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Chinese manufacturer receives approval to deliver N95 masks to California

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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to sell U.S. standard N95 masks to California and Washington^[2] after three previous applications were denied and one withdrawn.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.”

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