



JAN 26 2004

The Honorable Judd Gregg
Chairman, Committee on Health,
Education, Labor, and Pensions
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

Over the past year, Members of Congress have expressed concerns about research on human sexuality supported by the National Institutes of Health (NIH). Because of the sensitivity of this subject in general, as well as inferences that might be made following a perusal of the titles of research grants, I can understand why some Members have questions. Congressional offices have asked NIH to justify grants that appeared inappropriate to some observers. Last year, these concerns led to a proposed amendment to the House appropriation bill for NIH to defund several grants that had already been approved through our well-established, independent peer-review process. During my appearance on October 2, 2003, before a joint hearing of the Senate Health, Education, Labor and Pensions Committee and the House Energy and Commerce Committee, several Members raised similar concerns based on specific descriptions and characterizations of several NIH-funded grants.

I believe that it is my duty to ensure that any and all concerns expressed by Members of Congress be fully and transparently addressed. My goal is to preserve your trust in NIH and that of the public you represent. This trust has to be based on the historic ability of NIH to properly determine research priorities in response to current and future public health challenges and to maintain, through our world-renowned peer review system, the exceptional quality of U.S. biomedical research.

I directed NIH officials to conduct a comprehensive review of the human sexuality research that we support with a particular focus on the lists of grants that have been cited by some Members of Congress. I asked the Directors of the relevant Institutes and their staff to review each and every grant to help answer the following questions, which summarize, I believe, the essence of the objections raised by some Members.

- 1) Are these grants relevant to the public health needs of our country; i.e., is this research a good use of taxpayers' dollars and why?
- 2) Are the research and its methods scientifically and ethically appropriate?
- 3) Was the integrity of the process by which these grants were reviewed and funded at NIH compromised?

4) Is the funding for this research area disproportionate relative to the burden of sexually related diseases as compared to that of other diseases?

I will begin with the basic mandate for NIH contained in Section 301 of the Public Health Service Act, which requires that we conduct and support “research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man.”

Much of the success in improving the Nation’s health is attributable to research advances furthering the understanding of human biology. The constant battle against illness and disease, however, cannot be limited to biological factors but has to include behavioral and social factors as well. Unhealthy human behaviors have been estimated to be the proximal cause of over half of the disease burden in our country. Smoking, overeating, abuse of alcohol and illicit drugs, the spread of sexually transmitted diseases, and sex-related or other violent behaviors are at the core of many of the illnesses we are trying to prevent and control in our diverse society today.

Based upon the enclosed summary of the findings of the Institute Directors, I fully support NIH’s continued investment in research on human sexuality, and I believe that the peer review process, which is fundamental to the ability of NIH to conduct effective and high quality research, has worked properly and provided a level of valuable and independent review in this important area of research. While the enclosure specifically addresses only a few of the hundreds of grants examined, we would be pleased to answer any questions about any individual grant not addressed.

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Your views, and those of other Members, are very important to me, and as we take steps to follow up on concerns we have heard, I would welcome any additional thoughts you may have.

Sincerely,

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Elias A. Zerhouni, M.D.
Director

Enclosure



JAN 26 2004

The Honorable Edward M. Kennedy
Committee on Health, Education,
Labor, and Pensions
United States Senate
Washington, D.C. 20510

Dear Senator Kennedy:

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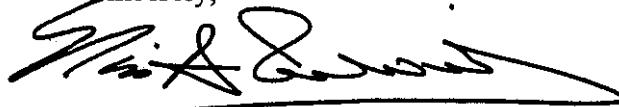
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JAN 26 2004

The Honorable W. J. "Billy" Tauzin
Chairman, Committee on
Energy and Commerce
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

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Elias A. Zerhouni, M.D.
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The Honorable John D. Dingell
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515

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SUMMARY OF INSTITUTE DIRECTORS' FINDINGS

PUBLIC HEALTH RELEVANCE

Sexually transmitted diseases (STDs) are common in the United States, with an estimated 15 million new cases reported each year. Nearly 4 million of the new cases occur in adolescents. More than 65 million people in the United States are living with incurable sexually transmitted diseases. Women generally suffer more serious STD complications than do men, including pelvic inflammatory disease, ectopic pregnancy, infertility, chronic pelvic pain, and cervical cancer from the human papilloma virus.

Between 800,000 and 900,000 people living in the United States are infected with HIV. The majority of them were infected through sexual contact. After years of progress, the transmission of the disease appears to be increasing again, not only in new generations of sexually active people but even in seniors. Alarming, the Centers for Disease Control and Prevention (CDC) recently reported that the rate of one STD, syphilis, increased in 2002 for the second consecutive year, following a decade-long decline of the disease. CDC also reported a high rate of co-infection of HIV among men diagnosed with syphilis.

The situation is much worse outside our borders. Worldwide, more than 42 million people are living with HIV/AIDS.

The vast majority of the grants that have raised the concerns of some Members are related to our efforts against HIV/AIDS and the at-risk populations we have targeted to prevent further spread of the disease. Understanding the risk factors posed by prostitution and illicit drug use, in addition to preventing initiation of sexual activity in teenagers, remain important to controlling the HIV/AIDS epidemic in the United States. Members have expressed concern that NIH seems to fund a number of similar scientific studies with the only difference being the ethnic origin or type of special population being studied. Unlike prevention or treatment interventions for diseases in which a single type of vaccine or medication can be applied to all patients, behavioral interventions have to take into account the cultural and social environment of the groups being studied. This is why we need to study all patients, including minorities, people living in different regions such as rural areas, people at different stages of life, and those of different gender identities. The context in which people live may be as important as the condition studied for scientific interventions to be discovered and effective.

Unfortunately, prostitution remains a major source of transmission of HIV/AIDS and is responsible for the spread of many diseases. Some Members have questioned the use of taxpayer dollars for the study of prostitutes. For example, some have questioned the value of studying this problem in relationship to trucker networks and their impact on disease transmission. I would like to share with you the analysis of that grant which our staff performed:

Grant Title: *Trucker Networks, Drug Use, and Disease Transmission*
Grant Number: *RO1HD042972-02*
Principal Investigator: *Yorghos Apostolopoulos*
Institution: *Emory University*

Description:

This project studies a potentially important mechanism for the spread of HIV/AIDS and other diseases in the United States. Scientists have shown that in sub-Saharan Africa, India, Southeast Asia, and other regions where HIV/AIDS is predominantly a heterosexual disease, long-distance truckers played a significant role in the spread of HIV/AIDS and other sexually transmitted and blood-borne diseases. This study examines the potential for a similar mechanism of disease transmission here in North America. There are more than 3.3 million U.S. and 300,000 Canadian long-haul truckers operating in the United States today. This research will produce estimates of the number of long-distance truckers currently infected with HIV/AIDS and other sexually transmitted and blood-borne diseases and will produce information about the situations and circumstances that are associated with long-distance truckers engaging in activities that put them--and tens of millions of others with whom they interact--at risk of being infected with HIV/AIDS and other diseases. Early results suggest that most HIV/AIDS transmission among long-distance truckers is primarily through heterosexual contact between truckers and women other than their wives and girlfriends during lengthy periods of time away from home, as well as through the use of intravenous drugs.

Public Health Impact:

The purpose of this grant is to produce scientific knowledge that can be used to reduce the number of people infected with HIV/AIDS and other sexually transmitted and blood-borne diseases every year in the United States. According to the CDC, as of 2001, 57,396 women in the United States have been infected with the HIV/AIDS virus through heterosexual contact. A significant share of these women is believed to have been infected by their husbands. Some of them pass on HIV/AIDS to their children; as of 2001, 8,284 children in the United States appear to have been infected in this way. This study will produce concrete, scientific findings that public health and law enforcement officials will be able to use to develop effective prevention programs to reduce the spread of HIV/AIDS and other diseases by long-distance truckers.

Research Questions:

- *What is the role of long-haul truckers in spreading sexually transmitted and blood-borne infections in the United States?*
- *What factors affect whether long-haul truckers are exposed to and expose others to sexually transmitted and blood-borne infections?*
- *What is the seroprevalence of HIV, Hepatitis B, Hepatitis C, syphilis, gonorrhea, and chlamydia among long-haul truckers and the people with whom they interact?*

This is just one example of the increasing vulnerability we know exists because of national and international sex trafficking in an interconnected world. Other grants in this category seek to

stop the spread of disease by developing effective interventions. In order to intervene, we must first understand how to prevent transmission by prostitutes of different ethnic and cultural backgrounds, and these people are hard to reach. We are certainly not promoting an illegal activity such as prostitution, as some have suggested, but we are trying to stop the devastation it can unleash on the spouse or child who becomes infected because of this activity. Indeed, this work could highlight the health risks associated with prostitution. Our goal is to help law enforcement and policy makers develop more effective approaches to reduce this risk. This is an important area of research in the best interest of the American taxpayers, given its potential costs--financial and human--to society if more effective methods are not deployed.

The consequences of sexual behavior involve more than just the transmission of infectious diseases. Some Members of Congress have also expressed concerns about a small number of studies of human sexuality and behavior unrelated to either STDs or HIV/AIDS sexual behavior. One example of an important public health issue addressed by these studies is teenage pregnancies, a problem that increases the risk of low-birth-weight babies by 50 percent, increases the risk of child abuse and neglect, increases school dropout rates, and even increases the risk of incarceration. Sexual crimes against adults and children, such as rape, incest and molestation, are also major public health concerns.

Sexual dysfunction, which affects tens of millions of American men and women and contributes to many societal problems including divorce, is another public health problem related to human sexuality. Over 43 percent of women and 31 percent of men experience sexual dysfunction each year. It is one of the least understood areas of human psychophysiology. It has an enormous impact on the stability of families and is a major cause of divorce. I share with you below our review of one of the grants some have questioned as unjustified:

Grant Title: *Conference on Reproductive Psychophysiology*
Grant Number: *1 R13 HD043068-01*
Principal Investigator: *Erick Janssen*
Institution: *University of Indiana*

Description:

This conference grant provided partial funding for a research meeting on sexual psychophysiology--the relationship between the physical and psychological factors underlying sexual functioning and behavior. The purpose of the conference was to review the research that has been conducted in this field, to review methods used in research on sexual psychophysiology, and to explore future research needs.

Public Health Impact:

Research on the physical and psychological factors underlying sexual functioning and behavior is relevant to the NIH mission to support research on healthy development. Sexual dysfunction affects 43 percent of women and 31 percent of men each year. In addition to harming marriages, it can signal the presence of disease and mental health problems. Problems of sexual dysfunction prompt many patients under treatment for hypertension and depression to

discontinue needed medications. Research on sexual function can help to identify treatments that, like Viagra, can improve the lives of millions of Americans. Research on the psychophysiology of sexual behavior also informs efforts to stem the spread of sexually transmitted infections such as HIV. Unhealthy decisions about sexual behavior result in part because decision-making capabilities can be compromised by the physiological effects of sexual arousal. Understanding these effects and their consequences for sexual abstinence will strengthen prevention efforts critical to our public health mission.

Research Question:

- *The objective of the conference was to review the research that has been conducted in the field of sexual psychophysiology, to review methods used in research on sexual psychophysiology, and to explore future research needs.*

NIH-supported research is attempting to understand all the mechanisms involved in risky or violent sexual behavior such as rape or sexual abuse of children. This research is aimed at understanding physiological as well as psychological mechanisms involved. Research supported by NIH and the private sector is having positive results: prevention programs have substantially reduced the spread of HIV; school and family-based programs designed to promote academic success and better family bonding have delayed sexual activity in teenagers and reduced risky sexual behavior. Researchers have identified similar brain reactions to both erotic cues and illicit drug use, pointing the way towards possible new approaches to reduce the rate of teenage pregnancies.

We also have been questioned about the wisdom of spending research dollars on one grant researching the sexual behavior of older men. As our population is aging, we need to understand the impact of these demographic trends. For example, CDC is now reporting an increasing incidence of STDs and HIV/AIDS in seniors. Our analysis of this research follows.

Grant Title: *Longitudinal Trends in the Sexual Behavior of Older Men*
Grant Number: *R03 HD39206*
Principal Investigator: *Andre Araujo [formerly C. Johannes]*
Institution: *New England Research Institute*

Description:

Although it is well known that men's sexual function declines with increasing age, the reasons for this decline are not well understood. Declining sexual function may be the result not only of physiological changes linked to age but also of potentially modifiable non-physiological changes. These include, for example, health behaviors, psychosocial factors such as anger and depression, social ties and marital status, and the use of medications. This project studied changes over time in a range of behavioral and cognitive factors associated with male sexual function and behavior. This study was a secondary analysis of data collected in the Massachusetts Male Aging Study (MMAS). It described and compared estimates of cross-sectional age trends in sexual behavior in two waves of the study and estimates of longitudinal changes in sexual behavior that occurred in this cohort of men as they aged. It sought to

determine to what extent the age-associated decline in sexual function results from age-associated changes in lifestyle, social status, social ties, psychosocial factors, etc., that may be amenable to modification.

Public Health Impact:

Healthy sexual function among men ages 40 and older has important implications for families. Nearly one out of ten new babies are born to fathers aged 40 and older, and these men are parenting well into their sixties. Sexual function and satisfaction are important for the continuity of marriages and the likelihood that children can experience stable two-parent families while they are growing up. Age-related changes in sexual function involve not only changes in cell tissue and endocrine function that occur at the oldest ages, they also involve biological, environmental and social factors that can occur at any age. Without a better understanding of age-related changes in men's sexual function, physicians may mistake the signs of disease for normal declines in function or they may miss modifiable factors that detract from sexual health. This research provides a cost-effective way of increasing knowledge relevant to an important aspect of healthy human development.

Research Question:

- *How do health and social status, medication use, lifestyle (e.g., smoking, exercise), psychological factors, and other modifiable factors influence cross-sectional and longitudinal age-trends in sexual function and behavior?*

We have far more to learn about human sexuality and its association to diseases and illnesses. Some of the research involves behavior that is criminal, such as prostitution and illicit drug use. Other research involves individual populations of people living in the United States who are particularly linked to the transmission of disease or illegal behaviors. Some of this research has unseemly titles because, frankly, the research involves looking at difficult, albeit real, components of the human condition.

THE REVIEW PROCESS AND QUALITY ASSURANCE

Research into human sexuality also undergoes the scrutiny of independent peer review and must adhere to all human subject protection requirements. The NIH peer review process includes a system of 170 chartered study sections and standing special emphasis panels. We have over 11,000 external experts participating in review panels, each of whom is nationally recognized for his or her area of expertise. These individual peer review groups, which examine each application for scientific and technical merit, are composed of 20 or more scientists. The members of each NIH study section are carefully chosen to represent a diversity of backgrounds, regions of the country, and scientific expertise. Membership on these review panels is not permanent; typically, members are appointed for four-year terms and consequently rotate off approximately every four years in an overlapping fashion. It is highly unlikely that such diverse and constantly changing groups would conspire to favor unduly one type of grant over another. Finally, before awards can be made, applications must be considered by an Institute's advisory

council, which by law is composed of at least one-third lay or community members. The process is highly competitive--less than a third of all applications are funded.

Prior to award of funding for any study that will involve participation by human research subjects, an Institutional Review Board (IRB) at the institution where the research is to be conducted and is covered by an assurance filed with the Office for Human Research Protections, Department of Health and Human Services, must review each grant application, research protocol, and Informed Consent document. These IRBs, which always include outside members representing the public, are charged with ensuring that the benefits of the proposed and ongoing research are weighed against the potential risks. Their review ensures that potential subjects will be provided with a comprehensible and accurate description of the risks and anticipated benefits of participating in the research and that appropriate safeguards are in place to protect the rights and welfare of human participants in research.

Also, please be aware that in research involving human subjects, federally funded researchers may compensate the subjects, not as an inducement but as a remuneration for their time for participation in research. This compensation is subject to the review and approval of local IRBs to ensure that a subject's decision to participate in research will be truly voluntary and that consent will be sought "only under circumstances that provide the prospective subject...sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence."

All of the grants associated with human sexuality underwent the standard peer review and IRB review process, without deviation. All of them are scientifically justified and received independent review scores in the fundable quality range. Each of them is connected to clear public health priorities.

In addition, most individual medical research does not lead directly to prevention or therapy. Most research results in findings that function as small pieces of a large puzzle that, combined, achieve the benefits the public desires. Sometimes it is difficult to understand the relevance of individual research until we see the entire picture.

RELATIVE PRIORITY

Behavioral research on human sexuality has led to enormous progress in understanding the behavioral causes of HIV and other sexually transmitted diseases that have caused death and suffering, destroyed entire generations across the world, and added enormous fiscal costs to America and the international community. Nearly everyone, regardless of his or her status in life, is vulnerable to the health risks associated with sexual behavior. NIH supports research into the causes and consequences of sexual behaviors due to the substantial burden on society of the related diseases and dysfunction that affect millions. Clearly, this has to be considered as one of our highest priorities in light of the enormous suffering and costs of illnesses associated with sexual behavior. Even so, the NIH investment in this area of research is only a very small part of our overall budget.