

Politics Invade Peer Review: NIH Behavioral Science Grants Under Attack

September 06, 2003

On July 10, 2003, the House of Representatives began debate on the Appropriations bill that would fund the National Institutes of Health for the fiscal year 2004. Rep. Pat Toomey, R-PA, introduced an amendment to halt funding for four NIH grants, two funded by the National Institute on Child Health and Human Development, one funded by the National Institute on Drug Abuse, and another funded by the National Institute of Mental Health.

Of the four grants targeted by the Toomey amendment, all are behavioral research, and three are related to risky sexual behavior. (Study abstracts available on Page 8.) The amendment was a direct assault on behavioral research. But the implications of this amendment go far beyond the grants in question, striking at the heart of NIH's extramural research enterprise, the peer review system.

The floor debate on the amendment was spirited, with the chair of the House Appropriations Committee, Bill Young, and the ranking Democrat, Rep. David Obey, WI, speaking against it. Also opposed to the amendment was Rep. Ralph Regula, R-OH, chairman of the subcommittee that oversees NIH appropriations. (See floor statements on Page 8.) Also speaking against the amendment was Rep. Brian Baird, D-WA, a clinical psychologist serving in Congress.

When the vote was finally taken, the amendment was defeated by only two votes, 212-210 with some in the Republican appropriations leadership crossing party lines to vote against the amendment.

As close as the vote was, it could have been even closer. Subsequent to the vote, Rep. Charles "Chip" Pickering, R-MS, stated for the record that he "erroneously voted against the amendment," and said, "I was under the impression the bill restricted general funding for the National Institutes of Health which provides needed funds for medical research in my district. I would have voted for the amendment and fully support the efforts to stop the NIH from funding the highly inappropriate programs itemized in the amendment."

After the amendment failed, Toomey engaged in a full court press on the issue, even appearing on MSNBC's "Hardball" where he was up against Rep. Barney Frank, D-MA. Toomey is rumored to be gearing up for a challenge to Sen. Arlen Specter, R-PA, in a primary next fall. Specter is the chairman of the committee that oversees NIH appropriations in the Senate and a long-time champion of increasing the NIH budget. There is speculation that Toomey is using this amendment to frame the issue as a political liability for Specter.

"I don't think these projects pass the common sense test," Toomey said. "They seem silly to me, to study the practices of Asian female prostitutes in San Francisco, or a study on the mental health of transgender and bisexual Native-Americans and those of two spirits, whatever that is. This kind of thing just doesn't make sense for our tax dollars."

Frank countered, saying “I can’t think of anything less good for scientific research in this country than for the United States House of Representatives to become the board that decides on projects one by one. Mental health is important. Sex is an important part of human activity. And studying mental health of people with regard to sex, yes, that’s a serious issue. Native-Americans are Americans. In fact, they were Americans before some of us were Americans, and I don’t see why it is necessarily wrong to study them. It’s also the case, when you’re talking about, for instance, prostitution. There’s a public health element here. Prostitutes often play a role in the transmission of disease, and I can see where public health authorities would decide that it was in their interests to, in fact, be studying them.”

As the *Observer* goes to press, the issue seems settled in the House, but there were rumors about a similar amendment in the Senate.

Research Abstracts Targeted in Amendment

The following are excerpted abstracts of four research grants targeted by the Toomey Amendment. Complete abstracts are available at www.crisp.cit.nih.gov.

Grant Number: 1R01HD043689-01A1

PI Name: JANSSEN, ERICK

Project Title: Mechanisms Influencing Sexual Risk- Taking

Sexual risk-taking contributes directly to high rates of sexually transmitted disease and the continued spread of HIV infection. Despite many years of research, the mechanisms that lead to risk-taking behavior are still poorly understood. Specifically, prior research has largely assumed that sexual decision-making depends on rational thought processes, and has not adequately addressed the role that emotional state plays in influencing behavior. This project will conduct systematic research on the mechanisms underlying the interrelationships among various types of positive or negative emotional state and sexual risk-taking. An additional objective of the research program involves the validation of a self-report measure that could be used to identify and target relevant populations in future prevention and intervention programs.

Grant Number: 5R03HD039206-02

PI Name: JOHANNES, CATHERINE B.

Project Title: Longitudinal Trends in the Sexual Behavior of Older Men

Sexuality has an enormous impact on the quality of life of aging men. Numerous studies have shown that the decline in sexual function and frequency of intercourse is strongly related to age, but that many men remain sexually active into their 80s and 90s. However, none of these studies provide unconfounded estimates of the normative decline in sexual behavior, especially with regard to behaviors (such as masturbation) that may be substituted for more rigorous activities. With the graying of the American population, these issues should become increasingly important. The proposed study will make use of the rich dataset of the longitudinal population-based Massachusetts Make Aging Study to examine trends over a 9-year period in a range of sexual behavior. As proposed, this research will provide the most comprehensive picture to date of the sexual behavior of aging men with respect to its trends over time, what factors contribute to these trends, and whether declines in sexual behavior are

associated with sexual dissatisfaction.

Grant Number: 5R01DA013896-02

PI Name: NEMOTO, TOORU

Project Title: HIV Risk Reduction Among Asian Women

The proposed study will describe drug use and HIV-related behaviors among Asian female commercial sex workers at massage parlors (Asian masseuses) in San Francisco. The study will also conduct an intervention and evaluate the efficacy of two intervention modalities: One which targets the environmental level (Massage Parlor Owner Education Program) and one which targets the individual level (Peer/Professional Counseling Program). Through this intervention study, the determinants of HIV-related risk and protective behaviors among the targeted Thai and Vietnamese masseuses will be identified. The objectives of the study are: 1) To describe drug use and HIV-related behaviors among Asian masseuses at massage parlors, where risk and urgent needs for interventions are evident but research has thus far been limited, 2) To examine the working conceptual model for the intervention, which is specific to masseuses' gender, culture, and occupation, 3) To develop and evaluate the intervention programs, in which the constructs of the conceptual model will be addressed at both individual and environmental levels to increase masseuses' protective behaviors against drug abuse, HIV/STD infection, and violence, and 4) To disseminate the study findings through local and national networks among AIDS service organizations (ASOs) and Asian American ethnic organizations and in professional journals.

Grant Number: 5R01MH065871-02

PI Name: WALTERS, KARINA L.

Project Title: Health Survey of Two-Spirited* Native Americans

American Indian and Alaskan Native lesbian, gay, bisexual, transgendered, and two-spirited individuals (two spirits) are a drastically understudied and underserved group, at risk for multiple health and mental health problems. There are no national, quantitative, representative studies of this population on any topic. We will test a theoretical model of stress and coping specific to this population. Sub-aims are to (a) establish preliminary prevalence rates of trauma and health outcomes (i.e., HIV sexual risk behaviors, alcohol and other drug use, and mental health indicators); (b) test the direct associations between trauma and health outcomes; (c) determine how cultural and spiritual coping factors moderate the effect of trauma on health outcomes; and (d) examine the mediating role of substance use on the trauma-HIV sexual risk behavior and trauma-mental health relationships. Through the course of this project, we aim to develop the research infrastructure at the six community agencies comprising our participant recruitment sites in order to facilitate future goals of designing and evaluating interventions to address the urgent needs of two spirits.

* The concept of "Two-spirited" relates to today's designation of gays, lesbians, bisexual and transgender persons of Native origins. Source: www.mcgill.ca/interaction/mission/twospirit.

The House, Divided

Following are excerpts from the debate on the amendment offered by Rep. Toomey. Though edited for length, the speakers are presented in the order in which they made their remarks, to preserve a sense of

the dynamics on the floor of the House. The full debate is available online at www.gpoaccess.gov/crecord.

If your legislator expressed the kind of reservations held by some of the speakers below, how would you answer? [Send us your thoughts](#), and we'll publish them in a future issue of the Observer.

The amendment is introduced.

Rep. Pat Toomey, R-PA:

I think we have all embraced the idea of significant increases in funding for NIH. I have, and I think that is a bipartisan agreement. And we are all proud that we have doubled funding for NIH over 5 years. But what this amendment is about is trying to find a little bit more hope for a few more families. My amendment does not cut a dime of funding for NIH. What it does do is it would require the NIH to reprogram the money that is going to a few grants which we think are just much less worthy of taxpayer funding than the kind of research the NIH is generally doing to cure these devastating diseases.

I want to mention four [research projects] that my amendment would specifically exclude and forbid further funding for. These are projects, grants that are under way now and have already been funded by the NIH in the past, and we would, with this amendment, shut off further funding for.

One of them is a study on the sexual habits of older men. A second is a study on San Francisco's Asian prostitutes and masseuses. A third one is a study on mood arousal and sexual risk-taking. And let me just share with my colleagues a highly sanitized and abbreviated summary of their grant application. If I actually read the whole thing, I suspect I would be admonished for the language I would be using on the House floor, so I will read just a little summary.

This is a proposal, which says: "In a series of laboratory studies, mood and sexual arousal will be induced and then their individual and combined effects on sexual risk-taking will be examined." Those are not my words. Those are the words of the applicant for the grants.

There is another study on American Indian transgender research. The proposal, which is based on the proposition that American Indian and Alaskan native lesbian, gay, bisexual, transgender, and two-spirited individuals are a drastically understudied and underserved group.

Mr. Chairman, I ask my colleagues, who thinks this stuff up? And, worse, who decides to actually fund these sorts of things? Well, unfortunately, the NIH has done so. These are the exceptions, and not the rule. This is not a general criticism of the NIH. But the point is these are not applications that are worthy of taxpayer funds.

Let me make the point that nobody here that I know of is saying we should ban this sort of research. If they want to do this sort of research, we need to fund this privately and not with taxpayer dollars. I simply want to make the point that there are so many far more important, very real diseases that are affecting real people; and that is what this kind of money could be used for, would be used for.

We leave it to the NIH to decide how to reprogram this. And as for those who suggest that we should not interfere with the process by which the NIH decides how to allocate their funds, let me strongly

disagree. We have an affirmative obligation in this Congress, as the body that controls the purse strings of the federal government, to supervise and provide oversight. And when a bureaucracy is making mistakes, we have an obligation to come here and correct that.

Ralph Regula, R-OH, Chair of the House Appropriations subcommittee responsible for the annual NIH budget (and second-most-senior majority member of the full Appropriations Committee):
Mr. Chairman, I rise in opposition to this amendment.

These projects have been picked out of a database that contains a single paragraph on each of 40,000 grants that NIH supports. Now, keep in mind that that represents a winnowing down from perhaps 120,000 applications. How do they pick the one out of three that will be funded? The NIH has an elaborate two-tiered peer review process that is mandated by the Public Health Service Act. Outside review panels of distinguished scientists from universities nationwide gather to review each application, which can easily run on to several hundred pages.

I think to pass judgment on these, you would have to read the several hundred pages to know what the ultimate goal is, rather than one paragraph. Then these recommendations are reviewed by advisory councils comprised of scientists and members of the public whose nominations are cleared through the Department.

NIH only funds about 30 percent, as I mentioned; and we can be confident that they are very careful because there are so many good objectives in the form of requests. They go through these very, very carefully with top-flight people to ensure that there is a worthy objective to be achieved in doing the research in question.

I strongly urge the Members to resist the temptation to select a few grants for defunding because they do not like the sound of them based on one paragraph out of what probably was a number of pages of information. It would set a dangerous precedent and put a chill on medical research if we start to micromanage individual NIH grants.

This has worked well over the years. We have had enormous progress because of these grants in achieving medical knowledge and giving the public a better health care system. I do not think this body wants to get into the process of reviewing 120,000 grants and trying to pick 40,000 out of that group for funding.

I strongly urge the Members to reject this amendment; and I urge my colleagues to take this issue to the proper committee, the Committee on Energy and Commerce, and if they feel that NIH needs to have its processes reformed, then that is the place to do it.

Rep. C.W. Bill Young, R-FL, Chair of the House Appropriations Committee:

Mr. Chairman, in the interest of time, I am not going to repeat some of the arguments. The gentleman has made a very persuasive argument, and I associate myself with those remarks. I just think that this would be a mischievous amendment and hope that we can defeat the amendment.

Rep. Chris Chocola, R-IN, author of a similar amendment:

I think this amendment is relatively simple. It lives up to our responsibility that we are really sent here to

do, and that is to be a good steward of taxpayer dollars.

Not only does the appropriations fund grants that the gentleman from Pennsylvania [Mr. Toomey] mentioned, it also funds a grant that studies human linkages with the panda reserve in China. Now, I do not think I am going out on a limb to say that no one in the Second Congressional District of Indiana is going to benefit from this study. I doubt I am taking too much of a risk to say no one in any congressional district in America is going to benefit from this study.

Mr. Chairman, I come from a business background, and I am a new Member of Congress; but when someone in our company wanted to spend money, we had to take the ultimate responsibility. And although the peer review process is probably pretty good, there comes a time when you have to say no, when you have to say this money is not spent in the best interest of the American people.

Since I do not know that we can identify people who benefit from this taxpayer money being spent on these grants, I do know, as the gentleman from Pennsylvania pointed out, the people in my district have juvenile diabetes, they have cancer, they have AIDS, they have horrible diseases like Crohn's, and that is what we should be spending NIH money on. We should be eradicating these horrible diseases that ruin families, ruin individual lives rather than grants that really benefit no one that we can identify.

I urge my colleagues to adopt this amendment.

Rep. Jeff Flake, R-AZ:

I have been concerned about this for a while. I sent a letter recently to NIH asking that they explain their decision to fund a study that is not covered here, it is another study, that paid women to watch pornography and to study arousal. The letter I received back was interesting. The NIH said, "The research methods used in the grant were scientifically established and met ethical research standards.

Now, I do not doubt that at all; but that is not the standard that we ought to employ here. The standard we ought to employ here is, is this a proper use of taxpayer funds, and I think on that level it surely fails.

I do not know how in the world, when we do not have enough money to fund things like the reaction of children to vaccines for childhood autism, that is one request that was actually denied because NIH came back and said we do not have sufficient money to do that, that is a serious disease affecting a lot of people. So we do not have enough money to do that; but then, in turn, we have enough money to fund a study to pay women to watch pornography. I think that is wrong.

The chairman noted there is peer review. Certainly there is. Again, the question we need to have answered is not whether this is scientifically based or reviewed, but is it proper for the taxpayers to fund. I would suggest that there is a lot of funding available out there from people like Larry Flint or others, but we should not be asking the American taxpayer to fund this kind of thing.

Rep. Randy "Duke" Cunningham, R-CA, a member of the Labor/HHS Appropriations Subcommittee: Mr. Chairman, I reluctantly stand opposed to this amendment. I understand why my colleagues want it. I do not think there is a thing in there I would support if asked to support. But I will say that I have hundreds of doctors and hospitals come to me every single day and ask me to direct NIH to do this or that. I personally believe that things and discoveries should be left up to NIH, that when something is

close to helping, we should allow them to do that.

In the past, many diseases were politicized, and funding was taken totally away from others, and I want to stay away from that. I think it is a bad precedent.

Rep. David Obey, D-WI, ranking Democrat on the House Appropriations Committee:

Mr. Chairman, years ago Senator Proxmire from my State used to have the Golden Fleece Awards. He was a good friend of mine. One year he made a whole lot of fun of a study on Polish pigs. They had a field day with it. Funny name, strange-sounding grant. Well, guess what? That study led to the development of a new blood pressure medicine which millions of people use today. The know-nothings in the Congress at that time would have eliminated that study. I do not think that would have been a good outcome.

I have served on the subcommittee that deals with NIH for a long time, and the one thing I came to understand very quickly is that the day that we politicize NIH research, the day we decide which grants are going to be approved on the basis of a 10-minute horseback debate in the House of Representatives with 434 of the 435 Members in this place who do not even know what the grant is, that is the day we will ruin science research in this country. We have no business making political judgments about those kinds of issues.

Now, I would say that I do not have any idea what these grants do. I can imagine, though, that perhaps this study on so-called sexual arousal is one way of trying to determine how you prevent child molestation or rape. I can also imagine with respect to the longitudinal study on sexual behavior of old men, NIH says this: "Without a better understanding of age-related changes in men's sexual functions, physicians may assume that declines in function are normal when they actually reflect early symptoms of disease such as diabetes and heart disease.

With respect to the study that relates to intervention for drug-using women sex workers, let us say you do not have any sympathy at all for the sex workers or their partners. I am concerned about the innocent partners of those partners. What about the wives of persons who go to these sex workers and then wind up getting disease? I think we ought to know as much as possible how to prevent transmission of disease, and what role drug use has in that process.

So without knowing anything about these, I return to my basic principle: We have NIH for a reason; we have peer review for a reason. I would rather trust the judgment of 10 doctors sitting around a table than I would 10 politicians sitting around a table when we decide how to allocate taxpayer money for those grants.

The reason NIH is there is so none of us bring our political biases to the table, and that is the way it ought to remain.

Rep. Brian Baird, D-WA, a clinical psychologist serving in the House:

Mr. Chairman, I want to dispute the comments of the gentleman from Indiana, and particularly the material he provided to his colleagues which said do not spend money for NIH panda research in China. In fact, the research has to do with population dynamics, the pressure on an ecosystem that supports the pandas, and the development of a population, including how those people can provide fuel and food for

their children. It is a study of human development.

There is a fundamental nexus between environmental quality, human health, and population pressures that impacts the world profoundly. The gentleman fails to recognize that and deceives his colleagues with the title of his amendment.

Rep. Rogers R-MI, a member of the Energy and Commerce Committee's Health Subcommittee, which oversees NIH programs:

Research on pandas sounds a little funny on its face, but when we look at it, and I can say it no better than a representative from Michigan State University, [who said:] "Perhaps at no other time in human history have the issues been so crucial as pandemics whose roots are found in animals spread across the globe: SARS, AIDS and monkeypox, to name a few. Dr. Lou's work is exactly the research needed to understand and plan for tomorrow's health issues."

They are getting into understanding and study of how some of these diseases get transferred from animals to humans. I would argue that is very, very important work, and we ought to invest in it.

Rep. Regula:

I urge my colleagues to vote against this amendment. We cannot start second-guessing and trying to review the work of NIH. They have very distinguished panelists, experts and scientists. They spend a lot of time on these. They have 120,000 applications. They do the best job they can, and they have been successful. I would urge my colleagues to go to the authorizing committee if they feel there should be some different procedures and bring that to their attention as they review these panel activities.

The Toomey amendment to discontinue funding for four NIH grants was defeated by a vote of 212-210.