

Academia Wins a Round on Raw Data

The spending bill for the Postal Service and the Treasury may seem an unlikely vehicle for legislation that could have affected virtually every scientist whose work is funded by the federal government. But last week, as a panel of House members met to approve spending for these agencies, they debated a proposal that would have required most researchers with government grants or contracts to make public their raw data.

The lawmakers voted down the amendment in part because of a frantic last-minute lobbying effort by universities and the Clinton Administration. They warned that it would impede the patenting of new discoveries and drive up administrative costs, among other dire consequences. But observers in the research community say they believe the proposal, which was backed by some heavyweight lobbying groups, may surface in Congress again. "To people who don't know how scientific publishing works, it sounds rational," says Keith Casey, director of federal and state government relations for Harvard University. "In that kind of situation, you always have to be worried."

The proposal stems from a bitter debate over new Environmental Protection Agency (EPA) air pollution rules. Industry groups, such as the American Petroleum Institute, and Thomas Bliley (R-VA), chair of the powerful Commerce Committee, have demanded access to raw data from a key study that EPA relied on for its new rules. The Harvard authors of the study have argued that turning over the data would violate agreements to keep medical information confidential (*Science*, 25 July, p. 467).

In July, several business lobbies and other groups—including the National Rifle Association, which in the last few years has been pushing for the release of data from a federally funded study on the risk of death in homes with guns—sent Appropriations Committee Chair Bob Livingston (R-LA) a letter advocating a federal policy of data availability. Representative Robert Aderholt (R-AL), a freshman and a member of the Treasury-Postal Appropriations Subcommittee, decided to try to attach an amendment to the Treasury bill that would apply across federal agencies. In a 24 July "Dear Colleague" letter to his fellow lawmakers, Aderholt explained that "sunshine is the best antiseptic" and by "allowing research to be open to peer study by the rest of the scientific community" the amendment would "raise the standard of scientific research in our nation and help eliminate duplication of efforts."

The proposal underwent many revisions—for example, an early exemption for the National Institutes of Health disappeared, while a

defense exemption was added. The final draft offered in a markup last week would have required recipients of federal research grants or contracts to submit to the government "a plan" for making "the results (including all underlying data and supplementary materials) ... available for public use and inspection." The data would be released "not later than 90 days after the date of the first public use of the research." Exceptions would have included proprietary information and "the portion of the information that would constitute a clearly unwarranted invasion of personal privacy," as well as Department of Defense and defense-related Department of Energy research.

Despite these exemptions, Administration officials and Democrats in Congress remained worried by the proposal. Representative George Brown (D-CA), ranking minority member of the Science Committee, wrote Livingston of his "deep concern" (*Science*, 1 August, p. 627). The White House Office of Management and Budget listed numerous problems, including impeding commercial agreements and the risk of harm if the data were analyzed by "those not familiar with the full details of how the data were collected." And Clinton science adviser Jack Gibbons told Treasury-Postal Subcommittee Chair Jim Kolbe (R-AZ) in a 30 July letter that

"the proposed legislation is fraught with problems," including a "major administrative and resource burden," and that "we believe that the critical issue is the absence of justification for a legislative fix."

What ultimately may have turned the tide, however, say several Hill staffers, was phone calls from universities to their representatives. The Appropriations Committee defeated the amendment by a vote of 19 to 34, with Livingston and other high-ranking members such as Jerry Lewis (R-CA) and Kolbe opposing it. "We strongly suggested that things should not move so quickly," says Margy McGonagill, a federal relations staffer at the University of Arizona in Tucson. Casey adds, "I don't understand how a rational implementation of this thing could exist."

But there are signs that the issue may come up again. Bliley wrote Aderholt in support of the idea, as did James Sensenbrenner (R-WI), chair of the Science Committee, whose 28 July letter concluded, "I look forward to working with you as you develop your initiative as it works its way through Congress."

"This is legislation that stood up and barked, and a lot of people paid attention. And this is just the beginning," says Brian Rell, chief of staff for Aderholt. A Democratic staffer on the Science Committee says he "wouldn't be surprised" if hearings were held in the fall. Adds Casey, "I think it's definitely something to watch."

—Jocelyn Kaiser

ASTRONOMY

Gemini Woos Australia to Replace Chile

Friction between Chile and the other partners in a U.S.-led consortium building twin, 8-meter telescopes in Hawaii and Chile is threatening to cause a cash-flow problem that could delay construction. Officials for the \$184 million project, known as Gemini, are so

1 September for Chile to pass an acceptable law and be reinstated as a partner. Otherwise, they hope to reach an agreement with Australia. Chilean officials say that the deadline is unrealistic. In the meantime, the incident has raised questions about Chile's status as a

prime site for world-class astronomy. "It's an object lesson in the problems of building an international facility in Latin America," says Matt Mountain, project director for Gemini, which is based in Tucson, Arizona. "To be fair to the Chileans, they're still experiencing the growing pains of a young democracy. But the project is running out of cash, and if nothing happens soon we'll have to delay work on the southern telescope."

With one instrument in each hemisphere, the Gemini telescopes will provide unique, high-quality coverage of the entire sky in the infrared, optical, and ultraviolet spectral regions. The United States is putting up half the money for the project, conceived a decade ago by the Associated Universities for Research in Astronomy (AURA), which operates the U.S.



Wintry weather. Conditions atop Cerro Pachon mirror Chile's relations with its Gemini partners.

concerned that they are negotiating with Australia to become a partner and pay the 5% share previously promised by Chile, where a 3-year legislative battle over the project's legal standing has so far blocked payment.

Gemini officials have set a deadline of

National Optical Astronomical Observatories (NOAO). The United Kingdom is contributing 25%, Canada 15%, and Brazil and Argentina are chipping in 2.5% each.

Chilean astronomers see membership in the Gemini consortium as a mixed blessing. On the one hand, they covet the chance to shape and benefit from a major new facility, and they regard Gemini as a shot in the arm for their discipline. "Gemini represents a chance to go from being a spectator to an actor, so we would feel a strong loss if Chile were to drop out," says Hernan Quintana, head of the astronomy department at Católica University in Santiago.

At the same time, they worry that the price tag, which includes annual operating expenses of \$700,000 in addition to \$9.2 million in construction costs, could squeeze funding for training, technology, and infrastructure—all of which would be needed to take full advantage of the telescope. "Chile now spends only \$1 million a year on all of astronomy, and we are fighting every day to operate our department," says astronomer José Maza of the University of Chile. "So \$700,000 is a lot of money to pay for the privilege of being a partner."

While the other partners have held up their end, the Chilean share—including \$1.1 million a year for 1995 to 1997—is being held hostage until legislators work out the terms of a new law governing all future scientific facilities on Chilean soil. The rules for existing telescopes operated in Chile by NOAO, the European Southern Observatory (ESO), and the Carnegie Institution were hammered out privately by military governments in decades past, and the agreements were managed by the University of Chile. Although Chilean astronomers were awarded free viewing time on the U.S. telescopes and the projects' employees received diplomatic immunity—a valuable perk for importing cars duty free, for example—the Chilean government was not a partner.

The current government feels its planned investment makes the facility a national asset, but defining its status has proven contentious. In May the lower house passed a bill that would remove diplomatic status for Gemini's employees. That move was the last straw for the project's board of directors, already angry that the legislative snafu had frozen Chile's payments since 1995. So they voted to ask the National Science Foundation, the official U.S. representative in the project, to begin negotiations with the Australian Research Council (ARC), the country's major funding body for universities.

Australia has jumped at the chance. "Astronomy is one of our flagship research fields," says ARC Chair Max Brennan. "If we can't afford the [comparatively modest] cost of joining Gemini, then we ought to pack up our gear and switch to tiddlywinks." U.S. and

Australian sources say that official acceptance from the education ministry could come as soon as midmonth.

But Gemini officials have given Chile until 1 September to meet its payment schedule and pass legislation that keeps the project's status on a par with ESO in all respects. If it does, Chile would be restored to full partnership and Gemini would bid good day to Australia. If not, Chile would retain only limited privileges under the category of host country, including rights to 10% of the viewing time on the southern telescope.

A bill pending in the upper house would satisfy Gemini officials, but it must then be reconciled with the earlier bill. Chilean sources say such swift action is doubtful. "If

AURA hadn't demanded changes, a law would have already been passed," says Oscar Rivera, Gemini project manager for CONICYT, Chile's national research agency. "But now it's very unlikely."

As the fight over partnership continues, Gemini officials face a more immediate, but temporary, obstacle to construction. A 1.5-meter snowfall atop Cerro Pachon, the Gemini site in northern Chile, has blocked dirt access roads and delayed work for 6 weeks as crews repair the damage. For project manager Mountain, however, it may offer a way to stay cool as the politics heats up.

—Jeffrey Mervis

With reporting by Elizabeth Finkel in Melbourne.

BIOTECHNOLOGY

NIH Nixes Appeal to Bypass Patent Law

National Institutes of Health (NIH) director Harold Varmus sided with Johns Hopkins University last week in a high-profile patent dispute with a feisty biotech company, CellPro Inc. of Bothell, Washington. But Varmus also poured cold water on the claims of both sides: Some anticipated medical benefits of a widely touted cell-sorting technique at the center of the dispute have not been proved, he said.

Varmus's decision was the second major blow to CellPro in just over a week. On 24 July, Judge Roderick McKelvie of the federal court in Wilmington, Delaware, ordered the company to pay Hopkins and its commercial partners triple damages, amounting to \$6,961,479, for infringing the university's patents. The penalty stemmed from a ruling McKelvie issued in March that Hopkins and its partners had exclusive rights to market a device that uses CD34 antibodies to separate stem cells from human blood or bone marrow. The cells are then infused to rebuild the immune system after the patients undergo toxic cancer therapy.

CellPro was the first company to develop a CD34 machine, and so far is the only company approved by the Food and Drug Administration (FDA) to market one. But Judge McKelvie ruled in March that CellPro was guilty of "misconduct" because it knowingly violated Hopkins's patents and the rights of Hopkins's partners, including Baxter Healthcare Corp. of Deerfield, Illinois, which has developed its own CD34 device. In addition to awarding damages to the Hopkins group last month, McKelvie told CellPro it must stop selling CD34 machines. CellPro issued a statement last week saying that it was "disappointed" with NIH's ruling, and its chief execu-

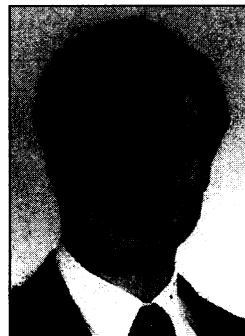
tive officer, Richard Murdock, announced that his company will appeal McKelvie's ruling.

Varmus was dragged into this dispute because CellPro had sought to bypass McKelvie's March ruling by appealing to NIH for an unusual waiver from U.S. patent laws that would have allowed it to continue marketing

its CD34 device. Twelve U.S. senators and 25 representatives wrote letters to Donna Shalala, secretary of Health and Human Services, Varmus's boss, on CellPro's behalf. And Murdock—who himself was treated for a rare cancer with CellPro's device—appeared in magazines, newspapers, and on television this spring touting his apparent cure (*Science*, 6 June, p. 1490).

CellPro, noting that Baxter had been slower than CellPro to put a CD34 device on the market, claimed that "thousands of victims of the most acute forms of metastatic breast cancer ... would be forced to undergo less optimal treatment with unnecessary suffering, and, in some cases, death" if the judge's order was enforced. It also warned that clinical trials would be cut short, increasing the likelihood that children with leukemia undergoing cell transplant therapy would die.

NIH was not swayed, however. In a formal memorandum, Varmus says he has decided not to exercise "march-in rights" under the Bayh-Dole Act of 1980, which allows the government to take control of a federally funded invention if it is not being developed fast enough. In particular, he said he wasn't persuaded that cell-separation machines make a big difference to the health of cancer patients. There is "considerable debate" among experts as to whether these machines offer



Upheld. Hopkins patent holder Curt Civin.