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A Literature Review of the United States of America's Reliance on Imported Mechanical Ventilators During the Pandemic

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ABSTRACT

This paper provides a literature review of United States of America's reliance on imported mechanical ventilators during the Covid pandemic. The abstracted and cited articles show that the United States was too reliant on imported mechanical ventilators, primarily imported from Asia which led to shortages as the cases of Covid surged at various points during the waves of Covid cases. This supply and demand imbalance was not just an inconvenience such as the toilet paper shortage and other supply chain disruptions of basic commodities; this supply and demand imbalance had life and death impacts for many first responders, health care workers, nurses, doctors, and the general public in the US. There is continued interest in this topic area in Congress as The Select Subcommittee on the Coronavirus Pandemic held a hearing in 2024 titled "Examining the White House's Role in Pandemic Preparedness and Response" to discuss the Office of Pandemic Preparedness and Response Policy's (OPPR) role in responding to and preventing future pandemics. This paper presents key graphs to visually display the changes in supply and demand throughout the pandemic. As many health professionals predict the possibility of future pandemics, there is a continued need to have US self-reliance on domestic produced mechanical ventilators. The paper concludes with an assessment that the US still needs to make further changes in federal manufacturing and health care public policy to become less reliant on imported mechanical ventilators for the next pandemic occurrence.

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Introduction

This paper provides a literature review of United States of America reliance on imported mechanical ventilators during the Covid pandemic. The abstracted and cited articles show that the United States was too reliant on imported mechanical ventilators, primarily imported from Asia which led to shortages as the cases of Covid surged at various points during the waves of Covid cases. This supply and demand imbalance was not just an inconvenience such as the toilet paper shortage and other supply chain disruptions of basic commodities; this supply and demand imbalance had life and death impacts for many first responders, health care workers, nurses, doctors, and the general public in the US. There is continued interest in this topic area in Congress as The Select Subcommittee on the Coronavirus Pandemic held a hearing in 2024 titled "Examining the White House's Role in Pandemic Preparedness and Response" to discuss the Office of Pandemic Preparedness and Response Policy's (OPPR) role in responding to and preventing future pandemics. This paper presents key graphs to visually display the changes in supply and demand over the duration of the pandemic. As many health professionals predict the possibility of future pandemics, there is a continued need to have US self-reliance on domestic produced mechanical ventilators. The paper concludes with an assessment that the US still needs to make further changes in federal manufacturing and health care public policy to become less reliant on imported mechanical ventilators for the next pandemic occurrence.

Methodology

This paper presents a literature review of articles and reports related to the US reliance on imported PPEs during the Covid Pandemic. Given the overlap in content of various articles, a few selected articles are presented in an abstracted format. Relevant graphs and charts from the articles and reports are included to visualize the US PPEs supply and demand imbalance throughout the Covid Pandemic.

Findings from Literature Review

As difficulties with domestic ventilator production and distribution persist as a challenge, it has become increasingly clear that the US needs to consider diverse policy options to effectively address future pandemics. According to the JAMA Network, US hospitals and various health systems responded to the limited supply of ventilators by increasing their supply orders for these devices. Though aimed at helping, the emphasis on ventilators overlooked the fact that simply stockpiling the devices alone does not guarantee ventilation. There are several factors that lead to effective ventilation such as well-trained personnel, compatibility with regional hospital equipment and device logistics [1]. Prior to the COVID-19 pandemic, the US

Strategic National Stockpile possessed about 20,000 devices, with the LTV-1200 (Vyaire Medical) as the latest edition. Subsequently, clinical methods have increasingly preferred high-flow nasal cannula oxygenation and noninvasive mechanical ventilation, which the LTV-1200 is not fit for. Additionally, monitoring ventilator readings remotely has become essential as staff aim to reduce time in isolation rooms, and newer devices are more equipped to achieve this. Therefore, a serious hurdle in stockpiling is to guarantee that equipment stays adequate for responses, requiring regular investment.

Despite these improvements and the progressing needs for remote ventilator monitoring, the early pandemic response exposed critical flaws in the federal stockpile, revealing that past government efforts to uphold an adequate inventory of ventilators were insufficient as the crisis developed. In 2001, the anthrax crisis caused the Bush administration to acknowledge that the U.S. was ill-equipped for a serious outbreak and triggered the development of BARDA to support healthcare advancements not taken up by private companies. BARDA encountered difficulties when contracting with Newport Medical Instruments for $4.3 million to manufacture 10,000 ventilators, as the project was terminated following Newport's acquisition by Covidien. Medtronic subsequently bought Covidien and stated that they were unable to produce ventilators because the instruments did not satisfy all government criteria and further development would be too costly. BARDA turned to Phillips and acquired a contract of 10,000 ventilators for $3,280 each in 2019. In April of 2020, Phillips failed to deliver a single ventilator as per their contract because the company was experiencing rapid business with other buyers who were paying $17,154 per ventilator as of March 2020. Even in the early stages of the deadly COVID-19 pandemic, the government displayed minimal urgency as they had General Motors manufacture 43,000 ventilators through the Defense Production Act [2]. The U.S government negotiated a new contract with Phillips where both parties provided guarantees that the ventilators will be delivered by August, long after the initial peak of the pandemic. Having General Motors develop the ventilators is a suboptimal choice because shifting assembly to a non-medical supplier will introduce delays as the company must take time to refurbish its facilities, educate staff and develop supply chains for medical-grade materials. Quality of care is threatened due to General Motors lacking the specialized skills and background in ventilator manufacturing. The inadequacy of Newport Medical Instruments, Covidien, Medtronic, and Phillips to honor their contracts placed the U.S. in the same vulnerable condition the initial BARDA initiative sought to avoid. noted three key regulatory options to accelerate ventilator production. Firstly, it's crucial to review and uphold existing contracts, such as the U.S enabling Phillips to prioritize a more lucrative deal, causing delays in completing their independent contract with the U.S. Due to the high-stress environment of the pandemic, Phillips effectively leveraged the demand in their products to prioritize customers willing to pay the highest price for their product. As the U.S. experienced a shortage of immediate alternatives, they were forced to accept Phillips' delays in order to avoid potential complications, such as compliance negotiations, that could arise from pushing Phillips forcefully. Proactive management of potential delays could have affirmed that Phillips modified their production plan to meet deadlines.

Secondly, the 1980 Bayh-Dole Act enforces intellectual property regulations for federally supported inventions. Since $13.8 million in funding was granted to Phillips for research and development, the federal government can exercise "march-in rights" to issue a license to another entity if Phillips does not address public needs with the invention. Unfortunately, the act has never been successfully applied, as it unfairly benefits patent holders while neglecting public welfare. As a result, the industry has capitalized on federal financial support without being held responsible for their legal obligations.

As a third point, Section §1498 of the US Code could have been applied to increase ventilator production by enabling the federal government to license inventions without patent holder authorization, given that fair compensation is received. The most relevant use of §1498 was seen in 2001 during the Bush administration, when the government attempted to acquire the antibiotic ciprofloxacin from Bayer. Bayer was unwilling to increase production and lower the price of the antibiotic until the Bush administration threatened to invoke §1498, after which Bayer quickly supplied the medication at the specified volume and price. Additionally, the Trump administration refused to exercise §1498 in 2017 to secure Hepatitis C treatments for Medicaid recipients, fearing that a high-cost litigation would ensue. The emphasis on using §1498 for reduced ventilator costs is expected to incite significant opposition because companies worry that it could trigger price controls. Should §1498 be implemented, it will provide a way to improve access to ventilators in the event of future public health crises.

The U.S. government invested heavily in acquiring nearly 200,000 ventilators with varying capabilities during the pandemic. JAMA Network states that to meet the intended benefit in future pandemics, the government must also invest in developing practical methods for implementing the equipment effectively. Branson et al. agree that the United States is not better positioned for self-reliance on ventilators in 2024 compared to the start of the pandemic. As the United States government pushed to speed up production of ventilators, many first-time ventilator developers were motivated by anticipated demands and an intent to deliver solutions. The United States Department of Defense (DoD), in collaboration with the U.S. Special Operations Command, created the Hack-a-Vent Challenge. This program crowdsourced 172 ventilator designs and, within 8 weeks, narrowed them down to 5 finalists, which were then quickly developed and assessed [3]. One device, CorVent, was awarded an EAU but was never used in patients. CorVent, a ventilator designed to accommodate multiple patients concurrently, never received full FDA clearance. The concept of shared ventilation (two to four patients per ventilator) was sparked by a controversial social media video that claimed to demonstrate a convenient technique to save lives by connecting four patients to one ventilator. Early in the pandemic, the FDA approved numerous ventilators designed for concurrent patient use under the EUA. However, none of these ventilators adequately dealt with the shortage, and nine of the devices initially sanctioned under the EUA were eventually revoked.

Misinformation spread through social media greatly affected the distribution of resources by the United States government, resulting in investments in projects that ultimately proved unbeneficial. According to Stanford University, fake news spreads through social media by gradually exposing individuals to various forms of misinformation, weakening their defenses and increasing their susceptibility over time [4]. Older adults, younger individuals, and those with minimal education background seem to be the most vulnerable to false information [5]. In order to manage the spread of health-related misinformation in future pandemics, it is imperative to establish a cross-governmental effort that assures coordination among national, state, and local levels. This approach must involve a formal process for the evaluation and analysis of medical falsehoods, with all levels of government working towards common goals (Sell et al., 2021). Although managing misinformation is essential

for future pandemics, it's also important to recognize the progress made in our pandemic response. To illustrate, the US is now much more equipped for managing ventilators relative to the start of the pandemic.

In response to the Administration for Strategic Preparedness and Response (ASPR) introducing additional mechanical ventilators to the Strategic National Stockpile (SNS), the American Association for Respiratory Care (AARC) has partnered with ASPR and SNS to offer vital resources for respiratory therapists. This features extensive information on all 15 mechanical ventilators in the SNS, supporting the preparation for ventilating a substantial population in a health crisis [6]. Comprehensive information can be easily accessed through the Ventilator Training Alliance mobile app, offering respiratory therapists fundamental ventilator training resources such as training videos and diagnostic guides. These advancements in ventilator support are reinforced by Cardinal Health's strategies to enhance supply chain resilience, including partnerships with data firms and the U.S. government to establish a real-time data system that detects pandemic hotspots and identifies regions with critical ventilator needs. According to Mike Kaufmann, CEO of Cardinal Health, the data analysis system precisely determines COVID-19 hotspots daily and estimates ventilator needs up to a week in advance, facilitating timely redistribution of ventilators to the areas with the highest demand [7].

The effectiveness of ongoing analytics and strategic redistribution of ventilators underscores the value of efficient medical device oversight in healthcare.

While domestic strategies have enhanced ventilator preparedness, an analysis of ventilator imports and exports between 2019 and 2021 emphasizes key changes in global trade throughout the pandemic which has shown in Fig.1. Covid-19 created an extraordinary rise in demand for ventilators in 2020, as the annual growth rate of ventilators increased by 66.2% between 2018-2019 and 2019-2020 (World Trade Organization, 2022). However, ventilator trading slowed in 2021, reflecting a 126.4% decrease in the annual growth rate during 2019-2020 and 2020-2021. The dollar value of US exports/imports in millions exhibited a doubling from 2019 to 2020, followed by a 20% reduction entering 2021. The sharp decline in 2021 is linked to the availability of COVID-19 vaccines, which stabilized the pandemic. Consequently, the existing stockpile of durable ventilators was assessed as sufficient, reducing the demand for additional purchases.

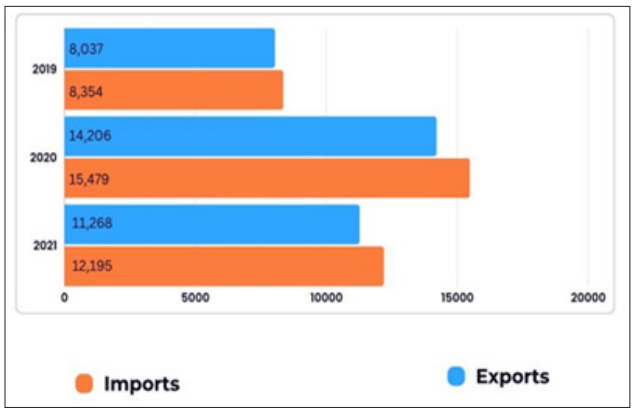

Figure 1: Trade in Ventilators, 2019-2021

Source: World Trade Organization, 2022

These elements emphasized how supply and demand played a vital role in driving ventilator market growth during this critical time and will continue to influence market dynamics and projections through 2027. The demand for ventilators in 2020 grew immensely as many patients experienced Covid-19 related issues that compromised their respiratory system. Segment #1 (acute care ventilators) and Segment #6 (emergency transport ventilators) on the graph below experienced the sharpest increase, while Segment #3 (home care ventilators) and Segment #4 (neonatal ventilators) displayed a minor decline. This trend is likely prompted by the spike in demand for emergency care resources in response to the pandemic, combined with a reduction in non-urgent healthcare visits as the public adhered to social distancing protocols and prioritized limiting exposure. To manage the influx of critically ill patients during the pandemic, healthcare systems shifted resources towards COVID-19 care, deprioritizing non-emergency and outpatient care. This adjustment resulted in reduced demand for neonatal and home care ventilators. In 2021, as the demand for ventilators stabilized, sales gradually decreased because many organizations had already acquired large sums of ventilators during the peak of the pandemic in 2020. The ventilator market approached saturation as manufacturers have scaled up production to meet the current supply needs. However, with the growing incidence of chronic diseases, the demand for ventilators is projected to stay elevated in the coming years. The U.S Ventilator market size value in 2022 was USD 1.02 billion and is expected to reach USD 1.25 billion in 2030.

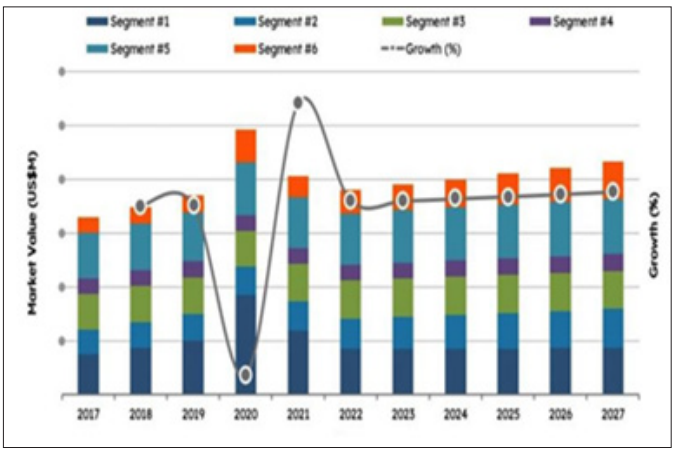

Figure 2: Ventilator Market Growth by Segment, United States, 2017-2027

Source: iData Research, 2021

Accordingly, the U.S. mechanical ventilator industry is estimated to reach a market value of USD 4.989 billion by 2033, increasing from USD 3.85 billion in 2023. The COVID-19 pandemic greatly expanded the ventilator market due to a major disparity between the supply and demand for mechanical ventilators. In 2023, as the ventilator demand stabilized following the pandemic, manufacturers observed a gradual reduction of sales due to the prior spike in purchases. Additionally, the conclusion of U.S Department of Health and Human Services contracts with Hamilton, Phillips, and Vyaire, together with the decline in acute care COVID-19 patients added to the deceleration of the ventilator market. However, as chronic diseases become more widespread, the demand for ventilators is projected to stay elevated, with advancements in technology stimulating the need for low cost and sophisticated models. Portable ventilators are expected to undergo the most rapid growth due to functionality in a range of care settings, including ambulatory centers and home healthcare. Furthermore, the Every Newborn

Action Plan (ENAP) launched by the World Health Organization to mitigate neonatal deaths from birth asphyxia is driving the increased demand for neonatal ventilators.

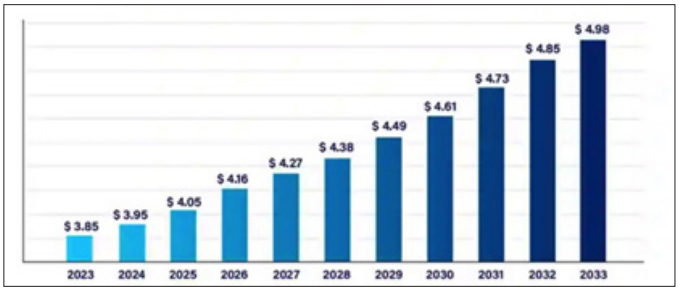

Figure 3: US Mechanical Ventilator Market Size, 2023-2033 (USD Billion)

Source: Nova One Advisor, 2024

Conclusion

This paper provided a literature review of United States of America reliance on imported mechanical ventilators during the Covid pandemic. The abstracted and cited articles showed that the United States was too reliant on imported mechanical ventilators, primarily imported from Asia which led to shortages as the cases of Covid surged at various points during the waves of Covid cases. This supply and demand imbalance was not just an inconvenience such as the toilet paper shortage and other supply chain disruptions of basic commodities; this supply and demand imbalance had life and death impacts for many first responders, health care workers, nurses, doctors, and the general public in the US. There is continued interest in this topic area in Congress as The Select Subcommittee on the Coronavirus Pandemic held a hearing in 2024 titled "Examining the White House's Role in Pandemic Preparedness and Response" to discuss the Office of Pandemic Preparedness and Response Policy's (OPPR) role in responding to and preventing future pandemics. This paper presents key graphs to visually display the changes in supply and demand over the duration of the pandemic. As many health professionals predict the possibility of future pandemics, there is a continued need to have US self-reliance on domestic produced mechanical ventilators. The paper concludes with an assessment that the US still needs to make further changes in federal manufacturing and health care public policy to become less reliant on imported mechanical ventilators for the next pandemic occurrence.

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