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17

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AIDS (Disease) = CA x Political aspects
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David L. Kirp and Hugh Maher

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AIDS was just beginning to be a major national issue four years ago when Margaret Heckler, then-Health and Human Services Secretary, insisted that the crisis would soon be over. There will be a vaccine "within two years," Heckler promised, an announcement that made page one news. Heckler's promise turned out to be a medical fantasy based on nothing more solid than a politician's wishes, and the Secretary was sent off to count sheep in Ireland.

Meanwhile, production of an AIDS vaccine has been postponed to the indefinite someday, as scientists have become more keenly aware of the daunting nature of the task. But as the awesome dimensions of the AIDS epidemic have become clearer, the human importance--as well as the political importance--of getting a safe and effective vaccine on the market as speedily as possible have only increased.

As with so many other matters concerning AIDS, the California Legislature has been first off the block in the effort to coax the drug companies into inventiveness. A bill passed last fall offers a \$6 million carrot to companies testing an AIDS vaccine. It guarantees the purchase of half a million units of the vaccine. It creates a fund, paid for by a surcharge on the vaccine, to compensate anyone who becomes ill because of the vaccine. And--most important to the pharmaceutical firms--it purports to rewrite the liability laws in order to protect the firms from seven-figure lawsuits.

Money and protection are just what the drug companies said they had to have, if marketing a vaccine was ever going to be commercially feasible. That's why the measure was praised to the skies when it was signed into law.

Some of that praise is deserved. But in the lawmakers' rush to do well politically by doing good, no one troubled to ask whether those drug companies were holding up the politicians by holding out--whether this was corporate welfare in a good cause. And the bill itself, though now being touted as a model for the nation, verges on incoherence in its treatment of the all-important liability issue. What kept a very good idea from becoming a very good bill can be traced directly to the arm-twisting game called Sacramento politics--and now that political game is about to be replayed in Washington.

In 1985, when the idea of an AIDS vaccine bill was first floated, politicians and public health officials were frustrated with the snail's pace of vaccine development. The Reagan administration wasn't about to carry on the research in-house. Senior health officials viewed the issue in classic market terms: The huge potential profits that awaited the company that unravelled the scientific mysteries should be sufficient incentive.

But the pharmaceutical houses and the high-flying biotechnology firms ignored the supposed lure of the marketplace.

All the big pharmaceutical companies echoed Merck, Sharp & Dohme, the nation's leading vaccine-maker: "We are putting our time, attention and funds

into other areas." Dr. Robert Gallo of the National Institutes of Health, one of the country's top AIDS researchers, lamented: "I go around giving lectures trying to goose companies into getting involved....We could still use a five or ten-fold increase in private sector participation."

The drug companies weren't being irrational. While the scientists who develop a vaccine can probably count on a Nobel Prize, the venture is a "bet the company" gamble. The outlay--for research and especially for testing--will be huge, and no one knows just how what the demand will be. After the swine flu vaccine debacle of the 1970s and the more recent spate of injuries stemming from the D-P-T vaccine administered to children, the public has grown skeptical about assurances of vaccine safety; any hint of risk could wipe out the market.

This is no mere hypotheses: a few years earlier, Merck had taken a financial beating with its Hepatitis-B vaccine. The company was aiming for a market close to the Centers for Disease Control's estimate of 8.7 million Americans at high risk for the disease. But fear spread that, because the vaccine was derived from the plasma of people who were likely to have contracted AIDS, the hepatitis vaccine might actually carry the AIDS virus. Although those anxieties were groundless, since the manufacturing process actually deactivates both viruses, they stopped the Hepatitis vaccination campaign cold. by the end of 1985, fewer than a million Americans had received even the first dose of the triple-dose vaccine.

An equally big fright was the prospect of mega-judgments in lawsuits brought by those who were injured by the AIDS vaccine. The trial lawyers had been developing new legal theories to snare even the most conscientious manufacturer. A rash of multimillion dollar lawsuits had led several companies to get out of

the vaccine business entirely; producing an untried vaccine for a brand new disease looked like market suicide. As Dr. William Haseltine of Harvard Medical School, who heads his own AIDS research team, commented: "It's easier and more profitable to develop a new Valium than an anti-viral specific for AIDS."

The biotech firms had a different slant on the issue than the pharmaceutical houses. These new companies were living on promise, not on product, and that promise was readily applied to AIDS. The newly-developed technological capacity to extract a protein from a virus meant that the biotech firms could conceivably manufacture a vaccine that was much safer than standard vaccines, which are made from the live virus.

Money as well as science also motivated these companies to go public with their interest in AIDS. As syndicated financial columnist Dan Dorfman wrote, talk of AIDS research in the biotech firms made these glamor stocks even more glamorous: "Sometimes, just a whisper that a firm is working on AIDS has been enough to buoy the price."

Yet biotech insiders were dubious about the prospects for an AIDS vaccine. Some of their misgivings were scientific. No one had developed a vaccine for a retrovirus; indeed, until a few years earlier, no one knew what a retrovirus was. And the AIDS virus was particularly devilish: there were several different varieties of the virus, and each of the varieties seemed capable of numerous mutations.

Liability was also a big fear. David Martin, Vice President for Research at Genentech, the leading firm in this infant industry, was quoted in the Wall Street Journal as saying that "liability problems would make questionable the

commercial value" of a vaccine. And Brian Cunningham, Genentech's legal counsel, recalls that he had earlier killed development of a proposed malaria vaccine. "The history of the vaccine industry is companies being sued to death," says Cunningham.

Genentech wanted to be a player in the AIDS vaccine game--to be "proactive," as company chief Robert Swanson put it. In October 1985, key figures from Genentech and Chiron, another biotech firm, as well as key California legislative staffers, met with Dixon Arnett, third-ranking official at the Department of Health and Human Services and a one-time California state legislator.

There is a "political critical mass" for a major federal initiative, Arnett said, but no deal was forthcoming. "Everyone was too interested in who would get credit to get the negotiations going," one participant remembers. And there was disagreement about what the biotech firms really needed in order to proceed: Genentech thought the liability issue was critical, while Chiron's attention was focused on securing some government financial backing.

As 1985 ended, Genentech decided to push for a vaccine bill in the California Legislature. The company had little experience lobbying in Sacramento, but its timing was right. As Don Francis of the Centers for Disease Control, who for the past several years has been detailed to work in California, declared: "We either have the government take over vaccine development or we have to make the market safe."

What Genentech wanted was a way to resolve its concerns about legal liability and marketability. It sought out San Jose Assemblyman John Vasconcellos for help.

Vasconcellos is a Sacramento legend. He is an unabashed child of the 1960s--the Self-Esteem Commission was his brainchild--who is nonetheless attentive enough to fiscal realities to head the Assembly's Finance Committee. Vasconcellos is a lawmaker who wears his principles on his sleeve; he is also close to the center of political power in the Capitol.

The idea of a state initiative that might prevent AIDS had natural appeal to him. As his aide, Michael Twombly, observes: "John is a preventative kind of person."

The measure that Vasconcellos introduced on February 21, 1986--the last possible day in the session--embodied all of Genentech's fondest hopes. It committed the state to buy \$20 million of the AIDS vaccine from its manufacturer, thus assuring a market; it appropriated \$6 million to subsidize clinical trials of potential vaccines; it established a state compensation fund, making California the "deep pocket" for those injured by the vaccine; most important, it limited legal liability to instances of negligence or willful misconduct by the vaccine-maker, setting a \$250,000 ceiling on recoveries for pain and suffering.

The vaccine bill faced two quick tests: it had to satisfy the Assembly's Health committee and Judiciary Committee. The Health Committee is supposed to ask the hard policy questions, but the measure sailed through without a single member asking about cost or inquiring whether California could effectively promote an AIDS vaccine. Indeed, during the tortuous process of passage, no legislator ever wondered aloud whether the vaccine bill made sense on the merits or what California (as distinguished from the federal government) was doing in the vaccine-promoting business.

But when the bill reached the Judiciary Subcommittee on the Administration of Justice, alarm bells started sounding. That subcommittee, the trial lawyers' stronghold, has historically been the graveyard for tort law reform--exactly what Vasconcellos was urging. Vasconcellos' proposed negligence standard for drug company liability reversed a decades-long history of expanding tort liability.

Under existing state law, drug-makers are responsible for any injuries linked to the use of their product--regardless of how meticulous they have been in making and marketing the drug.

The state's trial lawyers view this no-fault liability as a way of keeping companies honest. Drug firms have "some rather base motives," said Doug DeVries, a liability lawyer who handled some of the negotiations on behalf of the California Trial Lawyers Association.

No-fault is also a way of keeping up the trial lawyers' standard of living--which is why any attempt to rewrite the rules of the courtroom game had to reckon with the well-financed opposition of the barristers.

The trial lawyers knew they couldn't oppose the bill outright--for who could stand up against legislation that promised a speedier end to AIDS? Instead, they tried to nibble the measure to death. DeVries recalls delivering lectures about the meaning of strict liability and "hang-ups over semantics"; Vasconcellos remembers the trial lawyers' conduct as "insulting and less than forthright."

Fortunately for Vasconcellos, though, the subcommittee chairman, Lloyd Connelly, was an old ally. Connelly, like Vasconcellos a liberal Democrat, is a legislator's legislator, a man with a reputation as the smartest and most conscientious politician in the Capitol.

Connelly was determined to keep the bill alive. That meant somehow crafting a compromise between the trial lawyers and the Vasconcellos camp. Round and round, the staffers for the two lawmakers went. Gene Erbin, Connelly's consultant on the subcommittee, had spent the previous six years as a consumer lobbyist; he is a principled defender of litigation as a way of keeping companies honest. For Twombly, a newcomer to the Capitol whose first assignment for Vasconcellos was the vaccine bill, public health was his top priority.

What was needed to satisfy the trial lawyers was a bill that didn't threaten to return tort law to the days when victims had to prove a company's negligence. There was a standard at hand: In the case of Kearl v. Lederle Laboratories, a state appellate court had carved out an exception to the strict liability rule for drugs that are "unavoidably dangerous, but highly desirable products for society." The Kearl standard wasn't ideal from the drug firms' point of view, because it required a complex mini-trial to determine whether a drug is "unavoidably dangerous," but it was leagues better than strict liability.

The trial lawyers gave their initial approval, but then tried to undercut even the Kearl rule in the subcommittee by offering niggling qualifications. By that time, Genentech was ready to back off. "Either you get [Assembly Speaker] Willie Brown in here to fix it or we'll walk away from the issue," Genentech counsel Brian Cunningham said.

Brown, a trial lawyer himself, has close ties with the California Trial Lawyers Association, which heavily financed Democratic candidates' campaigns; he also has ties to Genentech. In an hour-long session, Brown acted as a skillful mediator, going back and forth between the two sides to hammer out a deal. "Are those your final concerns?" Brown asked both sides at the end of the exchange.

Shortly after Brown left the room, Genentech raised a concern that hadn't been discussed before. The trial lawyers hit the roof. Commented Vasconcellos: "Genentech was new up here. At times, they didn't know what was going on; they didn't understand the point-counterpoint."

The final sticking-point on liability concerned a technical but legally vital question. John Vasconcellos saw the bill as protecting an AIDS vaccine manufacturer from all liability except in instances of provable negligence; that is how he proposed writing the statute. The trial lawyers feared that this standard would keep them from inventing new grounds for legal liability--and would also be used as precedent to erode other consumer rights. They came up with language stating the specific grounds on which a vaccine manufacturer was protected against lawsuits, leaving everything else up for grabs.

In the subcommittee, which met on July 7, the ceiling on pain and suffering damages was raised to \$550,000, making the trial lawyers happier. But on the key liability provision, Vasconcellos prevailed. The trial lawyers were determined to win it all back in the full Assembly Judiciary Committee, which had scheduled hearings on the bill that same day. One more time the lobbyists and the legislative aides went at it, scribbling countless revisions of the pro-

vision in the corridors of the Capitol, in a last-ditch attempt to keep the bill alive.

Vasconcellos was furious at the trial lawyers. In front of the Judiciary Committee, with the TV cameras recording the event, he turned on Doug DeVries. "You're an asshole," he shouted. "I've never dealt with an asshole like you."

That afternoon the Judiciary Committee produced what it saw as a Solomonic solution: it embraced both the trial lawyers' language and Vasconcellos' language. This pairing of the inconsistent makes some political sense. But it makes no legal sense whatsoever. When and if a vaccine is produced in California, the courts will have to untangle the Legislature's impossible-to-determine intentions. For biotech companies jittery about lawsuits, that's an awfully fragile basis on which to proceed.

The real irony--which somehow escaped Genentech--is that the drug firms would actually have had an easier time in court if the Legislature had left the liability question entirely in the hands of the judges.

In several 1986 cases, California state courts had ruled that there was no need for an expensive and time-consuming Kearl-style mini-trial to establish that a vaccine is "unavoidably dangerous but highly desirable." If the California vaccine statute means anything on this issue, it means that the AIDS vaccine will confront a legal barrier that no other vaccine has to surmount.

The next stop for the vaccine bill was the Assembly Ways and Means Committee. In theory, Ways and Means scrutinizes the costs of all bills, and there were serious cost issues to be discussed. Why, for instance, did the biotech com-

panies require subsidies to do the kind of research they are in the business of doing? How big did the market guarantee have to be before a firm would show interest? Were these companies--which reportedly were already testing AIDS vaccines in their labs--soaking the state for money they really didn't need?

There may well be good answers to these tough questions, but none of the questions ever got asked. Since Vasconcellos, who chairs the Ways and Means Committee, made it plain that this was his top priority measure, it sailed through with only a single dissenting vote. The following day, it zipped past the Assembly, 71-5.

The Senate was another story. The trial lawyers weren't fighting against the bill any longer, but for the first time money became a crucial issue. Vasconcellos had to win over the green eyeshade crowd at the Appropriations Committee--and eventually win over Governor Deukmejian as well.

Dan Boatright, the Concord lawmaker who chaired the Senate Appropriations Committee at the time (he has since been deposed by Senate President Pro Tem David Roberti for plotting a senatorial coup), describes himself as a "good friend" of John Vasconcellos. Boatright reports that he recommended that Vasconcellos succeed him as chair of Ways and Means when he was elected to the Senate. He recounts an occasion when Vasconcellos, called upon to roast Boatright at a fundraiser, said: "I can't roast Dan Boatright--I love Dan Boatright."

But love and politics don't always mix. "Good friend" Boatright almost managed to kill the AIDS vaccine bill.

Boatright, who had just taken over the Appropriations Committee, quickly made the committee a personal power base, controlling almost every bill that moves through the Legislature. The year before, just 13 bills had been axed in the committee. During his 1986 term as chair, 195 bills were killed, in what Boatright's consultant Barry Brokaw calls an attempt to establish priorities.

Other legislative sources saw things differently: if Boatright was going to commit money to a bill, the senator was looking for something in return--a campaign contribution or a legislative quid pro quo.

Vasconcellos neglected to ask Boatright or veteran San Jose lawmaker Al Alquist for their help before the Appropriations Committee hearing. "I didn't do my homework," Vasconcellos says. "After negotiating so tenderly, getting all the parties on board, I thought I could coast."

that was careless politics, the kind of slight that Boatright might take personally. The senator was also worried about the financial implications of obliging the state to compensate anyone injured by the vaccine. Who could tell what that might someday do to the general fund?

"What if somebody sues us for \$50 million?" Boatright asked at the hearing. "Why should the state be the guarantor?"

While Boatright was attending to short-term costs, Vasconcellos was concentrating on the potential long-term savings, both in dollars and in human lives. "The risk of putting the state on the line to be the guarantor is less than the risk of AIDS. The state's exposure in terms of public health is what's so important."

Former committee chair Alfred Alquist of San Jose attacked the guaranteed purchase provision of the bill as corporate welfare. "I thought we were really bending over backwards in appropriating \$6 million for research," the senator said. "Mr. Vasconcellos wanting us to subsidize not only the development but also the market is a little too generous with the taxpayers' money."

Alquist wasn't only upset about the cost of the vaccine bill. He was also unhappy that AIDS was getting so much attention. "Millions of people are relegated to lives of uselessness because of Alzheimer's disease. How come you're not concerned about Alzheimer's?" he grilled Vasconcellos. The assemblyman's response, that three Californians die from AIDS each day, didn't persuade Alquist.

Alquist's concerns about gays had something to do with his opposition to the bill. While the senator is a liberal on most social issues, he hasn't been a supporter of gay rights; Alquist was one of a handful of Senate Democrats to vote against A.B.1, the gay antidiscrimination measure, when it had come before the Senate in 1984.

AIDS victims are less deserving of attention than the victims of drunk driving, Alquist told San Jose Mercury News reporter Susan Yoachum, because AIDS is a "behaviorally caused disease"--a gay disease, in other words.

In the midst of the Senate Finance committee meeting, with objections flying, Boatright delivered a set of verbal amendments which effectively gutted the AIDS vaccine bill. Essentially all that was left was the \$6 million for clinical trials.

Why did Boatright derail the vaccine legislation? The senator saw himself as being a responsible committee chair, worried, like fellow members of the committee, about how to husband scarce state dollars. Vasconcellos' staffers viewed it more personally, as tit-for-tat.

Two weeks earlier, the Assembly Ways and Means Committee, chaired by Vasconcellos, had killed a parole reform bill that had been a pet project of the senator's. Boatright had made no secret of his anger, and staffers speculated that the AIDS vaccine bill was the senator's revenge.

This kind of vendetta is a common enough occurrence in Sacramento. In late August, as the end of the legislative session approached, dozens of Assembly bills remained bottled up without discussion in Boatright's committee. In retaliation, the Assembly Ways and Means Committee adjourned for a week, leaving key Senate bills in limbo.

The vaccine bill passed out of the Senate Finance committee with Boatright's crippling amendments. But there was still one last chance to revive the bill: what had been undone orally could conceivably be restored in the rewriting. Away from the bright lights of the hearing room, Vasconcellos haggled with Alquist and Boatright.

That evening, "nursing his wounds," Vasconcellos cornered Alquist at a party celebrating the passage of the unitary tax bill, which the two lawmakers had jointly backed. The assemblyman extracted from Alquist what he regarded as a commitment to back a less crippling set of amendments than those proposed by Boatright.

A San Jose Mercury News account of the day's events, written by Susan Yoachum, gave the vaccine bill its second life. After the Finance Committee hearing, Yoachum had engaged Boatright in a shouting match; her article bristled with inflammatory language describing how the committee had "slaughtered" and "killed" bills, "State Senate Panel Guts AIDS Vaccine Research Bill," the headline read. To Boatright, whose senate district is partly served by the Mercury, the story was damning.

As soon as Boatright saw the article, he called Vasconcellos. And when Vasconcellos let him know what he understood Alquist's changed position to be, Boatright responded: "John, we're going with your amendments"--including, most importantly, the guaranteed purchase provision.

Alquist later complained to Yoachum that Vasconcellos had misrepresented his position in talking with Boatright, and that he still opposed the measure, but it was too late. Boatright had made up his mind--this time, permanently.

In order to retreat from his version of the vaccine bill without attracting too much attention, Boatright had to frame his substitution as a reconsideration of the original amendments. "A simple misunderstanding," the senator called it. Susan Yoachum disagreed: having exposed the committee's assault on the AIDS vaccine bill, she now wrote a piece in the Mercury attacking Boatright for restoring funding without getting the approval of the full committee.

That story made no one happy, says Yoachum. "I was told, in effect, 'You should do those kinds of stories on bad bills. But this is a good bill, so just look the other way.'" Vasconcellos, delighted with how things turned out,

commented that "that's how we do things around here when people are in agreement."

On the Senate floor, Boatright evaded some tough questions from suspicious colleagues, winning approval for the amendments that he had privately negotiate with Vasconcellos. The victims' compensation fund was still in the measure, but it would be funded by a surcharge on the vaccine, not by the state treasury. The state's guarantee to purchase the vaccine was made contingent on how the market responded. the final vote in the Senate was 37-0; in the Assembly, the amended version passed 75-2.

Vasconcellos had met earlier with Governor Deukmejian, looking for support for his key initiatives, including the AIDS vaccine bill. The Governor and his Finance Department shared many of the Senate Finance Committee's dollars-and-cents worries, but when the committee amended the bill to remove the state "deep pocket" provision, those concerns were allayed.

Deukmejian was inclined to support the AIDS vaccine legislation. He had just been hammered by the media for cutting back on AIDS appropriations and vetoing an AIDS antidiscrimination bill. With the gubernatorial election less than two months away and the Field Poll showing him losing ground to Tom Bradley, the Governor wanted no more bad headlines.

After getting Vasconcellos to make some technical changes in the bill, Deukmejian became a supporter. On September 30th, he signed the AIDS vaccine bill into law.

"We never saw California as the end--only as a good precedent for federal legislation," says Brian Cunningham, speaking for Genentech. Indeed, there is no good reason to imagine the universe of AIDS vaccine-makers and vaccine-takers as bounded by California, every reason to think that the best solution to this national problem would be a national solution.

In early February, Senator Edward Kennedy held hearings in Washington on the AIDS vaccine. Bob Swanson, Genentech's president, was one of the star witnesses. What's needed, Swanson told the senators, is protection from liability, a guaranteed market, and money for vaccine trials--exactly the same agenda that Genentech had taken to the California Legislature a year earlier.

The magnitude of what was being sought left Kennedy stunned. But the senator was plainly intrigued. The potential scope of the AIDS epidemic is even clearer in 1987 than it was when the possibility of federal action on encouraging vaccine development was first bandied around.

The absence of national leadership on AIDS is also clearer. In November, the prestigious National Academy of Science had excoriated Washington for doing too little, too late. While California Congressman Henry Waxman has made the AIDS issue his own, no senator has gone beyond rhetoric to push major AIDS legislation. An AIDS vaccine bill thus represents a major political opportunity as well as a humanitarian opportunity.

Meanwhile, as Washington's political machinery begins to turn, leading scientists continue to voice their skepticism about the likelihood of a safe and effective vaccine. On February 21, Dr. Walter Dowdle, head of the Centers for

Disease Control, issued a prediction very different from HHS Secretary's 1983 promise. A vaccine was years away, Dowdle said--if ever.

David L. Kirp, a professor of Public Policy at the University of California (Berkeley), is writing a book about AIDS and schoolchildren. Hugh Maher, an undergraduate Social Sciences major at the University of California (Berkeley), is writing his senior thesis on the California AIDS vaccine legislation.

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