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Chinese manufacturer receives approval to deliver N95 masks to California

By Sascha Matuszak

Chinese auto manufacturer BYD Auto Co. Ltd. received approval[1] from the United States National Institute for Occupational Safety and Health (NIOSH) to sell U.S. standard N95 masks to California and Washington[2] after three previous applications were denied and one withdrawn.

California signed a contract with BYD in April, at the height of the first wave of the COVID-19 pandemic, for just under USD 1 billion to supply the masks. BYD failed the NIOSH approval process, however, and the state was compelled to extend the deadline for delivery of the product several times before approval was finally granted June 7.

The process highlights a few issues regarding medical supply chains, the challenges of retooling manufacturing facilities to meet immediate demands, and the regulatory hurdles in place to protect health care workers and ensure medical supplies that enter the United States are high quality.

The inefficiencies and lack of resilience in medical supply chains were dramatically revealed by the COVID-19 pandemic. Despite repeated calls to diversify supply chains and build in resilience and redundancy, medical supply chains were unprepared for the demand driven by COVID-19, and nations around the world dealt with shortages of medical supplies and equipment from masks to gowns to ventilators.[3] As *RSCC* reported[4] in April, "As recent as October 2019, Janet Woodcock, director of the Center for Drug Evaluation and Research, testified before the U.S. Food and Drug Administration (FDA) that medical supply chains were dispersed, inflexible and vulnerable to shocks and surges."

Woodcock's recommendations were to locate and research all facilities that produce drugs for the U.S. market, including those the World Health Organization deems essential medicines and drugs used to counter biological, chemical, nuclear or radiation threats and influenza.

The inflexibility and dispersion applied not just to drugs, but also to equipment such as the masks BYD proposed to deliver to California. BYD, seeing an opportunity to turn a profit from inflated prices, low supply and high demand, attempted to quickly retool its facilities and produce face masks alongside automobiles. The result was a subpar face mask that required repeated tests to qualify. According to NIOSH,[5] BYD face masks did pass the NIOSH tests on June 5.

The NIOSH application process

The approval process for medical equipment, including masks and respirators, is rigorous. It requires on-site visits, samples, answers to a list of questions and time. The NIOSH, an arm of the Centers for Disease Control and Prevention, has online instructions[6] that describe the process and include links to the many procedures and documents required.

There is guidance[7] for the standards respirators must meet, applicable fees, as well as information regarding regulatory requirements, such as compliance with 42 C.F.R. § 84.[8] This rule stipulates how the NIOSH will evaluate respirators, how respirators will be categorized, testing procedures and the different levels of filter efficiency required to meet certain standards. This process was obliquely criticized in a *Wall Street Journal* report[9] that suggested the process "could hinder getting much-needed protective equipment to [health care workers] in a crisis, even when manufacturers respond quickly."

Despite the delays experienced by BYD and others, the alternative is subpar equipment sold by middlemen on online exchanges for exorbitant prices.[10] The problem in this case is not the process itself, but the fact that warnings regarding the nature of the fragmented and inflexible medical supply chain went unheeded. When markets demanded an immediate response to a crisis from a supply chain that was woefully unprepared for such a demand, delays became the norm.

Opportunities going forward

The NIOSH regulatory process is rigorous but straightforward. The resources a company needs to meet for an approval are available online. Even in the midst of a crisis, with thousands of different markets demanding immediate action, the process was able to grant approval within a few months.

What this means for suppliers and potential vendors is that the medical supply chain presents an opportunity for growth. Given the ongoing pandemic and the potential for more similar challenges in a globalized world, companies that are able to diversify their supply chain, meet and understand the approval processes for supply of critical medical equipment to needy markets, and produce quality equipment at market prices will thrive.

Additionally, it is possible that governments in North America, Europe and elsewhere will support companies that innovate within this industry with preferential policies. Indeed, Sen. Josh Hawley, R-Mo., introduced the Medical Supply Chain Security Act[11] in February 2020. The act would, among other things, give the FDA authority to require that manufacturers of medical devices notify it when they become aware of circumstances that may lead to the shortage of an essential medical device and allow the FDA to expedite the review of essential medical devices that require pre-market approval in the event of an expected shortage reported by a manufacturer.

Takeaways

- The approval process for medical equipment is rigorous and straightforward and provides protection for health care workers in the United States.
- The fragility of the medical supply chain has revealed a need for innovation in the industry.

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4 Sascha Matuszak, "Building resiliency into medical supply chains," *Report on Supply Chain Compliance* 3, no. 7 (April 2, 2020), https://bit.ly/30Vc2Sk.
5 NPPTL, NPPTL COVID-19 Response: International Respirator Assessment, test result, June 5, 2020,

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6 "Respirator Approval Information," Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, updated June 10, 2020, https://bit.ly/3fCHMjj.
7 Approval Tests and Standards for Air-Purifying Particulate Respirators, 85 Fed. Reg. 20,598 (April 14, 2020) , https://bit.ly/2YeETj2.
8 " 42 CFR Part 84 Respiratory Protective Devices," Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, last reviewed March 4, 1997, https://bit.ly/2UYAUVz.
9 Liza Lin, "Chinese Electric-Car Maker Gets U.S. Approval to Supply N95 Masks."
10 Sam Cooper, Stewart Bell, and Andrew Russell, "Coronavirus: Counterfeit Chinese-made face masks pulled offline after Global News probe," Global News, March 31, 2020, https://bit.ly/2YcS3gb.
11 Sascha Matuszak, "United States senator proposes changes to improve security of medical product supply chain," *Report on Supply Chain Compliance* 3, no. 5 (March 5, 2020), https://bit.ly/2Cf7egh.