

Donna Shalala and the Future of NIH

The new secretary of the Department of Health and Human Services says she has an activist agenda that scientists will like

Last week, Donna Shalala, the secretary of Health and Human Services (HHS), met for 90 minutes with editors and reporters for Science for a discussion of her priorities for research and her plans for the National Institutes of Health (NIH). It was her first extensive public discussion of these issues since taking office, and she ranged broadly over such topics as the funding prospects for NIH, how research fits into the Administration's plans for health care reform, and why she removed Bernadine Healy as NIH director. The only item she declined to discuss in specific terms was the appointment of Healy's successor, which had not been announced when the meeting took place.

The National Institutes of Health represents less than 2% of the budget of the sprawling Department of Health and Human Services. But HHS Secretary Donna Shalala says NIH is the component of her empire she knows best from her previous life as chancellor of the University of Wisconsin and from a stint on the NIH director's advisory committee. Shalala, a political scientist who jokes that "running HHS is easier than running a university because you don't have to worry about how the football team is doing," puts NIH among "the three or four top priorities in the department." And in an Administration carrying a banner of "change," that high profile is likely to send some fresh breezes blowing through biomedical research.

Shalala says she and her deputies are committed to providing NIH with sufficient resources, but she acknowledges that, given pressure to reduce the deficit, a major increase in the NIH budget is unlikely in the near term. The Administration's own budget request for NIH in fiscal year 1994, which begins on 1 October, in fact, would provide only a 3.2% increase, mostly targeted for research on priority areas such as AIDS and breast cancer. (Last week the House appropriations committee voted a 5.9% increase, spreading the additional money more evenly across institutes and reversing actual cuts proposed by Clinton for several institutes.) She predicts, however, that researchers "will be pleased with the '95

budget," which she says will include an investment in research on disease prevention as part of the health care reform package the Administration is putting together. And she says the package will contain "an adjustment" to protect clinical research at academic medical centers against new rules to contain costs.

Shalala's plans to "energize" HHS, as she puts it, have been delayed by the slow pace of appointments throughout the Clinton Administration. For example, the assistant secretary for health, Philip Lee, was nominated on 12 March but it wasn't until 16 June that the relevant Senate committee approved his nomination; at press time he was still awaiting final confirmation by the full Senate. Lee, who was assistant secretary for health and scientific affairs in the Johnson Administration, has been a professor of social medi-

replacement. Although UCSF virologist and Nobel Prize-winner Harold Varmus is widely expected to get the job, no announcement had been made on the eve of Healy's departure. Asked why she fired Healy, Shalala says she agrees with much that Healy tried to do, but, "My view was it was time for a change in the leadership at the National Institutes of Health. I wanted to take advantage of the opportunity of the change in administration to eliminate the old political baggage and perhaps get a new start for [NIH]."

In spite of the sluggish pace of appointments, Shalala speaks proudly of her efforts to attract talent to the department and to NIH, mentioning that as one of two yardsticks—the other being the budget—that biomedical researchers should use to judge her performance. And she says that one of her priorities is to help recruit top-notch sci-

entists by finding out what they want and trying to get it for them, citing as an example the hiring from the University of Michigan of Francis Collins, the new director of the National Center for Human Genome Research at NIH.

As for NIH's strategic plan, one of Healy's priorities during her tenure (see page 23), Shalala says its future lies in the hands of its next director. She says, however, that she would welcome any initiative from the new director on reorganizing both the intramural and extramural programs to account for changes in disciplinary boundaries. And she threw out a challenge to the new director: "Negotiate hard with us for some of the authority that will provide the flexibility to revitalize the national institutes." Indeed, the NIH director has so little independence from HHS that "no first-rate applicant ought to

take that job under its present bureaucratic arrangement," she says.

More broadly, Shalala says that she supports but "hasn't figured out" how to increase federal spending on university research facilities; in contrast, she says she "knows the solution" to improving the system of indirect costs, through which the government reimburses universities for the cost of sponsoring research, but that "political" obstacles block needed reform.



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cine at the University of California, San Francisco (UCSF) since 1969 and directs the Institute for Health Policy Studies at UCSF's medical school. His office oversees NIH.

Plans for NIH have also been delayed by a lengthy search for a successor to Bernadine Healy, who became NIH director in April 1991. In February, after Shalala told Healy that she would not be kept on, Healy announced that she would stay until 30 June to give the new Administration time to find a

Shalala says she likes and gets on well with scientists—this spring she called all 60 new members of the National Academy of Sciences to congratulate them, which “sort of startled them.” Here is Shalala, in her own words, on several issues affecting science (her remarks have been edited in some cases for brevity):

Priorities and prevention

I would describe us as energetic. We will have an agenda...[which includes] getting more resources for basic research. Remember, at the head of both HHS and assistant secretary for health you have people who have built laboratories and who understand the care and feeding of scientists and what kind of authority the leadership of science needs....The weakness is our relationship with Congress, not that they are not willing to put in money but that they also want to micromanage that money....

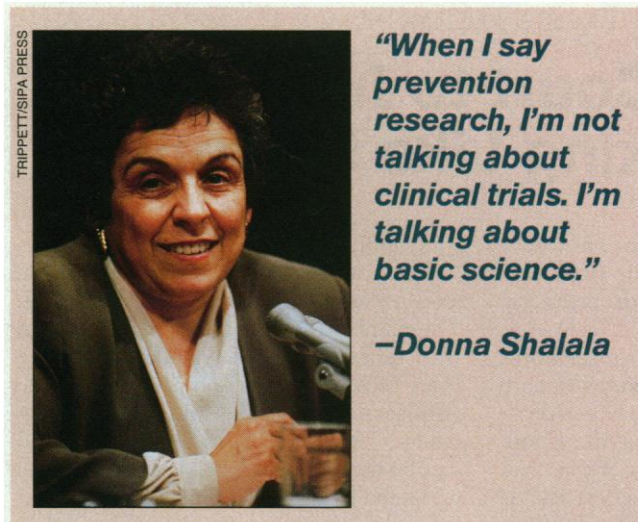
We will have a series of major initiatives, including health care reform, support for basic research, and an array of programs related to children that reflects our deep commitment to a clearer prevention strategy.

Now, when I say prevention research, I'm not talking about clinical trials. I'm talking about basic science.... If you ask the scientific community what they need, they will say that, if you really want to improve the health of Americans, then you have to make a strong investment in basic science. But I also think that we need to apply it. If we know that preschool immunizations make a difference, then we ought to be doing that stuff at the same time we are continuing to invest in basic science.

Research and health care reform

The last thing we should do is try to curb technology in our attempt to deal with costs or to slow down our investment in research. The cost thing cuts both ways, depending on what kind of technology. The issue is how you use technology, far more than whether we should keep producing technology. Rather than beating up on technology, we need to get scientists and administrators to think about the more appropriate use of it.

Phil Lee and I both have our tenure at major academic institutions with great medical centers, and if we're going to go home, we'd better have adjustments in the health care plan [to cover the cost of clinical research]. Whether we do it through an impacted aid program or through reimbursement rates, I haven't gotten into that other than to say to Phil, 'Watch it.' I didn't make him personally responsible for anything in health care except for the academic medical centers.... You only get one shot at these big-time initiatives, and we want to make sure that we include both public health and prevention, as well as a commitment to NIH.



Reforming NIH

We will take every opportunity to shove resources into NIH. But I want to take a look at whether we're spending too much on administration. If you've run great public institutions as Phil and I have, you know that you can run big-time science programs on much less money. I want to see if there is a way to put more money into science and less into administration. You know, I sound just like the scientists when I talk about the size of the bureaucracy in relationship to our investment in science.... When I talk about expanding NIH, I'm not necessarily talking about expanding the number of scientists at NIH, but making sure that we don't lose a generation of younger scientists and that we're funding the highest-quality grants....

There has been some deterioration [at NIH] in large part not because of the leaders of NIH but because of the leaders of the government. We've treated NIH like it's some bureaucratic agency. Bernadine Healy and I have had long conversations about these ridiculous bureaucratic personnel procedures that have her appointments going all the way up through the system [at HHS]. I mean, what in the heck does a bureaucrat in personnel know about the appointment of scientists? ...We need a reasonable delegation of authority to the assistant secretary of health and the director of NIH to allow them to run that enterprise with the kind of flexibility you need when you're dealing with a group of creative people....

We also need to think about how science is organized. The traditional arrangements don't reflect the way that discovery is taking place. And I will be very supportive of a new NIH director who wants to think about that type of thing.

A Manhattan Project against AIDS

I think it's ridiculous. It's the wrong word. I think that it's time for more focus, for more attention from the Administration. [But] the

Manhattan Project had the basic science done, and I like the concept of going to war and getting much more focused and raising the visibility of the effort. So don't misunderstand me—[the president] would have a heart attack if I suddenly say we're not going to do the Manhattan Project for AIDS. There is no question that we need...to make an even stronger commitment than we've made to date. And that's reflected in our budget priorities. But our ability to have an impact

depends on not having these scattered programs all over the place but really having a strategy for outreach, for research, and for clinical trials....

I'm holding off on selecting a director of the Office of AIDS Research [a post recently bolstered by Congress that will oversee and coordinate all AIDS research at NIH] until the NIH director comes on board. It's a critical appointment, but one that could create tension with the institute directors, and I want to make sure that the personalities and the politics fit together.

Scientific misconduct

When these issues first came up they weren't handled as they should have been because this is big-time serious. There was some self-inflicted damage there for science as well as for the great research universities and for the community in general.... It's a public policy issue of the highest order because in the end the only thing we have is our integrity....

Of all of the things I'm doing, [dealing with issues of scientific misconduct] may have the most impact on the future of science.

Centers for Disease Control

I hope to make an appointment [for the directorship of CDC] in the next 2 weeks. Recruiting good scientists takes some time so it will take us a little while to make the pitch and see if we can put a package together for someone.

We're beginning to shift things out of the assistant secretary for health's office into CDC and into other places. CDC will take the leadership role in immunization, for example, which I think everybody thinks is appropriate.

A Shalala report card

Forget what people are saying. Watch what we actually do. We have a vision of where we need to get to, and judge us by where we end up.

—Jeffrey Mervis