A Deadline for an AIDS Vaccine

After months of quiet debate among officials and researchers, President Clinton last week called for a vaccine within a decade. But many scientists are reacting with caution rather than euphoria

Researchers regularly woo politicians for funding, but they get nervous when those same politicians respond too amorously. They worry that political and scientific goals don't always make a happy marriage. That is why many senior scientists in the past few months have pushed for additional funding for AIDS vaccine research while arguing that the president should not set a public deadline for a vaccine. Instead, they got President Bill Clinton's 18 May clarion call for a vaccine within a decade—and no specific commitment of increased funding.

At a commencement speech at Morgan State University in Baltimore, Clinton proclaimed the vaccine "a new national goal for science in the age of biology," and compared it to President John Kennedy's challenge 36 years ago to land a man on the moon. Clinton pledged to create an AIDS vaccine research center at the National Institutes of Health (NIH) to spearhead the initiative, promised to enlist other countries in the endeavor, and challenged the U.S. pharmaceutical industry to make the vaccine "part of its basic mission." Leading AIDS vaccine researchers worry about the price that science might pay if it can't deliver. Yet, they also think the high profile Clinton has given their field—which has been struggling to come up with new approaches to the challenges facing it (see p. 1196)—may help them in future funding battles.

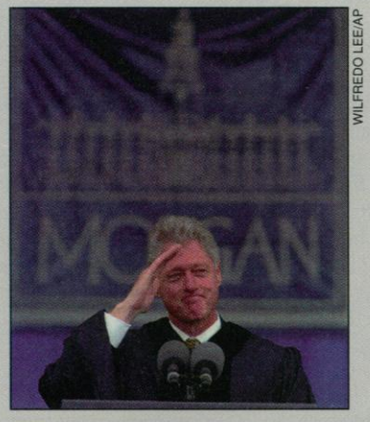
The vaccine push gathered strength at a 3 December meeting on AIDS research, in which Clinton, Vice President Al Gore, and then–Chief of Staff Leon Panetta gathered in the Oval Office with NIH director Harold Varmus; Anthony Fauci, head of the National Institute of Allergy and Infectious Diseases (NIAID); and Office of AIDS Research chief William Paul, among others. "One of the issues most strongly raised was the desperate need for a vaccine," Paul recalls. "There was a general recognition that this was really a goal worth pursuing."

During the spring, the Presidential Advisory Council on HIV/AIDS—a 33-member group made up of government, industry, aca-

Clinton Calls for 'Human Values' in Science

President Clinton's announcement of an AIDS vaccine initiative drew most of the attention in his commencement address last week at Morgan State University in Baltimore (see main text). But the speech as a whole presented a broad view of the promise of science and the dangers of misapplying it.

Speaking on 18 May, Clinton told graduates of the historically black university that "we must do nothing to stifle our basic quest for knowledge." But he added, "As we consider how to use the fruits of discovery, we must also never retreat from our basic human commitment to human values, the good of society, and our basic sense of right and wrong." Those issues, he said, are acute now because of the potential for abuse of new genetic technologies and cloning. Clinton's call for greater ethical sensitivity in applying research results irritated some scientists, however.



WILFREDO LEE/AP

Sensitive to science. Clinton at Morgan State commencement.

Administration officials say that the White House, motivated by the breakthroughs in biology, the new views of the universe coming from the Hubble Space Telescope, and the discovery of possible life on Mars, has long wanted to articulate a clear view of the pitfalls and promises of science. The president suggested the topic as one of the themes for his three commencement addresses, and Clinton's domestic-policy adviser Bruce Reed and John Podesta, deputy chief of staff, both strongly supported the idea, according to White House sources. The Office of Science and Technology Policy, led by Jack Gibbons, weighed in with a massive briefing book, and a large team of White House officials hashed out the details of the speech over the previous 2 weeks.

As examples of science gone wrong, Clinton cited the infamous Tuskegee syphilis experiments, in which African Americans with the disease were left untreated for decades, and Cold War research in the same era that subjected individuals to doses of radiation. "We must never go back to those awful days in modern disguise," said Clinton.

The leaps in biomedicine pose new risks, he said, calling for bipartisan legislation that would prevent insurance companies from using genetic data to deny coverage or set premium rates for some individuals. He also said, "We should resist the temptation to clone ourselves," although he stopped short of proposing legislation banning human cloning. "This is a decision no president should make alone. No president is qualified to understand all of the implications," Clinton added. A panel of bioethicists will offer their recommendations on cloning to the president in a few weeks (see p. 1185).

The gap between the research community and the public also was on the president's mind. "Science can serve the values and interests of all Americans, but only if all Americans are given a chance to participate." He cited past discrimination in academia, and called for the "voices and talents of everyone in this stadium—especially those of you who are going on to pursue a career in science and technology." And he cautioned against the hubris that can accompany the search for knowledge. "Science is not God," the president said, adding, "our deepest truths remain outside the realm of science."

Some of these admonitions irked Carl Feldbaum, president of the Biotechnology Industry Organization. He said the president "has gone too far if he means to imply that scientists ... aren't deeply concerned or actively involved in addressing the ethical and moral issues associated with their work." –A.L.

demic, and advocacy representatives—pondered possible next steps in HIV vaccine development as part of a broader examination of AIDS research. The council's nine-member research committee solicited opinion about AIDS vaccine R&D from a wide variety of researchers at an April panel discussion. While the researchers heartily agreed on the need for more financial support, they had little collective enthusiasm for some of the specific recommendations the council had floated.

A draft that was widely circulated prior to the meeting raised many eyebrows by recommending that the U.S. government spend $400 million on AIDS vaccine research and development each year—roughly three times the total now spent on the effort. It also called for steps that would force NIH to share more of the responsibility for AIDS vaccine R&D with the Centers for Disease Control and Prevention and other federal agencies.

But it was the draft's recommendation that Clinton set a national goal of developing an AIDS vaccine by a certain date that drew the most fire. "It's folly to give a date," Fauci told the council at the April meeting. Added Paul: "Promising a vaccine within a specific period of time, within a decade, is not a wise thing. ... It could lead to disappointment." But Yichen Lu of the Virus Research Institute in Cambridge, Massachusetts, disagreed. "We need a date ... to generate a sense of urgency," said Lu.

Lu's point of view won out in the council, which in April called for Clinton to "declare an urgent goal of developing a vaccine to prevent HIV/AIDS within a decade." The goal "is clearly feasible and should be considered of the highest priority for our government," the group stated. But the council rejected the proposal to triple vaccine funding, urging only "a significant and sustained increase in funds." And specific proposals for greater coordination among agencies and additional White House oversight were watered down.

The president accepted the council's advice, but he tempered his vaccine pledge by saying that "there are no guarantees. It will take energy and focus and demand great effort from our greatest minds." He added, however, that "with the strides of recent years, it is no longer a question of whether we can develop an AIDS vaccine; it is simply a question of when. And it cannot come a day too soon."

After Clinton's announcement, Fauci said that "most of us were uncomfortable with saying we'll have a vaccine by this date," but he added, "I don't have an inherent fundamental problem with a goal ... as long as it's made clear that this is not a guarantee." Paul echoes that: "I would have had trouble [if Clinton had said] 'We will have a vaccine in a decade.' "

The most immediate outcome of the announcement will be an AIDS vaccine center, which NIH will establish at Clinton's direction. The details of such a center are being hashed out now by the NIH AIDS Vaccine Research Committee led by Nobel Prize–winning virologist David Baltimore, which met on 9 May to discuss the project. It will start off as a "virtual center" jointly administered by NIAID and the National Cancer Institute (NCI), says Paul, before finding a physical home. Its major thrust, he says, will be to bring more immunology to the AIDS vaccine field, which has been dominated by virologists. The center also aims to attract vaccine developers from other fields. Paul adds that the center—formally called the NIAID/NCI AIDS Vaccine Center—may manufacture pilot lots of vaccines, a task now left to industry. That should help researchers test their ideas more quickly.

"The size is not fixed," he says. "In the early phase, it will be relatively small ... and obviously we will need to recruit senior people from outside." NIH officials will soon set up a search committee to select a director and other senior staff. Meanwhile, the Administration has requested up to $10 million for such a center in the 1998 budget, although it's not clear what its total cost would be. Money for the center, says Paul, will not come at the expense of extramural research funds.

There is little question that Clinton's initiative will create a more favorable environment in Congress and within the Administration for AIDS vaccine funding. "Think of what [the announcement] might mean next year when we're asking for money," says Fauci. "When the president of the United States starts putting that out, it can't hurt." So, while Clinton's embrace may be too close for comfort, researchers likely will cling to their newfound admirer.

–Andrew Lawler with Jon Cohen

Additional reporting by Eliot Marshall.

BIOETHICS

Panel Weighs a Law Against Cloning

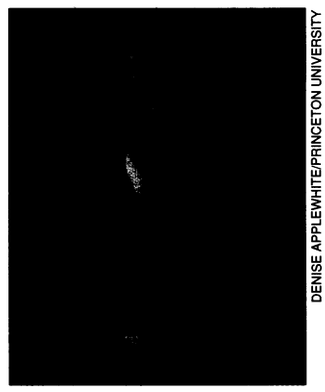
When a Scottish research team startled the world by revealing 3 months ago that it had cloned an adult sheep, President Clinton moved swiftly. Declaring that he was opposed to using this exotic animal husbandry technique to clone humans, he ordered that federal funds not be used for such an experiment—although no one had proposed to do so—and asked an independent panel of experts chaired by Princeton President Harold Shapiro to report back to the White House in 90 days with recommendations for a national policy on human cloning. That group—the National Bioethics Advisory Commission (NBAC)—has been working feverishly to put its wisdom on paper, and at a meeting on 17 May, members endorsed a near-final draft of their recommendations.

NBAC will ask that Clinton's 90-day ban on federal funds for human cloning be extended indefinitely, and possibly that it be made law. But NBAC members are planning to word the recommendation narrowly to avoid new restrictions on research that involves the cloning of human DNA or cells—routine in molecular biology. The panel has not yet reached agreement on a crucial question, however: whether to recommend legislation that would make it a crime for private funding to be used for human cloning.

In a draft preface to the recommendations, discussed at the 17 May meeting, Shapiro suggested that the panel had found a broad consensus that it would be "morally unacceptable to attempt to create a human child by adult nuclear cloning." Shapiro explained during the meeting that the moral qualms stem mainly from fears about the risk to the health of the child. The panel then informally accepted several general conclusions, although some details have not been settled.

NBAC plans to call for a continued moratorium on federal government funding for any attempt to clone somatic cell nuclei to create a child. Because current federal law already forbids the use of federal funds to create embryos for research or to knowingly endanger an embryo's life, NBAC will remain silent on embryo research.

NBAC members also indicated that they will appeal to privately funded researchers and clinics to refrain from trying to clone humans by somatic cell nuclear transfer. But they were divided on whether to go further by calling for a federal law that would impose a complete ban on human cloning. Shapiro and most members favored an appeal for such legislation, but in a phone interview, he said this issue was still "up in the air."



DENISE APPLEWHITE/PRINCETON UNIVERSITY

Moral stand. Commission chair Harold Shapiro.

Many NBAC members wanted to recommend that no regulations be adopted that would interfere with the cloning of animals, cells, or DNA. Others preferred a more muted approach, on