Healy Gets Off to a Fast Start

The new NIH director launched two politically popular programs in her first few days on the job, but the specifics of her long-term plans for NIH remain unclear

WHEN BERNADINE P. HEALY WAS PICKED TO head the National Institutes of Health (NIH) late last year, the biomedical research community breathed a sigh of relief. The White House had left the job vacant for 18 months at a time when pressures on the agency were mounting and biomedical researchers across the country were complaining loudly that their discipline was in a fiscal crisis. Leadership, they cried, was essential. But the relief was tinged with uncertainty: Did Healy have what it takes to set the $8-billion-a-year agency back on course?

Ken Heinen

It's much too soon to answer that question. Healy has been in the job for only 2 months and, after all, institutions as big as NIH don't turn on a dime. Like ocean liners, they change course in a stately fashion, with a long lag between the turning of the wheel and the movement of the bow. Nonetheless, in her first week on the job, Healy made two quick headline-grabbing moves: a new women's health program and a $30-million grants program to tide over researchers whose proposals fell just below the cutoff line.

Those proposals were well received, and in an interview with *Science* Healy unveiled some ambitious goals, including restoring the NIH intramural program to its former status as "the flagship of biomedical research," improving minority health care research, and raising public awareness of the importance of the biomedical enterprise. But for the moment those goals are—at least for public consumption—mostly talk. Healy is operating in a politically sensitive environment, where speaking out of turn can have serious repercussions. The good news is that she knows Washington's ways (see box). As Thomas S. Edgington, immunologist at the Research Institute of Scripps Clinic in La Jolla and president of the Federation of American Societies for Experimental Biology, points out, "Her experience in the political sphere is unprecedented" for an NIH director. But political sensitivities won't change one fact: Her options are constrained by tight funds. In the end, she may be judged not by how radical and innovative her programs are, but how well she's able to keep the nation's biomedical research effort going at a time when increases in the budget are tapering off.

For now, Healy has started her course adjustments. In addition to launching the women's health initiative and the new grants program, Healy quickly injected herself into the Administration's efforts to develop new rules on indirect costs—something her predecessors shied away from—and fired long-time intramural deputy director J. Edward Rall, converting his office, formerly next to hers, into a conference room.

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Healy's fast start is winning plaudits. "I'm extremely impressed," says Anthony S. Fauci, director of the National Institute of Allergy and Infectious Diseases, who was himself approached by the White House for the top NIH job. "She's very proactive, very energetic." "She's going to make some mistakes, but what she does that's positive will far outshine any mistakes that she will make."

Fauci's warm words echo a broad sentiment in the biomedical research community. And Healy will need all the good will she can get in tackling NIH's problems. Grant applicants in the past couple of years have faced the most dismal prospects of getting funding than at any time in NIH's history, and the chances of getting a big budget boost next year are not good. The reason: The budget agreement reached last year between Congress and the Administration puts severe limits on domestic expenditure, which means that NIH is facing stiffer competition than usual for a limited pot of funds.

It's therefore no surprise that Healy considers one of her most important challenges to be convincing the public—and by extension Congress and the executive branch—that inadequate funding for biomedical research would have tragic consequences. "The real danger is that we are going to mourn biomedical research, biomedicine, biotechnology the way we are mourning the electronics industry and the car industry," she says. "I'm not talking this way because I believe in a social security system for scientists," she adds, meaning that she does not believe scientists are automatically entitled to government support.

But even if funding does pick up, Healy won't be able to escape some difficult decisions about the way NIH manages its budget. Congress last year asked NIH for a detailed plan of how it would keep its finances in order and prevent grant numbers from fluctuating so widely. The exercise was largely completed by the time Healy arrived (*Science,* 21 December 1990, p. 1652), and she says it is mainly "common-sense practices, like freezing the indirect cost rate over the life of the grant so you can budget it appropriately, limiting the growth of the grant to 4% per year, doing your negotiation up front and then leaving the grant alone

rather than downwardly negotiating every grant that is supported." But there's more to come: Healy says she is planning to take a strategic look at the total NIH portfolio—how the agency funds research, how it is managing its resources, and what kinds of research are being funded.

The first concrete example of the new areas Healy would like to see explored is the Healthy Woman initiative she unveiled on 15 April. Focusing on the problems of cancer, cardiovascular disease, and osteoporosis, the initiative will have three components: a large, prospective surveillance program, a community-based prevention and intervention study, and randomized clinical trials of new therapies and therapeutic combinations. A key feature of the initiative is that it would force institutes to contribute human resources and dollars to a joint project, something they have been loath to do in the past. Healy estimates the project could cost as much as $500 million over 10 years.

Choosing this as her first major program was a political master stroke. In one move, she pleased a growing faction in Congress anxious to see more research on women's health issues and at the same time, by focusing on older women, deflected attention from the more sensitive issues involving women still in their reproductive years.

Healy would also like to see the $925-million intramural program play a more central role in pursuing high-risk, cutting-edge research. The Bethesda campus has been gripped by a severe malaise: Researchers have complained about the political restrictions on their research (especially in sensitive areas like fertility and contraception), a tangled federal bureaucracy, a lack of direction for the institutes, and low salaries (*Science*, 1 February, p. 508). While Healy is sympathetic to some of these problems, she also feels intramural scientists have failed to appreciate the unique opportunities working at NIH provides. "I think some of the intramural scientists have been spending too much time focusing on why they should be like a university and not enough time focusing on how they are different from a university and how there are competitive advantages to being different from the university and maximizing the unique potential of the NIH intramural program." Healy says the intramural program allows scientists to bring huge resources to bear on high-risk research "without having to write a grant, without having to go through a big peer review system, without having pink sheets that tell you 'it was a great idea, but we don't think it can be done.' " Although Healy will not spell out specific plans or a budget target she has for the intramural program, she does say that she intends to find a way to offer more attractive salaries for PhD scientists working on the Bethesda campus. Healy says NIH already pays competitive salaries for M.D.s.

As for extramural scientists, Healy believes that the strategic planning exercise—with some reforms in the indirect cost reimbursement system—will help relieve their financial problems in the long term. For the short term, there are the new grants—known as Shannon grants—Healy announced during her first week in office. "The Shannon awards will hopefully provide a stabilization, so you won't suddenly go from a grant that brings in $250,000 to nothing," she says. In addition to spending $14 million from her discretionary fund, Healy has indicated that she will shift an additional $16 million from other NIH programs to fund the new awards.

Although the final details of how the Shannon grants will be selected have yet to be worked out, one aspect is already decided: They will have a low indirect cost rate—and that has aroused concern among university administrators. While the national average of indirect costs is about 51% of modified total direct costs, the Shannon grants would pay an indirect cost rate of only 20%. "That's the hidden kicker in the whole thing," says Samuel Thier, outgoing president of the Institute of Medicine. Thier says universities will be put in a difficult position if they accept the Shannon grants on behalf of their faculty. "What it says is, 'You guys say you need these full indirect costs, [but] if you'll take the 20%, what are

Political Savvy With Connections

From the very beginning of the search for a new director for the National Institutes of Health (NIH), Bernadine P. Healy's name kept appearing on various short lists. To people who know her, that wasn't surprising. Her supporters believe she has the drive, the vision, and the political savvy to revitalize the agency and reassure the scientific community that there is an effective advocate for biomedical research inside the Bush Administration. For now, everybody seems to have a good word for Healy, but if she begins to shake up NIH as she has promised (see main story) her honeymoon period may be short-lived.

Healy was reportedly stung by reports that she was not first choice to be NIH director. National Institute of Allergy and Infectious Diseases director Anthony Fauci and Washington University chancellor William Danforth were lobbied to take the job; both ultimately declined. But Institute of Medicine president Samuel Thier says all that is history. "Nobody asks 2 years down the road which choice you were. They ask what you've done," says Thier. "She's clearly savvy enough to know that."

This is Healy's second tour of duty in Washington. From February 1984 until November 1985 she served as deputy director of the White House Office of Science and Technology Policy, where she worked on life science and regulatory issues. She was executive secretary of the White House Science Council's Panel on the Health of Universities. She formed close ties with D. Allan Bromley, one of the panel's co-chairmen. Bromley, who is currently President Bush's science adviser was a champion of Healy's nomination to her present post.

In addition to her formal role in government, Healy has served on numerous executive and Congressional advisory committees, most recently chairing an advisory panel for a report by the Congressional Office of Technology Assessment (*Federally Funded Research: Decisions for a Decade*). She was also, until the time of her appointment as NIH director, vice chairman of the President's Council of Advisers on Science and Technology.

Healy was born in New York City, attended Vassar College, and received her medical degree from Harvard University in 1970. She trained as a cardiologist at Johns Hopkins Medical School and joined the Hopkins faculty in 1976. She has been the president of the American Federation of Clinical Research and the American Heart Association. Immediately prior to joining NIH Healy was chairman of the Research Institute of the Cleveland Clinic Foundation. On weekends she commutes between Washington and Cleveland to be with her husband, Cleveland Clinic vice president Floyd Loop, and children.

Healy has a reputation as a tough administrator who is used to getting her way. "People don't really fight with her and win," says John Shainoff, a biophysicist at the Cleveland Clinic Foundation. "I take a little bit of pride that I argued with her and I survived, but there aren't many who would want to argue with her, because I think it's obvious to everyone very soon that she's a winner." ■ **J.P.**

you really saying?' "

University administrators are worried that the 20% limit on Shannon grants may signal some broader intentions on Healy's part to try to force universities into more cost-sharing type of agreements. Not so, says Healy. "This is not full funding, this is a co-investment in this individual." But she does believe that the federal government must take a hard look at who is actually paying for the infrastructure associated with university research, particularly with regard to industry support, which frequently involves little of no indirect cost money.

The universities' concerns about Healy's attitudes toward indirect costs are heightened by the fact that she is trying to make herself a key player in sorting out overall Administration policy on the issue. She has been meeting regularly with Health and Human Services Inspector General Richard P. Kusserow and assistant secretary for management and budget Kevin E. Moley to discuss how the department might change the way it funds research. They proposed a cap of 28% on administrative costs plus charges for libraries and student services. The White House Office of Management and Budget ultimately decided on a 26% cap covering administrative costs only. Healy believes this is a good start, but more moves will be needed.

Others worry that even with the best intentions, moving NIH into the indirect cost arena may prove hazardous. "How much leadership and common sense can she inject into something which has got a lot of other players?" Thier asks rhetorically. "The potential cost of moving out ahead on something which you don't really control may be very high." Thier worries most that any money saved by cutting indirect cost expenditures would go into improving the federal government's balance sheet rather than back into research.

For the moment, Bernadine Healy is walking a bit of a tightrope: garnering goodwill and headlines with some quick, flashy proposals and keeping her broader program plans close to her vest. Whether she can always control consequences of what she starts, it is clear that "moving out ahead" is very much part of Healy's style. The NIH is emerging from a 2-year holding pattern and starting on a new course, and Healy is so far showing no signs of shirking her command. ■ JOSEPH PALCA

MRI—Safety Issues Stimulate Concern

Magnetic resonance imaging, or MRI, which has come into widespread use in medicine in the last 10 years, is of tremendous value to clinicians because it provides previously unseen anatomical detail in soft tissues—and in three dimensions. What's more, until recently it was thought that these dramatic results came without risk to patients. But there are now indications that the latest MRI machines may not be entirely hazard free: A year ago, two reports of peripheral nerve stimulation in volunteers undergoing MRI by a new ultrafast technique sparked some concern.

A recent meeting, perhaps the first to specifically address MRI's biological effects, brought together physicists, engineers, physicians, and physiologists to discuss how safe the fast MRI methods—which rely on time-varying magnetic fields and have been commercially available for only 4 months—really are.* The consensus at the meeting was that MRI is probably safe, but researchers were unable to offer precise magnetic field limits for the new techniques that would provide adequate safety margins. The Food and Drug Administration (FDA) may eventually come up with new regulations, but not until more clinical information is available.

MRI exposes patients to three types of electromagnetic radiation: static magnetic fields, pulsed radiofrequency (RF) electromagnetic fields, and gradient (time-varying) fields. In these fields, atoms resonate at characteristic frequencies, giving off radiofrequency signals. Since the precise frequency depends on the molecule's tissue environment, MRI scanners can convert the emitted RF signals into images that show different types of soft tissue.

Through the use of a gradient field that can be spatially encoded, the new ultrafast imagers can gather enormous amounts of data in milliseconds compared to 10 minutes or more with a conventional MR imager. But that's not the new method's only advantage. Because scan times are in the millisecond range, the resulting images are not blurred by the patient's body movement or heartbeat. Such speed reduces the patient's time in the magnet, which allows more efficient use of instruments and may reduce the incidence of claustrophobia.

Gradient fields, however, present problems not seen with static fields: They induce electric currents in the body and thus have the potential—at least in theory—to trigger unwanted electrical events such as cardiac arrhythmias. The peripheral nerve stimulation events reported so far, however, have been merely annoying. For example, at Massachusetts General Hospital (MGH), in studies using a high-speed scanner produced by Advanced ANMR Systems of Woburn, Massachusetts, three reports of mild "twitching or itching" appeared in some 15,000 applications, Michael Rohan of ANMR told the conference. Although researchers do not know whether these reports constituted actual stimulation events or experiences unrelated to MRI, studies in those three subjects were terminated. Said Mark S. Cohen of MGH: "Such incidents have created no special concern on our part."

But that doesn't rule out more serious effects of nerve stimulation, particularly in patients who are already medically compromised in some way; for example, a patient with heart disease or a seizure disorder. "There is some concern that certain types of cardiac pathologies may alter thresholds of nerve stimulation," said J. Patrick Reilly of the Johns Hopkins University Applied Physics Laboratory, who reported on theoretical models he has been developing to try to predict excitation thresholds of peripheral and cardiac tissues for patients undergoing MRI. But Reilly is nowhere near a definitive conclusion. "There is so much uncertainty here," he says.

In light of the uncertainties, some at the meeting expressed concern that the FDA might impose guidelines that could restrict development of the technology. But T. Whit Athey, of the electrophysics branch of the FDA, who was present at the meeting, said regulatory agencies would probably wait to revise guidelines until more clinical information had been gathered. Athey did raise the possibility, in the future, of a two-tier standard, with one limit for the unhealthiest patients and a higher limit for generally healthy people. For the moment, however, the main task seems to be to find out what effect these high-tech medical wonders actually have on living tissue. ■ LISA BAIN

*"Biological Effects and Safety Aspects of Nuclear Magnetic Resonance Imaging and Spectroscopy," sponsored by the New York Academy of Sciences, held in Bethesda, 15–17 May.

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