



ADVANCING EMERGENCY CARE 

February 4, 2022

The Honorable Patty Murray
Chair
Senate Health, Education, Labor, and
Pensions Committee
428 Dirksen Senate Office Building
Washington, D.C., 20510

The Honorable Richard Burr
Ranking Member
Senate Health, Education, Labor, and
Pensions Committee
428 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Chair Murray and Ranking Member Burr:

On behalf of the American College of Emergency Physicians (ACEP) and our 40,000 members, I would like to thank you for providing the opportunity to comment on the bipartisan discussion draft for the Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act (PREVENT Pandemics Act). As you know, emergency physicians have been and continue to serve on the front lines combating the COVID-19 pandemic since it first arrived in the United States two years ago. Our collective experience, both as physicians providing direct patient care and as representatives involved in state, regional, and local planning of responses to all manner of threats and disasters, provides us with a unique perspective on the challenges, successes, and failures of our nation’s response to COVID-19. We sincerely appreciate your Committee’s continued efforts to provide concrete policy solutions that reflect the lessons learned from the pandemic response.

Unfortunately, our country’s response to infectious disease outbreaks, natural and man-made disasters, and other public health emergencies has been, and continues to be, consistently reactive. COVID-19 exposed glaring weaknesses, systemic failures, and an overall lack of preparedness by the world at large, even though previous outbreaks like the Severe Acute Respiratory Syndrome (SARS) and the Middle East Respiratory Syndrome Coronavirus (MERS-CoV) should have served as warning signs that larger catastrophes were possible, especially given the relative ease at which individuals can travel between continents. The pandemic has cost millions of lives across the world and disrupted every aspect of everyday life, and the full magnitude and scope of its impacts are almost incalculable. We **must** be better prepared for and ready to respond to future serious public health challenges than we were for COVID-19.

The overarching themes identified by this crisis and our country’s response to it are the need for improved collaboration and communication at the federal, state, and local levels, stability and resiliency in the medical supply chain, and significant investments in our nation’s community emergency departments (EDs) that serve as the safety net of care in this country. We recognize these are not insignificant challenges, especially in the context of a national and international threat, but they must be addressed because future outbreaks or major disasters are not a matter of if, but when.

This pandemic will end. Emergency physicians continue working on the front lines of the COVID-19 response, and we will continue to serve our communities 24 hours a day, 7 days a week, 365 days a year, well after the pandemic is behind us. Again, we are grateful you have provided us with this opportunity to offer our feedback on this important effort, and we look forward to working with you, the Committee, and the entire Congress to help inform legislative efforts to ensure we are better equipped for the next pandemic or major disaster.

Sincerely,

Gillian Schmitz, MD, FACEP
ACEP President

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Title I – Strengthening Federal and State Preparedness

Subtitle A – Federal Leadership and Accountability

ACEP strongly supports efforts to establish an independent, bipartisan body tasked with examining the emergence of COVID-19, assessing our nation's preparedness and response efforts, and evaluating the initial and ongoing response at the federal, state, and local levels. We agree that such a task force or commission should provide a comprehensive analysis of the gaps, failures, and successes throughout every aspect of the pandemic response and develop actionable recommendations that Congress can address to improve our readiness and response capabilities for future pandemics and other significant public health crises. We appreciate the Committee's inclusion of this critical review effort.

We also appreciate the Committee's work to provide additional authorities to improve the federal preparedness and response efforts by clarifying the roles and responsibilities of various federal agencies, roles, and programs that are responsible during public health emergencies, such as the Assistant Secretary for Preparedness and Response (ASPR) within the U.S. Department of Health and Human Services (HHS).

Since the enactment of the first Pandemic and All-Hazards Preparedness Act (PAHPA), ACEP has supported the role of the ASPR for the very reason that this position was intended to carry out these responsibilities of medical preparedness and response activities, especially during public health emergencies. We support efforts to provide greater clarity on ASPR's roles, responsibilities, and authorities that will help ensure it is strengthened as a response agency. These should not only be clearly delineated within the structure of a federal response, but should also be communicated to the public and private industry as well to improve coordination in the context of a pandemic. We would also again urge Congress to ensure that it is staffed with sufficient experts and provided with necessary resources to manage the health care issues that arise at the federal level.

We also agree that annual reviews of the agencies and programs responsible during public health emergencies is necessary, similar to the National Defense Authorization Act (NDAA). This annual authorization and oversight activity by Congress would provide opportunities to review the current structure of the nation's public health response activities, review current, emerging, or other potential public health threats, and make adjustments to the nation's response strategy as appropriate. To this end, requiring regular national- and state-level full-scale exercises every five years to identify and address gaps in our preparedness and response efforts is welcomed, especially for assessing the ability of the Strategic National Stockpile (SNS) to support responses to public health emergencies as appropriate, including sustained large-scale emergencies like the COVID-19 pandemic.

Finally, one of the most consistent challenges throughout the pandemic response has been the confusing, frequently changing, and often conflicting information and guidance disseminated to both the public and to the health care community. ACEP appreciates the Committee's effort to strengthen public health communication through the establishment of a Public Health Information and Communication Advisory Committee, as well as the other public health surveillance, data collection, and information/best practices dissemination provisions included throughout the other titles of this discussion draft. Given that emergency departments (EDs) are and will always be the forefront of public health emergency responses, ACEP strongly believes that the composition of this panel should specifically include a board-certified emergency physician member to appropriately inform this panel's work.

Subtitle B – State and Local Readiness

ACEP supports continued access to mental health and substance use disorder (SUD) services during public health emergencies. As you well know, our nation's mental health and SUD crises have also been exacerbated by the myriad impacts of COVID-19. EDs throughout the country have witnessed the worrisome trends in Americans' overall mental health and continued lack of access to desperately needed acute and long-term mental

health care services. As the health care safety net, the ED is often the first – and sometimes only – point of contact for individuals experiencing mental health crises or other behavioral health challenges, such as SUD or overdose. While the ED is the critical frontline safety net and the most appropriate setting for acute unscheduled care for individuals suffering from a mental health crisis, it is not ideal for long-term treatment of mental and behavioral health needs.

However, due to the fragmented nature of the mental health care infrastructure in the U.S., persistent lack of sufficient resources, and longstanding shortages of mental and behavioral health professionals, far too many Americans have limited options for the longer-term follow-up treatment they need and deserve. These challenges contribute to long ED wait times and aggravate “boarding” issues, a scenario where patients are kept in the ED for extended periods of time due to a lack of available inpatient beds or space in other facilities where they could be transferred. **Overcrowding and boarding are not failures of the emergency department; rather, they are symptoms of larger systemic issues that must be addressed to eliminate bottlenecks in health care delivery and reduce the burden on the already-strained health care safety net.**

Emergency physicians and other frontline clinicians see the effects of this lack of access every day. More than 100,000 Americans died due to overdose in 2021 – what some have noted as an “epidemic within a pandemic.” We have also seen sharp increases in ED visits related to mental health, especially for children and young adults. As a recent U.S. Department of Education report, [“Supporting Child and Student Social, Emotional, Behavioral, and Mental Health Needs”](#) notes, children have experienced isolation, bereavement, depression, worry, and other issues throughout the pandemic, leading to reports of anxiety, mood, and eating disorders, as well as increased self-harm behavior and suicidal ideation at nearly twice the rate of adults. **Pediatric emergency department visits related to mental health significantly increased during the pandemic – a 24 percent increase for children 5-11 years of age, and 31 percent for children 12-17.** These stressors affect childrens’ development and ability to learn in both the immediate and long-term with lasting consequences should their mental health needs not be adequately addressed.

The unprecedented physical and emotional toll of the COVID-19 pandemic on frontline health care professionals has also contributed to worsening physician mental health and increased levels of professional burnout. Optimal physical and mental well-being of physicians and other medical clinicians is necessary to ensure high-quality patient care. The stigma surrounding mental illness is a well-known barrier to seeking care among the general population, but it can have an even stronger impact among health care professionals. For most physicians, seeking treatment for mental health triggers legitimate fear of resultant loss of licensure (some state licensing boards continue to ask questions about clinicians’ mental health histories or past treatment), loss of credentialing at your site of employment (for similar reasons), loss of income, professional reprisal, or other career setbacks. Such fears have deterred many from accessing necessary mental health care, leaving them to suffer in silence, or worse.

A [poll](#) from ACEP and Morning Consult released one year ago showed that despite the growing toll that serving on the frontlines of the COVID-19 pandemic was having on emergency physicians, many were still hesitant to seek mental health treatment. The results of the poll, conducted among a national sampling of emergency physicians, found:

- More than eight in 10 (87 percent) of emergency physicians reported feeling more stress since the start of the pandemic, with an additional 72 percent experiencing burnout on the job.
- Despite increased levels of stress and burnout, nearly half (45 percent) of the nation’s emergency physicians did not feel comfortable seeking mental health treatment.
- When it came to seeking mental health treatment, 73 percent of emergency physicians felt there was stigma in their workplace.
- Nearly three in five (57 percent) of emergency physicians reported they would be concerned for their job if they were to seek mental health treatment.

- More than a quarter (27 percent) reported they had avoided seeking mental health treatment in fear of professional repercussions.
- Emergency physicians who reported not seeking mental health treatments for fear of professional repercussions cited job security, professional stigma, and future job opportunities as their reasons.

While COVID-19 certainly exacerbated the stress and burnout of emergency physicians, those concerns and the fear of seeking help existed long before the pandemic. As a country, we must show support for emergency physicians and other health care providers for their mental well-being, not just as we continue to combat COVID-19, but long after this crisis has passed.

ACEP is deeply grateful that the Senate and the House have now both passed the “Dr. Lorna Breen Health Care Provider Protection Act” (H.R. 1667 / S. 610), and we are hopeful the Senate will swiftly finalize approval of H.R. 1667 to ensure its enactment into law. This bipartisan legislation is named in honor of emergency physician and longtime ACEP member Lorna Breen, MD, FACEP, who died by suicide in April 2020 after treating COVID-19 patients and contracting the virus herself. Her loss is still deeply felt by ACEP and our members, and remains a tragic reminder that many of our colleagues continue to suffer in silence.

Thanks to the work already undertaken by Congress to fund these grants as part of the American Rescue Plan, the framework for these support services has been established, but the authorizing legislation is still needed. This legislation would not only provide more specific guidance to the federal agencies tasked with implementing these grants, but would also require a comprehensive study to be conducted on health care professional mental health and behavioral health and burnout. This study, which was not part of the American Rescue Plan because it did not meet the criteria required for inclusion in a reconciliation bill, would also examine barriers to seeking and accessing mental and behavioral health treatment by providers, including stigma and concerns about licensing and credentialing. **The grant money is very much appreciated and needed, but if health care providers are still reluctant to access these programs for fear of impeding their careers or losing their ability to practice medicine altogether, then they cannot fulfill their purpose.**

ACEP also appreciates the Committee’s attention to the issue of trauma care through the reauthorization of trauma care grant programs and improvement of emergency medical services and trauma care services during public health emergencies. Like you, we believe that it is essential to incorporate the lessons learned during the COVID-19 response to inform the provision of trauma care, and we would welcome the opportunity to work with the Committee to further build out this effort and help support the establishment of a coordinated National Trauma and Emergency Preparedness System (NTEPS) that can provide awareness of resources and surge capacity throughout the health care system, as well as the ability to load balance the system to match patients with appropriate resources and specialty expertise.

Currently, we rely on a patchwork of regional and state trauma systems that have developed to meet the needs of patients in need of acute care. We believe a national trauma system is needed to provide a rapid, effective, and coordinated response to public health emergencies. This coordinated should be built upon a framework of an interconnected network of Regional Medical Operations Coordination Centers (RMOCCs) to improve regional care delivery by facilitating the most appropriate level of care based on individual patient acuity, while also maintaining patient safety and keeping patients in local facilities that are capable of providing high quality care.

We envision these RMOCCs as having the following essential functions:

- Operationalize the regional plan for patient distribution and health system load balancing for any mass casualty or large public health event;
- Facilitate clinical expertise and consultation for all health-related hazards and coordinate the expertise into the regional plan through current hazard vulnerability assessments;

- Integrate all levels of healthcare leadership (public health, administrative, physician and nursing) from the regional health systems and hospitals into the framework of the emergency operations center and operational plans;
- Provide real time situational awareness of health care capability and capacity to all regional healthcare systems and other salient healthcare entities. This function includes data collection, analysis, and dissemination (i.e., hospital and EMS capacity data);
- Support dynamic movement of patients when required and load balance the medical facilities to mitigate the need for crisis standards implementation and resource rationing;
- Provide a single point of contact at both the RMOCC and at each hospital/health system for referral requests and life-saving resource sharing;
- Align and coordinate regional resources (e.g., supplies, equipment, medications, etc.) and personnel with the goal of maintaining regional systems for time sensitive care such as cardiac, stroke and trauma that may or may not be directly impacted by the surge event; and
- Provide a communication link to other RMOCCs to lead or participate in a broader coordinated multi-regional, state, or national effort. This includes both a multi-state response and nationwide network integration

Though some of these concepts are included in ASPR's *Draft Guidelines Regional Health Care Emergency Preparedness and Response Systems*, we and our partners in this effort continue to encourage ASPR to make Medical Operations Coordination Centers the centerpiece of the regionalized approach.

As it stands now, our country does not yet have a National Trauma System capable of mounting a rapid, effective, and coordinated response to future pandemics, mass casualty events, or other public health emergencies. Given our extensive experience in responding to these types of events, we would welcome the opportunity to work with you to help realize the promise of a truly coordinated medical preparedness and response system.

Title II – Improving Public Health Preparedness and Response Capacity

Subtitle A – Addressing Disparities and Improving Public Health Emergency Responses

We thank the Committee for including provisions to support evidence-based projects aimed at reducing health disparities and improving health outcomes. The ED often reveals the disparities and inequities that exist in our society, and COVID-19 has brought many of these into sharp relief.

ACEP has put significant resources into developing and maintaining the ACEP [COVID-19 Field Guide](#) to support emergency physicians' efforts to treat this disease and provide better, more informed care to patients. While these recommendations do not indicate an exclusive course of treatment or set a standard of medical care, they do provide information that can help supplement the individual's clinical judgment based on the unique circumstances of the case and availability of resources. I would especially like to acknowledge and thank my colleagues, Megan Hoffer, DO, and Aisha T. Terry, MD, MPH, FACEP, who authored the section of the field guide on "[Racial and Ethnic Minority Groups](#)."

ACEP continues working with its members to raise awareness of how epidemiological trends affect different populations, so they can better screen, test, and treat patients. We have encouraged our members to have a heightened suspicion for COVID-19 prevalence and disproportionate morbidity and mortality among underserved minority populations. We have further urged prioritization of aggressive education, adequate access to screening and testing, and proactive management strategies. All patients with mild symptoms who are discharged from the emergency department or hospital should be questioned about the people with whom they live and any risk factors they may have. It is also critical to ensure that there is adequate understanding of

recommendations among patients who speak a language other than English. A translator should be used to communicate with such patients, and they should be provided with educational material in their own language. Patients who are to be admitted to the hospital should have standard management of COVID-19 as outlined by published official recommendations.

In addition to our broader efforts to address health care disparities and inequities, ACEP has worked to raise awareness during the pandemic that some underserved racial and ethnic groups may have underlying comorbidities that may not be diagnosed or treated due to limited access to primary care. Certain populations have unique health considerations and should be treated as higher risk for developing severe COVID-19 infection. These populations benefit from more specific screening and treatment in the emergency department, in addition to other diagnostic management.

ACEP urges Congress and federal agencies to develop and support robust tracking of granular demographic data relative to COVID-19 incidence, morbidity, and mortality, and that such data collection tools and resources are easily translatable to new threats or public health challenges that emerge. This information is necessary to better understand the factors associated with the disproportionate impact of this disease on racial and ethnic minority groups and other historically underserved populations. Furthermore, this data should be collected and accessible in order to foster research and analysis of this phenomenon.

Identifying, reducing, and eliminating health care disparities is an essential part of our collective efforts to improve patient outcomes and ensure greater health equity, and it is a key priority for emergency medicine and ACEP as an organization. Given the work that medical professional associations continue doing in this space, we respectfully urge the Committee to specifically include such medical professional organizations as eligible entities for grants under Section 201.

Subtitle B – Improving Public Health Data

Among the weaknesses exposed by the COVID-19 pandemic is the continued lack of a sophisticated, integrated system for biosurveillance capabilities and public health data collection and reporting. Given technology that is currently available (and in many cases already in use at system, local, or state levels), it is incomprehensible that much of this data is still not publicly available in real-time or near-real-time.

While clarifying federal roles and authorities is important and existing public health systems are in desperate need of modernization, we again urge Congress to also look to the private sector or other public partners to fully realize the goal of increased biosurveillance capabilities. For example, throughout much of the pandemic, decision-makers turned to the Johns Hopkins University COVID-19 dashboard to get information about the number of tests, reported cases, deaths, and recovered individuals. Many other public and private entities also developed unique and innovative data collection technologies that have helped identify new disease vectors, provide predictive modeling to track the evolution COVID-19 and new variants, or help assess medical supply chains and surge capacity, among others.

In emergency medicine, we believe in the concept of “best practices.” Instead of reinventing or creating a government product, there should be more willingness to use what is available through other means and to leverage the new and innovative technologies that have emerged during the pandemic response.

ACEP also supports efforts to improve the exchange of public health data and reporting to public health data systems. A truly interoperable, seamless exchange of health data should be standard practice in everyday health care delivery, not just during public health emergencies. We urge legislators and regulators alike to exercise caution in how additional electronic data or information sharing standards are implemented and ensure that they do not impose additional burdens on physicians or further hinder clinical workflows, especially during times of crisis.

Subtitle C – Revitalizing the Public Health Workforce

ACEP urges the Committee to consider additional or new loan repayment, debt reduction, or loan forgiveness programs for emergency physicians and other frontline health care providers who respond to public health emergencies, including retroactive eligibility for those who have provided care during the COVID-19 pandemic. Even beyond the exhausting response efforts and overall burnout, the COVID-19 response has created unprecedented challenges for the health care workforce and imposed significant strains on staffing operations. These challenges have led many to leave the health professions, retire early, or reconsider their career paths and avoid the public health workforce, so Congress should consider additional incentives to help maintain a robust and healthy public health care workforce.

Additionally, Congress should extend Good Samaritan liability protections for health care professionals that provide volunteer medical services during the COVID-19 pandemic (per the Coronavirus Aid, Relief, and Economic Security (CARES) Act; P.L. 116-136) to cover future public health emergencies as well.

We also strongly urge Congress to implement liability protections for emergency physicians, other health care providers, and health care entities during public health emergencies by shielding them from lawsuits during the emergency (as well as at least 60 days following the termination of the emergency declaration); accounting for federal state or local guidance or recommendations in response to the public health emergency, safeguarding treatment decisions taking into account a lack of resources, including personnel, attributable to the public health emergency; and, excluding harm as a result of gross negligence or willful misconduct. Although the Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the HHS Secretary to provide some immunity from liability during public health emergencies, the protections are limited to claims that directly relate to or result from the administration or use of countermeasures (such as vaccines and treatments) to the specific disease, threats, or condition.

We think that broader liability protections than are allowable under the PREP Act are more appropriate during pandemics and other public health emergencies. Throughout the COVID-19 pandemic, emergency physicians have put themselves at immense personal risk each day while facing tremendous challenges in providing health care, including inadequate safety supplies and personal protective equipment (PPE), scarce or constantly changing information on treatment protocols, insufficient testing, and a lack of other essential resources needed to combat this disease. Despite these obstacles, we have and continue to go above and beyond, doing everything possible to treat the sick and bring comfort to others affected by the pandemic, in addition to providing “everyday” emergency care, often without regard for our own personal wellbeing.

The very health care professionals and facilities that are so dedicated to protecting and preserving the health of the American public should not face unwarranted legal action for our efforts to respond to COVID-19 or other public health emergencies, especially under challenging conditions, limited resources, or other factors out of our control. Yet we still face the threat of medical liability lawsuits, which may come long after public memory of our sacrifices is forgotten, for outcomes that were frequently beyond our control, given that the normal standard of care is impeded by limited capacity and access to needed medications, equipment, or other essential resources and supplies.

Subtitle D – Improving Public Health Responses

Translating research into evidence-based practices to improve preparedness and response efforts means that we are taking concrete steps to learn from the lessons of the pandemic. It is critical that these activities take into account the unique challenges that public health emergencies pose both within and beyond the clinical environment.

Title III – Accelerating Research and Countermeasure Discovery

It is clear that additional research is needed to fully understand both the immediate and long-term impacts of COVID-19 infection, and we thank you for promoting this effort to continue conducting this needed research. A portion of this effort should also examine the effects of COVID-19 infection specifically on the frontline health care workforce and if there are unique factors or patterns affecting health care workers in particular. Given our firsthand experience at the forefront of the COVID-19 pandemic, ACEP stands ready to be a resource and partner in this effort.

ACEP strongly encourages Congress to provide direct funding for the National Institutes of Health (NIH) Office of Emergency Care Research (OECR), which coordinates and fosters clinical and translational research and research training for the emergency setting.

Improving the rapid development of and availability of adequate diagnostic testing supplies should be prioritized – during the initial weeks of the outbreak in the U.S., for example, Seattle facilities had to slow down specimen collection and processing because of inconsistent availability of test reagents. Today – two years later and several waves into the pandemic – nationwide testing shortages persist and new “hotspots” still face limited testing availability that undermines our ability to truly understand the scope of infection and anticipate future new hotspots. While the Biden Administration’s recent efforts to distribute free at-home COVID-19 tests to individuals are appreciated, the tests are limited to four per household, questions remain about their ability to detect the Omicron variant (and future potential mutations), their availability comes only as the current wave appears to be subsiding, and the crushing demand for testing has overwhelmed pharmacies and labs and delayed results, often to the point of irrelevance.

Additionally, the delays that resulted from the internal difficulties experienced by the Centers for Disease Control and Prevention (CDC) to develop its own test at the start of the pandemic highlight this issue at the national/federal level. The problems that occurred with the CDC version of the initial test must be clearly understood so they are not repeated. We appreciate the Committee’s efforts to improve third-party consultation to review the validity, accuracy, and reliability of in vitro diagnostic tests, as well as providing HHS with the ability to contract with public and private entities to assist the public health response to pandemics and new infectious diseases.

There needs to be a much better plan for rolling out new tests quickly and effectively when they are designed. A standard testing plan to roll out testing at scale is absolutely essential and we should consider having dual-track development for new tests so if one test fails in development, there is a potential back-up. Quality standards can vary, but the establishment of a guiding set of principles (or another framework) could be helpful here.

Title IV – Modernizing and Strengthening the Supply Chain for Vital Medical Products

Ensuring a robust and resilient domestic supply chain that is capable of meeting surge capacity needs for essential medications, medical countermeasures, PPE, and other critical supplies, is integral to our success in combating the next pandemic. We commend the Committee for taking steps to improve the domestic medical supply chain and address significant shortcomings in the maintenance and operation of the SNS.

We appreciate the Committee’s efforts to establish “warm base” domestic manufacturing surge capacity and capabilities to produce medical countermeasures during public health emergencies. 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 itself 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.

Policies regarding altered manufacturing processes should 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.

With regard to the provisioning, maintenance, and distribution of supplies in the Strategic National Stockpile, we thank the Committee for taking steps to address a number of the shortcomings experienced during the COVID-19 pandemic. We maintain that the scope of any public health emergency situation should dictate how the SNS distributes supplies. In the case of COVID-19, as both a national and international health crisis, we continue to believe that the most effective method of distributing SNS supplies is through direct federal oversight through 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 after Hurricane Katrina as well 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.

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.

The issue of insufficient PPE and other ancillary medical supplies resulted in a notable amount of contention and animosity between different hospital services (e.g., emergency department vs. inpatient ward vs. critical care units), health care staff, and hospital administrators, as well as health care personnel and the CDC during the initial phases of the COVID-19 pandemic. Multiple incidents occurred in which health care staff were not allowed by hospital administrators to utilize personally acquired PPE to supplant that which 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 sufficient PPE to conform to contemporary guidelines.

Additionally, we must reevaluate what constitutes the definition of "sufficient" supplies. Many hospitals and other health care entities claimed to have sufficient stockpiles of PPE, but only because they changed their protocols and required 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.

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. The SNS should have rotating supplies with key regional assets to reduce stockpile deterioration and supply expiration. We thank the Committee for including provisions that require annual assessments of products the SNS plans to purchase and to ensure that items in the stockpile are in working condition or usable and ready for deployment. In addition to authorizing the HHS Secretary to sell excess SNS supplies when appropriate, Congress should also consider additional regular rotation and distribution of SNS supplies (that do not compromise national security) in order to avoid problems experienced during the COVID-19 pandemic, such as expired supplies or degraded materials that either broke or rendered the products useless (such as worn or brittle rubber bands on masks, nonfunctional ventilators, etc.). The Administration's recent efforts to distribute 400 million non-surgical N95 masks to the public via the SNS, for example, is a welcome example of how to reevaluate how, and for what purposes, we make the most effective use of these stockpiled supplies.

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.

Other federal flexibilities should be considered, including relaxing of standard requirements by the Centers for Medicare & Medicaid Services (CMS) or the Occupational Safety and Health Administration (OSHA) with regard to staff or supply shortages. Some hospitals and facilities are still experiencing rigorous inspections at a time when many critical supplies and staff remain in short supply due to factors outside their control. Further, every time these inspections occur, the limited staff who are on-hand must divert their attention away from patient care to handle any requests made by the surveyors.

Finally, in the event that a particular or preferred product is unavailable, there should be clearly delineated processes for determining the next product that can serve as a suitable replacement. Identifying the next step

and alternative products, while potentially less ideal, can help standardize the way the hospitals and health systems approach current and future shortages.

Title V – Enhancing Development and Combating Shortages of Medical Products

Subtitle B – Mitigating Shortages

Even before COVID-19, our daily medication shortages [were](#) crippling. We continue to face widespread shortages of daily medication needs for “routine” care, and these shortages are severely exacerbated during a surge. ACEP strongly urges Congress to identify a dedicated and reliable source of medications for essential emergency medications. COVID-19 has demonstrated that substantial reliance on foreign manufacturing, whether for medications or PPE, poses a serious risk to our nation’s ability to respond to large-scale infectious disease outbreaks, as those countries have severely limited exportation of these products to focus their use on domestic cases.

ACEP appreciates the provisions in this subtitle aimed at mitigating or preventing potential drug shortages. While extending expiration dates to the longest extent feasible may help mitigate or prevent a shortage, priority should still be on ensuring a stable and resilient supply chain for essential medications and medical products. We thank the Committee for including language to require manufacturers of devices critical to public health, including those intended for use in emergency medical care, to develop, maintain, and implement redundancy risk management plans like those required of drug manufacturers, as well as similar requirements for shortage notifications of medical devices.

Additionally, as frontline physicians who experienced firsthand the challenges and frustrations associated with receiving counterfeit PPE, we commend you for strengthening enforcement authority against entities selling counterfeit medical supplies and PPE. The penalties for knowingly making and selling counterfeit supplies should be substantial, as counterfeit products can be a matter of life and death for the health care workers who already put themselves at great personal risk to care for patients.

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.