The rapid adoption of telehealth by physicians and its widespread acceptance by patients is seen as a silver lining of the COVID-19 pandemic. Another could be the emergence of homegrown personal protective equipment (PPE), as one health system’s do-it-yourself manufacturing initiative has been given Food and Drug Administration (FDA) clearance to supply the rest of the nation.

The chemo-rated nitrile exam gloves manufactured by SafeSource Direct has earned 510(k) clearance from the FDA to be used in health care. The company’s two Louisiana facilities are capable of producing 108,000 gloves an hour, and plans call for building the capacity to make 2 billion gloves annually.

SafeSource Direct was founded through partnership between Alabama-based construction contractor, property developer Trax Development and New Orleans-based Ochsner Health. Ochsner a member of the AMA Health System Program, which provides enterprise solutions to equip leadership, physicians and care teams with resources to help drive the future of medicine.

Ochsner is a member of the Irving, Texas-based group purchasing organization, Vizient, who works with a wide range of organizations for cost-effective health care solutions. Less than two weeks after the FDA announcement, Vizient announced that—once the needs of Ochsner facilities are met—SafeSource Direct will focus on the Vizient’s members that are seeking a domestic and committed PPE supply.

**Weak links in supply chain**
Ochsner Health’s SafeSource Direct joint venture has received FDA approval for its exam gloves and will make 2 billion gloves a year.

New Orleans was one of the early hot spots for COVID-19. As the need for PPE skyrocketed, the local community pitched in and Ochsner received alcohol-based hand sanitizer from local distilleries, and noted New Orleans fashion designer NOLA Couture made gowns and masks.

But Ochsner, which operates 47 hospitals and has more than 4,600 employed and affiliated physicians, knew a long-term solution was needed.

In the spring of 2021, Ochsner partnered with Trax on a $150 million project to retrofit an existing manufacturing facility and to develop a new one.

SafeSource Direct also produces Level 1 and 3 surgical ear-loop and surgical-tie masks and standard three-ply Level 1 and 3 procedure masks, which were FDA cleared last spring.
The company has already delivered 1.5 million shoe covers to the Indian Health Service, and it is ramping up operations to start making N95 respirators, hair-bouffant head covers and isolation gowns.

“The FDA approval for health care is huge milestone, because—while the gloves can be used in many other industries—in health care, the gloves need to have the FDA approval for us to even entertain using them,” said Régine Villain, Ochsner’s system chief supply chain and support services officer.

“Getting over that hurdle was really important to open the gloves to the health care industry market,” Villain added. “We’ve been able to have a lot more accelerated conversations with multiple health systems across the country.”

While the gloves required FDA approval, other SafeSource products, such as the N95 respirators must pass inspection with the National Institute for Occupational Safety and Health.

Along with Vizient, SafeSource is also speaking with other GPOs and distributors.

“Vizient is a vehicle by which we’re introducing SafeSource products to the national stage,” Villain explained. “Ochsner is a Vizient institution, however, from a SafeSource point of view, we’re trying to be as agnostic as possible, and we’re turning over every stone and making sure that we are having conversations with all interested partners.”

Secure supply isn’t only benefit

Health systems and physician practices throughout the country were scrambling to find PPE in 2020 and 2021.

Villain recalled the “aha moment” when Ochsner leaders decided enough was enough.

“We were sitting in the boardroom one day and looked at each other and said: ‘You know what? This is insanity,’” Villain recalled. “We really need to be in the business of making our own PPE to protect our team and take better control of our destiny.”

Taking this to the next step, plans call for SafeSource to become a fully vertically integrated operation by manufacturing the liquid nitrile needed for gloves and the laminate fabric needed to make masks, gowns and bouffant hair covers in a nearby facility.

“We can't purport ourselves to be domestic manufacturers if the raw material is coming from overseas,” Villain said. “So, to solidify our ability to truly be resilient and be able to have others rely on us, we're going to go in the raw-materials space as deep as we can.”
While the capacity to produce liquid nitril is still being developed, SafeSource is already manufacturing laminate fabric and finding customers for it outside of health care.

All of this is building resiliency into their supply chain, more dependability for SafeSource customers, and more revenue for the health system.

“If we can solidify our space in that, that’s something additional—what we call ‘lagniappe’ here,” Villain said, applying the Cajun-French term used in New Orleans that means “a little something extra.”

The joint venture has already created more than 550 new high-wage jobs and will create around 2,200 new direct and indirect jobs within the next two years.

Buying its PPE from SafeSource also aligns with Ochsner’s environmental, social and governance priorities, Villain said.

It “eliminates the carbon emissions associated with shipping containers around the world, and it ensures that our products are not only high quality but also manufactured ethically,” she explained.