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## Ventilator Rationing During the COVID-19 Pandemic

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In March of 2020, the world was facing an unprecedented pandemic. COVID-19, a previously unknown virus, had been spreading across the globe and hundreds of thousands of people were infected. Without a vaccine or known treatment, leaders everywhere mobilized to prevent the disease's spread and save lives. The virus often attacked the respiratory system, making it impossible for some critically ill patients to survive without breathing assistance.

For the first time in United States history, all states, territories, and some federally recognized tribes were approved for major disaster declarations, granting them federal assistance in response to the unfolding crisis.<sup>1</sup> Following President Trump's declaration of a federal emergency on March 13, the Federal Emergency Management Agency (FEMA) began coordinating procurement and distribution of medical supplies, equipment, and drugs with public and private partners.<sup>2</sup> Best known for managing regional response efforts following hurricanes and other natural disasters, FEMA was confronting a new crisis with far-reaching economic, health, and social impacts.

The organization quickly set up a Supply Chain Stabilization Task Force led by Rear Admiral John Polowczyk to accelerate manufacturing and evaluate state needs.<sup>3</sup> However as global supply chains slowed dramatically due to the virus, the United States' reliance on overseas firms for medical manufacturing posed a major challenge. Face masks and other personal protective equipment (PPE), especially important for frontline medical care workers, proved relatively uncomplicated to produce domestically and could be re-used in extenuating circumstances. However, ventilators, the medical device used to "breathe" for patients in severe respiratory distress, were much more complex to manufacture.<sup>4</sup> Before March was over, state governors' requests for the life-saving machines outpaced supply.<sup>5</sup> With the possibility that medical facilities in the hardest hit states might not have enough ventilators to keep COVID-19 patients alive, FEMA would need to decide how to allocate their limited supply.

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## A Global Crisis

As countries around the world geared up to ring in the new decade, worrying news began to filter out of China. Reports of a mysterious virus had been circulating inside the city of Wuhan in Hubei Province. On December 30, Dr. Li Wenliang, an ophthalmologist at Wuhan Central Hospital, took to WeChat to warn colleagues about a cluster of patients displaying pneumonia-like symptoms: fever, trouble breathing, cough. He believed they had contracted SARS,<sup>6</sup> a relatively short-lived but sometimes fatal respiratory illness caused by a coronavirus that appeared in 2002. When a formal notice from the Wuhan Municipal Health Commission to city hospitals sent later that evening was leaked online, officials alerted the World Health Organization's (WHO) China office. On January 4, in their first public notice about the outbreak, the WHO posted to Twitter: "China has reported to WHO a cluster of pneumonia cases—with no deaths—in Wuhan, Hubei Province."<sup>7</sup>

By early March, that cluster had evolved into a widespread epidemic. Identified as a novel, respiratory coronavirus and named COVID-19,<sup>8</sup> the disease quickly spread beyond China's borders (see Exhibit 1).<sup>9</sup> On March 11, the WHO declared a global pandemic and the United States followed with a declaration of national emergency two days later.<sup>10</sup> While much was still unknown about COVID-19, it was becoming clear that this particular coronavirus was unique in its transmissibility, wide range of symptoms, and the degree to which it would disrupt public life. Leaders across the world were closing borders, shutting down nonessential businesses, and imposing mandatory quarantines in an attempt to control its spread. By late March, the mortality rate was estimated to be roughly 10 times that of the seasonal flu<sup>11</sup> and the number of Americans infected was doubling every three days (see Exhibit 2).<sup>12</sup> Urgent action was required to address the grim situation unfolding.

Watching as the health care systems in China and numerous European countries became increasingly strained, doctors in the United States began sounding the alarm, requesting supplies to manage patient care and protect health care workers. They knew that dwindling resources and overburdened frontline responders abroad foreshadowed what might lay in store at home.<sup>13</sup> In the absence of a vaccine or known cure for COVID-19, mechanical ventilators for critically ill patients and personal protective equipment for frontline medical workers would be especially critical to saving lives and slowing the rate of infection.<sup>14</sup>

## The Ventilator Market

The majority of people infected with COVID-19 experienced mild symptoms or no symptoms at all but those who developed the most severe respiratory infections needed breathing assistance to stay alive.<sup>15</sup> In these cases, mechanical ventilators were used to deliver oxygen to a patient's airways through a face mask (noninvasive ventilation) or directly take over the body's breathing processes via the trachea (invasive ventilation).

Research firm IBISWorld expected the market for ventilators to reach \$4.2 billion globally in 2020. This figure represented about a 50% increase over 2019, though revenues were expected to somewhat decline as the pandemic subsided—and /or treatments improved—to \$3.3 billion

over the five years leading to 2025. Ventilators designed for adult patients made up 80% of the total market, with neonatal ventilators comprising the remaining 20% of industry revenue. Note that while the sudden uptick in ventilator demand in 2020 was caused by the COVID-19 outbreak, more modulated longer-term industry growth was expected to be driven by a growing geriatric population and rise in the incidence of respiratory disorders worldwide.<sup>16</sup>

Twenty-five countries exported more than \$10 million of ventilators in 2018 (see Exhibit 3),<sup>17</sup> with European and North American-based firms accounting for the majority of ventilator production. Leading ventilator manufacturers tended to be diversified, multinational companies with facilities located around the world. As of 2020, major players in the industry included US-based Vyaire Medical Inc., Ireland-based Medtronic PLC, and Dutch-based Koninklijke Philips NV.<sup>18</sup> These firms and others produced about 50,000 ventilators per year.<sup>19</sup> With proper maintenance, the devices can last for 10 years.<sup>20</sup>

## A Challenged Global Supply Chain

While hospitals and other health care providers represented the largest purchasers of ventilators,<sup>21</sup> they did not stock enough units to meet demand in catastrophic, “black swan” events such as the terrorist attacks of September 11 or a global pandemic. An analysis by the Society for Critical Care Medicine estimated that approximately 200,000 ventilators were available in the United States at the onset of the COVID-19 outbreak.<sup>22</sup> The majority of these devices were portable or noninvasive machines intended for temporary use during patient transport or to deliver care for disorders like sleep apnea.<sup>23</sup> Only an estimated 62,000 machines were the type of full-featured, invasive ventilators known to adequately support patients with severe respiratory failure. Should the worst come to pass, health care officials predicted that one million individuals might require them.<sup>24</sup>

Stocking emergency inventory for an unknown health crisis simply had not been practical for American hospitals. The financial incentives baked into the country’s health care policy had created a system that was right-sized and running at near maximum capacity.<sup>25</sup> Most hospitals were not profitable to begin with<sup>26</sup> and ventilators were very expensive. Units cost between \$25,000 and \$50,000 each<sup>27</sup> before accounting for the regular maintenance and training required to operate the equipment. As a result, an average-sized American hospital might have 20 ventilators per 150 beds<sup>28</sup> and a large share of those would have been in use. In New York, for example, 85% of the ventilators in acute care facilities were utilized under normal, non-catastrophic circumstances.<sup>29</sup>

In the face of a potentially devastating ventilator shortage, discussions turned to ramping up production. Yet factories around the world were shutting down to prevent the disease from spreading to its workers, threatening health care’s global supply chains. Hundreds of components from vast networks of suppliers were required to build finished machines. Even if ventilator manufacturers were able to quickly add their own employees and production lines, many were dependent on international sources of raw materials, finished parts, and labor.<sup>30</sup> Dutch-based Koninklijke Philips NV, for example, ran into a roadblock when a small

supplier in the Philippines went into lockdown, cutting off the supply of a sensor used in their ventilators.<sup>31</sup>

Trade disruptions also left the United States in a vulnerable position. Roughly half of the intensive care ventilators in use in the United States were made by foreign companies,<sup>32</sup> with over half of the imports of ventilators and artificial respiration equipment in 2019 coming from Singapore and China.<sup>33</sup> As COVID-19 spread, government leaders imposed restrictions on medical supply exports in order to protect their own countries. By the end of March, over sixty countries had introduced export curbs on medical goods,<sup>34</sup> further restricting supply.

## **The Federal Government Steps In**

Hospitals typically purchased ventilators directly from manufacturers or wholesalers to meet demand.<sup>35</sup> In the midst of a global pandemic, however, the federal government put FEMA in charge of sourcing, purchasing, and distributing critical medical supplies.<sup>36</sup> Payments from individual hospitals, health care systems, or states could not solve the shortage. Stepping in, FEMA's supply chain task force promptly announced a "Whole of America" approach (see Exhibit 4)<sup>37</sup> to increase the availability of ventilators and other equipment and manage allocation. Rather than fighting for supplies in the market, states would look to FEMA to provide them with ventilators and other protective equipment. In turn, states could distribute the devices to hospitals as needed.

### **THE STRATEGIC NATIONAL STOCKPILE**

An immediate resource at FEMA's disposal was the Strategic National Stockpile (SNS), which held an estimated 12,700<sup>38</sup> ventilators at the outset of the COVID-19 pandemic. Initially named the Strategic Pharmaceutical Stockpile, the program was established by the Department of Health and Human Services in 1999 to accumulate drugs and vaccines for civilian use in case of a bioterrorist attack. Over time, the repository evolved to contain a broad range of medications and medical equipment available to combat various public health threats, including terrorist attacks, natural disasters, and other mass casualty events.<sup>39</sup>

The SNS was designed to supplement state and local inventories during regional crises.<sup>40</sup> In the event of an emergency, the federal government was responsible for deciding to deploy SNS resources, located in a series of warehouses across the United States facilitating rapid distribution. For example, SNS resources had been deployed after the 2001 World Trade Center bombing and anthrax attacks, Hurricane Katrina in 2005, the H1N1 influenza pandemic in 2009, and Hurricanes Harvey, Irma, and Maria in 2017, among other crises.<sup>41</sup> In the case of COVID-19, FEMA was given oversight of SNS supplies and would decide which states should receive the available ventilators.<sup>42</sup>

### **THE DEFENSE PRODUCTION ACT**

As state governors' calls for equipment quickly overwhelmed the federal cache,<sup>43</sup> government officials took further steps to increase SNS inventory. On March 18, President Trump issued an executive order invoking the Defense Production Act (DPA) in order to prioritize the production of medical supplies.<sup>44</sup> The DPA was first passed in 1950 to address production

needs during the Korean War and gave the federal government broad authority to direct domestic manufacturing.<sup>45</sup> By issuing contracts for ventilator production under the DPA, the government could expedite supply and ensure finished products were routed through the SNS.<sup>46</sup>

During the first weeks of April, the government issued a series of contracts (Exhibit 5) to companies including General Motors, Ford, Philips, and General Electric. FEMA also facilitated additional private sector partnerships to involve firms with extra raw material, workforce, or factory capacity in the effort.<sup>47</sup> In total, the contracts finalized by mid-April would supply 29,510 ventilators to the SNS by June 1, and 137,431 ventilators by the end of 2020.<sup>48</sup> A later analysis of federal contracting data by the Associated Press estimated that the stockpile would reach 100,000 ventilators by mid-July and almost 200,000 by the end of 2020,<sup>49</sup> a significant increase over the existing 12,700 SNS machines. These supplies could subsequently be distributed to states by FEMA to meet nationwide demand.

## State Governments

Though many states had their own limited stockpiles of medical equipment, some, including New York<sup>50</sup> and California<sup>51</sup> had let reserves dwindle as funding dried up following the 2008 recession. Governors quickly found themselves competing to replenish emergency supplies. The ventilator prices climbed drastically as states bid against one another for the remaining inventory of private manufacturers like Medtronic.<sup>52</sup> Forced to put money-making elective procedures on hold because of the virus, hospitals were especially strapped for cash. “Unless we start getting material from the national stockpile,” one leader commented, “I don’t know where we are going to get it.”<sup>53</sup> In addition to FEMA’s existing inventory, a historic overhaul of factories was adding thousands of machines to the national supply under DPA contracts.<sup>54</sup> These ventilators could be particularly vital to states’ emergency response should a second wave of the virus strike in the fall, as many health experts were predicting.<sup>55</sup>

Yet unknowns surrounding the federal ventilator supply and statewide demand made placing orders challenging. For starters, governors had little clarity around the number of ventilators being added to and deployed from the SNS. Repeated questions about the stockpile’s inventory, how many ventilators had been distributed, and how many were on order from manufacturers went unanswered.<sup>56</sup> Even Polowczyk, FEMA’s supply chain task force lead, was operating on guesswork. On March 29, he told news outlet Axios, “Today, I, as leader of FEMA’s supply chain task force, am blind to where all the product is.”<sup>57</sup>

Even in late March, FEMA’s distribution decisions remained inconsistent,<sup>58</sup> leaving state leaders scratching their heads: “Officials in Illinois say they asked for 4,000 and got 450. New Jersey sought 2,300 and got 300 . . . Virginia requested 350 ventilators but has not received any.”<sup>59</sup> All states received only a fraction of the ventilators they ordered. In contrast, states saw drastically different fulfillment rates for surgical masks: “Florida, a state of 21 million, got all 180,000 N95 masks it wanted. Oregon, a state of 4 million, only received 40,000 of the 400,000 masks it requested, and New Jersey, a state of 9 million, got 85,000 of the 2.9 million masks it



feels it needs.”<sup>60</sup> Without specific formulas or explanations for these allocations, some states even raised the possibility that politics could be influencing distribution.<sup>61</sup>

Finally, state governors were not necessarily equipped to understand their own states’ needs. Officials did not always have immediate visibility into where existing ventilators were located and which machines were available. Some states, including Ohio<sup>62</sup> and Michigan,<sup>63</sup> had to issue emergency orders asking medical facilities to regularly self-report health care resources and capacity. Predicting future need was also difficult as much about the transmission of COVID-19 was still unknown and epidemiological models forecasted a wide range of possible outcomes.<sup>64</sup> When would the virus reach its peak in each state? Would there be a second wave before a vaccine reached the market? With the efficacy of using ventilators to treat the disease being questioned by some doctors, would treatment protocols change?<sup>65</sup>

Requesting too many ventilators could also stir up controversy. President Trump had already publicly expressed distrust regarding New York’s request for 30,000 ventilators, accusing Governor Cuomo of inflating demand and hoarding supplies.<sup>66</sup>

## FEMA’s Decision

Like the states, FEMA was also operating without a centralized registry for medical equipment or a firm understanding of the disease’s transmission and treatment. To better control the situation, evaluate demand, and manage states’ requests, FEMA implemented a formal request process for ventilators.<sup>67</sup> As of April 1, states would need to provide detailed responses to a series of questions regarding current ventilator and hospital capacity (Exhibit 6). With this questionnaire, officials hoped to make data-driven decisions about states’ true needs.

In making allocations, however, FEMA would need to provide answers to questions that reached beyond their survey. Their decisions could have life and death consequences, and a variety of other ethical and practical considerations had to be weighed. President Trump publicly stated that if ventilators were issued to hospitals prematurely, it would be difficult to get them back from states and redistribute the equipment.<sup>68</sup> For the ventilators to be useful, states and their hospitals would also require access to trained personnel and additional supplies, including the drugs required to facilitate mechanical ventilation. Even if FEMA had perfect information about these variables, it was not clear what a “fair” method for allocating ventilators would be.

## Discussion Questions

### FEMA

- How should FEMA divide its available ventilators among states when there are not enough to go around? What is a metric to evaluate the fairness of the federal government’s allocation?
- Should FEMA listen to state needs as communicated through the requests, or independently assess the severity of COVID-19 in each state?

- FEMA will be adding supply and receiving orders on a rolling basis. How could they make use of information about past demand or future supply in their allocation decisions?

#### **STATES**

- State governors did not have complete information about their health care systems' current supply of ventilators or future demand. They were also uncertain about how many ventilators the federal government could actually add to the SNS, when these would be delivered, and how they would be allocated among states. Given these circumstances, how should a governor communicate their needs to FEMA?

#### **GENERAL**

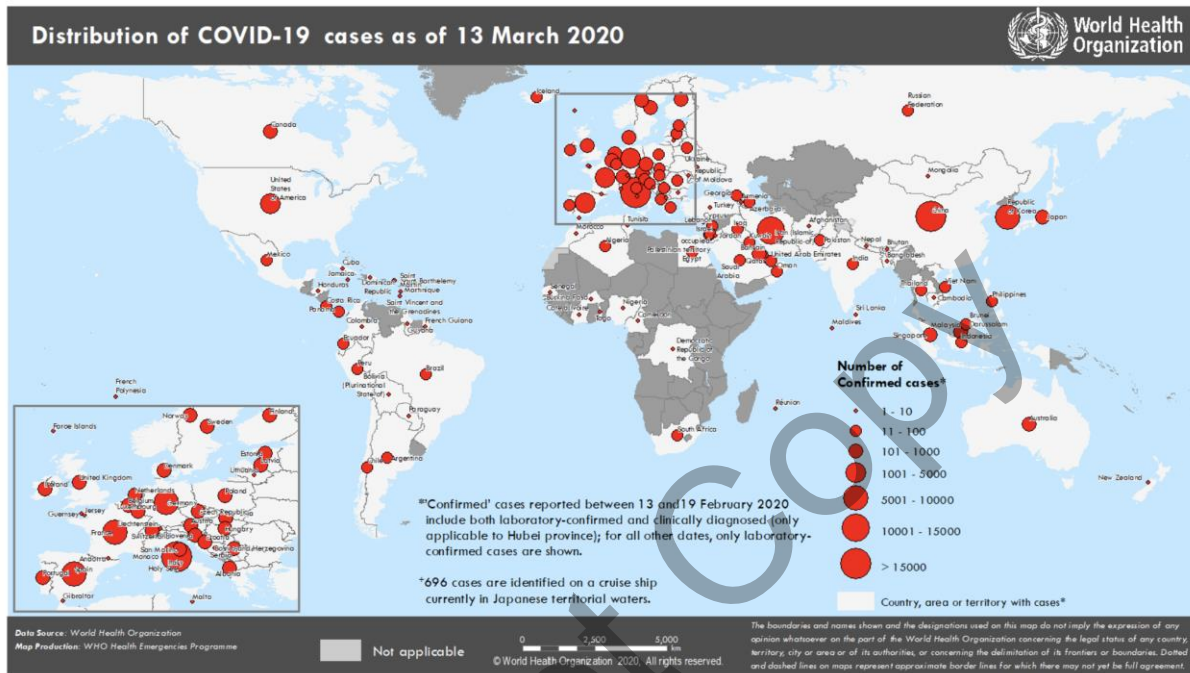
- What role should the federal government play in addressing the shortage? How should public and private sectors balance responsibility?
- What principles could be applied to better align incentives and coordinate supply chains in future medical crises?

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# Exhibits

## Exhibit 1

### COVID-19 Case Distribution



Source: [https://www.who.int/docs/default-source/coronaviruse/situation-reports/20200313-sitrep-53-covid-19.pdf?sfvrsn=adb3f72\\_2](https://www.who.int/docs/default-source/coronaviruse/situation-reports/20200313-sitrep-53-covid-19.pdf?sfvrsn=adb3f72_2)

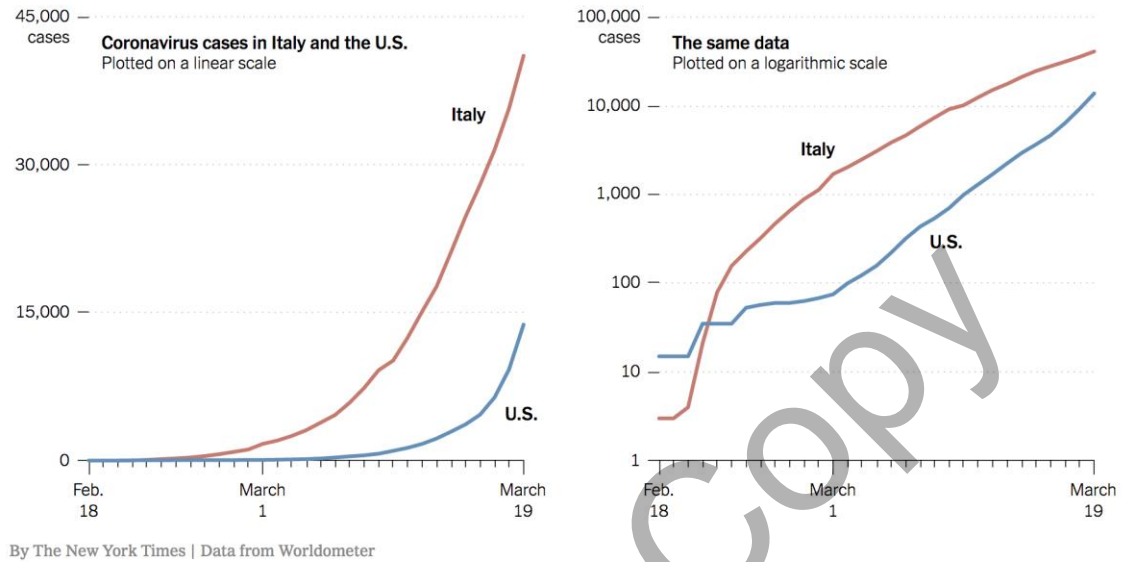


## Exhibit 2

### Coronavirus Case Curves

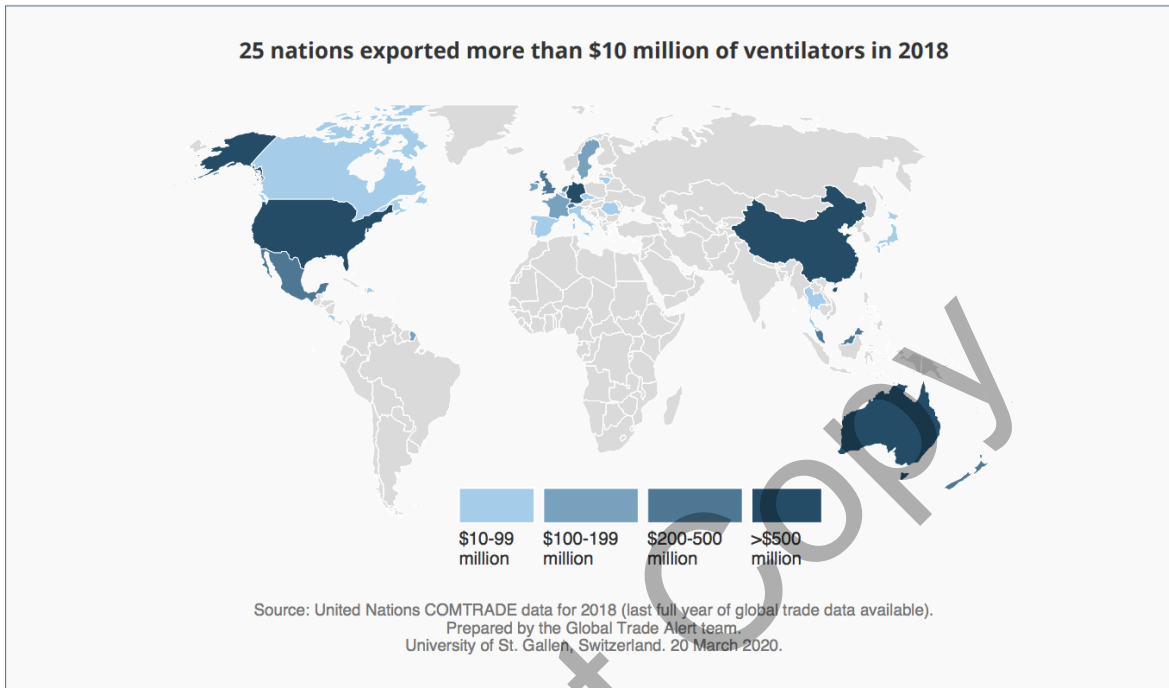
#### Bending the Curve

Logarithmic scales can emphasize the rate of change in a way that linear scales do not. Italy seems to be slowing the coronavirus infection rate, while the number of cases in the United States continues to double every few days.



Source: <https://www.nytimes.com/2020/03/20/health/coronavirus-data-logarithm-chart.html>

### Exhibit 3 Ventilator Exports by Country



Source: <https://www.globaltradealert.org/reports/51>

# Exhibit 4

## Whole of America COVID-19 Response

### Whole-of-America COVID-19 Response

Locally executed, state managed and federally supported effort to meet the demand for critical supplies



Source: <https://www.fema.gov/news-release/20200725/fema-covid-19-supply-chain-task-force-supply-chain-stabilization>

## Exhibit 5

### Excerpt from April 13, 2020 Department of Health and Human Services Press Release

General Electric's contract, at a price of \$64.1 million, is for 2,410 ventilators produced by June 29, with 112 by May 4 and 736 by June 1.

Hamilton's contract, at a price of \$552 million, is for 25,574 ventilators produced by July 3, with 850 by May 8 and 4,404 by May 22.

Hill-Rom's contract, at a price of \$20.1 million, is for 3,400 ventilators produced by July 13, with 400 by June 1.

Medtronic's contract, at a price of \$9.1 million, is for 1,056 ventilators to be produced by June 22, with 200 by May 4 and 678 by June 1.

ResMed's contract, at a price of \$31.98 million, is for 2,550 ventilators produced by July 13, with 400 by May 4 and 1,150 by June 1.

Vyaire's contract, at a price of \$407.9 million, is for 22,000 ventilators produced by June 29, with 1,200 ventilators by May 4 and 9,100 by June 1.

Zoll's contract, at a price of \$350.1 million, is for 18,900 ventilators produced by July 3, with 1,010 by May 4 and 4,410 by June 1.

Source: "HHS Announces New Ventilator Contracts, Orders Now Totaling Over 130,000 Ventilators, HHS.gov, April 13, 2020, <https://www.hhs.gov/about/news/2020/04/13/hhs-announces-new-ventilator-contracts-orders-now-totaling-over-130000-ventilators.html>.

## Exhibit 6

### Excerpt from March 31, 2020 FEMA Advisory

To submit a request, states and tribes will work through their FEMA/ HHS regional leadership. In order for a request to be processed, the state/tribe must provide detailed responses to the following five questions:

1. How many usable ventilators, ICU beds, and convertible ventilators are currently available within the state or tribe?
2. What is the current hospital bed and ICU bed occupancy rate in the state/tribe?
3. How many new ICU beds does the state/tribe estimate it can stand-up and the number of ventilators, or FDA-approved ventilator alternatives, it can or is standing up?
4. What is the decompression ability of hospitals in the state/tribe (i.e.: are there currently field hospitals or alternate care facilities established)?
5. How many anesthesia machines are in the state/tribe **and** have they been converted?

Source: FEMA Advisory, "Coronavirus (COVID-19) Pandemic Ventilator Request," "The Council of State Governments: COVID-19 Resources for State Leaders, April 1, 2020, <https://web.csg.org/covid19/2020/04/01/coronavirus-covid-19-pandemic-ventilator-request/>.

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