

July 1, 2020

The Honorable James E. Clyburn
Chairman
House Select Subcommittee on the
Coronavirus Crisis
2157 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Steve Scalise
Ranking Member
House Select Subcommittee on the
Coronavirus Crisis
2157 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Clyburn and Ranking Member Scalise:

On behalf of the American College of Emergency Physicians (ACEP) and our 40,000 members on the front lines of the COVID-19 response, thank you for the opportunity to provide comments and recommendations regarding access to personal protective equipment (PPE) and other ongoing medical supply chain challenges. ACEP is a national organization representing emergency medicine physicians who provide the safety net of care to Americans when other options are not available, and as you well know, our members have been at the forefront of providing care to COVID-19 patients since the pandemic arrived in the United States. Our experience as both physicians providing direct patient care, dealing with the families of those infected with COVID-19, and as representatives involved in state, regional, and local planning of the response has provided us with a unique perspective on the challenges, successes, and failures of our nation's response to the virus.

If there is an overarching theme identified by this crisis and our nation's response to date, it is the need for improved collaboration and communication, as well as a significant investment in the nation's community emergency departments (EDs) that provide the health care safety net and a first line of defense for responding to the virus. We understand the challenge in bringing together the myriad federal, state, and local resources to efficiently and effectively respond during times of crisis, especially when it is not isolated in a single local or regional community, but rather is a national and international threat. However, this is an obstacle that we must overcome to both combat COVID-19 and to be able to effectively respond to future outbreaks or other public health challenges.

While by no means an exhaustive list, we have identified several key areas we believe are critical for Congress to address: ensuring that emergency physicians and frontline health care workers have the PPE they need, addressing existing supply chain issues and building resiliency, improving federal coordination and distribution of needed supplies, and preparation for future pandemics or public health crises. These issues are further detailed below:

Ensuring Adequate Supplies of PPE for Frontline Physicians and Health Care Workers

As we work to improve coordination between various federal, state, and local entities and simultaneously push for improved treatments and a hopeful cure for COVID-19, we must address the immediate need to ensure sufficient supplies of PPE. This committee has previously heard testimony from emergency physicians and other frontline health care professionals about the overwhelming demand for PPE (such as N95 masks, gowns, face shields, and other critical protective items) that remain in frustratingly short supply. Thousands of emergency physicians and other frontline health care workers continue to risk their lives each day to provide care and have been forced to reuse what are supposed to be single-use protective supplies, threatening the safety of both the health care workforce and patients alike. Unfortunately, as we are now in

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the midst of another dramatic increase in COVID-19 cases and hospitalizations in new hotspots throughout the country, the basic supplies needed to protect the health and safety of emergency physicians and other health care workers will simply not be available in the quantities needed.

Many hospitals and other health care entities are claiming they have “sufficient” stockpiles of PPE, but that is only because they have changed their protocols and require emergency physicians (and others) to utilize a single mask, or other PPE, for an entire shift (or longer) when that mask is designated as a one-time-use product. This very issue was highlighted at the Senate Homeland Security and Governmental Affairs Committee hearing on June 9, 2020, when it was revealed that the Federal Emergency Management Agency (FEMA) was basing its analysis that it would have a sufficient stockpile of PPE in the fall on the assumption that frontline health care workers would be reusing their N95 masks and surgical gowns. This, of course, significantly increases the risk of contamination and possible infection for both emergency physicians and our patients. **The definition of an adequate supply of PPE must be based on the equipment’s intended use as a single-use item. We urge Congress and the Administration to exhaust all options to establish a stable, reliable supply chain to ensure these supplies are truly single-use.**

Emergency physicians are reusing N95 respirators, masks, and other equipment because we are in the middle of a public health crisis and have no other option. Some health systems and facilities have employed decontamination procedures for filtering facepiece respirators (FFR) like N95 masks, but these methods are still not approved by the Centers for Disease Control and Prevention (CDC) and there is only limited data on their effectiveness. Additionally, some emergency physicians have found that certain decontamination methods only work with particular brands or styles of respirators or masks, or that the procedures may shrink the mask or cause critical parts to become brittle and break. These issues may have harmful secondary effects as well by potentially rendering the equipment less effective (i.e., an ill-fitting mask does not provide the same level of protection) or reducing compliance. Congress should fund federal research that is needed to determine what sterilizing procedures (if any) are truly effective and to help disseminate best practices throughout the health care system. Such knowledge will not only help inform our COVID-19 response, but will also be a critical investment in our overall preparedness for future outbreaks or other disasters.

ACEP also found it quite disturbing that the CDC’s recommendations regarding PPE were lower for emergency physicians and other frontline personnel than its own established requirements for what CDC lab workers wear when dealing with the same agent. This went unnoticed by the general public, but it did not by those who have worked in the high-risk infectious disease world.

These shortages have also led to a notable amount of contention and animosity between different hospital services (emergency department vs. inpatient ward vs. critical care units), health care staff, and hospital administrators, as well as health care personnel and the CDC. Multiple incidents occurred in which health care staff were not allowed by hospital administrators to utilize personally acquired PPE that the hospital was conserving or could not supply. Furthermore, across the country, various levels of "airborne" vs. "droplet" precautions, protective measures, and cleaning protocols were utilized, sometimes because of the lack of PPE to conform to contemporary guidelines.

We also need to acknowledge we cannot simply stockpile our way to resilience. The nation is too large for a single, static stockpile to accommodate demand. Instead, the “stockpile” must include a Defense Department-like plan to immediately ramp up manufacturing at many times baseline when an outbreak starts. The SNS should have rotating supplies with key regional assets to reduce stockpile deterioration and supply expiration. Additionally, this country needs better medical PPE that is designed for increased safety when donning and doffing this equipment in high-threat environments. The PPE used in medicine today is still basically repurposed from industrial settings, which do not have the same threat of live agents. We need to completely rethink how PPE is designed for safety, comfort, and sustainability; the single use paradigm for medical PPE is not effective from a cost, waste, space, and surge perspective. Given these shortcomings in our PPE supplies, strong consideration should be given to transition to half (or full) face respirators instead of surgical and N95 masks and there should be greater emphasis on appropriate, reusable supplies, such as cloth gowns, elastomeric respirators, etc., which are not as quickly exhausted as disposable supplies.

Supply Chain Issues and Building Resiliency

Current cost reduction practices in health care such as just-in-time supply chain and inventory management create a first level of vulnerability for individual staff and facilities. Significant consideration should be given to whether federal, state, or local

resources will be designated to provide financial incentives to hospitals and other health care facilities that maintain critical PPE stockpiles. Hospitals that have the storage capacity, the central supply tracking capability to rotate the pandemic PPE through their regular PPE supply, and the personnel required to manage these systems should be able to apply for federal incentives. In exchange for this annual monetary supplement, the hospitals would agree to house and maintain the materiel. The federal financing would also be tied to supply oversight requirements, such as temperature control, rotation time requirement, etc., for the PPE and other material.

Industry consolidation has led to a small number of suppliers, sometimes just one, which creates a second level of vulnerability when multiple facilities, and even states, compete for the same inventory or that supplier themselves faces a disruption. We recognize fair and reasonable reimbursement should be afforded to manufacturers who produce critical supplies and we suggest new financial mechanisms (tax breaks, government subsidies, grants, etc.) be put in place to incentivize companies to invest in excess manufacturing capacity that is vital to health surge capabilities and the production of essential emergency medications, which are also needed on a daily basis but often have low profit margins.

However, it is vital that any conversations regarding altered manufacturing processes begin with an emphasis, if not mandate, on domestic production of PPE, ventilators, normal saline, medicines (all medicines; not just antidotes and certain antivirals), and any other products deemed necessary for the nation's emergency preparedness. This also needs to include the manufacturing of specific materials needed to make the supplies, such as the filter material for masks. The goal should be domestic utilization of this manufacturing capability on a daily basis so the business model remains viable and production capabilities remain consistent. This will also make it easier to surge production when necessary as the production lines will already be available.

These supplies (and shortages of them) have direct impacts on patient care. For example, the air filter material for masks, melt-blown nonwoven fabric, is in such extreme shortage that some manufacturers are sold out through the end of 2021.¹ But this material is used for far more than just N95 masks – it is also used for disinfectant wipes and in surgical wound care, in addition to a variety of other industrial applications, which has even broader supply chain implications. Other shortages, like the reagents needed for COVID-19 tests, stress the health care system by limiting our ability to fully understand the scope and spread of infection in our communities.

Existing laws, such as the “Berry Amendment” (10 U.S.C. 2533a) that mandate Department of Defense procurement to give preference to domestically-produced products and materials may be instructive in terms of legislative precedent. Further, securing a reliable domestic manufacturing supply will help prevent faulty or counterfeit products from entering the U.S. supply chain and will also help prevent unscrupulous third-parties from exploiting desperate health care providers, a serious problem that several states have experienced during the pandemic², and we note our appreciation for Congress' attention to this issue.

Improving Federal Coordination and Distribution of Supplies

Another significant challenge lies in the federal coordination, tracking, and distribution of supplies. Fundamentally, ACEP believes the scope of the emergency situation should dictate how the Strategic National Stockpile (SNS) distributes supplies. COVID-19 is a national (and international) health crisis and, in this setting, we think the most effective way to disseminate these supplies is through direct federal oversight that provides a coordinated, centralized distribution network. During a pandemic, it is inefficient and ineffective to have hospital systems, other health care providers, states, and the federal government in competition for these already limited supplies. Otherwise, the entities/governments with the greatest resources will obtain all, or a majority, of the PPE and other vital equipment even though the spread of the virus is not contained by arbitrary state or local jurisdictional boundaries. While creating this type of competitive marketplace may be good for business interests, it is not in the best interest of public health and safety. The point of the Strategic “National” Stockpile is for its use across the nation.

We recognize that a larger scale, protracted event such as COVID-19 may result in heterogeneous occurrences and demands. In order to streamline requests for, and dissemination of, SNS materials, it may become necessary for cities and states to submit their requirements to a regional medical coordination center, which likely will have better and more current information and contacts regarding shortages and location-specific concerns. However, it is imperative that there be transparency in what is available in the SNS, where those resources are distributed, and realistic timelines of when those materials will arrive.

¹ <https://www.cbsnews.com/news/n95-mask-shortage-melt-blown-filters/>

² <https://abc7news.com/coronavirus-face-mask-shortage-where-to-buy-masks-in-the-bay-area-california-healthcare-workers/6104173/>

Although it is reasonable to keep SNS cache locations secret, their general regional locations should be disclosed. This will enable local disaster planners to estimate how much access they will have, and how quickly, to supplies in the event of a disaster that interrupts transportation routes (e.g., an earthquake that damages bridges in and out of San Francisco).

States should be responsible for monitoring the type, capabilities, and total number of existing hospitals operating within their borders and communicating this information as needed to the federal government. This will help ensure supply distribution plans can be appropriately tailored to the “needs on the ground” and not rely upon potentially outdated data.

We need a much more transparent, rational, and consistent plan for how SNS assets and other medical countermeasures are allocated. The plans to assess needs and distribute newly developed tests, treatments, or vaccines should include environments both inside and outside the hospital setting for essential health care personnel (e.g., using PPE on public transportation traveling to-and-from work). Special analysis must also be paid to how the redistribution of finite health resources could lead to unintended consequences for patient care (e.g., hydroxychloroquine ran out for patients with lupus during COVID-19).

The federal government may consider working with large, national retail businesses or technology industry leaders to help with logistics and distribution. The location of these retail outlets as distribution points for treatments and vaccine dissemination can supplement the community health care resources. Ideally, these locations would be selected with the input of local public health officials working in consultation with Disaster Medicine physicians.

Preparing for the Next Public Health Crisis

While insufficient replenishing of the SNS has been years in the making, other factors have contributed to the lack of necessary equipment as well, such as inventory that did not evolve over the past couple of decades (masks/respirators) and failures to provide sufficient oversight of federal contracts to manufacture ventilators. However, the current situation we find ourselves in is a major failure due to lack of planning and lack of adequate ongoing support for the SNS. Unfortunately, it is too easy to decrease support when all is well and no immediate threats are on the horizon. This has been true at the national and state levels and readiness has been further compromised at the local level by “just-in-time” inventory, leaving no room for surge requirement of supplies.

As noted previously, we are only now beginning to understand our supply chain vulnerabilities where much of our vital equipment is being manufactured outside of the United States in countries that can then deny us customary access when a surge arises. The SNS must be guaranteed adequate ongoing support with a more robust, evergreen inventory and domestic production. We must also fix the issue of ongoing shortages of common drugs during normal times. These are only exacerbated during times of increased national utilization when we run the risk of running out of routine drugs needed to support ventilated patients (paralytics and sedatives) and patients in need of palliative care (opioids and sedatives). To not have access to these agents in a time of need results in needless and unimaginable patient suffering.

Once again, we appreciate the opportunity to share these comments and experiences on behalf of the emergency physicians who have been on the front lines of this pandemic from the very beginning. The novel coronavirus represents the greatest public health threat we have faced in modern times. Our knowledge and understanding of its full impact changes every day, and our treatment protocols are updated constantly as new information, guidance, and best practices evolve. ACEP thanks you for your continued attention to the COVID-19 pandemic and we look forward to working together with you to protect the health and well-being of all Americans.

Sincerely,



William P. Jaquis, MD, MSHQS, FACEP
ACEP President