A Homeland Security Whodunit
In Massive Bill, Someone Buried a Clause
to Benefit Drug Maker Eli Lilly
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It amounted to only two paragraphs at the end of a 475-page bill to create the Department of Homeland Security. But the brief provision -- designed to shield vaccine makers such as Eli Lilly and Co. from lawsuits seeking billions of dollars for families of autistic children -- has generated a whirlwind of controversy and a mystery as to its origin.

The paragraphs appeared just days before the House was to vote on the legislation. House Republicans rammed the bill through during Congress's "lame duck session" and sent it to the Senate, where Democrats, demoralized by the Nov. 5 election results, could not to stop it.

And so, with little debate, Congress granted broad legal protection to the makers of Thimerosal, a preservative in childhood vaccines that has been circumstantially linked to rising rates of autism and pediatric developmental problems. It seemed a lobbying coup for Lilly and its allies. Yet, strange to say in Washington, no one seems to want to take credit.

Pharmaceutical lobbyists, Eli Lilly representatives and lawmakers with the most knowledge of the Thimerosal issue have denied any role in the provision's last-minute appearance. Now, White House budget director Mitchell E. Daniels Jr., a former Lilly executive, is the latest person to formally deny a part. He did so in a sharply worded response to an accusatory letter by Rep. Henry A. Waxman (D-Calif.).

Daniels said the provision was not approved or developed by the White House Office of Management and Budget, adding: "I also want to make clear that I personally had no involvement whatsoever with these provisions. I spoke to no one about these provisions, either inside the administration or outside the administration. . . . I did not have any communications with anyone from Eli Lilly regarding the issue. Indeed, I had not even heard of Thimerosal until I received your letter, which is not surprising because Eli Lilly stopped making Thimerosal a decade before I began working there and the lawsuits appear to have been filed after I left."

Since the provision's appearance, some Democrats and trial lawyers have charged that it represented a timely payback for the pharmaceutical industry's financial support in the midterm elections. "President Bush and conservative Republicans are going to give the pharmaceutical companies whatever they ask for," said Michael Williams, an Oregon lawyer who represents several families of autistic children and believes billions of dollars could be at stake.

Under the provision, a raft of Thimerosal lawsuits will be redirected from state courts to the federal Vaccine Injury Compensation Program, which caps damages and sharply limits who can file suits against vaccine makers. Proponents say the provision merely closes a loophole, which had been exploited by trial lawyers claiming that Thimerosal was a vaccine "contaminant" not
subject to existing legal regulations. If action was not taken, advocates say, the lawsuits could have driven vaccine makers out of business.

The provision was drafted more than a year ago by Sen. Bill Frist (R-Tenn.) as part of a broader bill to revise the vaccine program. That bill, which Frist had hoped to begin action on next year, includes measures favoring plaintiffs as well as manufacturers. It would raise the cap on damages, extend the statute of limitations for filing suit and allow the parents of autistic children to sue on their behalf.

An aide to retiring House Majority Leader Richard K. Armey (R-Tex.) said Armey's staff put the Thimerosal provision in with no prodding from the pharmaceutical industry or the White House.

But several corporate lobbyists said that is not credible. Whoever was responsible had to have detailed knowledge of the legal issues, had to know Frist had drafted the larger bill, and had to understand exactly which provision applied to Thimerosal because the brand name does not appear in the text. Two sources said an official at the Department of Health and Human Services gave the final approval, a statement that HHS spokesman Bill Pierce adamantly denied.

What is clear is that as recently as two months ago, lobbyists for Lilly and other drug makers were on Capitol Hill trying to get the entire Frist vaccine bill inserted into the homeland security legislation. But, the lobbyists said, they were as surprised as anyone when the two-paragraph item was included.

One senior Republican Senate aide said a member of Frist's staff received a call just days before the House passed the homeland security bill, saying he had heard a rumor that the Thimerosal provision was included. The Frist aide said the lobbyist was confusing that provision with another measure to protect makers of smallpox vaccines. The next day, the aide said, Frist's staff found the Thimerosal provision in the bill as they scanned it in the Senate cloakroom.

"We don't know how it became part of the House bill," said Rob Smith, a Lilly spokesman. "We didn't know it was part of the bill, and it was a surprise to us."

The provision could be the lobbying coup of the 107th Congress. A series of ongoing academic studies should be able to conclude within the next three years whether Thimerosal, a mercury-based additive, can be scientifically linked to an upswing in autism, Williams said. Absent the two-paragraph provision, such a conclusion could open the legal floodgates.

Yet corporate lobbyists who might be expected to crow about saving their clients potentially billions of dollars have stayed mum. That may be in part because the deed was done rather clumsily, one lobbyist said. The provision was not even hidden. Instead, it was simply tacked on at the end of the bill. That has brought down a wave of unwanted publicity on vaccine makers, especially Lilly, the inventor of Thimerosal.

"They didn't even make an effort to be clever about it," the lobbyist said.
WASHINGTON, Nov. 28 — Lobbyists for Eli Lilly & Company, the pharmaceutical giant, did not have much luck when they made the rounds on Capitol Hill earlier this year, seeking protection from lawsuits over a preservative in vaccines. Senator Bill Frist, Republican of Tennessee, tucked a provision into a bill that went nowhere. When lawmakers rebuffed a request to slip language into domestic security legislation, a Lilly spokesman said, the company gave up.

Now, in a Washington whodunit worthy of Agatha Christie, the provision has been resurrected and become law, as part of the domestic security legislation signed on Monday by President Bush. Yet in a city where politicians have perfected the art of claiming credit for deeds large and small, not a single member of Congress — or the Bush administration — will admit to being the author of the Lilly rider.

"It's turning into one of Washington's most interesting parlor games," said Dave Lemmon, spokesman for Senator Debbie Stabenow, Democrat of Michigan, who has promised to introduce legislation to repeal the provision. "There's a lot of guessing, a lot of speculation as to who did this."

The provision forces lawsuits over the preservative, developed by Eli Lilly and called thimerosal, into a special "vaccine court." It may result in the dismissal of thousands of cases filed by parents who contend that mercury in thimerosal has poisoned their children, causing autism and other neurological ailments. Among them are Joseph and Theresa Counter of Plano, Tex., devoted Republicans whose party allegiance has run smack into family ties.

The Counters' 6-year-old son, Joseph Alexander, was normal and healthy until he was 2, they say. Then he took an unexplained downward slide. Today, the boy struggles with words. He cannot zip his pants, snap buttons or tie his shoes. His parents say tests eventually showed that he had mercury poisoning, which they attribute to vaccines. They sued last year.

"I know that our legislative system can be very, very messy at times," said Mr. Counter, a political consultant, who with his wife has spent many thousands of dollars on medical care and therapy for their son. "But for them to attempt this, in the dead of night? It disgusts me. This morning, I am ashamed to be a Republican."

With lawmakers now scattered across the country, Washington is rife with
speculation about who is responsible for aiding Lilly, a major Republican donor. During the 2002 election cycle, the company gave more money to political candidates, $1.6 million, than any other pharmaceutical company, with 79 percent of it going to Republicans, according to the Center for Responsive Politics, a nonprofit research group that monitors campaign finances.

Critics of the provision, mainly Democrats and trial lawyers, are quick to point out that the White House has close ties to Lilly. The first president Bush sat on the Lilly board in the late 1970's. The White House budget director, Mitchell E. Daniels Jr., is a former Lilly executive. The company's chairman and chief executive, Sidney Taurel, was appointed in June by President Bush to serve on a presidential council that will advise Mr. Bush on domestic security.

The White House, however, has said that it did not ask Congress for the provision. Rob Smith, a spokesman for Lilly, said that the company's lobbyists "made absolutely no contact with Mitch or anyone in his office about this," and that Mr. Taurel "did not at any time ask" for any favors.

"It's a mystery to us how it got in there," Mr. Smith said of the provision.

Senator Frist has said it is a mystery to him as well. As the Senate's only doctor, he sought to include the provision in legislation that would promote the availability of vaccines. But the vaccine bill is stalled; Senator Edward M. Kennedy, the Massachusetts Democrat who is chairman of the Senate health committee, opposes it. Mr. Frist's spokesman said he did not seek to have the provision included in the domestic security bill.

On Capitol Hill, Congressional aides-turned-detectives have traced the emergence of the provision to the Veterans Day weekend. Flush from their party's victories on Election Day, and with a mandate from President Bush to pass a domestic security bill, Republican negotiators in the House and Senate holed up for three days in the Capitol to hammer out the details, said Richard Diamond, spokesman for the retiring House majority leader, Representative Dick Armey of Texas.

One aide said the language mysteriously appeared in the House version of the bill in entirely different type than the rest of the measure, as though someone had clipped it out of Mr. Frist's legislation and simply pasted it in. Mr. Diamond said all the negotiators supported the move, but would not say who was responsible.

"If you want to give somebody credit for it," he said, "Mr. Armey takes ultimate credit. It's his bill. We are happy to wrap ourselves around it, but Mr. Armey is not a doctor, like Senator Frist. He's the source of the language."

Whether thimerosal is truly harmful is the subject of intense scientific
controversy. Earlier this year, the National Academy of Sciences issued a report saying there was no scientific evidence either to prove or disprove a link between thimerosal and brain disorders like autism. But the academy did find that such a link was "biologically plausible," and so it urged pharmaceutical companies to eliminate thimerosal, which has already been removed from many vaccines, as quickly as possible.

The Lilly rider closes a loophole in a 1986 law that requires victims to file claims with the vaccine court, which awards payments from a taxpayer-financed compensation fund, before going to civil court. But the law covered only vaccines themselves, not their ingredients, which meant people like the Counters could sue ingredient manufacturers like Lilly directly.

While Washington debates the origins of the provision, families are fuming. Some say the government fund will do them no good, because they have missed the statute of limitations — three years from the date symptoms first appear — for filing claims. Scott and Laura Bono of Durham, N.C., say that while their son Jackson, now 13, showed symptoms similar to autism six or seven years ago, it was not until August 2000 that they learned he had mercury poisoning. They filed suit just the other day.

Aware of the controversy, lawmakers in both parties have pledged to alter the thimerosal rider, but are arguing about how to do so. While many Democrats want it repealed, Republicans have suggested that they may simply alter the language to apply to future cases only.

"I'll believe it when I see it," said Mr. Waters, the Counters' lawyer.

In the meantime, Mr. Smith, the Lilly spokesman, said his company would soon go to court to seek dismissal of the suits.

That news made Theresa Counter cry.

"It just makes me sick," she said. "I cannot tell you how devastating it is to think that we might have to start all over."