# HEALTHY FUTURE TASK FORCE
# SECURITY SUBCOMMITTEE

*Representatives Richard Hudson (NC-08), Jim Banks, (IN-03), and Tom Cole (OK-04)*

## REQUEST FOR INFORMATION

**Background**:

In June 2021, House Republican Leader McCarthy announced the creation of seven issue-specific task forces designed to identify and develop policy solutions to issues facing the American people. Reps. Richard Hudson (NC-08), Jim Banks, (IN-03), and Tom Cole (OK-04) were named to the Healthy Future Task Force, specifically leading the Healthy Future Task Force Security Subcommittee.

As staff work to develop proposals and policy solutions, the Subcommittee is seeking feedback from relevant stakeholders on policies specific to our Subcommittee. The Subcommittee has crafted the attached Request for Information (RFI), focusing on three issue areas: Pandemic Preparedness; Public Health; and Supply Chains and Medical Independence from China.

**RFI Process:**

RFI responses will be due on January 31, 2022.

Please submit responses to:
Molly Brimmer at molly.brimmer@mail.house.gov (Rep. Hudson)
Andrew Keyes at andrew.keyes@mail.house.gov (Rep. Banks)
Shane Hand at shane.hand@mail.house.gov (Rep. Cole)

At this time, the Task Force Subcommittee will only be accepting responses from those to which we have directly requested. If other stakeholders wish to submit feedback, please reach out to Molly Brimmer, Andrew Keyes, and Shane Hand directly.

On behalf of the Security Subcommittee, we thank you in advance for your time and consideration in sharing your specific thoughts, expertise, and perspective on these issues.

# PANDEMIC PREPAREDNESS

1. In its *Public Health Emergency Medical Countermeasures Enterprise Multi Year Budget: Fiscal Years 2018-2022,* the Department of Health and Human Services acknowledged the Strategic National Stockpile (SNS) "faces the challenge of maintaining a stockpile of [medical countermeasures] against a plethora of low-probability, high-consequence threats, while continuing to develop important countermeasures against other threats, and maintaining the capacity to rapidly respond to novel threats like emerging or re-emerging infectious diseases."
    a. What steps can Congress take to ensure the sustainability of our medical countermeasure (MCM) response capabilities?
    b. Are there additional flexibilities and authorities the SNS needs to adequately stockpile MCMs and to act nimbly in response to emerging infectious diseases and during public health emergencies?
    c. To stretch scarce Federal resources further, what additional authorities or flexibilities does the SNS require to transfer expiring stockpile items to other Federal agencies, State governments, or non-governmental entities and use profits from these transfers to acquire new MCMs?
    d. What challenges does the SNS face when distributing MCMs to State and local partners? What steps can Congress take to fix these challenges?

2. The Coronavirus Aid, Relief, and Economic Security (CARES) Act explicitly required the SNS to maintain, in addition to already enumerated items, supplies of "personal protective equipment, ancillary medical supplies, and other applicable supplies required for the administration of drugs, vaccines and other biological products, medical devices, and diagnostic tests in the stockpile."
    a. Are there other products and MCMs Congress should explicitly require the SNS to stock?
    b. What challenges might the Federal government encounter to maintaining this stockpile?
    c. Are the SNS's current annual review procedures sufficient for evaluating inventory needs and manufacturing, procurement, and deployment challenges?
    d. Should additional Federal (or even non-Federal) entities be included in the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), which provides input on SNS stockpiling decisions? Are there shortcomings in the SNS's coordination with current PHEMCE members? If so, how best can these shortcomings be fixed?

3. Operation Warp Speed was an unquestionable success, delivering the fastest vaccine developed and approved on record. Much of its success is due to accelerated pathways for development, testing, and approval of vaccine candidates.
    a. What changes to the vaccine development and approval process proved most beneficial to the timely development of COVID-19 vaccines? What changes might the federal government have made that would prove more beneficial still?
    b. As Congress looks toward the reauthorization of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act, how might Congress codify what worked during the COVID-19 pandemic for future pandemics?

4. Supplemental appropriations for the United States' early pandemic response and proposed transfers of funds illustrated the need for the Department of Health and Human Services (HHS) to act quickly and draw upon all available funding, despite the existence of the Infectious Disease Rapid Response Reserve Fund and the Public Health Emergency Fund. How can Congress better equip these funds, and other resources, to provide HHS with the support it needs to act nimbly with dedicated funding and without waiting for Congressional action?

5. The COVID-19 pandemic highlighted the efficacy of removing inefficient regulatory barriers that may stall public health and recovery responses. While many federal barriers to the immediate risk were addressed, long-term impediments remain that could discourage State, local, and private sector investment in pandemic preparedness.
    a. What regulatory barriers could be modified, consolidated, harmonized, or repealed to better ensure Federal and State public health agencies are better situated to quickly adapt and efficaciously respond to protect public health in a future PHE?
    b. What barriers exist that impede private sector investment in resources and capabilities – such as early warning systems, vaccine development, and domestic manufacturing – which could prove beneficial in future pandemics and public health emergencies?
    c. What regulatory barriers and burdens could be allayed, consolidated, repealed, or otherwise modified that would better situate local communities to remain economically viable and resilient in the face of future public health emergencies?
    d. What revisions and updates to public health and communicable disease law may be required in light of issues raised during the public health response to the COVID-19 pandemic?

6. The National Academies of Sciences, Engineering, and Medicine (NASEM) released a study report in November 2021, *Ensuring an Effective Public Health Emergency Medical Countermeasures Enterprise*, that provides recommendations for a re-envisioned Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). Four priority areas of improvement emerged from committee deliberations: (1) articulating PHEMCE's mission and role and explicating the principles guiding PHEMCE's operating principles and processes, (2) revising PHEMCE operations and processes, (3) collaborating more effectively with external public and private partners, and (4) navigating legal and policy issues. Please provide feedback and responses to relevant recommendations in this report.

7. The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) has historically focused on and invested in strong public-private partnerships, pairing together the foundation and support of the U.S. federal government (USG) with the expertise and on-the-ground, in-the-field experience of the private sector. Throughout the COVID-19 pandemic, we have relied on the success of public-private partnerships such as Operation Warp Speed and Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV).
    a. What regulatory barriers could be modified, consolidated, harmonized, or repealed to ensure these public-private partnerships continue to be supported and best utilized to both prepare for and respond to future pandemic and public health emergencies?
    b. Are there other barriers that exist that impede private sector interest and investment in public-private partnerships?

c. How can the U.S. federal government better support, encourage, and invest in promoting and advancing public-private partnerships with the private sector?
d. Please identify any specific gaps in issue areas or programs that would benefit from additional support and promotion of public-private partnerships.

8. What other policy considerations should Congress examine concerning reauthorization of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act?

9. Please share any brief additional comments or recommendations that were not properly addressed with the above prompted questions.

## PUBLIC HEALTH

10. Community Health Centers (CHCs) play an essential role in the provision of health services to disadvantaged and low-income populations, regardless of their ability to pay. In 2019, nearly 30 million Americans, and 1 in 5 rural Americans, received services from a CHC.
    a. How can Congress better utilize CHCs to deliver high-quality, low-cost to Americans?
    b. How can Congress assist CHCs in providing improved care coordination services to patients?
    c. What temporary flexibilities provided to CHCs during the COVID-19 pandemic merit permanent extension?
    d. Mandatory funding for CHCs was most recently reauthorized in 2019 through FY2023 as part of the Consolidated Appropriations Act, 2021 at $4 billion annually. As Congress looks toward its next reauthorization, what programmatic changes should Congress consider, and what activities might CHCs be able to pursue with more robust funding?

11. CDC's Public Health Emergency Preparedness (PHEP) Program is comprised of several subprograms, among which are the PHEP cooperative agreement program and CDC Preparedness and Response Capability. PHEP cooperative agreements assist public health departments respond to numerous public health threats, such as infectious diseases; natural disasters; and biological, chemical, and radiological events. Through both real funding decreases and inflation, funding for the PHEP Program has been reduced 48% since FY2003.
    a. What level of funding is advisable for PHEP? Are there specific program components that should be prioritized for increases?
    b. What additional activities would this increased funding permit CDC and State, territory, and local grantees to pursue?
    c. How might a revitalization of PHEP enable the United States to better respond to public health threats and emergencies?

12. The COVID-19 pandemic highlighted how chronic medical conditions elevate an individual's risk of severe illness, hospitalization, and death. This elevated risk extends beyond COVID-19 and is tied to poor outcomes on numerous measures of health. Worryingly, 6 in 10 Americans have a chronic medical condition, and 4 in 10 have two or more. The Centers for Disease Control and Prevention (CDC) operates numerous programs and offices dedicated to chronic disease prevention and health promotion.
    a. What challenges, if any, do CDC's disease-specific programs have in addressing comorbid conditions?
    b. How might these challenges be better addressed under CDC's current programmatic structure?
    c. Are there alternatives to current disease-specific programming that address multiple underlying conditions and promote healthy living?
    d. What flexibilities or authorities would be required to promote such cross-programmatic efforts?

13. Chronic diseases such as heart disease, diabetes, cancer, and Alzheimer's are the leading drivers of America's $3.8 trillion in annual health care spending. How can CDC, and other relevant federal

agencies, better address lifestyle choices that lead to chronic illness and promote prevention strategies?

14. Social determinants of health are another key driver of healthcare spending. Individual behavior and social and environmental factors are estimated to account for 60% of health care costs.
    a. To what extent do federal health programs already account for and address social determinants of health?
    b. How can Congress best address the factors that influence overall health outcomes in rural, Tribal, and other underserved areas to improve health outcomes in these communities?
    c. What flexibilities or authorities are needed to promote the adoption of policies and strategies in federal health programs to address these social determinants?
    d. What innovative programs or practices, whether operated by non-governmental entities or local, State, or Tribal governments, might Congress examine for implementation on a national scale?

15. The COVID-19 pandemic has called attention to some populations' distrust of public health departments and officials, whether through historical wrongs or because of skepticism of more recent public health measures. How can Congress work to bolster Americans' confidence in public health institutions?

16. Vaccines are perhaps the greatest public health tool, yet the COVID-19 pandemic demonstrated how widespread vaccine hesitancy is nationwide, fueled by misinformation campaigns or Americans' lack of knowledge about the importance and efficacy of vaccines. Prior to the pandemic, vaccination rates for numerous vaccine preventable diseases were in decline, resulting in what were previously rare epidemics of measles in some U.S. cities. During the pandemic, lockdowns and hesitancy to visit health care sittings has resulted in millions of children, and even adults, missing important routine vaccinations.
    a. How can the federal government work to reverse both short- and long-term declines in vaccination against vaccine preventable diseases?
    b. How can the federal government better support State and local partners in educating Americans on the efficacy and safety of vaccines and combating misinformation?
    c. Some Americans remain unvaccinated for many vaccine preventable diseases, not because of opposition to vaccines, but because of lack of insurance coverage or access to health care services. How can the federal government better address the needs of this population?

17. The beginning of the COVID-19 pandemic illustrated the insufficiency of States' public health laboratory testing capacity and surveillance activities. What specific problems contributed to the challenges many States encountered? Which problems remain to be addressed by Congress, and what solutions might Congress pursue to enhance public health laboratory testing capacity and surveillance?

18. The annual cost for all individuals with Alzheimer's or other dementias will total $355 billion for health care, long-term care, and hospice care in 2021, with Medicare and Medicaid covering $239

billion of these costs. Due to an aging population, the costs of Alzheimer's and other dementias will exceed $1.1 trillion (in 2021 dollars) by 2050.

a. What challenges do the federal government and its partners face in increasing early detection and diagnosis of Alzheimer's and other dementias?
b. How can the federal government better support prevention efforts and risk reduction activities through current, or new, efforts?
c. With an expected doubling of the number of Americans living with Alzheimer's over the next three decades, how can Congress better prepare for this increased demand for care and caregiver support?

19. Through its treaties with Tribes and enacted legislation, the federal government has obligated itself to provide health care services to Native Americans, yet indigenous populations routinely experience poorer health outcomes than their peers. How can the federal government improve its efforts to provide quality health care services and support in accordance with its legal obligations?

20. The COVID-19 pandemic highlighted the need for agile, adaptable public health agencies unencumbered by activities and actions beyond the scope of their core mission.
    a. What reforms can be made to modernize and streamline Federal public health agencies?
    b. What reforms, if any, are needed to Federal public health agencies to ensure an unencumbered, agile, and adaptable public health response? What actions covered by such agencies fall outside the scope of their core missions and should be moved, repealed, streamlined, or otherwise addressed?

21. How can Congress better utilize existing programs to address the maternal health crisis?

22. What other policy considerations should Congress examine concerning improving public health and public health infrastructure?

23. Please share any brief additional comments or recommendations that were not properly addressed with the above prompted questions.

## SUPPLY CHAINS AND MEDICAL INDEPENDENCE FROM CHINA

24. The United States sources 80 percent of its active pharmaceutical ingredients (APIs) from overseas and is particularly dependent on APIs from China. Furthermore, the U.S. Defense Logistics Agency, which operates under DOD, estimates 25 percent of pharmaceutical ingredients used in U.S. military hospitals originate from China, even if the drugs themselves are manufactured elsewhere.
    a. What policies, both foreign and domestic, have resulted in our diminished ability to produce our own APIs?
    b. What policy changes might the federal government implement to encourage domestic investment in the production of APIs?
    c. Are there examples from other nations to which the U.S. might look for inspiration?
    d. What regulatory barriers could be modified, consolidated, harmonized, or repealed to better ensure the U.S. is best positioned to improve our domestic production of APIs?
    e. What current barriers exist that impede private sector investment in the resources and capabilities that would support a more robust investment in domestic production and manufacturing?

25. Approximately 40 percent of the generic drugs sold in the United States have just one manufacturer each, and a supply chain disruption could cause a serious drug shortage. U.S. dependence on drugs from China raises the likelihood of drug shortages should the Chinese supply be disrupted.
    a. Where are the greatest vulnerabilities in the drug and medical supply chains?
    b. What steps can the United States take to diversify its supply chains?
    c. How can the United States work with international partners to ensure the reliability of supply chains during public health emergencies?
    d. What policies, both foreign and domestic, have resulted in our current diminished domestic supply chain and reliance on international partners?
    e. What regulatory barriers could be modified, consolidated, harmonized, or repealed to better ensure the U.S. is best positioned to improve our supply chain issues?
    f. What current barriers exist that impede private sector investment in the resources and capabilities that would support a more robust investment in domestic production and manufacturing?

26. For what drugs, biologics, and medical devices is the United States most reliant on foreign manufacturers? From which countries are these sourced, and to what extent does this reliance pose a national security threat, if any?

27. How might the federal government identify and implement public-private manufacturing models to improve and maintain domestic manufacturing capacity for drugs, vaccines, and medical countermeasures?
    a. What regulatory barriers could be modified, consolidated, harmonized, or repealed to ensure the federal government is supporting public-private partnerships to both prepare for and respond to future pandemic and public health emergencies?
    b. Are there other barriers that exist that impede private sector interest and investment in public-private partnerships?

c. How can the U.S. federal government better support, encourage, and invest in promoting and advancing public-private partnerships with the private sector?
d. Please identify any specific gaps in issue areas or programs that would benefit from additional support and promotion of public-private partnerships.

28. In 2016, Congress passed the 21st Century Cures Act, which authorized the Biomedical Advanced Research and Development Authority (BARDA) to establish a public-private partnership to foster and accelerate the development of MCMs, something BARDA has yet to do. In April 2020, the National Institutes of Health launched Accelerating COVID-19 Therapeutics Interventions and Vaccines (ACTIV), a public-private that has successfully coordinated research for the prioritization and development of promising therapeutics and vaccines, demonstrating the promise such partnerships hold for the development of MCMs. How might Congress use existing authorities to spur the development of such partnerships across federal health agencies and repurpose COVID-19-focused initiatives to address future pandemic-potential pathogens?

29. How might certain tax incentives help to spur, encourage, and/or increase domestic production of medical devices; active pharmaceutical ingredients (APIs); drugs; and other medical supplies, products, and countermeasures? What current or future tax policies might hinder adoption of domestic production for these products?

30. What revisions and updates to current policies may be required in light of issues raised during the public health response to the COVID-19 pandemic?

31. What other policy considerations should Congress examine concerning improving supply chains and achieving medical independence from China?

32. Please share any brief additional comments or recommendations that were not properly addressed with the above prompted questions.