of galaxies toward unseen masses, suggested much larger amounts of dark matter—more than 10 times the amount of visible matter. If the universe as a whole contained that much dark matter, the dark matter would have to consist of exotic particles. The reason: Based on the mixture of elements in the universe, theorists calculate that the Big Bang could not have produced more than 10 times as much ordinary matter as is visible.

But there was still room to argue that the clusters and flows were exceptional—that dark matter was scarcer elsewhere in the universe. In that case nonluminous ordinary matter could be bulking up the large clusters and flows. Mushotzky thinks the new observation will be harder to explain away, however. His 1.3 million light-year-wide gas cloud reveals at least as much dark matter as the large clusters, and it lies in a small cluster of galaxies—a structure far more typical of the universe as a whole.

His colleague Burstein stumbled on the first hint of invisible matter when he was using a ground-based telescope to examine a pair of galaxies belonging to an ordinary small cluster. One of the two galaxies looked crushed, as if it was running into a wall of gas. A look with ROSAT, which picks up the x-rays emitted by hot gas, confirmed the suspicion by revealing the cloud. And the cloud, in turn, pointed to the presence of additional, invisible mass.

The cloud didn't seem to have been produced by a recent explosion, which meant that it was either stable or in the midst of a slow collapse. The couple of little galaxies by themselves didn't have nearly enough mass to hold such a cloud steady. Based on the size and temperature of the cloud, Mushotzky and his colleagues were able to calculate just how much extra, unseen matter had to be lurking.

But Harvard University x-ray astronomer Jonathan Grindlay, while impressed, sees some weak links in the argument. He's not convinced that Mushotzky and his colleagues have ruled out the possibility that the gas is still expanding after an explosion. And he adds that there's a slight risk that the cloud of gas is really a much smaller one associated with a more distant cluster of galaxies. Either way, the amount of dark matter would be much lower—with less need for exotic particles.

Theorist James Peebles of Princeton University also warns against jumping to conclusions about fancy forms of matter. "I don't see how the observation of one clump can tell you about the kind of matter in the whole universe," he says. Though the region looks representative, he says, there's no way to know without taking a wider sample.

But dark matter expert Anthony Tyson of AT&T Bell Laboratories thinks the evidence for exotic dark matter was strong even before the latest observation. "I like baryons myself," he says, but the weight of evidence has convinced him to accept something else. Nonbaryonic matter may seem far-fetched, adds Mushotzky, but it would be even stranger to find a swarm of stray planets or burned-out stars in the region of the gas cloud. "Where would they have come from?" he asks. "These other candidates are even more bizarre."

–Faye Flam

GENE THERAPY

Healy Approves an Unproven Treatment

Last week, National Institutes of Health (NIH) Director Bernadine Healy gave the go-ahead for a patient suffering from advanced brain cancer to be treated with an experimental gene therapy that has not yet been sanctioned by NIH's own review procedures. The decision immediately drew protests from members of the NIH advisory committee that is supposed to vet all gene therapy proposals. They complained that it makes a mockery of NIH's process for ensuring that such experiments are approved only on the basis of safety and good science. And they may have still more to complain about in the future, if—as Healy apparently intends—the case leads to guidelines that will permit similar compassionate exemptions from full review to be granted on a more regular basis.

The case involves a last-ditch effort to save a San Diego woman whose plight had been brought to Healy's attention by Senator Tom Harkin (D–IA). Last fall, Harkin, who chairs the Senate appropriations subcommittee that handles NIH's budget, asked Healy to allow exemptions to the NIH review process when the treatment might aid a dying patient. To launch a gene therapy trial, scientists normally must win approval from both NIH's Recombinant DNA Advisory Committee (RAC) and the Food and Drug Administration (FDA), a process that can take months. Harkin worried that this delay would preclude treatment, advocated by Ivor Royston, president of the San Diego Regional Cancer Center, for the 51-year-old California woman, who did not have months to live.

Healy initially wrote back to Harkin saying that "there have not...been enough studies on this proposed treatment to even begin consideration on a compassionate plea basis." Because nearly every patient treated with gene therapy so far is dying and would qualify for the same consideration, she wrote, "it is not possible to make decisions as to which case is more worthy than others.... Attempting such kinds of decisions would compromise the review process and not be in the best interests of such patients."

On 28 December, however, Healy did a startling about-face. She approved treatment for the woman and called for an emergency meeting of the RAC on 14 January to draft guidelines for the compassionate use of unapproved gene therapies. She did not publicly explain her change of mind.

Healy's decision paves the way for Royston to treat the woman with a vaccine made from her own cancer cells that have been genetically altered to make interleukin-2, an immune stimulant. Animal studies suggest that IL-2-producing cancer cells boost an immune attack on tumors anywhere in the body. Royston filed a single-patient protocol for the treatment with NIH on 7 December.

Now RAC will not get a chance to review Royston's protocol, and members are fuming. "This is the worst thing I have seen," said Dusty Miller, a RAC member from the Fred Hutchinson Cancer Research Center in Seattle, Washington. "It throws the RAC review to the wind. The implications of this are that the RAC is no longer needed. If somebody wants to put recombinant split pea soup into people, that's fine." E. Peter Geiduschek, a RAC member from the University of California, San Diego, wondered whether the "P in PHS (Public Health Service) stood for political, privilege, or public. I think the way things were done reflects no credit on the Department of Health and Human Services and NIH." And John H. Barton, a RAC member from Stanford Law School, worried that Healy's decision may have violated NIH's own guidelines for RAC.

Healy was not available for comment last week, but NIH deputy director Lance A. Liotta sought to justify the decision. He pointed out that RAC has already approved the vector used to transfer the IL-2 gene—it's being provided by Bernd Gansbacher of Memorial Sloan-Kettering Cancer Center, who has won RAC approval for his own gene therapy experiments. Royston has also received the go-ahead from his own institutional review board and biosafety committee, and FDA has approved the treatment as safe. Moreover, RAC has sanctioned a small number of human tests by research groups that pioneered the idea, although they are using different target cells.

"This is a unique situation, based on a moral dilemma. We decided not to penalize this one patient," Liotta said. He quickly added, however, that "our intent is to have this never happen again. All future requests will have to follow the new guidelines set up by the RAC." Given the reaction of some RAC members to Healy's decision, however, they may have a difficult time agreeing to new guidelines when the committee meets next week.

–Larry Thompson

Larry Thompson is a science writer living in Bethesda, Maryland.