

# Lack of Vaccines Goes Beyond Flu Inoculations

**Eight Shortages Have Occurred Since 2000;  
Fewer Shots From Tetanus to Chickenpox**

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The almost instant shortage of flu vaccine caused by a bad influenza season points to a deeper, more chronic problem: The malfunctioning of the small but vital marketplace for preventive vaccines in America.

The influenza-vaccine shortage, reported Friday by the only two suppliers of flu shots, is more than a one-time mismatch of supply and demand. This is the eighth major shortage of preventive vaccines in the U.S. since the beginning of 2000.

Shortages of vaccines for diphtheria, tetanus, chickenpox and measles have occurred since then. Flu vaccines have been in short supply for three of the past four years. Now, doctors and clinics around the country say they are running low on supply as Americans rush to get some protection from the most severe outbreak in years, one that already has killed several youngsters in Colorado and elsewhere.

Vaccine shortages "aren't a one-time act of nature," says Frank Sloan, an economist at Duke University, who served as chairman of an Institute of Medicine study that explored vaccine issues in a report issued last August.

The report by the institute, an arm of the National Academy of Sciences, noted that there has been a steady erosion in the number of vaccine producers over the past three decades. In the 1970s, there were 25 vaccine makers; today -- because of slim profit margins and legislative and liability issues -- there are just five. With such a small number of producers, shortages can develop quickly as a result of manufacturing problems or a bad guess on the expected demand.

Many vaccines, such as those for tetanus and chickenpox, have only a single supplier in the U.S. market. The flu vaccine has only two: Aventis Pasteur, a unit of the large French drug company **Aventis SA**, and **Chiron Corp.** A newcomer, **MedImmune Inc.**, has recently launched a nasal spray vaccine, FluMist. **Merck & Co.** and **Pfizer Inc.** are among the drugmakers that no longer make flu vaccines.

Stockpiling of various vaccines is one solution to reducing the shortages, at least for some vaccines. The institute's report noted that "of the 10 vaccines that the [Centers for Disease Control and Prevention] has targeted for stockpiling, only three were stockpiled in 2002." Among those were vaccines for measles, mumps and rubella, as well as a small stockpile of polio vaccine.

The report noted that stockpiling is expensive and that the CDC has been conservative about developing stockpiles to minimize the financial risk. However, the flu vaccine can't be stockpiled every season, so manufacturers have to start every year from scratch, according to public-health officials.

## AN ABUNDANCE OF SHORTAGES

Recent supply shortages of major vaccines:

Vaccine	Shortage	Reason
DTaP (diphtheria, tetanus, acellular pertussis)	4Q 2000– 3Q 2002	Producers Baxter and Wyeth withdrew. Remaining producers had insufficient capacity to meet demand)
Tetanus	4Q 2000– 3Q 2002	Wyeth withdrew from production
MMR (measles, mumps, rubella)	January 2001-Jul-02	Merck, sole producer, interrupted production over issues related to manufacturing practices
Varicella (chicken pox)	4Q 2001– 2Q 2002	Production ceased because of unexpected delays in modification to production facilities
Pneumococcal conjugate	October 2001– present	Unexpectedly strong demand overwhelmed supply, plus a production bottleneck in early 2002
Influenza	2000–2001 flu season	Multiple manufacturers had difficulty growing flu strains, combined with heightened demand
Influenza	2001–2002 flu season	Production delayed; only two-thirds available by October
Influenza	Began early December 2003	Strong demand, triggered by severe flu outbreak, outpaced manufacturers' supply

Source: National Academy of Sciences' Institute of Medicine

For makers of all types of vaccines, the Institute of Medicine's report traced the decline in manufacturers' interest to the fact that the U.S. government -- predominantly through the Vaccines for Children program run by the CDC -- buys slightly more than 50% of the vaccines in the U.S., and keeps prices low. (The percentage is much lower for flu vaccines, which are given to many more adults than children.) The government's role in the vaccine market "raises an issue of monopsony power," says Duke's Dr. Sloan, referring to the economic situation when a single buyer -- in this case the government -- has the power to keep prices low. Under the Vaccines for Children program, the CDC negotiates a discounted price with the manufacturer. It then allocates to each state a credit balance, which states can use to buy vaccines from the manufacturer at the discounted price. The program offers free vaccines to uninsured children under 18 years of age or to those who are eligible for Medicaid or care from federally qualified health centers.

The report concluded that the price squeeze, coupled with a heavy regulatory burden, has discouraged investment and driven drug companies out of the vaccine business. The U.S. vaccine market is only a couple of billion dollars a year in sales, and many pharmaceutical companies can make more money on other products than on hard to make and market vaccines. Manufacturing vaccines involves the complex transformation of live organisms into pure, active, safe and stable vaccines. Many vaccines must remain in a narrow temperature range during storage and delivery, called the "cold chain." Moreover, each batch must be tested and approved before being released.

Legal liability also is a problem. Manufacturers are supposed to be insulated from lawsuits on pediatric vaccines but plaintiffs' lawyers have found ways around that. In addition, the vaccine industry also has a wobbly distribution network, where at any given time there can be surplus in one region and shortages in another. This year, for instance, Texas has been hard hit by flu, but there was a dearth of fall deliveries of vaccines. "There were many places -- doctors, clinics, hospitals -- that told me that they hadn't received the vaccine. That was in October," says Paul Glezen, professor of virology at Baylor College of Medicine in Houston. The report by the institute also stated that health-care providers such as doctors and clinics faced unusual burdens in carrying out vaccination programs, noting that "reimbursements for vaccines and administrative fees barely cover the costs of vaccine purchase. In many cases, providers lose money on immunization."

Besides the problems of the vaccine market overall, the flu vaccine has its own peculiarities that could bedevil efforts to alleviate shortages. The government isn't a big buyer of adult flu vaccine; manufacturers emphasize direct sales to doctors and hospitals. Many employers offer mass vaccination in the workplace.

At a time when the issue of Medicare coverage of prescription drugs has dominated debate in Washington, there is little time or interest in Congress or the White House in wrestling with problems in the vaccine supply. Meantime, the cost of immunizing children and vulnerable adults is skyrocketing, as new, expensive recommended vaccines come out of the lab. The cost of immunizing children has risen to \$385 in 2001 from \$10 in 1975, when adjusted for inflation, and may triple to more than \$1,000 per child by 2020.

The Institute of Medicine's blue-ribbon panel wants to require that all insurers and health plans in the U.S. cover vaccines, with the government subsidizing these purchases. The poor would get vouchers for vaccines. But the report recommends that the subsidy would cover vaccines for everybody, including those with private insurance -- or at least all children, the elderly and high-risk adults between the ages of 18 and 64.

The hope is that the subsidy, which would cost about \$1 billion to \$2 billion a year, would improve the low vaccination rates among the poor and among sick adults. Public-health advocates argue it would be a worthwhile investment, because each dollar spent on vaccines results in benefits many times that amount in preventing disease and death.

But many drug companies and insurers, as well as their Republican allies in Congress, balk at imposing a government requirement. At a conference last week at the American Enterprise Institute, a conservative think tank in Washington, some industry officials worried that, even if Congress provided some money to implement such a plan, it could be cut off in the future and leave the suppliers in the lurch. Others disliked a proposal in the report that a panel of "experts" would assess the social value of vaccines, especially future products, and set the prices to be paid to the makers and marketers of these drugs.

"We'd rather take our chances with the market," says Christine Grant, vice president for public affairs and government relations at Aventis.

About 150 million people are considered at high risk for the flu -- children, people over age 50 and those suffering from chronic diseases. One of the big uncertainties in forecasting demand for vaccines is that only 70 million to 80 million people annually are vaccinated, leaving a huge number who might panic and get vaccinated once a severe outbreak begins, as has happened this year.

Ms. Grant of Aventis says that in the past few years the company produced too much flu vaccine and ended up throwing away some of it; more-mild flu seasons produced only modest demand.