NEWS

NIH soon to be leaderless

Plaudits for departing director Elias Zerhouni may be echoing through the US National Institutes of Health (NIH) in Bethesda, Maryland — but underlying them is uncertainty about who will take over, and when. The White House has not yet named an acting director.

After six and a half years at the helm of the NIH, the world's largest biomedical research agency, Zerhouni announced last week that he will leave by the end of October. With this announcement, he sidestepped any notion that his decision is linked to the outcome of the 4 November presidential election. But it ushers in a transition period that will stretch for at least several months. The next US president will not take office until 20 January 2009, and high-level presidential nominations like that of NIH director can be achingly slow to make.

"We are all worried about what is going to happen in the interim and who the next director of NIH will be," says Story Landis, director of the National Institute of Neurological Disorders and Stroke, one of the NIH's 27 institutes and centres.

Zerhouni leaves as the $29-billion agency faces great financial stress. Its budget doubled between 1998 and 2003, but since then its purchasing power has eroded by 10% as slight budget increases have failed to keep up with biomedical inflation. Many say that Zerhouni's work in the face of nearly flat funding has, of necessity, been the defining feature of his directorship (see 'Difficult times to make an impact').

Anthony Fauci, the long-time director of the National Institute of Allergy and Infectious Diseases, remembers advising the newly appointed Zerhouni: "Elias, what happens to you is going to rely very heavily on circumstances that are totally beyond your control." The two men still joke about it.

Elias Zerhouni: leaving this month.

R. L. WOLLENBERG/NEWSCOM

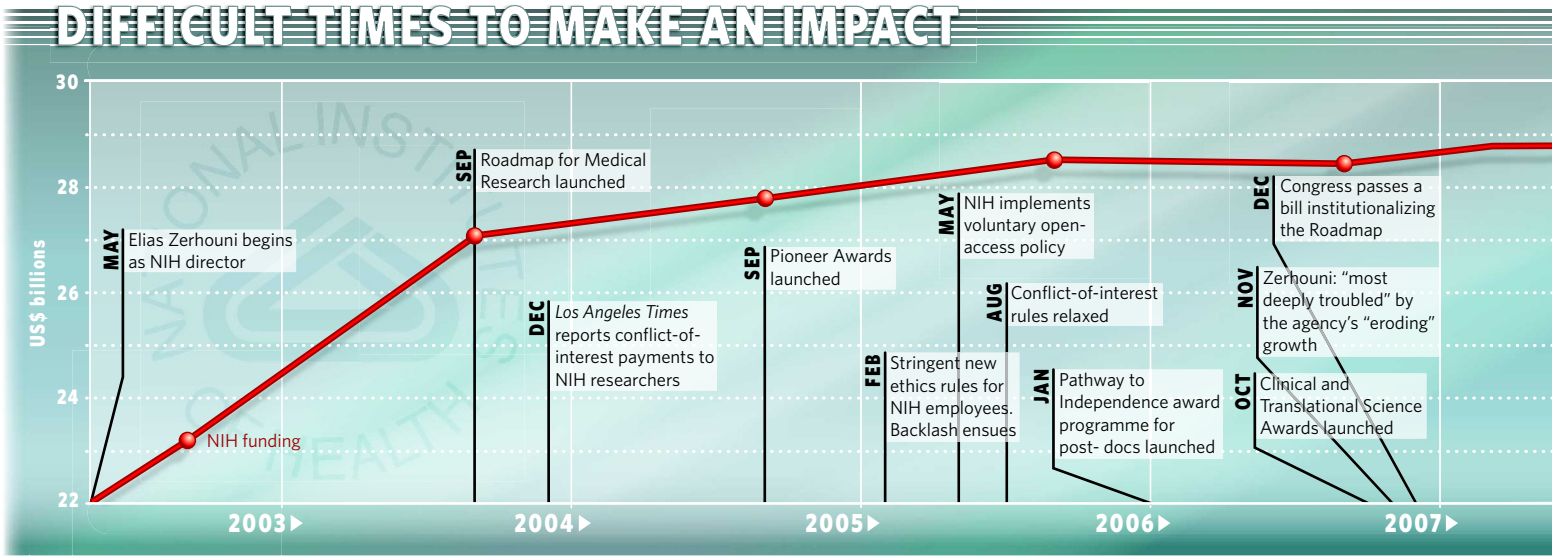
Zerhouni had faced challenges before. As the fifth of seven sons of a homemaker and a maths and physics teacher, he arrived in the United States from his native Algeria at the age of 24 with $369 in his pocket. By the time he was recruited to the NIH in 2002, he was one of the top experts in magnetic resonance imaging (MRI), and, among other things, had pioneered magnetic tagging — an MRI method that can be used to track heart motions in three dimensions. He had also risen to become executive vice-dean and chair of radiology at the Johns Hopkins School of Medicine in Baltimore, Maryland.

But it was soon apparent that the NIH gig wouldn't be a cake walk. "He comes into NIH and almost as soon as he gets there the good old days are over," says Howard Garrison, public-affairs director at the Federation of American Societies for Experimental Biology (FASEB) in Bethesda. As the agency's budget stagnated, success rates for grant applicants — especially first-time grant-seekers — plummeted. Zerhouni responded in 2006 with the 'Pathway to Independence' awards for young scientists, and managed to bring the number of first-time awards back up to 1,600 last year after it had dropped below 1,400 in 2006.

One early and much-criticized initiative was his 'Roadmap for Medical Research', a series of measures promoting trans-institute, high-risk, innovative research. As the budget for this grew from $132 million in 2004 (0.47% of the total NIH budget) to $495 million (1.7% of the total NIH budget) in 2008, it was perceived by some as too costly during a time of scarcity. In April 2006, Andrew Marks, then editor-in-chief of the *Journal of Clinical Investigation*, penned an angry editorial that began by telling Zerhouni: "Obviously you are not a scientist."

To this day, Zerhouni remains unfazed by criticism of the Roadmap. "I needed to do something to recognize that the boundaries of science have changed," he says.

Zerhouni also battled a conflict-of-interest



scandal at the agency, after Congressional examiners uncovered lucrative payments to moonlighting intramural NIH researchers by drug companies with financial stakes in agency recommendations or research. Zerhouni implemented tough new ethics rules for staff scientists — which he softened only a little after an outcry on the Bethesda campus.

"He's had to manage great expectations and stagnant resources," says Tony Mazzaschi, senior director of scientific affairs at the Association of American Medical Colleges in Washington DC. "And in that environment, he was able to add power to the director's role. That's not any mean feat."

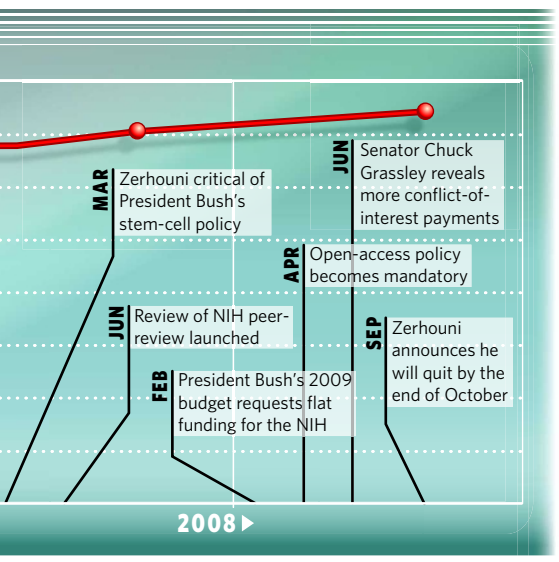
The question is who will come next. Washington is rife with speculation, most of which will turn out to be wrong. "When Elias became director, his name was nowhere on anybody's radar screen," says Fauci. Fauci's own name is inevitably floated whenever the NIH directorship is vacant. And any shortlist could include a stable of current and former institute heads, from heart institute chief Elizabeth Nabel to Francis Collins, who recently departed as director of the genome institute.

One other top medical spot in the Washington area got filled this week. Robert Tjian, a biochemist at the University of California, Berkeley, will take over the presidency of the Howard Hughes Medical Institute in Chevy Chase, Maryland, next spring from departing leader Tom Cech.

Zerhouni's expected choice of acting director in his wake, deputy director Raynard Kington, is said to be a finalist for the chancellorship of the State University of New York. Doubtless the wisest shortlist reads: to be announced. ■

Meredith Wadman

See Editorial, page 565.



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Hwang work granted patent

Australia is to grant a patent for Woo Suk Hwang's cloning method, even though the Korean scientist lied about using it to create human embryonic stem cells. But the patent is unlikely to prevent researchers from carrying out such work.

In 2004 and 2005, while at Seoul National University, South Korea, Hwang published a series of papers in which he claimed to have created a stem-cell line from a cloned embryo. An international patent describing his method was filed in 2004 by the university's patent office. The application was based on an embryonic-stem-cell line that Hwang's team had produced and deposited in an official stem-cell bank in accordance with the Budapest Treaty, which oversees the depositing of biological organisms for patent purposes.

In fact, the stem-cell line had been created not from a cloned embryo, but by a process called parthenogenesis, in which an egg develops into an embryo without being fertilized. Hwang was later charged with fraud, embezzlement and violation of the country's bioethics laws, he was sacked from the university and his high-profile papers were editorially retracted because of their fabricated data. Proceedings against him are ongoing.

In June 2006, six months after Hwang's work was discredited, the university's patent office made applications in eleven countries, most of which were refused. But the patent passed all the requirements of Australia's patent office, IP Australia: it was new, inventive, fully described and adequately defined.

IP Australia does not check for utility — that is, whether the patented procedure can actually produce what it claims. A representative there says there is no way they could test every claim that comes across their desks. Unlike most countries, the Australian patent office does not require authors to sign statements saying that their data are true.

IP Australia announced it was accepting the patent on 12 June, pending its standard 3-month period in which others can oppose it. No one opposed it.

Because of the extraordinary circumstances of this patent, it is now 'on hold'. IP Australia has another 3 months to grant the patent. During that period, the applicant could withdraw or amend it, or some "overriding right to refuse" could deny it. IP Australia is continuing to investigate the matter, but according to the representative, it is likely to be granted.

"There is no statutory basis to refuse to grant a patent on the basis that the scientific data in a patent application is a misrepresentation or fraudulently obtained," wrote David Johnson, acting commissioner of patents at IP Australia, in a statement last week.

But Australia should refuse the patent on other grounds, according to David Earp, chief patent lawyer at Geron, the California company that holds international rights — including Australia — to an earlier patent that covers the cloning technique used to produce Dolly. "Geron retains all rights for use of [the cloning procedure] in human application, including the creation of embryonic stem cells," he says.

"The broad claims of the recently accepted Hwang patent are not distinguishable from the [Dolly cloning] technology, and so the decision by the Australian patent office to grant them appears to have been in error," Earp says.

> "IP Australia is not endorsing the research that underpins the patent."

The patent is unlikely to be a powerful one. It would come into play only if the university's patent office tried to restrict a group in Australia from using the method. But such a group could challenge the patent in court on the grounds of utility, noting that the data were fraudulent and that the cell lines were derived from a parthenote, not a clone.

Johnson points out that even though misrepresentation cannot stop a patent from being granted, it "is grounds for revocation by the Court". He adds that "IP Australia is not endorsing the research that underpins the application".

The university's patent office has applications pending in the United States, Canada, India and China.

Only a few people around the world are currently experimenting with human embryonic cloning. "Until a thorough investigation into the patent and its claims has been completed we cannot make any conclusions about the impact it would have on our project," says Julia Schaft of the firm Sydney IVF, which last month became the first Australian group to receive a licence to attempt the technique. ■

David Cyranoski