

Vice News

# China Is Making Tons of PPE Respirators Good Enough For Asia and Europe. But U.S. Hospitals Can't Buy Them.

Fear of lawsuits and red tape are keeping them out of the hands of American frontline medical workers.

By **Daniel Newhauser**  
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WASHINGTON — Barbara Filippone has been exporting hemp fabric from China for decades, but since the novel coronavirus hit the United States, she's been putting her Asian connections to work on another popular product: Masks.

Through her business partner in China, she established relationships with factories in Shandong Province and made plans to ship particle-filtering respirators directly to American hospitals. Yet despite dire pleas by nurses for more of these masks, Filippone has been having trouble getting them into health care workers' hands.

“There's a lot of bureaucracy, paperwork, that's wasting time,” said Filippone, speaking on the phone from her office in Colorado. “All it takes is a factory in China to a healthcare facility, not all this red tape.”

Hundreds of factories in China are churning out millions of masks being used to suppress the virus across Asia and Europe, but importers can't get them to the front lines of the fight against COVID-19 in the United States because they haven't been certified by the Food and Drug Administration. Confusing government regulations preferring American products, old-school billing practices, and hospital administrators scared of being sued are keeping masks out of the hands of nurses and first responders during the coronavirus pandemic.

Two things immediately need to be done, according to these nurses and suppliers: First, President Donald Trump needs to either massively ramp up U.S. respirator production or formally and uniformly ease restrictions on foreign respirators, opening up the Chinese market. Second, hospitals need to start paying up front, instead of using their normal billing practices of paying a month or two down the line.

Even beyond the strained diplomatic relations and global shipping disruptions, governments and medical institutions have been too slow to adapt to the urgency of this quickly developing crisis. Nurses have shared horror stories of using cotton rags, bras, porous surgical masks or anything on hand to cover their mouths to keep from contracting COVID-19.

Meanwhile, nurses who are lucky enough to have access to U.S. government-approved N95 respirators have been instructed to re-use them, often so many times that they're barely effective anymore. The government said earlier this month it has only 1% of the 3.5 billion N95s it would need to fight this virus. That isn't enough.

3M, the major manufacturer of these masks, has pledged to produce more than 1 billion N95s by the end of the year. Yet in the meantime, the government and hospitals have been slow to allow other respirators onto the market, like the Chinese KN95, which may not meet FDA regulations but offers comparable levels of protection, and is certainly more effective than a piece of cotton or gauze, let alone a bra cup.

These other respirators are available, and nurses need them now, according to people on the front lines. But many hospitals are too spooked to buy respirators unless they're manufactured by 3M, Honeywell, or a smattering of other companies who have paid for the FDA to certify their Chinese factories.

“The rest of the world finds it perfectly acceptable to use these masks, but not the United States because the FDA fairies haven't gone and blessed it,” said Matt Wolf, a Los Angeles-based tile importer, who has been trying to use his China connections to funnel masks to hospitals. “Those were the same masks that were able to get China healthy during COVID-19. Same exact thing, and yet the hospital administrators are saying, ‘Oooh, I don't think we can take those yet.’”

## How the N95 became the standard

Prior to the 2000s, it was common for frontline health care workers to wear only surgical masks. Largely spurred by the fear of tuberculosis, regulations started to change, said Linda Rosenstock, who oversaw regulations mandating N95 respirators in health care settings as the director of the CDC's National Institute for Occupational Safety and Health under President Bill Clinton.

“We just said, ‘No, healthcare workers are our frontline emergency responders and they're too vulnerable with that. It's just not meant for that job,’” she said. “The battle then was our fellow scientists thought we were being overly protective of workers and that they were fine.”

In a cruel twist of irony, N95s are in short supply now, and those very regulations meant to protect health care workers are leading to an environment where those floppy surgical masks are the only thing between nurses and the coronavirus. Rosenstock agreed that, absent sweeping federal action to ramp up N95 production, these other respirators are a better choice.

“Whatever regulatory burden might be preventing those from being put into the use here, if available, should be absolutely dealt with,” she said. “That’s a given.”

Since the pandemic started to spread, the FDA issued guidelines, as recently as this week, expanding the kinds of respirators hospitals can employ. Australian, Brazilian, European and Japanese respirators were approved, and Trump signed a law last week exempting American manufacturers from liability for sending N95s to health workers.

At the same time, the FDA instituted fees or mandates on letters from mask-making factories. And the CDC advised that Chinese KN95s be used only as a last resort. That has led to confusion and delay, as regulatory hurdles slow the process down and hospitals are interpreting the guidelines in all kinds of different ways.

“The FDA cannot get out of its own way. Why doesn't the FDA just say, ‘Okay, let's use what the Brits are using, what the Canadians are using, what every normal country is using?’” said MIT Professor Yossi Sheffi, who advises

hospitals on supply chain management. “They think that only N95 works? I mean, this is insane at this time, it's insane. It's like you're fighting a war, and somebody comes from the outside and says, ‘I can give you some guns and tanks and airplanes.’ And you say, ‘No, let me develop my own.’”

Sheffi said as a result, hospitals are terrified they'd be sued for buying these suboptimal masks to outfit their staff — and they might be right. That's why the government needs to step in and give them certainly that they wouldn't be liable.

“We live in the most litigious society on Earth. I mean, they'll go bankrupt for sure,” Sheffi said. “If the nurse is using a handkerchief to cover her mouth, and something happened, it's the nurse's fault. If the hospital orders 100,000 masks and one person dies or something bad happens then it's the hospital that is on the hook.”

## Second-tier respirators

Hospitals are definitely stretched thin, but they do share some of the blame. Filippone and Wolf, the two respirator suppliers, both said hospitals could make the choice to use the second-tier respirators, liability be damned. Some hospitals, both suppliers said, have come around to that idea just this week.

At the same time, though, hospitals are tied in knots by their own bureaucracy. They're used to receiving shipments, invoicing and paying at the end of the month. That's not acceptable to factories and small-time suppliers, who need money up front to keep the materials coming and the assembly line running. That leads to a kind of stand off: Cash-strapped hospitals are scared to shell out money in case they'd get ripped off by Chinese factories they don't know, and those factories are reluctant to accept an IOU because they need money to keep producing goods.

Bad actors are price gouging or ripping people off for 3M brand model 8210 N95s, charging as much as \$30 for a respirator that used to cost \$3 or \$4. Meanwhile, people like Filippone and Wolf say they are trying to bring in the Chinese certified KN95s or other classes of masks into the country for close to \$3 per mask and little or no profit.

“What needs to happen differently is we have to adjust to the changing supply chain,” Wolf said. “Factories demand full prepayment for the masks before they even ship them, and so if hospitals don't get on board with that, they're not going to get the masks. No one's going to take the risk.”

All this results in horrifying conditions for nurses. Tami Strzelecki is a Michigan-based nurse who's been quarantined, presumed positive after being exposed to coronavirus on the job. She can't know for sure, though, because tests aren't readily available.

“A lot of hospital systems right now are protecting themselves and not their health care professionals,” she said. “They're saying, ‘Hey, we're following the CDC guidelines,’ even though the CDC guidelines are pretty much garbage right now.”

Hospitals should worry less about the potential lawsuits that could come from acting, she said, and more about the ones that will definitely come if they don't act now.

“They don't want to give out faulty masks,” she said. “But at the same time, why are they not seeing that they're going to get sued by the thousands or millions of healthcare professionals that get ill, die, hospitalized because they were exposed?”

*Alex Chitty contributed reporting*