Bernadine Healy Bows Out

The controversial NIH director was told she would not be kept on, but FDA head David Kessler has been singled out as one of the few Bush appointees to be retained by Clinton

Three weeks into Bill Clinton's Administration, Bernadine Healy, the high-profile director of the National Institutes of Health (NIH), says she could no longer stand being in the dark about whether she would have a long-term place in the new regime. So on 10 February, Healy, who is known for her bluntness, went to her new boss, Health and Human Services (HHS) Secretary Donna Shalala, and asked about her future. Shalala apparently matched Healy in bluntness. "She let me know it wouldn't work out in the long term," says Healy. Two weeks later, on 26 February, Healy announced at a press conference that she would be stepping down.

In her 2 years as NIH chieftain, Healy (a cardiologist who was recently described in a TV profile as "Clint Eastwood in suits and high heels") managed to duel—and sometimes outduel—a lot of high-profile Washington gunslingers. Perhaps the most powerful of the lot was Congressman John Dingell (D–MI), whom she fought to a draw. By defending (publicly at least) the Bush Administration's ban on fetal tissue research, she managed to outrage a lot of women in Congress who might otherwise have been expected to be her allies. Though no one's saying so for attribution, in the end, the clout of her political enemies helped push Bernadine Healy out the door.

Healy's discomfort at being ousted can only have been increased by the fact that on the day she announced her departure, HHS announced that Food and Drug Administration (FDA) commissioner David Kessler, another Bush appointee, will be kept on by the Clinton Administration. Kessler, who has pumped up the FDA's enforcement arm and helped speed the approval of new medicines since taking over in December 1990, is credited with helping to restore morale at his agency. An attorney as well as a pediatrician, Kessler has fought to keep FDA free of political influences and has won the praise of researchers, industry, and patient advocates.

RICK KOZAK

A question of style. Healy's bluntness made her highly visible, but won her many enemies.

Healy has certainly made her mark on NIH. Since becoming director in March 1991, Healy has drafted a "strategic plan" to help direct biomedical research funded by NIH, which has a $10.3 billion annual budget. She also pushed through a $625 million Women's Health Initiative that will stage large clinical trials to study diseases specific to women, and she significantly expanded the Human Genome Project (see sidebar).

But Healy's accomplishments became clouded by politics. As with everything concerning appointments and dismissals in Washington, the real reasons for Healy's short, sharp drop are hidden beneath several layers of studied ignorance. When asked why she was being asked to leave, Healy said, "I don't really know." The official version from Shalala, a press release that commended Healy for being "a strong leader and a strong advocate for NIH programs," also failed to offer any reasons.

One layer down, however, Avis LaVelle, Shalala's press secretary designee, says Shalala decided to let Healy go after monitoring her performance for the past few weeks. That monitoring was hardly Shalala's first exposure to Healy; until taking over at HHS, Shalala had been a member of the NIH director's advisory committee. But, says LaVelle, "it's one thing to be on Dr. Healy's board. It's another thing to be Dr. Healy's boss." After observing Healy from that new vantage, says LaVelle, Shalala decided that "what was going on there was not at the caliber of what she desired at her division." LaVelle would not give specifics, but did say "it's more operational and a style thing."

One level below that comes the list of

Healy Highlights

Though Bernadine Healy has her share of detractors, no one can accuse the first woman to head the National Institutes of Health (NIH) of slacking off on the job. Here are some of the peaks and troughs of her 2 years at the helm:

- Women's Health Initiative: One of Healy's first moves was to back this $625 million project, which by the end of the year will have 16 centers around the country studying ways to prevent and treat stroke, breast cancer, heart disease, and osteoporosis in women.
- The Human Genome Project: Though Healy had a public row with Nobel laureate James Watson over NIH's decision to patent uncharacterized gene fragments and his personal investments in biotechnology companies—resulting in his resignation as head of the $1 billion-plus project to map the human genome—she has since expanded the project and hired a respected researcher, Francis Collins, as Watson's replacement.
- Fetal tissue: Healy waffled on the issue, toeing the Bush Administration line when necessary, fighting it when possible. In the end, it helped speed her demise.
- Representative John Dingell: The Democratic Congressman from Michigan locked horns with Healy early on when he accused her of meddling with the scientific integrity investigations of National Cancer Institute AIDS researcher Robert Gallo and Nobel laureate David Baltimore. Healy publicly told Dingell his charges were "preposterous."
- NIH Strategic Plan: Due out in the next few weeks, before Healy departs, this comprehensive review of NIH attempts to set the agency's agenda for the 21st century, emphasizing the importance of harvesting the fruits of basic research—preventions and treatments that can improve health.

–J.C.

political grudges against Healy. Shortly after taking office, she dueled with Dingell on scientific integrity issues. She tangled with Nobel laureate James Watson, a spat he claims effectively pushed him out of his job as head of NIH's Human Genome Project. She blasted Congress for earmarking money to the Department of Defense to fund research on breast cancer and one company's AIDS vaccine.

The final stroke for the Democratic women in Congress came in a clash over the Women's Health Initiative. Representative Patricia Schroeder (D–CO) was outraged by a 20 May 1992 letter Healy wrote to then HHS Secretary Louis Sullivan in which Healy recommended that Bush veto the NIH reauthorization bill because it contained "highly intrusive language" that "micromanages" some NIH research. She specifically noted that the women's health section was "unnecessary."

The Congressional Caucus on Women's Issues, which Schroeder and most other congresswomen belong to, felt that the letter was "a serious breach of trust," says Schroeder. "Healy is making it sound like she's the one who did the Women's Health Initiative," says Schroeder, who believes legislation is necessary to follow through on NIH's verbal commitment, "and she's the one who did it in." (Bush did veto the legislation, but his main objections had to do with fetal tissue research, also included in the bill.) Healy insists "scientific flaws" led her to oppose the legislation. "I'm a feminist," she says incredulously. "That's the amazing thing."

Schroeder actively lobbied Shalala to replace Healy, but Shalala didn't initially go along. "If anything, Dr. Shalala resisted that pressure," says LaVelle, adding that "if some people on Capitol Hill had their way, [Healy] would have been out that door one minute past noon on the day President Clinton was sworn in." But, when Shalala's own "monitoring" was added to the mix, Healy had to go.

Healy, who says she was "saddened" by the decision, said she will stay at NIH until as late as 30 June, to help provide an orderly transition. After that, she intends to return to her previous post as head of the Cleveland Clinic Foundation's Research Institute in Ohio. Shalala said in a statement that she "will be conferring with scientific leaders and the White House to establish a process for the selection of Dr. Healy's successor." As for Healy, she said at the press conference at which she announced her departure that NIH "claims a piece of my soul." Given the rambunctious nature of that soul, Healy's tenure surely will not be forgotten soon.

–Jon Cohen

BIOMEDICAL RESEARCH

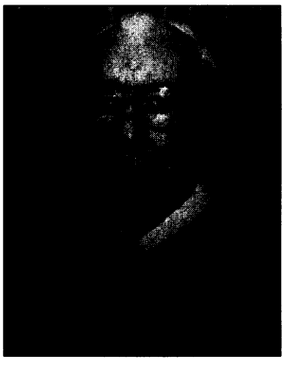
Animal Regulations Overturned

For the past few years, biomedical researchers have been complaining that the cost of research involving animals has been going through the roof. But if a decision last week by federal judge Charles Richey is upheld, it's going to get even worse. Ruling on a case brought by two animal rights groups, Richey threw out guidelines that had been drawn up by the U.S. Department of Agriculture (USDA) for dog and primate care at U.S. research laboratories and instructed USDA to come up with tougher regulations.

The ruling is expected to exacerbate a tense 2-year standoff between scientists and animal activists. During this time, USDA—the agency responsible for monitoring all U.S. animal experimentation—has been trying to implement a set of compromise guidelines drawn up in 1991 under pressure from the White House. The product of 6 years of negotiations, they represented a partial victory for scientists because USDA agreed not to prescribe detailed standards for animal care. But animal activists succeeded on one major point: The rules spelled out minimum cage dimensions and environmental conditions for primates. This forced many facilities to make expensive alterations. Douglas Bowden, director of the Regional Primate Research Center at the University of Washington, estimates that he has spent $400,000 converting cages since the 1991 rules appeared. Half that money, he says, was spent on enlarging cages by 2% to 10%.

But the rules' vagueness about other living conditions angered some animal activists. As a result, the Animal Legal Defense Fund and the Society for Animal Protective Legislation brought a federal suit in U.S. District Court in Washington, D.C. against the USDA. Charles Richey—the same judge who ruled last year that rats, birds, and mice used in the lab must be considered subject to the Animal Protection Act—heard the case and agreed with the activists. Congress, he found, intended the regulations to be more detailed than USDA's 1991 version, so USDA must try again.

For example, with regard to primates, Richey ruled that USDA should have made explicit provisions for group housing and spelled out the necessary conditions for achieving primates' "psychological well-being." His decision also attacked USDA for setting the minimum cage size smaller than the agency originally had proposed.



Too vague. Judge Richey wants more specific rules.

The decision, unless appealed, is likely to renew a disagreement about the form the regulations should take. Most scientists believe that USDA should continue to rely on "performance-based" guidelines, which require that animals be healthy and content, leaving it to individual veterinarians to decide how to care for their animals. But animal activists argue that only "engineering standards"—such as specific cage size or exercise duration—can prevent abuse. Currently, the rules require engineering standards only for primate cage dimensions and environmental conditions; the activists would like to extend them to the amount of dog exercise, the amount of primate socialization, and more. Decisions about such details, says Valerie Stanley, the lawyer who argued the case for the two activist groups, should not be left to the labs themselves, but should be made by "an entity that is not so concerned with fiscal constraints."

Predictably, scientists resent the suggestion that they cannot be trusted to treat their animals well. Researchers defend the "innovative housing" clause that now gives them some flexibility, saying that, far from being a loophole, it encourages institutions to design cages that best suit their animals. For example, says Nelson Garnett, acting director of animal welfare in the Office for Prevention of Research Risks (OPRR) at the National Institutes of Health, an innovative cage for an arboreal species might be twice as tall as a standard cage. Yet it might also have a slightly smaller floor area than the required minimum. Removing the exemption, Garnett and others say, would spawn uncreative housing tailored to meet only the minimum standards. "If that flexibility is taken away, the animal loses," says Thomas Wolfle, director of the Institute of Laboratory Animal Research.

USDA hasn't decided yet whether it will appeal. If it does not, it faces the difficult task of developing regulations both sides can live with. And if Judge Richey is involved, the outcome could be hard on research labs. Richey made clear in his ruling that he preferred the regulations USDA proposed in 1989, which called for bigger minimum cage size than the 1991 rules.

Increasing primate cage size or building group housing at large facilities, says John Miller, acting director of the OPRR, would "cost enormous amounts of money" at a time when most animals already receive good care.

–Traci Watson