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There May Be Liability Concerns for a Private Sector Willing To Step Up To Produce Sorely Needed Medical Supplies To Fight COVID-19—But States Can Address the Problem

There is no excuse for allowing legal uncertainty to slow down the will and capacity of American producers to do their part in providing treatment and protection to health care workers on the front lines. Our governors can act, and they should do it now.

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As the number of documented national cases of COVID-19 mounts, pleas grow louder from state, local, and medical officials over the desperate lack of critical supplies—particularly personal protective equipment (PPE) and ventilators. Gov. Andrew Cuomo has pleaded with the federal government to cover—or commandeer businesses to help cover—an anticipated shortfall of 23,000 ventilators in New York state. This week also saw open letters from a consortium of mayors and municipal leaders and the leading associations of medical professionals asking the White House to invoke the Defense Production Act (DPA) to mandate increased production of masks, respirators, and gowns for health care workers battling the virus. While the Trump Administration has sent conflicting signals about its willingness to do so, there are immediate actions that governors can, and should, take to address this desperate need for supplies. Hotbed states like New York, California and Washington simply cannot wait.

We have been inspired to see a number of private companies—from major multinationals to small businesses and individuals equipped with 3-D printers—step in to help. But, privately, many may rightly be hesitating before beginning mass donations or repurposing their production lines due to legal liability concerns. The concerns are twofold. First, because many needed supplies and devices have patent-protected components, the donors may worry they could be blocked from producing them or later sued for patent infringement. Second, the donors may worry that, in the event any supplies—particularly if brought rapidly into production—do not function perfectly against COVID-19, they might

be held liable for illness or injury suffered by health care providers or patients. Though patent infringement suits are fairly unlikely, given the potential PR backlash against the litigants and other legal reasons, these concerns are real and likely are having a dampening effect on, or at least delaying, altruistic donations of labor and supplies.

We believe state governments have it in their power to shield private companies from both risks, and to do so in short order through executive action. On March 17, the Secretary of Health and Human Services (HHS) Alex Azar, under powers granted by the Public Readiness and Emergency Preparedness (PREP) Act, formally declared immune from liability any "Covered Persons" who manufacture or distribute "Covered Countermeasures" in connection with governmental activities to combat COVID-19. This includes "qualified" products that could "diagnose, mitigate, prevent, treat or cure" the pandemic. The governors of the 48 states that have declared states of emergency to fight the virus have the power to issue blanket authorizations under this PREP Act declaration for the donation of supplies to health care providers as part of the pandemic response in their states. By formally authorizing would-be donors "to prescribe, administer, deliver, distribute or dispense" protections or treatments for COVID-19, they will help shield donors as "Covered Persons" providing "Covered Countermeasures." Such authorizations will assist in bringing the donations within the umbrella of liability immunity provided under the PREP Act and the HHS declaration and protect against IP and product liability.

This recommendation comes with an important caveat: Not all (nor all perceived) health care supplies will meet the PREP Act definition of "Covered Countermeasures." The products generally must be "cleared or approved" under the FD&C Act, but the FDA is actively granting emergency use applications and maintains a list of COVID-19 emergency use approvals on its website. The FDA also has a dedicated email address for questions about approvals for personal protective equipment.

In addition to, or as an alternative to, any blanket PREP Act authorizations, state executive branches could attempt to cloak manufacturers in sovereign immunity for purposes of meeting supply shortfalls caused by COVID-19. For example, in California, the government possesses the power to "commandeer" private operations to meet an ongoing emergency, much like the President's power under the DPA. There are solid—if perhaps novel—arguments that the exercise of this power would turn a manufacturer subject to such an order into an "arm of the state," cloaking it in sovereign immunity and immunity under the Eleventh Amendment of the Constitution.

The blanket declarations we are recommending are not the perfect solution. Ideally, President Trump would act on the requests from the American Medical Association (AMA) and others to invoke the DPA in issuing orders to all possible producers to dramatically expand output of critical supplies—and thereby issue them blanket legal immunity. But as the world tragically has witnessed, every hour counts when it comes to combating this virus. There is no excuse for allowing legal uncertainty to slow down the will and capacity of American producers to do their part in providing treatment and protection to health care workers on the front lines. Our governors can act, and they should do it now.

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