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## White House Debate on Smallpox Slows Plan for Wide Vaccination

By WILLIAM J. BROAD

**T**his article was reported by Lawrence K. Altman, William J. Broad and Denise Grady and was written by Mr. Broad.

Intense debates in the Bush administration over smallpox vaccinations have delayed critical decisions in the nation's program against germ terrorism for months, participants say.

They say officials, including at times Vice President Dick Cheney, have argued that the nation should move quickly to vaccinate widely even in the absence of a bioterrorist attack. But others, including President Bush, have been more cautious, worrying about the vaccine's risk of causing serious illness or death.

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The result has been confusion and delay, even as preparations for some immunizations move ahead.

Though state health officials have been asked to prepare to vaccinate health workers who might confront any smallpox cases, they have not been told how many workers they should immunize. Federal health officials said this month that the government should also consider making the vaccine available to everyone who wants it — an option that would require complex public education campaigns and extensive logistical preparations — but President Bush has not announced his decision.

The hesitancy reflects the magnitude of the issue and the difficulty of resolving it, given the uncertainties over whether the United States faces a smallpox attack and how the population would respond to the hazardous vaccine, both physically and emotionally.

Still, emergency plans are advancing. The Pentagon is completing plans to vaccinate up to 500,000

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troops. Last month, federal health officials sent the states a detailed blueprint for preparing to vaccinate all Americans. Its particulars include two-pronged needles, paper gowns, cots, medical screeners, security officers and vaccination times per patient of 30 seconds to two minutes.

Moreover, the upholding of mass vaccinations as a viable option, which officials from the Centers for Disease Control and Prevention and other health agencies did on Oct. 4, was a large expansion from the modest plans endorsed as recently as a few months ago. The about-face has caused government officials, health experts and the public alike to pay new attention to questions about smallpox, the vaccination that prevents it and the likelihood of its use as a weapon.

A disease of high fevers and open sores contracted by inhalation, smallpox was one of humanity's great scourges. Until it was declared eradicated in 1980, it killed up to a third of those who contracted it — as many as 500 million people died in the 20th century alone.

Today, only the United States and Russia have publicly declared stocks of the virus. But if clandestine supplies exist — and terrorism experts say they do — smallpox could be a potent weapon of mass destruction, one that could put all of the United States at risk.

American officials fear that Iraq may have the smallpox virus and might use it. That, officials say, is a crucial factor driving the Bush administration's accelerated planning for smallpox defenses.

Extensive reviews of documents and interviews with germ authorities show only circumstantial evidence that Iraq has the virus — plausible enough, most experts say, to warrant the defensive efforts under way, but as a senior official with access to intelligence data conceded, not conclusive. "That's the problem," he said.

Caught between worries about vaccination side effects and Iraqi germ attacks, Washington is preparing for wide protections and quietly encouraging allies to do the same.

"Every week that goes by, we're in a better position to deal with this, even a substantial outbreak," a health official who briefs the White House said. "We've got to be ready to respond."

The ScourgeA Deadly Weapon  
That Floats in the Air

American officials worry about smallpox because they know that the United States and Soviet Union prepared decades ago to use the virus as

a weapon.

Though infected volunteers, so-called smallpox martyrs, could spread the disease, each country developed more efficient methods. Moscow made a liquid, Washington a powder, said Jonathan B. Tucker, an arms expert and author of "Scourge," a book on smallpox.

Smallpox virus weaponized this way can float in the air over long distances, potentially infecting thousands of people.

In 1966, the United States Army considered sowing smallpox on the Ho Chi Minh Trail in Vietnam, former officials say. But that idea was dropped, and by 1969, President Richard M. Nixon had renounced all germ weapons and championed a global treaty to ban them. The treaty was unveiled in 1972 and signed by more than 100 nations, including Iraq.

As doctors were redoubling a global effort to eradicate smallpox from the wild, an effort that succeeded in 1980, Soviet scientists secretly developed the means to make 100 tons of smallpox a year. In one Soviet field test, American and Russian experts say, the virus escaped and sailed nearly 10 miles over open water to start an outbreak.

After the Soviet Union collapsed in 1991, many Soviet smallpox experts found themselves impoverished, leading Western experts to fear they might be tempted to sell the virus or their knowledge of how to weaponize it, or both. In 1994, the Defense Intelligence Agency cited an unidentified source as saying Russia had shared smallpox technology with Iraq and North Korea in the early 1990's.

But Iraq could have developed its own supply of the virus from a natural outbreak that struck there in 1971 and 1972, infecting at least 800 people.

"It is most unlikely that Iraq would have missed the opportunity," Richard O. Spertzel, a microbiologist who in the 1990's led the United Nations biological weapons inspections of Iraq, told a House committee last December.

In 1994, United Nations inspectors examining Iraqi medical facilities found an industrial-size freeze dryer, 4 feet high, 5 feet wide and 5 feet deep, the type of dryer microbiologists use to put germs into a kind of suspended animation that extends their life span.

The dryer was labeled "smallpox machine" in Arabic, an inspector recalled.

Iraqi officials insisted the dryer was not for smallpox but for the vaccinia virus, the active ingredient in the smallpox vaccine. The answer was judged plausible since the vaccines are often freeze-dried for storage.

But in 1995 the Iraqis admitted to a clandestine program for making germ weapons. A cache of documents Baghdad turned over to the United Nations that year included at least three papers on smallpox, Dr. Spertzel said in an interview.

A final clue, he said, came from Dr. Hazem Ali, a senior virologist involved in Iraq's biowarfare program, who told inspectors he had worked on camelpox, a relative of smallpox that infects camels.

His statement was judged a cover story. Dr. Spertzel said, "I'd say there was a high likelihood they were messing around with smallpox instead of camelpox."

In 1998, the Central Intelligence Agency told the White House that Iraq probably kept clandestine stocks of the smallpox virus for military use.

Biologists say growing the smallpox virus would be easy for Iraq or any group familiar with basic microbiology. It multiplies readily in chicken eggs and can be harvested on a large scale. Any state or group proficient in germ warfare could turn it into a weapon.

"There are no significant hurdles," said Ken Alibek, a former top Soviet germ warfare official now at George Mason University. "Iraq would be able to do it."

No smallpox detectors exist. So if a smallpox attack occurred, the authorities would probably learn of the strike in two weeks or so — the disease's incubation period — when sick people started to exhibit symptoms and head for clinics and emergency rooms.

Vaccination against smallpox can be effective after exposure to the virus, but only up to four days afterward, so it would come too late for the first wave of victims. For them, doctors would have little to offer but comfort as the disease ran its course.

At a Senate hearing in July, Richard Butler, who from 1997 to 1999 directed the United Nations hunt in Iraq for weapons of mass destruction, called the possibility of Baghdad's having smallpox a "deeply disturbing" issue that required "urgent attention."

## The Defenses Vaccine Stockpiles And Outbreak Plans

As worries about germ terrorism grew in the late 1990's, Washington began a low-profile program to rebuild national stocks of smallpox vaccine and update vaccination plans. When routine smallpox vaccination ended in the United States in 1972, only 15.4 million doses were left. In 2000, the Centers for Disease Control and Prevention contracted with Acambis of Cambridge, Mass., for 40 million more, at a cost of \$343 million.

After the Sept. 11 attacks, that effort expanded, with the goal of having enough vaccine for every American, by late this year or early next.

The plan has old and new elements. Clinical studies showed that the 15.4 million Dryvax doses could be diluted five times to yield 77 million doses. To that would be added 209 million new doses by Acambis Baxter, making a total of 286 million — enough for every American.

Meanwhile, the drug company Aventis Pasteur disclosed that it had, in cold storage, an additional 75 million to 90 million old doses, which

officials now view as an emergency backup. Studies are under way to see if they, too, could be diluted.

For security reasons, storage sites and exact vaccine inventories are kept secret.

As the stockpile took shape, Bush administration experts and officials began to clash over who should be vaccinated and when. The most pressing issue was pre-attack immunizations of emergency personnel and doctors who would vaccinate wider groups of people.

Officials said President Bush and Vice President Cheney eventually became deeply involved in the disputes, with Mr. Bush hesitant and Mr. Cheney more willing.

Minimalists argued for vaccinating only 15,000 health workers, citing the vaccine's dangerous side effects and the June recommendations of the Advisory Committee on Immunization Practices, a panel reporting to the federal government that made that suggestion.

On the other side, maximalists by July were pushing for 500,000 individuals or more, arguing that a sizable number of protected people would be needed in the event of a serious outbreak. Officials at the time said an announcement of that number was imminent.

Complicating the decision were doubts about "ring vaccination," the tactic used to eradicate the disease, in which health workers would isolate infected patients and vaccinate people around them. But critics of the approach argued that while ring vaccination worked with natural outbreaks, it would be ineffective in an attack involving thousands of people infected simultaneously.

Douglas Holtz-Eakin, chief economist at the White House Council of Economic Advisers, went so far as to argue that a major attack could virtually shut down the economy and cost \$177 billion per week. At a public meeting in June, he asked if even truck drivers and airplane pilots should be vaccinated.

This summer, outside the administration, some experts began calling for vaccinations soon for anybody who wants them, arguing that this would help lessen chaos in a bioterror attack.

A senior official who has briefed President Bush said no consensus had been reached, even as the idea of wide vaccination gained adherents. "The president is clearly concerned about the adverse effects of the vaccine," the official said.

Smallpox vaccine is not given by injection; rather, it is scratched into the skin with about 15 jabs of a special needle that carries two thin prongs. Suspended between them is an exact amount of vaccine. Vaccinators must be taught the immunization technique, but doctors say it is not hard to learn.

The license for the old vaccine has expired, leaving it classified as an "investigational" drug. As a result, anyone who receives it must read about its risks and sign a declaration of understanding, paperwork that slows and vastly complicates the vaccination process. Tommy G.

Thompson, the secretary of health and human services, has said the government is trying to license the vaccine like any other as soon as possible.

At least a million undiluted doses of Dryvax are expected to be licensed in the next few weeks, officials said. Meanwhile, the licensing of the Acambis Baxter vaccine, which requires detailed safety and effectiveness testing because its manufacturing technique is new, is not expected before the end of next year. The Aventis emergency stockpile is not to be licensed, officials said.

In the event of an outbreak, there is a critical adjunct to vaccination: isolating the sick to contain the contagious disease. States are under pressure from federal officials to revise their patchwork of quarantine laws to make them uniform and address concerns that giving police powers to public health officials could violate basic liberties.

Dr. David Fleming, deputy director of the Centers for Disease Control and Prevention, said people in quarantine would receive "the best care if they became ill."

Though doctors have no recent experience with smallpox, they hope that modern drugs and treatments might save more lives than was the case in past epidemics.

#### The Side EffectsRisks That Include Rashes and Death

The immunizations for most diseases are made with dead or crippled germs. By contrast, smallpox vaccine is made with a live virus, a smallpox relative called vaccinia, that can multiply aggressively in people with impaired immune systems, cancer or certain common skin conditions.

When vaccination was routine, complications from vaccinia killed about one person in a million and struck one in 10,000 with serious skin infections, brain inflammations and other ills. Since routine vaccination halted, millions of Americans have contracted the AIDS virus, which can suppress the immune system, and some 200,000 others take immunosuppressive drugs because of organ transplants. Also, rates of skin disorders like eczema are much higher now.

People with eczema, or even a history of it, are at risk for a condition called eczema vaccinatum, which can produce high fever, a severe rash, scarring and even death. Patients whose immunity has been lowered by illness or by medicines used to prevent transplant rejection have an increased risk for a potentially fatal reaction known as progressive vaccinia, in which the sore that normally forms at the vaccination site expands abnormally, damaging tissues all over the body.

Pregnant women, babies and patients with cancer and autoimmune diseases like lupus are also at risk for severe reactions.

Even if they are not vaccinated themselves, vulnerable people can be infected by someone who has recently been vaccinated, since the live

virus can be shed from the sore at the vaccination site for weeks. So health officials are looking at special bandages to keep shedding to a minimum.

Many experts contend a drug called vaccinia immune globulin or V.I.G., can counter some adverse reactions. Obtained from the blood of vaccinated people, it contains the proteins known as antibodies that the immune system forms to combat germ invaders.

Few people have been vaccinated in recent years, and the nation has only enough V.I.G. to treat up to 700 patients. At a cost of about \$100 million, the government recently contracted with a Canadian company, Cangene, to produce thousands of doses of V.I.G. by late this year or early next.

But V.I.G.'s effectiveness has never been tested in a rigorously controlled study. Dr. John F. Modlin, chairman of the Advisory Committee on Immunization Practices, said he was skeptical that it worked. "It seems to me an important issue if we are going to spend tens of millions of dollars" to build up a supply, Dr. Modlin said.

Dr. Anthony S. Fauci, director of the National Institute of Allergy and Infectious Diseases, said the government was making more of the drug "because you don't have anything else."

So officials are hunting for a safer vaccine. One is a modified vaccinia called M.V.A., which has an unusually low rate of adverse reactions. In late July, the government asked companies to submit proposals for developing the vaccine and producing up to 30 million doses.

That effort will take several years, Dr. Fauci said, adding that M.V.A. "is not in the Iraq picture."

A more futuristic alternative is antivirals, an emerging class of drugs that fight viruses directly. One, known as cidofovir, is undergoing federal study in animals to see if it can help allay the side effects of smallpox vaccination or perhaps even fight the disease itself. That would be a breakthrough, making treatment possible for the first time and possibly saving many lives.

Because cidofovir has to be injected and can damage the kidneys, the National Institute of Allergy and Infectious Diseases is supporting research to develop a form that can be taken by mouth, making administration easier and possibly safer. The findings are encouraging.

The Global Response  
Israel Is the First  
To Start Vaccinations

Vice President Cheney, at the start of his 12-country tour in March to drum up support for the removal of Saddam Hussein, reportedly warned the British prime minister, Tony Blair, that a military attack on Iraq could be met by germ reprisals. On April 12, British officials announced that they had placed an order for 30 million doses of smallpox vaccine.

Other countries are following suit, often at the urging of the United States.

In August, Israel became the first nation known to have started vaccinating emergency workers against smallpox.

"They're doing it," said Edward H. Kaplan, a Yale public health specialist who recently talked to Israeli health officials. "And the total time it took them to figure it out was quite a bit less than here."

Dr. Kaplan nonetheless praised the new American planning for mass vaccinations.

"Finally, we have something that says we're taking this possibility quite seriously," he said of a smallpox attack. "It says, 'If something happens, we can deal with it,' and maybe it lessens the chance that this kind of thing would happen."

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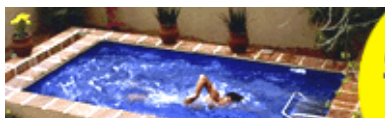
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