

# Many Missteps Led To Mask Shortages

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## FULL TEXT

A new virus had rapidly spread across the globe and Tuomey Healthcare System in South Carolina couldn't get more protective masks for its hospital workers. A run on them had created a shortage.

That was the 2009 "swine flu." Tuomey later stockpiled protective gear, but over the years didn't replenish some expired items. This year, it found that elastic bands on some of its masks were brittle.

The swine flu, an outbreak of H1N1 flu, turned out to be a dry run for a major pandemic. But neither hospitals nor manufacturers nor the government made sweeping changes to be ready for one.

Instead, each part of the medical-industrial equation acted in its own interest, and didn't set aside resources that might have better prepared America for the coronavirus crisis. Each ignored warnings of shortages of protective equipment in case of a pandemic – shortages that handicapped the struggle against the virus early on and continue today.

A Wall Street Journal examination found:

The hospital industry, in a bid to increase profit, slashed inventory of all supplies. Rather than bulk up after the swine flu, hospitals turned to inventory-tracking software to winnow stocks of protective gear and other supplies.

Manufacturers got bitten during the swine flu, ramping up production only to be left with few buyers when that crisis abated. Many mask and other device makers rebuffed later calls to build back emergency capacity.

The U.S. government focused more on preparing for terrorism than for a pandemic. The government lacked a permanent budget to buy protective medical gear for its Strategic National Stockpile.

The Trump administration further weakened the safety net as it rejiggered the Health and Human Services Department's main emergency-preparedness agency, prioritized other threats over pandemics, cut out groups such as one that focused on protective gear and removed a small planned budget to buy respirator masks for the national stockpile, according to former officials.

"The problem is a medical supply chain and a health-care system that we have built to be economically efficient . . . in exchange for resiliency," said Tara O'Toole, a Department of Homeland Security undersecretary of science and technology in the Obama years. "We have allowed ourselves to completely lose control over supply."

A White House spokesman blamed the prior administration for any lack of preparedness and said: "President Trump took bold action to protect Americans and prepared a whole-of-government response, in close coordination with state and local leaders, to Covid-19 when we had no true idea the level of transmission or asymptomatic spread."

Manufacturers, hospitals and the government all lost critical time because of the disarray in the protective-equipment supply chain.

U.S. manufacturers currently make every month around 50 million N95 respirators, among the most crucial items. By June they expect monthly production of 80 million N95 respirators, commonly called N95 masks. That remains far short of the nearly 300 million that HHS in March estimated U.S. health-care workers would need each month during the pandemic.

The N95 story reveals failures of readiness at all levels.

Hospitals

After the 2009 flu, health officials told industry and government leaders hospitals would be seriously short on protective gear in a major pandemic and urged steps to forestall shortages. The officials were part of a working group drawn from HHS and the Centers for Disease Control and Prevention.

For hospitals, supplies are typically their second-largest expense, after labor. "Every dollar you save in the supply chain drops to the bottom line," said Eugene Schneller, a professor at Arizona State University's W.P. Carey School of Business whose research focuses on hospital supplies.

In the years after the swine flu, the sector continued to shift to inventory-tracking software and distributor contracts to pare their storeroom shelves. The move raised efficiency but also heightened the risk of shortages if events disrupted markets.

In 2012, a health-policy nonprofit called the Association of State and Territorial Health Officials surveyed hospitals with CDC funding and found less than half of respondents had a mask stockpile.

At Tuomey, Mickey Sparrow, who was involved in the survey and then oversaw supplies for the Sumter, S.C., hospital, said he kept at least a week of hospital inventory on hand plus a stash of about \$50,000 of masks and other emergency supplies. "This is money sitting up there on a shelf gathering dust," he said.

Prisma Health, which took over Tuomey in 2017, said it reduced the hospital's inventory but took its own precautions. The coronavirus pandemic, however, exceeded the emergency planning projections of Tuomey and Prisma.

Christopher Powell, who oversees the supply chain for Tuomey and some other Prisma hospitals, said the disease has created demand no model would have projected.

### Manufacturers

Before spot shortages of respirator masks developed during the 2009 flu, makers were warned it could happen. HHS representatives gave presentations in 2007 to U.S. producers of N95 masks, saying all sectors must help prepare to meet needs in case of a pandemic.

At the time, around 30% of N95 respirator masks were made overseas, as well as 90% of surgical masks. 3M Co. produces the majority of U.S.-made N95 masks.

During the 2009 flu, manufacturers rushed to make more. 3M spent \$55 million to expand production lines in the U.S. and Singapore.

The revved-up industry production turned into a glut as the swine flu crisis abated in 2010, sooner than expected. In 2014, CDC officials met with about 10 manufacturers to discuss worrisome data the officials were getting about capacity. Even in the most conservative scenario for a pandemic, the U.S. would need 1.7 billion to 3.5 billion respirator masks, and would need 7.3 billion in the highest-demand scenario, according to models the CDC reported the next year. That was far above stocks and U.S. production capacity.

Manufacturing executives say companies were leery of building stockpiles because of their experience in 2009. Canada-based Medicom Group said it installed extra capacity at its plant in Augusta, Ga., for the swine flu but disassembled it after demand dried up. "If we do not have a long-term agreement, how can we invest more and more dollars into equipment that is going to sit and rot?" said CEO Ronald Reuben.

3M said it invested in surge capacity at all its plants following the 2002-03 SARS outbreak and used it to boost production during the 2009 flu and the current pandemic.

In 2014, officials at HHS's Biomedical Advanced Research and Development Authority, or BARDA, told Senate staffers the U.S. could boost domestic production by encouraging hospitals and U.S. agencies to buy American and by setting up federal emergency production lines, according to a presentation reviewed by the Journal. None of it happened.

### The Government

The Strategic National Stockpile, created as a pharmaceutical storehouse in 1999 for potential chemical and biological terrorism, was expanded over the years to address other hazards, including natural disasters and pandemics.

Congress never allocated specific ongoing funding for pandemics, despite priorities set by a governing board of

the directors of several government health organizations.

Its only significant funding for personal protective equipment came in 2006, as part of \$5.6 billion set aside for pandemic preparedness. This enabled the CDC to buy 104 million N95 masks and 52 million basic masks that year for the national stockpile. Most of the N95s were distributed during the 2009 flu and not replaced.

Greg Burel, who ran the stockpile through last year, said it focused on drugs that otherwise might not be produced, such as for combating a chemical or biological attack.

The CDC and HHS working group studying respirator supply concluded that in a pandemic, expanding capacity to produce the needed masks would take anywhere from six weeks to four months.

The group recommended ongoing stockpiling at the regional, state and federal levels.

Modest implementation of its plans began, such as setting up a permanent team at HHS to focus on respirator masks. That team pushed for the group that decides budget priorities for the national stockpile – called the Public Health Emergency Medical Countermeasures Enterprise, or Phemce – to put some money from the stockpile budget toward masks needed in a pandemic. A Phemce budget plan released in 2017 had a line item indicating a plan to allocate \$15 million annually to buy respirator masks and ventilators in future years.

A group within HHS also planned a system to monitor hospital use of PPE.

Robert Kadlec, named in late 2017 to lead emergency planning for HHS, made biodefense issues a greater priority than pandemics, according to former officials. Dr. Kadlec moved the national stockpile's operations from the CDC to his own group at HHS. He restructured the Phemce budget-planning group, consolidating power in its top leaders.

The respirator-mask team stopped meeting as a result, according to a spokeswoman for Dr. Kadlec and HHS. And monitoring of hospitals' use of personal protective equipment didn't happen because there wasn't money for it and hospitals were reluctant to share data, she said.

The line item for \$15 million a year to buy respirator masks and ventilators was removed in the budget document that came out in 2018. A spokeswoman said other budget money went to buy ventilators, though not masks.

The spokeswoman said Dr. Kadlec's reorganization was done "to enhance and evolve the federal capability for emergency response."

On Dec. 4, 2019, Dr. Kadlec told Congress a 12-state simulation showed the U.S. lacked sufficient manufacturing capacity for protective gear in a pandemic. He called supply-chain issues "among the most significant challenges" and "a matter of national security."

Coronavirus relief legislation enacted this year included \$16 billion for the stockpile to buy respirator masks, drugs and other medical products. Hospitals also won money from Congress to purchase PPE in case of a coronavirus surge in this fall. HHS has contracts to buy 600 million N95 masks over 18 months.

Slow off the mark

The first reports of coronavirus in China came in late December. The Trump administration played down the risk at first. U.S. hospitals' concern grew, though, and in late January, some moved to buy more protective gear. By then, suppliers were limiting orders.

Without federal coordination, manufacturers began to take action themselves. Executives of 3M met on Jan. 20 with University of Minnesota epidemiologist Michael Osterholm, who says he told them the China outbreak was going to expand into a pandemic. 3M began ramping up production at a South Dakota plant.

By early February, Chinese officials told producers there, including 3M, they had to sell all the masks they made in China to the government.

On Feb. 10, a Trump administration budget for next fiscal year proposed cutting money for FEMA's disaster-relief fund by nearly 70%. A White House budget spokeswoman said this was set based on past and anticipated disasters. (In March, Congress approved \$45 billion more for FEMA.)

States, hospitals and others soon began saying they were in dire need of personal protective gear. Officials at HHS's emergency-planning agency told congressional staffers on Feb. 14 there could be a shortfall of billions of masks.

Eleven days later, HHS Secretary Alex Azar told a Senate hearing the U.S. had 30 million N95 masks but would need 270 million more. The next day, he said he had misspoken. He said there were 30 million surgical masks in the stockpile but just 12 million N95 masks, five million past their expiration dates. Mr. Azar didn't respond to a request for comment.

Some hospitals were soon rationing masks and reporting delays in getting shipments from China.

Many masks from China were made in the province around Wuhan, where the disease began. It was quarantined.

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Rachael Levy and Tom McGinty contributed to this article.

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