

Scripps Backs Down on Controversial Sandoz Deal

The Scripps Research Institute and Sandoz Pharmaceuticals Corp. have succumbed to pressure from Congress and the National Institutes of Health (NIH) to renegotiate a controversial agreement that would have given the Swiss company first rights to nearly \$1 billion in federally funded research. The proposed agreement would have given Sandoz broad control over Scripps' research and researchers and allowed the company to review the grant proposals and consulting agreements of scientists at the institute.

Richard Lerner, president of the La Jolla, California, institute, told *Science* last week that the offending language will be removed. But he said Sandoz still intends to invest a total of \$300 million over 10 years, beginning in 1997, after a 10-year agreement between Scripps and Johnson & Johnson expires.

The unprecedented agreement was attacked last week at a hearing conducted by Representative Ron Wyden (D-OR) at which NIH Director Bernadine Healy called the agreement a "dangerous" aberration. Healy said NIH has surveyed 375 university-

industry agreements, and none of them contains the most controversial provisions of the proposed Scripps-Sandoz deal. Nevertheless, she said, NIH will develop guidelines for all universities negotiating such agreements with industry.

The proposed contract, which Scripps announced last fall (*Science*, 4 December 1992, p. 1570), had been expected to be signed formally by 1 July. But that was before Wyden, whose investigations into the price of new drugs has led him to examine arrangements between government-funded research institutions and industry, picked up on press reports criticizing the unprecedented scope of the deal. In March, Wyden held a hearing on the agreement at which Healy criticized it as potentially destructive and possibly illegal. At that time, Scripps defended the contract and argued that NIH's lawyers had misinterpreted it.

Now, after 3 months of additional review, NIH has stepped up its criticisms. In a six-page letter sent to Scripps on 11 June, NIH's legal advisor said the agency "... is concerned that the agreement unduly restricts scientific

research supported by the government, appears to be contrary to the letter and spirit of the Bayh-Dole Act [a 1980 law that, for the first time, allowed industry to acquire the rights to federally funded research done by universities and private research institutions] and may impinge unreasonably upon scientific freedom..."

At last week's hearing, Healy told Wyden that she found it "not at all surprising that one [newspaper] columnist called the agreement 'a leveraged buyout' of a taxpayer-supported institution." She called the proposed contract an "aberration, by virtually every measure" and a "dangerous exception" to the standard arrangement with industry, adding that she was concerned that the agreement may "tempt rash, wholesale indictments" of the otherwise productive system in place to transfer federally funded technology.

Healy said that NIH was prepared to restrict all of Scripps' future NIH grants to retain government co-ownership of technology, a step that would effectively scuttle the deal with Sandoz. Scripps declined to testify, fearing what one official called a "witch-hunt." Instead, the company said in a statement that its agreement is "not only completely consistent with the letter and spirit of the Bayh-Dole legislation, but also is in the best interests of science and the public."

Nevertheless, although Scripps still disagrees with much of NIH's interpretation of the contract, Lerner told *Science* that the

SCRIPPS-SANDOZ: SOME OFFENDING PASSAGES

Initial Agreement	NIH's Concerns	Expected Changes*
Sandoz would provide Scripps "general funding" for research of its choice in return for an exclusive worldwide license to all Scripps inventions related to medical or manufacturing products, excluding existing research agreements with third parties.	The agreement appears to restrict competition and exclude organizations other than Sandoz from having reasonable access to Scripps' technology.	About half of the Sandoz funding will go to a fund to which Scripps researchers would apply for grants. Sandoz will receive rights only to that research. The rest of the money will go to a general fund to support infrastructure and recruiting.
A "Joint Scientific Council" with a one-person Sandoz majority would monitor the relationship and have broad authority to influence the direction of research by Scripps scientists.	Anticompetitive effects because the council would establish procedures for reporting inventions, picking technologies to patent, and reviewing third-party consulting agreements.	Sandoz will not have a controlling majority of the panel.
Sandoz would be allowed to review invention disclosures stemming from federally funded research at Scripps before the disclosures are filed with the government.	Could delay the commercialization of inventions funded by the government. Permits Sandoz to delay products that might compete with its own products.	Deleted.
Sandoz would have the right to review proposed consultancy agreements by Scripps employees. Scripps researchers would be prohibited from accepting funding that involves licensing or option rights, unless Sandoz declines to fund the research itself. Sandoz may transfer Scripps research to its own facilities for further research and development.	Could inhibit collaborations and limit access of other companies to Scripps research. Allows Sandoz to review proposed agreements with other companies that may contain proprietary information.	Consultancy review deleted. Restriction on third-party funding made moot by new grant mechanism, under which Sandoz only has rights to that research which it directly funds.
Scripps would seek a waiver to the requirement that products from federally funded research be manufactured in the United States.	Could violate federal law, especially since Sandoz is owned by a Swiss company that has large European manufacturing facilities.	Deleted.
Sandoz would be given two slots on the Scripps board of trustees and would be allowed to terminate the agreement if Scripps appoints a chief executive officer unacceptable to Sandoz.	Level of involvement would permit Sandoz to monitor and perhaps restrict competition in the commercialization of products from Scripps research.	Deleted.

*Details are still being negotiated.

institute plans to delete or amend "each and every one" of the elements that are controversial (see table). "We never had any intention to do the kind of things that NIH says the agreement permits," he says, but "we're happy to take out of the agreement anything that NIH finds egregious."

Although the changes are expected to be worked out over the next several months, Lerner says that one major shift will be to eliminate the language giving Sandoz first rights to all research at Scripps, leaving it with the rights only to the research it directly funds. Scripps is also expected to remove clauses giving Sandoz representation on its board of trustees and control of a joint Sandoz-Scripps scientific council. The council will be recast as a review panel, comparable to an NIH study section, to which Scripps scientists would apply for funding.

Lerner says that these changes will not reduce Sandoz's financial contribution, which will be divided between a grants program and a "no strings attached" general fund to support Scripps' infrastructure and recruiting. When the contract was first drawn up last year, he says, the two parties had not yet established a relationship of "trust" and the resulting language was conservative. "In the absence of trust," he says, "it's an issue for the lawyers."

Wyden staffers and NIH officials said that they were encouraged by Scripps' promise to modify the contract but withheld final judgment pending review of the revised agreement. Scripps gave NIH a copy of the original contract only 2 days before the first Wyden hearing and declined to make it publicly available. But last week, Scripps and Sandoz agreed to disclose it after removing some financial details. They planned to deliver a copy to the Wyden committee early this week.

The flap has already led NIH to decide to make its policies on industry research agreements more explicit. Healy announced at last week's hearing that a task force, created earlier this year to review the commercialization of intellectual property rights from NIH-supported extramural research, will draft guidelines for all such agreements.

The task force, composed of NIH scientists, program officers, technology-transfer specialists, and lawyers, has already surveyed more than 100 institutions involved in research agreements with industry. Its work, Healy said, will be published in the *Federal Register* "not as rules, but as recommendations our grantees can consider when negotiating such agreements."

Learning from the Scripps-Sandoz ordeal and NIH's own painful experience in writing conflict-of-interest guidelines, the task force will solicit public input before completing its work.

—Christopher Anderson

BIG SCIENCE

Clinton Backs SSC, Space Station

In a double-barreled endorsement of big science and engineering, President Clinton announced last week that he wants Congress to fund both the international space station and the Superconducting Super Collider (SSC).

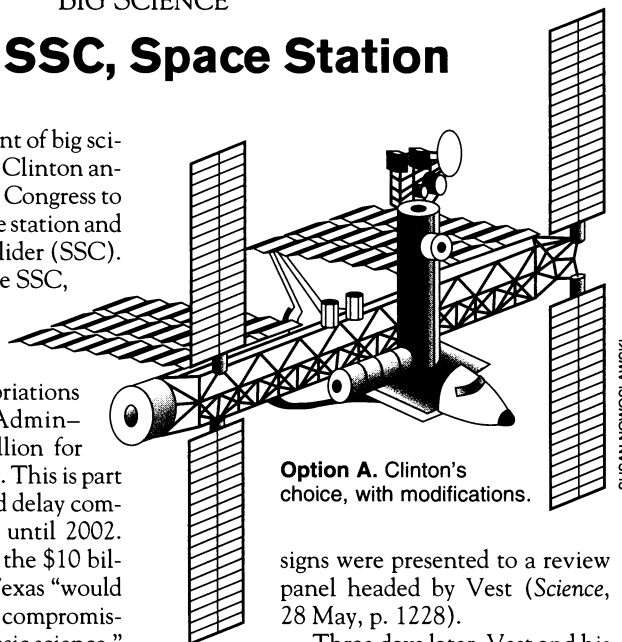
As a sign of his support for the SSC, on 17 June Clinton released a letter sent to Representative William Natcher (D-KY), chairman of the House appropriations committee, reiterating the Administration's request for \$640 million for the year beginning on 1 October. This is part of a new funding plan that would delay completion of the SSC by 3 years, until 2002. Clinton wrote that abandoning the \$10 billion accelerator being built in Texas "would signal that the United States is compromising its position of leadership in basic science."

On the same day, Clinton declared that he will back a new plan for the space station, following the lead of an advisory panel headed by Charles Vest, president of the Massachusetts Institute of Technology. Clinton has chosen a "scaled-down version" of the design that's been under study and revision for the past 9 years. To pay for it, the White House wants \$1.85 billion for hardware and another \$250 million for science payloads and associated costs in 1994.

Clinton's support may help, but it may not save these projects. Both are threatened by continuing pressure to cut federal spending—and the pinch is even tighter because the cost of other items in the bill that funds the space station (particularly housing subsidies) are on the rise. Indeed, even a strong backer of the station such as Representative George Brown (D-CA) a few weeks ago gave the project no more than a 50:50 chance of survival.

The SSC also faces an uncertain future. Based in Texas, the project is considered to be at greater risk now that voters there have replaced a Democratic U.S. senator, Bob Krueger, with a Republican, Kay Bailey Hutchison. The House is expected to vote on both projects in the coming week, but supporters are focusing their attention on the Senate, which has been more sympathetic to big science in the past.

Clinton supported both projects during the presidential campaign, but his latest vote of confidence in the station came after an arduous, 90-day exercise in which teams of scientists and engineers studied new ideas for reducing its costs. Most members of this brainstorming crew came from the National Aeronautics and Space Administration (NASA), joined by a few from the international partners—Canada, the European Space Agency, and Japan. On 7 June three alternative de-



Option A. Clinton's choice, with modifications.

signs were presented to a review panel headed by Vest (*Science*, 28 May, p. 1228).

Three days later, Vest and his colleagues delivered a 78-page report to the White House. Clinton agreed with its recommendation for a new, staged design known as "option A," and combined it with elements of "option B" derived from the original blueprints. A decision on whether to include the Russians, requiring a complex logistical shift to a higher orbit at 51.6 degrees, has not been made, and may not be made for some time. But other details will be presented to Congress in a letter being drafted by presidential science adviser Jack Gibbons.

To date, the station has consumed \$9 billion; Clinton has said he's willing to put up another \$10.5 billion over the next 5 years to finish it. This is more than the Administration said in March that it wanted to spend, but White House officials last week claimed that the new design will save \$4 billion to \$7 billion compared to the Bush Administration's plan. Members of the House appropriations committee have already told Congress that any increase in funding above estimates made in March will have to come out of NASA's budget.

The Administration also has embraced the Vest panel's recommendation for changes within NASA. White House officials said it wouldn't have been possible to build "any station" with the existing "labyrinthine, circular" management structure. The Vest panel said NASA should sharply cut its staff and contractor support, and NASA says that it will aim for a 30% reduction in contractor staffing and a reduction of 1300 NASA employees.

With changes like these, Clinton hopes to convert what has been a sinkhole for R&D funds into a showpiece of science and technology. But as a White House official conceded last week, "We have a lot of technical details to work out."

—Eliot Marshall