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United States Senate

Senator Tom Coburn, MD
Russell Senate Office Building, Room 172
Washington, DC 20510-3604
Phone: 202-224-5754
Fax: 202-224-6008

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

COMMITTEE ON THE JUDICIARY

RANKING MEMBER
SUBCOMMITTEE ON HUMAN RIGHTS AND THE LAW

Putting Aside Politics When it Comes to Patients' Lives

October 30, 2007

Dear Colleague:

As a two-time cancer survivor and a practicing physician for two decades, I share your goal of improving health care in America and finding cures and treatments for those afflictions that can devastate the lives of many of us, our family, friends, and neighbors.

We have the power to win the war against many diseases in our lifetimes. We owe it to the nation, and indeed to the world, to do it right. Along with the President, Congress should determine overall spending levels for the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC), but should rely upon the scientific experts at NIH and CDC to evaluate scientific potential and set research agendas, based on sound science and the priorities necessary for our nation's health and biosecurity. Clearly, Congress has a duty and responsibility to ensure federal funds allocated for medical research are being properly and ethically spent, but in most cases Congress should defer scientific judgment to scientists and the peer-review process.

Congress has made significant investments in health care spending and medical research over the past decade including doubling the NIH's budget. Congress has appropriated more than $28 billion for the NIH this year and over $9 billion for the Centers for Disease Control and Prevention (CDC). These agencies play crucial roles in the fight against cancer, heart disease, Alzheimer's disease, tuberculosis, HIV/AIDS, and other diseases and medical conditions.

Congress has an important role in the war on disease. We must hold the agencies' feet to the fire and ensure they are meeting their mission of reducing the morbidity and mortality rates for the diseases that kill Americans and others. The American people who struggle against disease, however, do not want Congress micromanaging scientific priorities and promise, including mandating exactly how much NIH or CDC spend on a particular disease, body part, or research project. They want us to hold the agencies accountable for misspending dollars or failing to meet their mission. Disease-specific earmarking politicizes science and undermines the medical expertise, experience, and judgment of the scientists at those agencies in which we are investing so much, and the patient and provider communities they work with and on whom they rely. It is precisely this principle that has resulted in the longstanding, bipartisan tradition that Congress not earmark or micromanage NIH funding.

3310 MID-CONTINENT TOWER
401 SOUTH BOSTON
TULSA, OK 74103-4007
PHONE: 918-581-7651

100 NORTH BROADWAY
SUITE 1820
OKLAHOMA CITY, OK 73102
PHONE: 405-231-4941

711 SW D AVENUE
SUITE 202
LAWTON, OK 73501
PHONE: 580-357-9878

www.coburn.senate.gov

All of us want to see an end to disease and death. It breaks our hearts to hear the stories our constituents and patient advocacy groups can share with us. Passing a bill on a specific disease may seem like the easiest way to show we care, but is not the best or wisest way to advance medicine or improve the health of all Americans. This practice may, in fact, have unseen negative consequences on other promising programs or research.

NIH Directors that have served in both Democratic and Republican Administrations have asked, practically begged, Congress to stop disease-specific legislating. The scientific community, embodied in the peer-review system used at NIH and other private research institutions are much more likely than politicians (even doctors like me) to have a fuller understanding of not only the human and economic costs of a disease, but also of the scientific challenges and opportunities that exist both in specific areas and in broad biomedical research. Bounded by funding and guided by ethical parameters from Congress, the scientific community at the agencies and their provider and patient partners are best positioned to direct funding to those projects most likely to help those agencies achieve their missions of reducing disease and death.

Basic research, the foundation of most advances in disease-specific research, will inevitably suffer in a politically based system of allocating scarce dollars. The discovery of penicillin resulted in cures for countless diseases—syphilis, scarlet fever, gonorrhea, rheumatic fever, tonsillitis, diphtheria, and pneumonia. In this case, the basic science about Gram-positive bacteria led to effective cures for these diseases. Mandating a program for each disease would have diluted resources and slowed the way to finding cures.

A recent legislative effort would have required that $1.3 billion be spent on one specific disease. The entire NIH Institute primarily responsible for research on that disease has a total budget of $1 billion this year—which means, had the bill passed, that disease-specific bill would have eclipsed research funding for the numerous other diseases that particular Institute was responsible for addressing. When funds are siphoned away from promising research to fund initiatives that may be politically popular but perhaps not as scientifically promising, medical advances may be set back. What's more, each time a disease bill passes, the critical workforce at these agencies have to drop what they are doing and react to comply with the new law. Years of strategic planning, and programs in the middle of important work or on the cusp of breakthroughs, may get tossed aside, delayed or interrupted, while staff scurry around rearranging organizational charts, writing new reports and setting up a new commission to satisfy the directives of well-meaning politicians.

According to the newest International Classification of Diseases (ICD), there are 2,036 categories of diagnoses and 12,161 subcategories of diagnoses. It would be impossible and ridiculous for Congress to pass legislation on each and every disease. At least 82 bills were introduced last Congress about individual diseases. What makes the sufferers of those 82 diseases more important than the sufferers of the other 1,954? Is it because they were better organized or had lobbyists? Sometimes, the diseases that are more deadly get less attention and scientific progress for the perverse reason that they don't have any survivors to raise money or lobby Congress. How can politicians pick winners and losers with patients' lives? The answer is: we should not. These decisions should be made by medical experts and scientists, in close collaboration with the patient and provider communities, not by politicians.

Congress does have an important role to play. However, instead of continuing to legislate a patchwork of disease-specific mandates and earmarks, Congress must first examine how to improve and modernize all scientific agencies. Last year, Congress passed long-overdue legislation to modernize NIH. The Director is now responsible for planning strategically, balancing and coordinating the research portfolio, and allocating resources to ensure the greatest return on investment. Those who suffer from diseases also will now know exactly what is being done to alleviate their ailments with every NIH dollar tracked through an electronic reporting system. The passage of the NIH Reform Act demonstrated that we can support research at the NIH without micromanaging science.

These principles don't just apply to biomedical research. They apply to public health programs as well. We can not allow politics to compromise public health or distract our already-overstretched public health workforce. Unlike the NIH, whose success is judged by hard-to-quantify "scientific breakthroughs," the Centers for Disease Control and Prevention (CDC), and other public health agencies can and must be held to quantifiable outcomes related to reduced morbidity and mortality. Rather than settling for passing bills that create new smart-sounding programs, glossy reports, and advisory councils, we can and must dive into the hard work of making sure CDC and other public health agencies are setting measurable targets in all disease areas, and achieving those goals. When they don't, we need to know why and help them make the reforms or funding shifts necessary. I hope my colleagues will join me in beginning the time-consuming, but necessary process of modernizing the CDC. In order to protect the health of the greatest number of people rather than the few with the best lobbyists or most famous spokesperson, Congress has a responsibility to hold the agencies accountable for misspending dollars or failing to meet their mission.

Both the NIH and CDC have broad authorities to pioneer the latest medical research and aggressively protect the public health. Having just completed the reauthorization of the NIH, I hope we can next turn to a reauthorization of the CDC. I look forward to participating in disease-specific hearings and oversight to ensure agencies are staying on mission. I believe that new disease-specific mandates should only be a last resort after oversight, hearings, and investigations have indicated a gross failure in investment on the part of the federal agency.

With that context, I want to be clear that I will not provide my consent to any request for unanimous Senate passage of new disease-specific legislation that:

- Duplicates existing federal efforts;
- Does not contain accountability, transparency, and performance standards;
- Creates a new federal program that duplicates another program(s);
- Does not sunset at a date certain so Congress can evaluate its impact before determining whether or not it should be continued;
- Restricts the ability of CDC or NIH to ethically respond to new and emerging disease threats;
- Interferes with the scientific peer-review process;
- Includes a disease- or body-part-specific research mandate or disease-specific new program;
- Is not the "last resort" after a series of oversight hearings, letters, and investigations have demonstrated a gross failure or inability on the part of a federal agency.

I believe that protecting our nation's health and securing new medical research deserves the full and careful consideration of the Senate. Congress has a responsibility to set ethical and financial parameters and to oversee the success of agencies at achieving their missions within those parameters. Federal agencies have the responsibility to implement the most effective research and public health programs. We cannot let politics and good intentions interfere with progress.

Sincerely,

Tom Coburn, M.D.
United States Senator