

RESEARCH COMPLIANCE

News and Analysis for Colleges, Universities and Teaching Hospitals

NIH 'Welcomes Back Its Own' With Collins, While Many Challenges Demand Attention

When Francis Collins stepped on to the stage at 10:30 a.m. at the Natcher Auditorium on his first day as the 16th director of the National Institutes of Health (NIH), he was greeted by thunderous applause and a standing ovation.

But minutes into his address to staff, that celebratory air gave way to one of almost fear as Collins pointedly laid out the challenges and threats to the "crown jewel" that is NIH — the primary one being maintaining funding at current levels boosted by stimulus money.

Collins, who joined NIH in 1993 and most recently was the director of its National Human Genome Research Institute, went on a media blitz in his first weeks on the job; after his staff address on day one, Aug. 17, he later held a press conference.

On Sept. 9, he held an "unprecedented" meeting at NIH for "constituents," including research organizations and patient groups, and two days later he spoke on National Public Radio's (NPR) "Science Friday" program, where he was by turns jovial, serious, and upbeat, declaring that he was insulted that the host called him a "Washington bureaucrat."

But as disparate as his audiences were, his comments were similar, and he addressed a number of the same topics. Like other directors before him, Collins is expected to leave his mark on NIH with some sort of signature programs, like the Roadmap and funding programs for young investigators that his immediate predecessor, Elias Zerhouni, launched.

In this regard, at the NIH meetings and the press conference, Collins described five "themes" that he had

for the agency. Admitting that he had just come on the job, Collins said these themes were a focus on global health initiatives, translational science and research, "taking advantage of advances in high-throughput technologies to understand the fundamentals of biology and how specific diseases are activated," and supporting health reform through data sharing on costs and effectiveness.

'Reinvigoration' of Research Pledged

The research community will find his fifth theme most relevant: "The need to reinvigorate and empower the biomedical research community through stable and predictable funding increases, through high-quality training programs, for particular focus on encouraging young scientists, making sure our peer review system is rewarding risky and innovative approaches, emphasizing the diversity of the workforce, and using the NIH Common Fund creatively."

He also promised that he would not favor one institute or center over another in his decisions.

Collins pointed out that the average age at which a scientist receives his or her first NIH grant has crept up to 42, an issue he said NIH needs to address. He also said that currently NIH only funds about 20% of applications it receives. "That is clearly not a healthy circumstance," with a "healthy" rate being more on the lines of 30%, he said on NPR.

Noting the connection between consistent funding and support of researchers who are "in a fragile state," Collins said concern over NIH finances keeps him from sleeping and will require a concerted effort to convince Congress that NIH is worth the increased investment.

"This is probably the one that I worry about the most; the one that wakes me up in the middle of the night is what is going to happen to the resource support of this amazing organization when the stimulus money runs out," he said. "[T]his is going to be a tough, tough issue [on which] to try to seek a good outcome. We'll have to make the case for NIH in multiple ways. We'll have to continue to make the case that research fund-

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ing is good for the economy, because I don't think the economy is about to get better tomorrow."

Under the American Recovery and Reinvestment Act (ARRA), NIH received a two-year funding infusion of \$10 billion; its 2009 funding before this was \$30 billion and advocates are pushing for \$40 billion for fiscal year 2011. "The estimates are that success rates might fall to historic lows if we are not able to keep some momentum going after this two-year boost, this wonderful boost of ARRA funding," Collins said.

He noted even the \$200 million that NIH set aside in ARRA funds for "Challenge grants" had proven woefully insufficient: "When all the dust settles, we are able to fund 3% of the 20,000 grant applications received." He said that cancer and autism were two diseases that, because research had already progressed, were worthy recipients of a great deal of ARRA funds; he did not provide any specifics.

Ready to Get Started

Some have complained that because NIH had an acting director for so many months, NIH lost ground in advocating for itself. Collins, who assisted President Obama during the transition, was more than eager to get started in his new job. He described the vetting process as "beyond belief" and said, "I thought I had a boring life but apparently no life is boring enough for the FBI."

Collins also made a number of interesting comments on a variety of topics:

◆ *On how he's been spending his first month:* "Much of what I have done in my first three-and-a-half weeks of being here is to review hundreds of summary statements of some of these [ARRA] awards to see what's there, and I must say, there's very exciting stuff, and we are doing everything we can to be sure that part gets funded. But this is a constant struggle."

◆ *On his well-known religious beliefs:* "[I'd really like to reassure people that I don't think there is need here to worry that somehow the new director of the NIH has a religious agenda; I do not. I do think that we as human beings have the opportunity to, when we are stepping out of the details of daily life, to think about the big questions, and I do think it's a mistake for science to imagine that it is the only way to try and answer some of those really large questions like why am I here anyway, what's life all about, and does God exist. But those are not scientific questions. As the director of the NIH, it seems to me to be utterly inappropriate for me to spend my time exploring those or expend government resources in the scientific community addressing those kinds of issues."

◆ *On increasing opportunities for academic researchers:* "Here again, we've arrived at a juncture in the last

three-to-four years of being much more empowered to be able to take the fundamental information that's being learned about ... diseases and move that into the development of new treatments. And we can do that now, I think, increasingly, with partnerships between academic investigators who are now better empowered to get involved in therapeutic development than ever and, working with the private sector, tackle a long list of rare diseases and neglected diseases of the

NIH Announces Site for hESC Requests, Names Review Panel

The National Institutes of Health began accepting requests for human embryonic stem cell (hESC) lines to be approved for use in NIH-funded research on Sept. 21, the same day it named the members of a committee that will review the submissions for compliance with the agency's new policy (*RRC 7/09, p. 1*). Submissions may be sent to <http://stemcells.nih.gov>.

The chair of the Working Group for Human Embryonic Stem Cell Eligibility Review is Jeffrey R. Botkin, professor of pediatrics, Department of Pediatrics, and adjunct professor of medicine, Department of Internal Medicine-Division of Medical Ethics, at the University of Utah School of Medicine; he is also associate vice president for research integrity at the University of Utah and a former member of the Secretary's Advisory Committee on Human Research Protections.

As described in NIH's stem cell guidelines, "the Working Group will consider two other categories of hESCs and make recommendations to the ACD [Advisory Committee to the Director] regarding their eligibility for use in NIH-funded research."

"After considering the analysis done by the Working Group, the ACD will make recommendations to the NIH Director regarding the eligibility of particular hESCs for use in NIH-funded research. The NIH Director will make the final decisions regarding the eligibility of the hESCs and list those deemed eligible on the NIH Human Embryonic Stem Cell Registry. Once an hESC line is listed on the Registry, there is no need for further submissions requesting review of that particular line," NIH said.

Link: www.nih.gov/news/health/sep2009/od-21.htm.

developing world and increasingly moving those into the common diseases as well.”

◆ *On whether NIH would allocate resources based on disease burden, such as Alzheimer’s, Parkinson’s, and stroke that occur during aging:* “If you talk simply about burden of disease, then rare diseases would be neglected so that can’t be the right answer. But it must be in there somewhere in terms of the number of people affected and the severity of the illness. ... [W]e do have a variety of criteria that are constantly evolving, and this is maybe one of the topics that gets discussed most often amongst institute directors when we gather at retreats around Thursday mornings to figure out where NIH is going.”

◆ *On new arrangements with drug companies for treatment of “orphan diseases” and other treatments initially developed with NIH funding:* “Now out of the other end of [an NIH project, Therapeutics for Rare and Neglected Diseases] should come a successful

project, an attractive compound in which one would hope that at that point would be of interest to a biotech or a pharmaceutical company to want to license. ... An arrangement where the compound is licensed, the company then takes it through clinical trials and FDA approval, but the license involves a royalty that would then return to the government to support research if in fact the product makes some money.”

Collins also signaled his support for making research findings available on an open access basis and pledged openness and transparency as hallmarks for his tenure. Lastly, he encouraged feedback; comments may be sent to NIH-LISTENS@nih.gov.

Link to NIH employee videocast: <http://videocast.nih.gov/Summary.asp?File=15247>. **Link to constituent videocast:** <http://videocast.nih.gov/Summary.asp?File=15263>. **Link to NPR “Science Friday”:** <http://tinyurl.com/lcj3kk>. ✧