managed. There has even been talk of these republics joining in an economic federation of "Turkestan," which would reach from the Caspian Sea to Mongolia.

With such possibilities in the wind the government will not want to alienate Suleimenov, who as a member of the U.S.S.R. Supreme Soviet has developed ties to Gorbachev and Foreign Minister Eduard Shevardnadze. He could be politically valuable to the present government as it seeks to negotiate with the 15 constituent republics a "union treaty" that would keep the Soviet Union from falling apart.

If testing is finished in Kazakhstan, there will be no place to test on the scale contemplated by the military-and indeed probably no place left to test at all. As the reaction to last month's test at Novaya Zemlya indicates, it would be politically difficult to shift the test program there. This Arctic island is a poor place to test in any case. Although atmospheric testing was carried on intensively there in the late 1950s and early '60s, Novava Zemlya has been used on the average only about once a year since testing went underground following the Limited Test Ban Treaty of 1963. The constraints are severe: Arctic cold, frozen rock, high winds, difficult access, and-today-defiant visits by Greenpeace activists and protests by the U.S.S.R.'s Nordic neighbors.

International pressure on both the United States and the Soviet Union to stop testing is expected to come next January at a conference to be held at the United Nations to consider converting the partial test ban treaty of 1963 to a complete ban.

Mexico and five other nonnuclear weapons nations—Peru, Venezuela, Indonesia, Sri Lanka, and Yugoslavia—were the prime movers behind the calling of the conference. When the United Nations adopted a resolution last year recommending the conference, 127 nations voted for it, 22 abstained, and only two voted against it—the United States and Britain. But as original parties to the treaty, these two countries can block any amendment.

There thus seems every possibility that if there should be a new Soviet testing moratorium and the White House hangs tough, the U.S. test program will be politically besieged, both domestically and internationally. Part and parcel with the political resurgence of the Soviet constituent republics, Suleimenov and his Nevada movement have set in motion a political dynamic that makes for the best chance yet for a comprehensive test ban treaty. **LUTHER J. CARTER** 

Luther Carter, an independent Washington writer, is writing a book on "civilizing the atom" under a MacArthur grant.

## Orphan Drug Compromise Bush-Whacked

Waxman is so vexed he

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legislation next year.

For 3 years biotechnology firms, pharmaceutical companies, politicians, and consumer groups had been pitted against one another in what often appeared to be a no-win battle to amend the Orphan Drug Act. The stakes were enormous: hundreds of millions of dollars in profits on some orphan drugs, and the fate of victims of rare diseases who have relied on the act's incentives for the development of drugs that might otherwise be too unprofitable. Not surprisingly, everyone had a different idea of just what was fair. But then Congress, in one bold stroke, satisfied all camps. It unanimously approved a compromise last month that was so artful even

the biotech lobbyists agreed not to fight it. But all the effort may have been for naught: Last week President Bush refused to sign the measure.

The vetoed measure—H.R. 4638—

closes loopholes in the Orphan Drug Act, passed in 1983 to encourage development of drugs for diseases that afflict 200,000 patients or fewer. The act's chief incentive was to give the first firm to develop an orphan drug a 7-year monopoly. The measure worked better than expected, leading to the development of more than 400 drugs, 49 of which have been approved—a remarkable increase over the 1970s, when only 40 drugs were developed for rare diseases.

But a few companies took advantage of the loopholes to edge out their competitors for drugs that turned out to have a much larger market than predicted when they won orphan status. Take human growth hormone and three drugs used to treat AIDS— AZT, erythropoietin, and aerosol pentamidine. Their inventors gained a monopoly on these expensive medications and reaped hundreds of millions of dollars as the market for each grew to more than 200,000.

This summer Representative Henry A. Waxman (D–CA) hammered out a compromise that would have changed that. It would have allowed more than one company to market an orphan drug if the competitors could prove they had begun development and clinical trials of the drug within 6 months to a year after the first company began its work. It would also have revoked a drug's orphan status if the patient population exceeded 200,000.

Although biotech lobbyists weren't thrilled with the amendments, they were

better than earlier proposals, which would have revoked a drug's orphan status once it earned \$100 million. Congress also placated the industry by stipulating that the changes would apply only to new drugs and not to existing orphans.

So when word began spreading around Washington last week that Bush planned a pocket veto, lobbyists and congressional aides tied up each other's phone lines spinning hypotheses to explain the White House's eleventh-hour thumbs-down. It took the White House Council on Competitiveness to come up with an official line: Bush opposes the bill because by allowing more

> than one company to market a drug, it would "endanger the success of the program." He also thinks revoking a drug's orphan status once the market grows beyond 200,000 patients

would "send a troublesome signal" to firms that had made significant investments on the assumption that they could have the market to themselves for 7 years.

But this explanation didn't squelch rumors that there was yet another reason for the veto. Some insiders say Health and Human Services Secretary Louis W. Sullivan sought the veto because the bill included a provision calling for an advisory committee to examine the effects of the Orphan Drug Act and government policy on drug development for rare diseases. (Sullivan did ask Congress in a June letter not to alter the act.)

Whatever the reason for the veto, reaction to it has been harsh. "The totally infuriating thing is that we finally got consensus," one congressional source told Science. "We got this bill through the House and Senate unanimously, and all the while the Administration was not saying a word. And now it's vetoed because someone in the White House thinks he knows what's best for the industry." Capitol Hill staffers were especially irked by the fact that the veto came after Congress had adjourned. Waxman is reportedly so vexed he's threatening to reintroduce a stricter bill next year, which includes a \$100-million cap on profits that any single orphan drug can earn. And that's got the biotech and drug industry lobbyists quaking. "We'd hate to see a return to an earlier version," says Lisa Raines, a lobbyist for the Industrial Biotechnology Association.

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