

# Millions of vaccine doses to be burned

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In this Dec. 22, 2009 file photo, swine flu vaccines are sorted at the Bill Graham Civic Auditorium in San Francisco. A whopping 40 million doses of swine flu vaccine expired on Wednesday, June 30, and will be destroyed \_ an amount that is believed to be a record loss of flu vaccine.(AP Photo/Marcio Jose Sanchez, File)

(AP) -- About a quarter of the swine flu vaccine produced for the U.S. public has expired - meaning that a whopping 40 million doses worth about \$260 million is being written off as trash.

"It's a lot, by historical standards," said Jerry Weir, who oversees [vaccine](#) research and review for the U.S. [Food and Drug Administration](#).

The outdated vaccine, some of which expired Wednesday, will be incinerated. The amount, more than twice the usual leftovers, likely sets

a record. And that's not even all of it.

About 30 million more doses will expire later and may go unused, according to one government estimate. If all that vaccine expires, more than 43 percent of the supply for the U.S. public will have gone to waste.

Federal officials defended the huge purchase as a necessary risk in the face of a never-before-seen virus. Many health experts had feared the new flu could be the deadly global epidemic they had long warned about, but it ended up killing fewer people than seasonal flu.

"Although there were many doses of vaccine that went unused, it was much more appropriate to have been prepared for the worst case scenario than to have had too few doses," said Bill Hall, spokesman for U.S. Department of Health and Human Services.

Most leading health experts generally agree with that.

Millions of doses of flu vaccine generally go unused every year and are marked for burning, but in recent years the leftovers amounted to closer to 10 percent of the supply, rather than the 25 percent expiring now. Government flu experts couldn't recall throwing away anything close to 40 million doses before.

The new H1N1 swine flu emerged in April last year, hitting children and young adults particularly hard. It was difficult to predict how deadly it might be or how easily it might spread. Federal health officials pushed five vaccine manufacturers to produce a vaccine as quickly as possible. What's more, they wanted a lot of it - many experts thought most people would need two doses for it to work.

The government placed three orders last year for a combined total of nearly 200 million doses - an unprecedented amount and almost double

the amount of vaccine produced in recent years for seasonal flu.

About 162 million doses were meant for the general public. Another 36 million included doses for the military and other countries.

But demand never took off, for several reasons:

- Tests of the vaccine soon showed only one dose was enough to protect most people.

- Much of the vaccine was not ready until late 2009, after the largest wave of swine flu illnesses passed.

- Swine flu turned out not to be as deadly as was first feared. About 12,000 deaths have been attributed to it - or roughly a third of the estimated annual deaths from seasonal flu.

So while people were waiting hours for swine flu vaccinations in some cities in October and November, by January local health departments were trying gimmicks to get anyone at all to come in for a shot.

Government officials have known for months that they were looking at a huge surplus. According to an Associated Press calculation based on federal purchasing information, the dollar value of the 40 million expired doses is about \$261 million. The government didn't release an official figure, but Hall said the AP estimate was approximately correct.

In Europe, where nations also found themselves with millions of unused doses, some commentators have attacked the World Health Organization, which declared swine flu a global epidemic, or pandemic. The critics have questioned the motivation of some WHO advisers who had links to the pharmaceutical industry.

Some critics have simply lamented that a lot of anxiety was raised and money wasted, not just during the swine flu scare but also in government responses to bird flu and SARS, a respiratory virus that swept parts of Asia in 2003.

"Each time the so-called experts told us that millions of people would be killed worldwide by the respective viruses. We have learned that the experts were utterly wrong," said Dr. Ulrich Keil, a professor at Germany's prestigious University of Muenster and a WHO adviser.

"This behavior is irresponsible because the angst campaigns ... confuse the priority setting in public health," he said. The death toll from influenza epidemics is much smaller than the number killed annually by chronic illnesses like heart disease, cancer, stroke and diabetes, he added, in an e-mail.

Unused flu vaccine is a common problem. The June 30 expiration date is set by the FDA and has less to do with the vaccine's shelf life than the desire to tweak the recipe each year to protect against the three flu strains expected to cause the most illness.

"It's not necessarily because it's degraded or not potent," said Dr. Mark Mulligan, an Emory University vaccine researcher.

In the past year, about 114 million doses of seasonal flu vaccine were distributed. The government thinks most of that was used - demand was unusually high because of fears about [swine flu](#).

In the flu vaccination campaign for this coming fall, [swine flu vaccine](#) is being combined with two seasonal strains in single doses. Manufacturers have told the government they expect to make about 170 million doses.

An influential government advisory panel this year recommended that

virtually all Americans get flu shots each year. Still, that doesn't mean it will all get used.

"No doubt there will be unused doses. This happens every time," said Dr. John Treanor, an immunology specialist at the University of Rochester Medical Center.

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