientific community as necessary to validate research findings, but not any of the following: preliminary analyses, drafts of scientific papers, plans for future research, peer reviews, or communications with colleagues. This "recorded" material excludes

physical objects (e.g. laboratory samples). Research data also do not include:

(A) Trade secrets, commercial information, materials necessary to be held confidential by a researcher until they are published, or similar information which is protected under law; and

(B) Personnel and medical information and similar information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, such as information that could be used to identify a particular person in research study.

(ii) *Published* is defined as either when:

(A) Research findings are published in a peer-reviewed scientific or technical journal; or

(B) A Federal agency publicly and officially cites the research findings in support of an agency action that has the force of law.

(iii) *Used by the Federal Government in developing an agency action that has the force and effect of law* is defined as when an agency publicly and officially cites the research findings in support of an agency action that has the force and effect of law.

YOUTH VIOLENCE INITIATIVE INCLUDED IN SENATE FUNDING BILL *DH*

Observing that "[m]any familial, psychological, biological and environmental factors contribute to youths' propensity toward violence," the Senate report accompanying the Labor, Health and Human Services and Education appropriation's bill included a youth violence initiative. The Initiative, the subject of a recent Senate hearing (See *UPDATE*, September 27, 1999), is funded through the reallocation of current dollars totaling \$850 million. According to the report, these funds in combination with increases in funding for NIMH, NIDA, and NIAAA "will provide resources to address school violence in a comprehensive way."

The Office of the Surgeon General (OSG) within the Office of Public Health and Science is directed to take the lead role in coordinating the federal initiative and is provided \$4 million to further its leadership. "Sufficient funds have been included for a Surgeon General's report on youth

violence . . . [to] review the psychosocial and environmental determinants of violence, including a comprehensive analysis of the effects of the media, the Internet, and video games on violent behavior and the effectiveness of preventive interventions for violent behavior, homicide, and suicide.”

The report also directs the Secretary of Health and Human Services to establish a Federal Coordinating Committee on the Prevention of Youth Violence to be chaired by the Surgeon General and co-chaired by representatives from the OSG, and the Departments of Justice, Education, and Labor.

Ten (\$10) million in funding is provided to establish 10 National Centers of Excellence at academic health centers. The Committee provided \$2.5 million for a National Resource Center on Youth Violence Prevention. Among other things, the NIMH is encouraged to address “less dramatic problems that delay cognitive and social and emotional development” which may lead to later serious conduct problems and may be resistant to change. The Institute is also encouraged to support research that develops and evaluates interventions for early disruptive behavior in preschool and community settings.

The Committee notes that there are “four cross-cutting areas in need of further research action across all agencies: community interventions, media, health provider training, and information dissemination.” NIMH is directed to “ensure that research focuses on: examining the feasibility of public health programs combining individual, family and community level interventions to address violence and identify the best practices; developing curricula for health care providers and educators to identify pediatric depression and other risk factors for violent behavior; studying the impact of the media, computer games, Internet, etc., on violent behavior; and disseminating information on families, schools, and communities to recognize childhood depression, suicide risk, substance abuse, and health care.”

Further observing that drug abuse is a risk factor for violent behavior, the Committee encourages NIDA to support research on the contribution of drug abuse, its co-morbidity with mental illness, and treatment approaches to prevent violent behavior. Similarly, NIAAA is encouraged to examine the

relationship of alcohol and youth violence with other mental disorders.

NSF SOLICITS INFORMATION TECHNOLOGY GRANTS

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With \$105 million from the Congress in its FY 2000 budget, the National Science Foundation (NSF) has issued a program solicitation notice for its interdisciplinary Information Technology Research Program (ITR). The full notice can be found at <http://www.nsf.gov>.

The notice distinguishes between proposals seeking more than \$500,000 and those requesting less. The large grants require a letter of intent by November 15, 1999, a pre-proposal due on January 5, 2000, and the full proposal due on April 17, 2000. Those proposals seeking less than \$500,000 need a letter of intent by January 5, 2000 and the full proposal on February 5, 2000.

The solicitation covers a large number of topics related to Information Technology. NSF notes that “the proposals must approach research activities in innovative ways rather than suggesting routine applications of existing technology.” In almost all the areas, NSF encourages researchers to collaborate across disciplines and with international scientists.

There are a number of topics where social and behavioral scientists are encouraged to seek funding. The major area is *Social and Economic Implications of Information Technology*. Issues included under this category are: IT access equity; universal participation in networks; infrastructures and digital economies; privacy issues related to new uses of digital information and archived communications; surveillance, monitoring, and tracking of network activities; the development of trust in distributed social settings and exchanges with strangers; intellectual property issues and rights related to electronic publishing, digital libraries, fair use in educational settings; and cross-cultural issues related to any of the above. Development of new data and indicators that would facilitate tracking IT use and creation of new research methodologies to study the socio-economic implications of IT are also appropriate.

Specific areas of emphasis include: the economic and technical systems that comprise the digital economy, electronic markets and Internet commerce; the causes and effects of unequal participation in IT by different social groups; the interdependence of technologies, institutions, and communities; and the evolution and functioning of IT-based collaboratories and distributed work environments. Also relevant are studies of: how laws, ethics, and social norms may be changing in relation to IT; of public access to government information; and of the involvement of IT in public decision-making.

Other topics under the solicitation are: *Human-Computer Interface, Information Management, Software, Information Technology and Workforce, Advanced Computational Science, Scalable Information Infrastructure, and Revolutionary Computing.*

Human-Computer Interface should address the understanding of human perceptual, cognitive, and social abilities and their relation to interface design. *Information Management* proposals ought to focus on online information content — the nature of the material, what is new, and how it will be provided in a sustainable and permanent way. *Information Technology and Workforce* proposals should develop new methods for educating people in IT or explore the use of learning technologies in educating K-16 students for IT careers. This topic area also includes research on methods to increase IT literacy and skills among the general student and public populations.

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NIDA CELEBRATES A QUARTER CENTURY OF SCIENTIFIC PROGRESS

The National Institute on Drug Abuse (NIDA) held a day-long symposium September 27 at the National Institutes of Health's Clinical Center as part of a year-long celebration of a quarter century of scientific progress against drug addiction. The symposium highlighted 25 years of research that has

been instrumental in changing the perception from drug abuse as a character flaw, to a clear understanding that drug abuse is a preventable behavior and that addiction is a treatable brain disease, noted NIDA Director Alan Leshner.

NIDA, established in 1974 to bring "the power of science to bear on the Nation's drug abuse problem," has provided "groundbreaking scientific discoveries about the nature of drug abuse and addiction, and what to do about them. Together, these discoveries have established that addiction is a quintessential biobehavioral disorder — a brain disease with embedded behavioral and social aspects." Leshner noted that "at the time of NIDA's inception, many people incorrectly viewed drug addiction as simply a moral problem. Today, thanks to the research accomplishments of thousands of scientists, . . . we have moved far beyond simplistic ideologies to a better understanding of complex biological, behavioral, and social components of drug abuse and addiction."

NIDA, said Leshner, is proud of its "scientific accomplishments" and the "tremendous progress" it has made thus far. The symposium, said Leshner, is an opportunity to reflect on NIDA's past accomplishments and "to embark upon a new millennium of promise."

Shalala Praises NIDA for "Bold and Brilliant Work"

Health and Human Services Secretary Donna Shalala, NIH Deputy Director Ruth Kirchstein, and White House Office of National Drug Control Policy Director General Barry McCaffrey joined NIDA in its celebration. Shalala, recognizing NIDA as the world's leading braintrust on the causes and consequences of drug abuse, spotlighted three insights NIDA-supported research has provided: 1) clarifying how and where drugs work in the brain to cause their addictive effects; 2) providing complex models to explain drug-taking behavior to improve treatment and rehabilitation strategies; and 3) producing ground-breaking work on nicotine addiction — work that has led to the development of more accessible and cost-effective treatments such as nicotine gum and skin patches. Thanking NIDA for its "bold and brilliant work," Shalala stressed that "we are beginning to more clearly understand the lure of illicit drugs . . . and how they seduce human beings into risking harm to

their bodies, to the health and welfare of others, to the fabric of their relationships, and to their very lives." Shalala concluded, "I am proud of your past, honored to be a part of your present and excited about our future."

Herbert D. Kleber, from the College of Physicians and Surgeons of Columbia University, stressed that "future treatment approaches for drug abusers will continue to involve the combination of pharmacological and behavioral interventions." Kleber noted that "current pharmacotherapies, both successful and failed, have generally relied on medications developed for non-drug abuse indications, while successful behavioral interventions have derived either from preclinical laboratory data or cognitive psychology."

Kleber echoed predictions he made in 1978 and predicted that in the next decade the nation will have a large number of addicts; cocaine will remain endemic with only a gradual decrease in the numbers of users; heroin use will continue to increase to at least 1 million users from 800,000 plus users before leveling off; methamphetamine will remain a problem in the western U.S.; and marijuana use will continue to rise and fall periodically as it has in the past. The primary drugs of today will remain the primary drugs of the next decade, he emphasized.

He underscored that the next few decades will see the development of agents to block existing drugs of abuse. Despite this expected development, he stressed that because human nature will not have changed the majority of addicts will want nothing to do with any of these. Therefore, he concluded, better behavioral interventions will be critical. The interventions, he said, will need to be targeted rather than general, including interventions to increase compliance with a blocker, and skills to avoid relapses while a drug abuser is taking an agonist or reparative agent. Kleber warned that there will be a need "to reach out to new disciplines and knowledge bases to craft these new behavioral tools."

NIDA' Future

NIDA's goals for the 21st Century include:

- ◆ Broaden research on gender-differences in drug abuse and addiction, particularly in women.

- ◆ Design, develop, and test new behavioral therapies in diverse patient populations.
- ◆ Analyze the organization and financing of drug abuse treatment and its benefits to the larger health care system.
- ◆ Identify the protective and resiliency factors that enable some individuals with multiple risk factors to avoid drug abuse, so that more effective prevention techniques can be developed.
- ◆ Strengthen the research infrastructure by providing additional opportunities for research training and career development for clinical researchers, and improved mechanisms for training and mentoring of minority researchers.
- ◆ Expand the use of scientific information to educate the public about the nature of drug abuse and addiction.
- ◆ Broaden the dissemination of research findings to improve drug abuse prevention, treatment, and policy.

Clinical Trials Networks Launched

In an effort to dramatically improve treatment throughout the country, NIDA has awarded \$55 million over five years to establish a clinical trial network. The network is designed to "more rapidly move promising science-based drug addiction treatments into community settings." The five centers awarded grants in September are collectively known as the foundation for the National Drug Abuse Clinical Trials Network (CTN). CTN will provide a research infrastructure to test drug addiction treatments in real life settings with diverse populations. The CTN was recommended by the 1998 Institute of Medicine Report, *Bridging the Gap Between Research and Practice*, as the single mechanism most likely to improve drug abuse treatment.

When it is complete, the CTN will include 20 to 30 regional research centers. Yale University, University of Pennsylvania, Johns Hopkins University, University of California at Los Angeles, and Oregon Health Sciences University will be the core institutions of the first five regional centers. Each core will be linked to five community treatment programs throughout the region.

CDC EMBRACES SOCIAL AND BEHAVIORAL SCIENCES

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The Centers for Disease Control and Prevention (CDC) is seeking to increase and strengthen the involvement of external partners in CDC's prevention research through the Office of Prevention Research (OPR), located within the Office of the Director. Meeting with the COSSA-supported Coalition for the Advancement of Health Through Behavioral and Social Science Research (CAHT-BSSR), Lynda Doll, a Senior Behavioral Scientist at OPR, told coalition members that the CDC's attitude toward the behavioral and social sciences has changed enormously. CDC now, she said, seeks to embrace and include social and behavioral scientists in its prevention research process. CAHT-BSSR is co-chaired by COSSA's Associate Director for Government Affairs Angela Sharpe.

Doll emphasized that while the CDC's change in attitude has continued under current Director Jeffrey Koplan, it was former CDC Director and current Surgeon General David Satcher who really pushed for an increased look at prevention and subsequently an increased role for the behavioral and social sciences. Doll indicated that she will work closely with Marjorie Speers, Assistant Director for Behavioral and Social Sciences at CDC.

CAHT-BSSR members agree with Doll's assessment of the agency. "The CDC has made great strides and has outpaced the National Institutes of Health in incorporating the social sciences, particularly, anthropology, in disease prevention and intervention," said Peggy Overbey, Director of Government Affairs for the American Anthropological Association. CDC's focus on populations and the real-life, human context of health and disease explains in part their desire to engage the social sciences, she continued. "The Office of Prevention Research is in the position to advance these efforts across the CDC. We support the OPR and staff and look forward to working with them every step of the way."

Richard McCarthy, Executive Director for Science of the American Psychological Association observed that "Lynda Doll has established an outstanding record of involving behavioral scientists in the research programs of CDC. In her new position in the Office of the Director, she continues

to build upon her previous successes by encouraging greater involvement of behavioral scientists in the extramural funding programs of CDC. She is respected as a scientist and an administrator and I anticipate that interesting opportunities will develop because of her dedication."

Office of Prevention Research

The OPR facilitates and funds extramural prevention research in support of CDC's mission to prevent disease, injury, and disability. The office was established because of the CDC's recognition that "prevention research is critical to identify the most effective strategies to address this country's pressing public health problems." Prior to moving to the newly established OPR, Doll, who has been with the CDC for 13 years, was Chief of the Behavioral and Social Science Division in the Division of HIV/AIDS Prevention. The Office's Chief, Ruth Berkelman, who has a strong interest in interdisciplinary research, specifically sought out Doll to work with her in the Office.

In addition to strengthening the involvement of the extramural community, a goal of the OPR is also to support the conduct of CDC's extramural prevention research and its transfer to health practice by: fostering excellence in prevention research; developing and promoting CDC's extramural application review policies and procedures; and disseminating the results from CDC's prevention research for public health action.

To accomplish their goal of fostering excellence in prevention research with direct applicability to public health practice and policy, said Doll, the OPR will seek to strengthen the CDC's prevention research by encouraging internal and external input into the prevention research prioritization and implementation. Like the NIH, the CDC is currently working to develop its research agenda. In addition, the agency is working to improve the visibility of CDC's extramural prevention research program, including increasing the multi-disciplinary and cross-CIO [Centers, Institutes and Offices] prevention research conducted and supported by the agency. The OPR will work to strengthen the CDC's understanding of the best methods to translate and disseminate scientific results from prevention research.

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