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2023-2026 NHSS comments, regarding "National Health Security Strategy" March 10, 2022
Regarding : 02/14/2022 Notice by the Health and Human Services Department
Document Citation: 87 FR 8266 Page 8266 Document Number 2022-03046

To whom it may concern:

During the acute phase of a pandemic produced by a rapidly spreading pathogen, a paradigm shift needs to take place with a realization that action based upon best available data is needed and inaction is also an action which can have significant consequences. Overall, the United States lacked a coordinated response with no entity who was clearly in charge.

During the endemic phase, society needs to determine at what level of viral spread can be tolerated, both from the cost of treatment, to lives lost and ruined due to chronic disability. Cost and long-term disability data to allow this calculation needs to be collected and made readily available to the public.

1. The United States must maintain a strategic stockpile of masks, personal protective equipment, and therapeutics in order to have a rapid and effective response to a pandemic. Items in this stockpile need to be manufactured in the United States and not dependent upon a foreign supply chain. To maintain a supply of non-expired items, whenever possible, stockpiled items should be continuously used by the healthcare industry, allowing the stockpile to be resupplied with fresh items.

2. A system of rapid development and deployment of new therapeutics needs to be enacted. We need to remember that even a delay by a day can cause thousands of lives lost. During a pandemic emergency, the vaccine committees of the FDA and CDC should be combined. Having two committees which meet on staggered schedules is inefficient. If the committees disagree there is public confusion. If the committees agree then there has been redundancy and delay.

Vaccine development for a new pathogen should be streamlined. Vaccine modification for the emergence of new variants to a wild-type pathogen should be fast tracked similar to what is done with the flu vaccine. Modifications to an mRNA vaccine for use against a variant, often involves only changes to the encoded spike protein. In this case, there should be little increased risk in safety. Efficacy and durability may not be known, but by the time a full evaluation is completed, we may often be confronted with facing a new variant. Currently, we seem to always be at least one variant behind in vaccine development.

For modified mRNA vaccines which are intended for prevention of infections caused by a new variant for which an authorized vaccine exists against the wild-type viruses, consideration should be given to truncating phase II and III studies and to the formation of a new vaccine distribution category "experimental authorization". This authorization would allow expedited distribution of the vaccine to those at high risk for the pathogen and require both added consent to obtain the vaccine and use of V-Safe to

document future complications.

3. The United States needs to clearly and vigorously counter misinformation, both on social media and that which is articulated by some of our leaders. There was misinformation and disinformation which resulted in public confusion, which blunted the United States' pandemic response and inhibited vaccinations. Our country is only 63rd worldwide in the number of individuals who have become fully vaccinated. The origin of disinformation needs to be established. Early on, the European Union found the disinformation effort was highly organized and, at least in part, had its roots in foreign adversaries.(1)

4. Decouple the CDC from financial and political influences.(2) Recommendations need to be made on the characteristics of the virus and not based upon venue. The virus does not care if it is in a church or a bar. It will continue to spread. The CDC needs to lead the world in disease prevention, not tailor its recommendations in response to pressures within the United States.

5. Incorporate One Health to identify and mitigate spread from animal hosts. Throughout this pandemic there has been little attention to the role of animals. Omicron may well have its origins in rodents(3) and there have been multiple articles regarding white-tailed deer, affirming the possibility of this species becoming a reservoir for SARS-CoV-2 and potentially spreading a highly mutated virus back to humans.(4)

6. A National Public Health System is desperately needed. This will serve as an infrastructure for rapid testing, treatment, vaccine distribution and real time data reporting. Expanding the United States' Department of Veterans Affairs' Fourth Mission, including dedicating facilities for Infectious disease, may serve as the beginning of this infrastructure. The Veterans Affairs' Fourth Mission is to aid the United States in confronting public health emergencies.

> "VA's "Fourth Mission" is to improve the nation's preparedness for response to war, terrorism, national emergencies, and natural disasters by developing plans and taking actions to ensure continued service to Veterans, as well as to support national, state, and local emergency management, public health, safety and homeland security efforts."(5)

In large surges, assimilating private sector hospitals and nursing homes into dedicated infectious disease facilities may become necessary.

7. Build, maintain and operate an infrastructure for the disabled and those at chronic risk for severe COVID-19. This may include over 45% of the United States' adult population.(6) This infrastructure would include, but not limited to, dedicated early shopping hours with masking in retail establishments, and expansion of high-speed internet to expand at home delivery capacity.

8. The United States needs to adequately track healthcare acquired infections in both patients and healthcare personnel. Complete and accurate data regarding acquisitions are practically non-existent. The metric implemented for hospital acquired (onset) cases throughout most of the pandemic was defined as:

> "Total current inpatients with onset of suspected or laboratory-confirmed COVID-19 fourteen or more days after admission for a condition other than COVID-19."(7)

With an average incubation period and hospital stay of less than 5 days this metric will capture only a very small percentage of cases.

Hospital acquired pathogens should be defined as the rate of new cases which occurs after hospital admission which is greater than the rate of disease which is occurring in the community.

9. Frontline worker safety and benefits are of utmost importance. High-quality protective gear needs to be available for all workers, along with clearly defining requirements for a safe workplace environment, including detailed ventilation specifications. In addition, there is a need for Federal supported sick leave, presumptive disability and death benefits for frontline workers who are placing themselves at risk during a pandemic emergency, especially when effective therapeutics are not widely available.

10. Provisions should be enacted regarding harassment and threats by the public towards healthcare workers.

11. Public health has specific guidance and recommendations for stopping the spread of pathogens by routes involving food, body fluids, human contact and surfaces. However, clear and specific guidelines to mitigate the spread by aerosolization are lacking. Ventilation requirements regarding the number of complete air exchanges (or their equivalent with air sanitization) for all types of indoor public settings and occupancy levels are needed. This is of utmost importance as the United States enters into the endemic phase of the SARS-CoV-2 pandemic.

The above list is not complete and there are many other areas which need to be addressed and the details negotiated and delineated with impacted entities. We would encourage the Office of the Assistant Secretary for Preparedness and Response (ASPR) to support and integrate with the proposed U.S. Senate's Pandemics Act(8) along with the formulation of a Task Force to investigate the United States' pandemic preparedness and response, along with the initial emergence of SARS-CoV-2.

Thank you for considering these comments.

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References

1. Emmott R. Researchers: Russia deploying coronavirus disinformation to sow panic in West, EU document says. Reuters. Mar. 18, 2020. https://www.reuters.com/article/us-health-coronavirus-disinformation/russia-deploying-coronavirus-disinformation-to-sow-panic-in-west-eu-document-says-idUSKBN21518F

2. Lenzer J. Centers for Disease Control and Prevention: protecting the private good? BMJ 2015;350:h2362 https://www.bmj.com/content/350/bmj.h2362.full

3. Branswell H. Some experts suggest Omicron variant may have evolved in an animal host. STAT. Dec. 2, 2021. https://www.statnews.com/2021/12/02/some-experts-suggest-omicron-variant-may-have-evolved-in-an-animal-host/

4. Kavanagh KT. Mutated SARS-CoV-2 Detected in White-Tailed Deer in Ontario. Infection Control Today. Mar. 1, 2022. https://www.infectioncontroltoday.com/view/mutated-sars-cov-2-detected-white-

tailed-deer-ontario

5. U.S. Department of Veterans Affairs. VA Fourth Mission Summary. Updated Jan. 27, 2022. https://www.va.gov/health/coronavirus/statesupport.asp

6. Adams ML, Katz DL, Grandpre. Population-Based Estimates of Chronic Conditions Affecting Risk for Complications from Coronavirus Disease, United States. Emerg Infect Dis. 2020 Aug; 26(8): 1831–1833. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7392427/

7. COVID-19 Guidance for Hospital Reporting and FAQs. For Hospitals, Hospital Laboratory, and Acute Care Facility Data Reporting. Department of Health and Human Services. Updated: January 6, 2022 https://www.hhs.gov/sites/default/files/covid-19-faqs-hospitals-hospital-laboratory-acute-care-facility-data-reporting.pdf

8. Murray and Burr Release Discussion Draft of Bipartisan Pandemic and Public Health Preparedness and Response Bill. U.S. Senate Committee on Health, Education, Labor & Pensions. Jan. 25, 2022. https://www.help.senate.gov/chair/newsroom/press/murray-and-burr-release-discussion-draft-of-bi-partisan-pandemic-and-public-health-preparedness-and-response-bill