

January 31, 2022

The Honorable Richard Hudson United States House of Representatives Washington, DC 20515

The Honorable Jim Banks United States House of Representatives Washington, DC 20515

The Honorable Tom Cole United States House of Representatives Washington, DC 20515 Dear Representatives Hudson, Banks, and Cole:

Thank you for the opportunity to provide input to the Healthy Future Task Force's Security Subcommittee. Together, our nonprofit, nonpartisan organizations represent millions of patients and consumers who face serious, acute, and chronic health conditions. We have a unique perspective on what individuals and families need to prevent disease, cure illness, and manage chronic health conditions. We are united in our long-standing support of the Centers for Disease Control and Prevention (CDC) and its National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) as a key pillar of our nation's public health security enterprise.

Our organizations, which often come together to support funding for CDC and specifically NCCDPHP, came together to jointly respond to the Task Force's request for information because of the commonalities between and interconnectedness of the chronic diseases and conditions of the patients we represent. Indeed, many patients face multiple chronic conditions and comorbidities. The appendix contains responses to questions that reflect the broad expertise of our organizations and illustrates the myriad challenges and opportunities in preventing and managing chronic disease. It is important to note that many of the recommendations presented in the responses to the questions posed by the Task Force are policy priorities for individual organizations based on the interests and needs of their specific patient constituencies and may not be endorsed by all the organizations who contributed to this letter. Such examples were provided by individual organizations to show the implications and expertise that we bring to these critical issues. Regardless of chronic disease or condition and/or the policy recommendations proposed, there are four cross-cutting themes that emerge:

- The United States has failed to adequately and consistently prioritize funding for the *prevention* of chronic diseases and conditions and the *promotion* of health and well-being.
- This failure has made our nation more vulnerable to severe illness and death from infectious disease.
- The exorbitant and increasing cost of the nation's "sick care" system is not sustainable for individuals, families, communities, employers, and policymakers.
- This challenge is *surmountable* and *reversable* with sufficient investment in upstream strategies that help make the healthy choice the easy choice.

Background

Chronic diseases represent 7 of the 10 leading causes of death¹ and account for 90 percent of the nation's \$3.8 trillion in annual health care costs.² In addition to annual costs for patients, chronic disease often leads to economic burden in many other ways. For example, in 2017, caregivers of those living with Alzheimer's and other dementias provided an estimated 18.4 billion hours of unpaid care, at an economic value of more than \$232 billion.³

¹ Centers for Disease Control and Prevention. <u>Leading causes of death</u>. *Morality in the United States, 2019*. Accessed online February 17, 2021.

² Buttorff C, Ruder T, Bauman M. <u>Multiple Chronic Conditions in the United States</u>. Santa Monica, CA: Rand Corp.; 2017 and Martin AB, Hartman M, Lassman D, Catlin A. <u>National Health Care Spending In 2019</u>: <u>Steady Growth for The Fourth Consecutive Year</u>. *Health Aff*. 2020;40(1):1-11.

³ Alzheimer's Association. 2018 Alzheimer's Disease Facts and Figures. *Alzheimers Dement* 2018;14(3):367-429. Available at: <u>alz.org/facts</u>

Most chronic diseases can be prevented with supportive, evidence-based programs that facilitate eating well, being physically active, avoiding or quitting tobacco, avoiding excessive drinking, avoiding injury, and getting regular health screenings and vaccines.

Yet, the burden of chronic disease is growing faster than our ability to ease it, putting an increasing strain on the health care system, health care costs, productivity, educational outcomes, military readiness, and well-being.⁴ The COVID-19 pandemic has only exacerbated these challenges. Indeed, COVID-19 and chronic disease are very much intertwined—the risk of severe COVID-19 increases because of the presence of certain underlying medical conditions in a person.⁵ For example:

- COVID-19 poses elevated health risks— including severe illness and death— for people with chronic conditions and may lead to heart attacks, stroke, kidney failure, lung damage, blood pressure abnormalities, neurological conditions, and other long-term health complications in people who have survived the virus.
- Currently, only 26 percent of men, 19 percent of women, and 20 percent of adolescents in the United States report sufficient levels of physical activity. New data from CDC report that more than 1 in 5 adults is inactive in all but four states.⁶ Individuals gained, on average, 19 pounds during pandemic-related shelter-in-place disruptions. Obesity, a leading risk factor for many chronic diseases, makes individuals more susceptible to infectious disease. Indeed, patients with obesity, particularly those with severe obesity, experienced some of the worst outcomes of all patients hospitalized with COVID-19, including increased risks for blood clots, the need for breathing assistance and dialysis, and death. The added risk from severe obesity was magnified in younger patients, specifically adults under age 50.⁷ Despite the health benefits, physical activity levels have worsened during the COVID-19 pandemic as individuals limit everyday activities such as going to work or school, using fitness facilities, and accessing outdoor and community areas.⁸
- Cancer patients are among those at a high risk of serious illness from an infection because their immune systems are often weakened by cancer and its treatments. Cancer patients living in medically underserved communities are more susceptible due to reduced immune function combined with historic disparities. ⁹ One study, using cross-sectional data from Quest Diagnostics in the United States, found that breast cancer experienced a 52 percent decline and colorectal cancer a 49 percent decline in identification of new cancers in patients. ¹⁰ Importantly, these declines are not evidence of a decline in the number of cancer cases, just of those being diagnosed. This means there are individuals in the United States that likely have cancer but are not yet aware.

⁴ Heidenreich PA, Trogdon JG, Khavjou OA, et al. Forecasting the future of cardiovascular disease in the United States: a policy statement from the American Heart Association. Circulation. 2011;123:933-944.

⁵ Centers for Disease Control and Prevention. <u>People with certain medical conditions</u>. 2021.

⁶ Centers for Disease Control and Prevention. <u>CDC Releases Updated Maps of America's High Levels of Inactivity</u>. 2022.

⁷ Centers for Disease Control and Prevention. <u>Obesity, Race/Ethnicity, and COVID-19</u>. 2021

⁸ Lin AL, Vittinghoff E, Olgin JE, Pletcher MJ, Marcus GM. Body Weight Changes During Pandemic-Related Shelter-in-Place in a Longitudinal Cohort Study. JAMA Netw Open. 2021 Mar 1;4(3):e212536. doi: 10.1001/jamanetworkopen.2021.2536.

⁹ Sharpless NE. COVID-19 and Cancer. Science. Jun 2020: Vol. 368, Issue 6497, pp. 1290. DOI: 10.1126/science.abd3377.

¹⁰ Kaufman HW, Chen Z, Niles J, Fesko Y. Changes in the Number of US Patients With Newly Identified Cancer Before and During the Coronavirus Disease 2019 (COVID-19) Pandemic. JAMA Netw Open. 2020;3(8):e2017267. doi:10.1001/jamanetworkopen.2020.17267.

- Being a current or former cigarette smoker increases an individual's risk of severe illnesses from COVID-19.¹¹ Smoking is responsible for half a million premature deaths every year due to heart disease, cancer, lung disease and other causes. Tobacco use harms every organ of the body. Despite the intervening pandemic, kids continue to be lured by flavors and are becoming regular e-cigarette users. More than two million middle and high school students used e-cigarettes in 2021. The frequency of use by teens is especially alarming, with 43.6 percent of high school students using e-cigarettes regularly (20 or more of the past 30 days) and more than one in four (27.6 percent) are vaping daily.¹² This regular use underscores how addicted youth have become to e-cigarettes.
- Deaths from ischemic heart disease and hypertensive diseases in the United States increased during the COVID-19 pandemic, while globally, COVID-19 was associated with significant disruptions in cardiovascular disease testing. The COVID-19 pandemic caused health care delivery disruptions across the globe in 2020, including delays in cardiovascular disease diagnosis and timely treatment.¹³
- The COVID-19 pandemic has caused barriers and delays to needed care for people with epilepsy, including suspensions of epilepsy monitoring units (EMUs), inpatient and outpatient electroencephalograms (EEGs), and epilepsy surgery.¹⁴ Documented indirect consequences of the pandemic on people with epilepsy include: increased seizure frequency and seizure intensity, decreased adherence to anti-seizure medications, impaired mental health, and, in some instances, increased substance or alcohol abuse—all of which can increase the potential for premature death, including from Sudden Unexpected Death in Epilepsy (SUDEP).¹⁵
- Despite concerted efforts by dialysis organizations, nephrologists, and other clinicians to slow its spread, COVID-19 continues to run rampant through dialysis facilities.¹⁶ According to data from the United States Renal Data System, 15.8 percent of the roughly 500,000 patients on dialysis in the United States had contracted COVID-19 as of the end of 2020.¹⁷ During the 2020 winter wave, weekly deaths of dialysis patients due to COVID-19 peaked at nearly 20 percent and annual mortality during 2020 was 18 percent higher than in 2019.¹⁸COVID-19 is causing increased morbidity and mortality, forcing shortened treatment times for patients, and exacerbating shortages in staff and supplies that impede access to the life-sustaining treatment that is dialysis. Additionally, COVID-19 has caused Acute Kidney Injury in non-kidney patients who recover from COVID-19 and leaves patients potentially more susceptible to developing chronic kidney disease in the future. Stagnant funding for kidney disease research, awareness, and early detection led to a 40 percent increase in

Society membership. *Epilepsy Curr. 20(5),* 316-324. doi: 10.1177/1535759720956994. ¹⁵ Thorpe, J., et al. (2021). Evaluating risk to people with epilepsy during the COVID-19 pandemic: preliminary findings from the

¹¹ "Certain Medical Conditions and Risk for Severe COVID-19 Illness." Centers for Disease Control and Prevention. Centers for Disease Control and Prevention, n.d. https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions. html.

¹² Park-Lee E, Ren C, Sawdey MD< et al. *Notes from the Field* E-Cigarette Use Among Middle and High School Students – National Youth Tobacco Survey, United States, 2021. MMWR Morb Mortal Wkly Rep 2021;70:1387-1389. DOI: <u>http://dx.doi.org/10.15585/mmwr.mm7039a4</u>.

 ¹³ <u>COVID-19 Pandemic Indirectly Disrupted Health Disease Care.</u> *American College of Cardiology*. January 11, 2021.
 ¹⁴ Albert, D.V.F., Das, R.R. & Husain, A.M. (2020). The Impact of COVID-19 on epilepsy care: a survey of the American Epilepsy

COV-E study. *Epilepsy & Behavior 115: 107658.* doi: <u>10.1016/j.yebeh.2020.107658</u> ¹⁶ United States Renal Data System. 2021 *USRDS Annual Data Report: Epidemiology of kidney disease in the United States.* National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2021.

¹⁷ Ibid ¹⁸ Ibid

the number of people in kidney failure from 2009-2019¹⁹. Unfortunately, in 2021, COVID-19 mortality resulted in the first reported decline in the number of patients on dialysis in the United States in the 50-year history of the Medicare End-Stage Renal Disease (ESRD) Program²⁰.

- Transplant recipients and other immunocompromised patients are at heightened risk for severe COVID-19 outcomes, and many are still not producing antibodies after multiple vaccinations. According to the US Renal Data System, 41 percent more transplant patients died in 2020 as opposed to 2019 and excess mortality continued even through the second quarter of 2021²¹.
- Vision impairments and eye disease often contribute to or are complicated by other serious and chronic health conditions, including diabetes, stroke, depression, social isolation, cognitive decline, and falls-related injuries or death. As we have learned during the global pandemic, several of these conditions are analogous to the most serious consequences of COVID-19 with early surveillance data from the CDC indicating that 30 percent of COVID-19 patients had diabetes and 4.8 percent had a neurologic or neurodevelopmental disability (including visual impairment).²²
- People with dementia have twice the risk of developing COVID-19 as other adults, and Black individuals living with dementia are three times as likely to contract COVID-19 as their white counterparts.²³
- Exposure to air pollution is a major driver of negative health outcomes and has also been shown to interact with COVID-19. A 2020 study looking at the impact of fine particle pollution exposure on COVID-19 death rates at the county level, found that a small increase in long-term average exposure was associated with an 11 percent increase in the COVID-19 death rate.²⁴
- A new CDC report shows that children and teens 18 years and younger who have had COVID-19 are up to 2.5 times more likely to have a diabetes diagnosis after infection. Nearly 1 in 5 adolescents aged 12-18 years, and 1 in 4 young adults aged 19-34 years, are living with prediabetes.²⁵ Obesity now affects 1 in 6 children and adolescents in the United States, putting them at disproportionate risk of developing prediabetes.²⁶

¹⁹ Ibid

²⁰ Eldeib, D. (2021, December 28). *They were the pandemic's perfect victims*. ProPublica. Retrieved from https://www.propublica.org/article/they-were-the-pandemics-perfect-victims

²¹ https://adr.usrds.org/2021/supplements-covid-19-disparities/13-covid-19-supplement

 ²² Stokes EK, Zambrano LD, Anderson KN, et al. Coronavirus Disease 2019 Case Surveillance — United States, January 22–May
 30, 2020. MMWR Morb Mortal Wkly Rep 2020;69:759–765. DOI: http://dx.doi.org/10.15585/mmwr.mm6924e2

²³ Wang Q, et al. <u>COVID-19 and dementia: Analyses of risk, disparity, and outcomes from electronic health records in the US</u>. *Alzheimer's & Dementia*. 2021, Feb 9. doi: 10.1002/alz.12296

²⁴ Wu, X., Nethery, R. C., Sabath, M. B., Braun, D. and Dominici, F., 2020. Air pollution and COVID-19 mortality in the United States: Strengths and limitations of an ecological regression analysis. Science advances, 6(45), p.eabd4049.

²⁵ Barrett CE, Koyama AK, Alvarez P, et al. Risk for Newly Diagnosed Diabetes >30 Days After SARS-CoV-2 Infection Among Persons Aged <18 Years — United States, March 1, 2020–June 28, 2021. MMWR Morb Mortal Wkly Rep 2022;71:59–65. DOI: http://dx.doi.org/10.15585/mmwr.mm7102e2external icon

²⁶ Centers for Disease Control and Prevention. (2021, April 5). *Childhood obesity facts.* Centers for Disease Control and Prevention. Retrieved from

https://www.cdc.gov/obesity/data/childhood.html#:~:text=For%20children%20and%20adolescents%20aged,to%2019%2Dyear %2Dolds

- The latest (2022) <u>estimates</u> from the Centers for Disease Control and Prevention (CDC) are that more than 130 million adults are living with diabetes or prediabetes.²⁷ Roughly one 1 out of every 9 Americans has diabetes while 1 out of every 3 adults has prediabetes.²⁸ Medical costs for people with diabetes are more than twice as high as for people without diabetes and the total cost of diabetes and prediabetes for our healthcare system is estimated to be \$327 billion in the United States.²⁹ People with diabetes are not only more vulnerable to COVID-19, but we are now also seeing the unique situation of onset of Type 1 diabetes in children who have been infected with COVID-19.³⁰
- Early data indicate that survivors of COVID-19 are at increased risk of not only developing chronic disease in the future, but also experiencing long-COVID symptoms that could increasingly impact our health care system.³¹ Reports indicate that more than 9 million Americans have reported symptoms of long-COVID, and among people who were symptomatic when they tested positive for COVID-19, 44 percent still had at least one symptom 30–45 days later, and 39 percent still had symptoms 7–9 months later.
- The results of the Flatten Inaccessibility survey, which was co-managed by fifteen organizations that were interested in gauging the effects of COVID-19 on adults with visual impairment, indicates that our nation has failed to address the needs of those who live with visual impairment and chronic eye diseases to anticipate their needs ahead of this public health emergency.³² Survey results indicated:
 - 68 percent of participants feared they would not be able to get themselves or loved ones to COVID-19 test sites or their health care providers if they got sick.
 - 59 percent of participants felt their underlying health conditions made them particularly vulnerable to COVID-19.
 - 20.7 percent reported telehealth systems and at-home COVID-19 test kits were not accessible for the visually impaired.
 - 56 percent of participants feared their ability to social distance and ask for help, physical assistance, or using touch.
 - \circ 60 percent reported the technology needed for work and school was not accessible.
 - 90 percent reported receiving no training in new technology needed for remote school or work.

The pandemic is the earthquake that has triggered a tsunami of chronic disease. Before the pandemic, 3 in 4 adults were not getting enough physical activity, 9 in 10 adults and youth were not consuming

²⁷ Centers for Disease Control and Prevention. National Diabetes Statistics Report website.

https://www.cdc.gov/diabetes/data/statistics-report/index.html. Accessed January 31 ,2022.

²⁸ Centers for Disease Control and Prevention. National Diabetes Statistics Report website.

https://www.cdc.gov/diabetes/data/statistics-report/index.html. Accessed January 31,2022.

²⁹ Centers for Disease Control and Prevention. *Diabetes Report Card 2019*. Atlanta, GA: Centers for Disease Control and Prevention, US Dept of Health and Human Services; 2020.

³⁰ Barrett CE, Koyama AK, Alvarez P, et al. Risk for Newly Diagnosed Diabetes >30 Days After SARS-CoV-2 Infection Among Persons Aged <18 Years — United States, March 1, 2020–June 28, 2021. MMWR Morb Mortal Wkly Rep 2022;71:59–65. DOI: http://dx.doi.org/10.15585/mmwr.mm7102e2

³¹ Rosen blum, L. P., Chanes-Mora, P., McBride, C. R., Flewellen, J., Nagarajan, N., Nave Stawaz, R., & Swenor, B. (2020). Flatten Inaccessibility: Impact of COVID-19 on Adults Who Are Blind or Have Low Vision in the United States. American Foundation for the Blind.

³² Results. Flatten Inaccessibility. (2021, May 17). Retrieved from <u>https://flatteninaccessbility.com/results/</u>

enough fruits and vegetables.³³ Now, during the pandemic, these problems have been vastly intensified. The coronavirus pandemic has also exacerbated the significant disparities in health equity and access, particularly for vulnerable communities such as the elderly, racial and ethnic minority groups, communities with low-income, those who live with chronic diseases, and those living with disabilities – creating a crisis within a crisis. These disruptions in health care and changes in health behaviors have had a compounding effect on health outcomes. Our routinely underfunded public health and chronic disease infrastructure is already unable to keep pace with current need. The persistent inequities in resource allocation, access to health care and other health stressors that vulnerable communities experience must be addressed. We must enhance our capacity to handle the influx of chronic disease and long-COVID patients. It is through this lens we offer the below responses in answer to your questions.

Sincerely,

American Cancer Society Cancer Action Network	Lymphatic Education & Research Network	
American Diabetes Association	National Eczema Association	
American Heart Association	National Kidney Foundation	
American Lung Association	National Pancreas Foundation	
Arthritis Foundation	National Scleroderma Foundation	
Digestive Disease National Coalition	NephCure Kidney International	
Empowering Epilepsy	Patient Services, Inc (PSI)	
Epilepsy Alliance America	Prevent Blindness	
Epilepsy Foundation	Pulmonary Hypertension Association	
Fabry Support & Information Group	Restless Legs Syndrome Foundation	
Good Days	TSC Alliance	
Hemophilia Federation of America	United for Charitable Assistance	
International Foundation for Gastrointestinal Disorders	United Ostomy Associations of America, Inc.	
	UsAgainstAlzheimer's	
Interstitial Cystitis Association	WomenHeart: The National Coalition for Women with Heart Disease	
Livestrong		
Lupus and Allied Diseases Association, Inc.	YMCA of the USA	

³³ Blackwell, D. L., & Clarke, T.C. (2018, June 28). *State Variation in Meeting the 2008 Federal Guidelines for Both Aerobic and Muscle-strengthening Activities Through Leisure-time Physical Activity Among Adults Aged 18-64: United States, 2010-2015.* National Health Statistics Reports. Retrieved from https://www.cdc.gov/nchs/data/nhsr/nhsr112.pdf

Appendix A: Contact Information for Contributing and Participating Organizations

Organization Name	Point of Contact for Organization	Email Address
American Cancer Society Cancer Action Network	Illy Jaffer	Illy.Jaffer@cancer.org
American Diabetes Association	Chris Fox	cfox@diabetes.org
American Heart Association	Emily J. Holubowich, MPP	emily.holubowich@heart.org
American Lung Association	Erika Sward	Erika.Sward@Lung.org
Arthritis Foundation	Anna Hyde	ahyde@arthritis.org
Digestive Disease National Coalitio	n Jackson Rau	rau@hmcw.org
Empowering Epilepsy	Leigh Goldie, M.Ed.	Leigh@empoweringepilepsy.org
Epilepsy Alliance America	Lisa Gallipoli	lisa.gallipoli@epilepsyallianceamerica.org
Epilepsy Foundation	Laura Weidner	lweidner@efa.org
Fabry Support & Information Grou	p Jack Johnson	info@fabry.org
Good Days	Randie Odebralski	rodebralski@mygooddays.org
Hemophilia Federation of America	Miriam Goldstein	m.goldstein@hemophiliafed.org
International Foundation for Gastrointestinal Disorders	Ceciel Rooker	ctrooker@iffgd.org
Interstitial Cystitis Association	Lee Lowery	llowery@ichelp.org
Livestrong	Livestrong	kathryn.mccaslin@livestrong.org
Lupus and Allied Diseases Association, Inc.	Kathleen Arntsen	kathleen@ladainc.org
Lymphatic Education & Research Network	William Repicci	wrepicci@lymphaticnetwork.org
National Eczema Association	Michele Guadalupe	michele@nationaleczema.org

National Kidney Foundation	Lauren K. Drew	lauren.drew@kidney.org
National Pancreas Foundation	David Bakelman	David@pancreasfoundation.org
National Scleroderma Foundation	Mary Wheatley	mwheatley@scleroderma.org
NephCure Kidney International	Joshua M Tarnoff	JTarnoff@NephCure.org
Patient Services, Inc (PSI)	Gwen Cooper	gcooper@uneedpsi.org
Prevent Blindness	Kira N. Baldonado, MPH	kbaldonado@preventblindness.org
Pulmonary Hypertension Association	Katie Kroner	KatherineK@PHAssociation.org
Restless Legs Syndrome Foundation	n Karla Dzienkowski, RN, BSN	karla@rls.org
TSC Alliance	Kari Luther Rosbeck	krosbeck@tscalliance.org
United for Charitable Assistance	James M Romano	jromano@careandcurepartners.com
United Ostomy Associations of America, Inc.	Jeanine Gleba	advocacy@ostomy.org
UsAgainstAlzheimer's	Niles Godes	ngodes@usagainstalzheimers.org
WomenHeart: The National Coalition for Women with Heart Disease	Amy Friedrich-Karnik	afriedrich@womenheart.org
YMCA of the USA	Katie Adamson	katie.adamson@ymca.net

Appendix B: Pandemic Preparedness

Question #1

Prioritizing Strategic National Stockpile (SNS) supplies and deployment to support congregate care, residential, and group home facilities is a smart and efficient way to ensure our most vulnerable citizens are protected in times of crisis. These settings may include skilled nursing facilities, in-patient rehabilitation, psychiatric facilities, group foster homes, in-patient hospice facilities, and dialysis clinics, but should generally encompass any state-sanctioned facility where people are either residing or receiving routine care in a congregate environment with limited ability to isolate or socially distance. These are our most vulnerable citizens who need the most support with regard to medical supplies and support infrastructure (e.g., electricity and clean water) and should have priority for such support, supplies, and evacuation.

EXAMPLE: Patients with Kidney Disease

More than 500,000 Americans with kidney failure rely on multiple dialysis treatments per week to survive. They are immunocompromised and, as the COVID-19 pandemic has shown, face a unique danger in the case of infectious disease. During the winter 2020 wave, weekly deaths of dialysis patients due to COVID-19 peaked at nearly 20 percent, and annual mortality during 2020 was 18 percent higher than in 2019.³⁴ COVID-19's impact on people with kidney diseases has resulted in the first decline in the number of patients on dialysis in the United States in the 50-year history of the Medicare End-Stage Renal Disease (ESRD) Program.³⁵ Staff and supply shortages have resulted in dialysis facility closures, shortened treatment times, and backlogs in moving patients among dialysis, hospitals, and Skilled Nursing Facilities (SNFs). Although expediting access and training patients to dialyze at home facilitates social distancing and potentially reduces the strain of staffing shortages in the long term, this potential solution will not solve an acute problem like the current pandemic. In an emergency, immediate action is required to ensure that dialysis facilities have access to needed supplies and staff.

A strategic reserve of emergency warehouse workers, truckers and other distribution services is essential to timely and effective deployment of SNS resources. Looking forward, new technologies that would allow need-point creation of specific materials or mitigate the need for them all together should be investigated to mitigate the need for storage, expiration management, and deployment. For example, greater outreach to emergency preparedness personnel within the states by ASPR on the availability of dialysis devices and the process to request them is needed. In turn, states can then educate and work with hospitals, nephrologists and dialysis facilities to educate them on this available resource in the SNS. Ideally, this kind of community outreach and coordination would be in place before an emergency arises, so having established points of contact in advance that have already established working relationships is key to efficient deployment in emergency settings.

Question #2

It is important to learn from our experience with COVID-19 in planning for future emergencies. While each emergency is unique, certain advance preparations can help smooth the response to a variety of future situations. The Coronavirus Aid, Relief, and Economic Security (CARES) Act provisions were a great start and helpful response to the current pandemic, however, in considering our emergency response plans going forward, it is essential to prioritize communication, early engagement, and logistical support. The Strategic National Stockpile (SNS) annual review should also include outreach to

 ³⁴ United States Renal Data System. 2021 USRDS Annual Data Report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2021.
 ³⁵ Ibid

community partners, an update of communication and point of contact lists, and communication with community partners on the availability and methods of requesting stockpiled material.

Specifically for kidney patients, while it is helpful that the SNS does stock some dialysate and dialysis machines, the recent COVID-19 pandemic has shown they are insufficient to meet demand and are not being efficiently utilized. There must be clear and efficient communication with hospitals, nephrologists, and dialysis facilities about the availability of these supplies and streamlined systems for requesting and fulfilling requests from the SNS. And as indicated above, stocking the supplies is only half the battle: having the logistical support, including warehouse workers, trucks, and truckers, to get the supplies to the requested facilities in a timely manner is just as important. Storage, expiration management, and deployment logistics are all issues that could be alleviated by employing novel technologies in assisting with need-point creation of personal protective equipment (PPE) and other medical supplies. 3-D printing, driverless vehicles, and drone delivery should all be tested before a need arises to determine feasibility for use in an emergency. Supporting more patients in utilizing home dialysis and peritoneal dialysis would alleviate some pressure on facilities and staffing needs, but, as stated above, that is a long-term answer and would not be immediately deployable in an emergency.

Finally, as the lead agency of the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), ASPR should improve its coordination and outreach to state, territorial, tribal and local jurisdictions, as well as manufacturers and logistics companies in the private sector to allow for better understanding of their needs and barriers to emergency planning and preparedness. There should be regional, satellite ASPR/PHEMCE offices providing integrated health and medical support to local communities so that trust, connections, and relationships can be built before an emergency arises and so that government officials can have a better understanding of the unique needs of the communities they are serving. Specifically related to kidney patients, ASPR/PHEMCE should consult with the ESRD Networks to get a better sense of the needs of patients in specific areas and be connected to the kidney community in the event of an emergency.

Question #3

While we applaud the general success of Operation Warp speed, some patient organizations contend that it was not equally successful or equally accessible for all patient communities. Despite the high rates of infection and mortality, some patients, including those who required dialysis, were not prioritized for access to immunization when the vaccines were first available. There must be more inclusion of immunocompromised patients in vaccine trials going forward, as many current indications for emerging COVID-19 therapeutics exclude people certain chronic conditions, including kidney failure, because these individuals are often excluded from clinical trials. Our organizations urge that vulnerable patients be prioritized for vaccination moving forward.

In the case of dialysis patients, even though evidence shows that the immune response to vaccination is blunted in dialysis patients. Furthermore, although antibody levels decline more rapidly in dialysis patients than in the general population, dialysis patients were not prioritized by the Food and Drug Administration (FDA) or the CDC when third doses of the vaccine were approved in August. In addition, dialysis patients were also excluded from the groups eligible to receive prophylactic long-acting antibody therapy targeting the SARS-CoV-2 virus. Lastly, the National Institutes of Health (NIH) did not receive funding for COVID-19 research to help people with kidney diseases or failure in any of last year's relief packages. Estimates indicate that there could be over one million Americans in kidney failure by 2030, and these high-acuity patients with multiple comorbidities must not be forgotten in our emergency planning and preparedness.³⁶

Question #4

The COVID-19 pandemic magnified a realization that had already been identified in previous public health epidemics, including the 2015-16 Zika virus, the 2009 H1N1 flu pandemic, and the e-cigarette or vaping use-associated lung injury (EVALI) crisis in 2021: our nation's public health infrastructure and workforce is not funded at levels to sustain it during "normal" times let alone at levels that would enable it to expand to the degree necessary to handle public health crises. The Public Health Infrastructure Saves Lives Act (S.674) is legislation that several of our organizations support as it would provide an additional \$4.5 billion in additional mandatory funding for CDC as well as state, territorial and local health departments for overdue and much needed infrastructure investments.

In 2012, the Institute of Medicine (IOM) (now the National Academy of Medicine) published a report titled *For the Public's Health: Investing in a Healthier Future,* which included a section entitled "Reforming Public Health and its Financing." ³⁷ Among the IOM's recommendations were:

"To achieve a more effective national public health effort, the nation will have to change how it allocates health expenditures in general and public health funds specifically. Spending on population-based public health prevention efforts is a very small proportion of overall national health expenditures. The allocation of public health spending also is not commensurate with need or with achieving the greatest value: conditions responsible for the highest preventable burden of disease are considerably underfunded."

Many of our organizations have called for a tripling in funding for CDC's National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) to expand the current patchwork of existing disease-specific programs to all jurisdictions nationwide. Chronic disease problems—including rising rates of obesity, tobacco use, alcohol use, and sedentary behavior – occurred before the pandemic and have only been made worse by the pandemic. A robust investment, appropriate to the magnitude of the problem, will allow CDC's NCCDPHP to fulfill its mission.

No doubt future crises will require occasional supplemental funding, but those public health crises will be easier to manage and address if a modern and robust public health infrastructure and workforce are well-funded and have sufficient capacity.

Question #5

We appreciate the recognition that in times of public health emergencies, certain regulatory barriers will need to be removed to respond to the emergency at hand. For example, we appreciate that during the current COVID-19 public health emergency (PHE), the Department of Health and Human Services (HHS) was able to use its flexibilities to provide better access to telehealth services, which allowed providers another mechanism with which to treat their patients. The existing statutory flexibilities have helped to ensure that the nation's health care system is better prepared to respond in times of crisis.

³⁶ McCullough, K. P., Morgenstern, H., Saran, R., Herman, W.H., & Robinson, B.M. (2019, January 1). *Projecting ESRD Incidence and Prevalence in the United States through 2030*. American Society of Nephrology. Retrieved from https://jasn.asnjournals.org/content/30/1/127

³⁷ Committee on Public Health Strategies to Improve Health; Institute of Medicine. For the Public's Health: Investing in a Healthier Future. Washington (DC): National Academies Press (US); 2012 Apr 10. 2, Reforming Public Health and Its Financing. Available from: https://www.ncbi.nlm.nih.gov/books/NBK201015/

However, we would caution that the declaration of a PHE should not serve as an opportunity to remove all regulatory barriers. Many of the so-called regulatory "barriers" exist to ensure patient safety. As consideration is given to which regulatory requirements should be lifted during a PHE, requirements related to patient safety must never be among those under consideration. While each emergency is unique, it is essential to identify in advance which rules and regulations can be waived or amended in an emergency setting. For example, a current regulation by the Centers for Medicare and Medicaid Services (CMS) requiring the use of pre-filled saline syringes is causing problems in dialysis facilities because there is a shortage of these products. Waiving this regulation would alleviate some of the strain while still allowing patients to get their life-sustaining dialysis treatments.

Additionally, authorities should review the current state-level standards of care and staff/patient ratio requirements to see if there are ways to modify the regulations without impacting safety during this critical time such as regulations barring nurse managers from participating in care delivery. Facilities should be able to know and plan in advance what emergency measures they will and will not be able to take to conserve supplies, extend staff capabilities and cope with patient overflow.

Question #8

Clinical trials are key to advancing new standards of care that can improve survival and quality of life for people with medical conditions, including those caused or exacerbated by a pandemic. To be successful, trials must enroll an adequate number of participants in a timely manner. However, patient enrollment in clinical trials is an ongoing challenge, and some demographic groups are underrepresented, including certain racial and ethnic groups, older adults, rural residents, and those with limited incomes. Excluding willing trial participants slows down the development of countermeasures during a pandemic and could result in the development of therapies that have not been tested in representative populations.

Cost to trial participants is often a barrier to their enrollment, especially non-medical or ancillary costs like transportation, lodging, or food related to trial participation. These ancillary costs can occur when no local trials are available, and patients must travel to distant trial sites or when there is a need for more frequent clinic visits for additional trial-related treatment or monitoring. The additional costs can lead to disparate participation rates between high- and low-income patients. Offering to reimburse patients for ancillary costs associated with trials can increase overall enrollment and may also increase participation from underrepresented groups. Some trial sponsors provide financial support for ancillary costs. Those that do not often cite concerns about running afoul of federal research participant protections that could subject them to civil monetary penalties. As a result, a number of our organizations support the bipartisan DIVERSE Trials Act (H.R.5030/S.2706), which would create a statutory safe harbor so that trial sponsors could provide patients with financial support for the ancillary costs associated with their clinical trial participation.

In addition to facilitating financial support of patients, The DIVERSE Trials Act also allows trial sponsors to provide patients with technology necessary to facilitate remote participation in clinical trials (e.g., tablets for answering surveys or facilitating televisits) and requires HHS to issue guidance on how to conduct decentralized clinical trials to improve demographic diversity.

Question #9

Sustained, robust, and consistent investments in evidence-based programs, especially at CDC, is necessary for our nation to be safe and secure from global and domestic public health threats—be they

infectious or noninfectious. The failure to invest in programs to prevent and manage chronic disease results in billions of health care costs each year and jeopardizes our economic and personal well-being.

We look forward to working with the Task Force to ensure robust investments are made that will increase health equity and the overall health of the nation.

PUBLIC HEALTH

Question #10

Community health centers are perfectly positioned to meet the comprehensive health care needs of patients while also reducing costs and preventing greater morbidity and inequity. Many Americans live in areas of the country that are rural, underserved, or considered a health shortage area. A health shortage area is an area, according to federal guidelines through the Health Resources and Services Administration (HRSA), wherein there are only a certain limited number of providers available to serve a designated population figure.³⁸

Federal policy needs to create incentives that drive qualified providers to serve in rural and underserved areas, equip communities with appropriate infrastructure such as broadband to support communications, extend appropriate telehealth flexibilities, and stabilize community health facilities (such as federally qualified health centers, critical access hospitals, school-based health centers, and community health centers). Additionally, federal policies must be put in place to expand the community and public health workforce with supportive mechanisms that promote early detection, prevention, health promotion, and disease state monitoring.

It is imperative that robust community health centers be matched by robust public health and prevention efforts outside clinical settings at the community level. A 2012 Institute of Medicine (now the National Academy of Medicine) report stated clearly that prevention of disease is the "most efficient and effective" way of achieving community health:

"Although some clinical care interventions can help to prevent a disease process in an individual, they cannot be used efficiently throughout a population to address pressing community health challenges. Those challenges, such as growing rates of obesity and diabetes, increase health care costs, diminish American productivity and competitiveness, and probably limit the opportunities available to the next generation of Americans because of increasingly poor health. Taking action as early and at the level of population, long before diabetes is diagnosed in one obese person, or chronic bronchitis is diagnosed in one smoker, is the most efficient and effective route to disease prevention."³⁹

Robust, sustained, and predictable investments in CDC population-level, evidence-based health programs will ultimately pay dividends, resulting in lower health care costs, better security and readiness, and a healthier nation.

³⁸ Health Resources and Services Administration. <u>What is Shortage Designation?</u> 2021.

³⁹ Committee on Public Health Strategies to Improve Health; Institute of Medicine. For the Public's Health: Investing in a Healthier Future. Washington (DC): National Academies Press (US); 2012 Apr 10. 2, Reforming Public Health and Its Financing. Available from: https://www.ncbi.nlm.nih.gov/books/NBK201015/

EXAMPLE: Vision Care Remains Scarce

Current data indicate that 24 percent (721) of 3,006 American counties have <u>no</u> ophthalmologist or optometrist. The National Rural Health Association estimates approximately one fifth of the nation's population lives in rural America with only 10 percent of the country's physicians practicing in rural communities.⁴⁰ For patients, this means that a needed or failed preventive vision screening or presence of a chronic illness may require them to travel—which means time away from work or home responsibilities, added costs, and difficulty with appointment availability—to seek the level of care required to ensure they maintain their vision health. Adding these additional burdens to a patient makes adherence to care very difficult, in some cases, and could lead to worsened eye health and potentially loss of vision. In addition, population demographics of rural areas tend to be older adults at risk of or living with a chronic illness.

Clinical interventions, such as those in primary care settings and in community health centers, are especially critical for rural and health shortage areas. For many underserved and low-income communities, federally funded community and rural health centers may be the only source of eye and vision care services. Broad efforts to improve community access, address chronic disease, enhance connectivity to support services, and promote independence, economic well-being, and enhance quality of life across the age spectrum too often exclude vision and eye health. Without integrating vision care with other aspects of the health care system, patients with visual impairments will remain disadvantaged in these settings and health disparities will remain. Integrating evidence-based vision health efforts into public health interventions ensures a multilevel response to preventing vision loss and promoting overall eye health without drawing critical resources away from equally important public health efforts.

Question #12

Chronic diseases and infectious diseases are inextricably linked. The COVID-19 pandemic highlighted how chronic medical conditions elevate an individual's risk of severe illness, hospitalization, and death. Specifically, COVID-19 poses elevated health risks for people with chronic conditions, and may lead to heart failure, stroke, kidney failure, chronic lung disease, blood pressure abnormalities, neurological conditions, and other long-term health complications in people who have survived the virus.

Six in ten Americans live with at least one chronic disease, like heart disease and stroke, cancer, respiratory disease or diabetes.⁴¹ These and other chronic diseases are the leading causes of death and disability in America, and account for 90 percent of the nation's \$3.8 trillion in annual health care costs.⁴² These numbers will likely worsen as the long-term health effects of the pandemic and COVID-19 infection among survivors unfold.

The CDC's National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) helps people and communities prevent chronic diseases and promotes health and wellness for all by:

- Measuring the numbers of individuals with chronic diseases or chronic disease risk factors;
- Strengthening health care systems to deliver preventive services and have highly trained health
 professionals that keep people well, diagnose diseases early, and help manage chronic
 conditions;

 ⁴⁰ Gibson DM. The geographic distribution of eye care providers in the United States: Implications for a national strategy to improve vision health. Prev Med. 2015 Apr;73:30-6. doi: 10.1016/j.ypmed.2015.01.008. Epub 2015 Jan 17. PMID: 25602911.
 ⁴¹ Buttorff C, Ruder T, Bauman M. <u>Multiple Chronic Conditions in the United States</u>. Santa Monica, CA: Rand Corp.; 2017.

⁴² Martin AB, Hartman M, Lassman D, Catlin A. <u>National Health Care Spending In 2019</u>: Steady Growth for The Fourth

Consecutive Year. Health Aff. 2020;40(1):1-11.

- Improving communities and public settings to make healthy choices convenient and conducting awareness campaigns and trainings to create supportive, safe environments;
- Connecting clinical services to community programs that help people prevent and manage their chronic diseases and conditions; and
- Addressing widening health disparities and advancing health equity.

Together, our organizations continue to advocate for a tripling of the NCCDPHP's budget to \$3.8 billion—representing 1/10th of 1 percent of the \$3.8 trillion our nation spends on health care, 90 percent of which is dedicated to treating chronic disease.

The COVID-19 pandemic has underscored the serious gaps in our public health infrastructure resulting from years of chronic underfunding. A strong public health enterprise that prevents and protects all individuals and families living in the United States from all diseases and preventable conditions— communicable and noncommunicable—requires robust, sustained investment.

Helping Americans understand how to manage their risk and undertake the needed prevention and control strategies for chronic conditions that impact tens of millions in the United States will take far more funding, by disease and risk factor, than we have invested to date. Congress must make the needed investment in NCCDHP's mission and proven programs by building national, state, and community-level capacity to scale and deliver on what works.

After more than a decade of stagnant funding, a commitment to triple NCCDPHP's budget is long overdue given the increasing threat chronic diseases pose to individuals living in America both pre- and post-pandemic—including an aging population and rising rates of obesity, tobacco use, alcohol use, and sedentary behavior. A robust investment, appropriate to the magnitude of the problem, will allow NCCDPHP to fulfill its mission by:

- Expanding the current patchwork of existing disease-specific programs to all jurisdictions
 nationwide. Chronic disease is a nationwide problem that requires a nationwide solution and
 investment in every state. For example, the CDC's State Physical Activity and Nutrition Program
 (SPAN) can only support evidence-based strategies to improve nutrition and physical activity in
 16 states. Implementing these programs can help prevent obesity and reduce the risk of chronic
 disease. The WISEWOMAN program, which helps uninsured and underinsured women reduce
 their risk for cardiovascular disease though preventive screenings and health services, is limited
 to 27 states. Expansion would help combat the nation's leading cause of death of women.
- Increasing funding for new cross-cutting, chronic disease prevention programs in the Social Determinants of Health Program and Chronic Disease Education and Awareness (CDEA) Program to address challenges and risks that are common to several different chronic diseases, as well as provide resources to the wide array of chronic diseases that are without a standalone program. For example, despite being a leading cause of death and disability in the United States, chronic obstructive pulmonary disease (COPD) does not have a standalone program at CDC. The CDEA program offers a chance for stakeholders working with diseases that do not have standalone funding, including COPD, to apply through a competitive application process for resources to work on expanding education and awareness. In this instance, the COPD community could use

such resources to further activity on the National COPD Action Plan and increase proper identification and treatment of the millions living with COPD that have yet to be diagnosed.

• Provide new, flexible funding for the NCCDPHP director to address new and emerging chronic disease challenges that are not currently addressed by the existing disease-specific budget construct, including the emerging chronic disease cohort of COVID-19 "long-haulers," for example.

Additionally, vision loss prevention and eye health promotion efforts at the CDC's Vision Health Initiative (VHI) rely on surveillance, epidemiology, and applied public health research. Prevalence data is used to develop and integrate public health practices and policies through state and community health programs and partnerships. However, due to consistent underfunding of our national public health system, programs such as the VHI located within the Division of Diabetes Translation under NCCDPHP have been unable to collect foundational visual health data since 2008. Consequently, our best available national-level data on vision loss and eye disease is nearly 15 years old. This means that we are responding to 2022 threats to vision and eye health using data that predates these threats.

From a vision and eye health perspective, Congress should also review the recommendations of a 2016 report issued by the National Academies of Sciences, Medicine, and Engineering (NASEM), *Making Eye Health a Population health Imperative*, which includes a number of recommendations that made a direct call for federal government action around improving equity in vision and eye health, including equipping CDC with the foundational level of funding necessary to conduct adequate, national-level surveillance using reliable surveillance instruments, and to develop community-based approaches that impact the populations most in need based on up-to-date prevalence data to promote vision health and reduce chronic disease.⁴³

Many of our organizations urge the Task Force to consider lessons learned from previous years. In the 1980s, funds for states to manage and control disease, including for tuberculosis (TB), were block granted. The harmful consequences were well documented. For example, TB rates skyrocketed in New York City between 1985-1992, and the cost to recover from the failure to make sustained and predictable investments in TB funding cost New York City \$1 billion (in 1991) to end the resulting multi-drug resistant TB outbreak.⁴⁴

In summary, we support a tripling of NCCDPHP's budget to scale up the current patchwork of diseasespecific programs to all states, expand funding for new cross-cutting programs, and provide new, flexible funding to address emerging chronic disease challenges. Further, we oppose consolidation of NCCDPHP's current disease-specific programs in the name of flexibility. Both the disease-specific programs and cross-cutting, flexible funding is necessary to address our nation's chronic disease challenges. It is well documented that consolidation of federal funding leads to funding cuts. We also fear that consolidation leads to less transparency and accountability, not more, for NCCDPHP.

⁴³ National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Population Health and Public Health Practice; Committee on Public Health Approaches to Reduce Vision Impairment and Promote Eye Health; Welp A, Woodbury RB, McCoy MA, et al., editors. Making Eye Health a Population Health Imperative: Vision for Tomorrow. Washington (DC): National Academies Press (US); 2016 Sep 15. Available from: https://www.ncbi.nlm.nih.gov/books/NBK385157/ doi: 10.17226/23471

⁴⁴ Frieden T. R., Fujiwara P. I., Washko R. M., Hamburg M. A. Tuberculosis in New York City—turning the tide. New England Journal of Medicine. 1995;333(4):229–233.

Question #13

As the Task Force is well aware, chronic disease is responsible for a tremendous share of our nation's collective health burden. Chronic diseases can be prevented and/or managed through supportive public health interventions, including tobacco prevention and cessation; however, chronic disease continues to be a major problem in the United States. The nation can and must be doing more to prevent and manage the many chronic diseases that are rampant across the country.

Many chronic illnesses can be prevented or mitigated by encouraging individuals to adopt healthier lifestyles. Excluding skin cancers, at least 42 percent of newly diagnosed cancers in the United States are potentially avoidable, including 19 percent of cancers caused by smoking and at least 18 percent caused by a combination of excess body weight, alcohol consumption, poor nutrition, and physical inactivity.⁴⁵ Additionally, up to 40 percent of Alzheimer's disease can be prevented by managing similar risk factors.⁴⁶ Enacting policies that encourage the adoption of a healthier lifestyle will not only reduce the risk of developing cancer, but will also reduce the risk of developing other chronic diseases (such as Alzheimer's, heart and lung disease, and diabetes) as well.

The CDC plays an unparalleled and indispensable role in addressing chronic disease in the United States. During the pandemic, the infectious disease aspect of CDC's mission has, understandably, been placed in the spotlight. While CDC's work on infectious disease is vital, the agency's mission and reach extends much further.

The value of CDC's work on chronic disease cannot be overstated. The only problem is that there is not enough of it. CDC needs far more robust, consistent, and reliable funding to adequately address the tsunami of chronic disease facing this country. For fiscal year 2022 (FY22), our organizations have called for a tripling of the budget for CDC's National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), for a total of \$3.75 billion. Such funding would enable NCCDPHP to better meet the challenge by expanding the current patchwork of existing programs to all jurisdictions nationwide and by implementing new efforts to address health challenges currently without programs, including the chronic disease cohort of COVID-19 "long-haulers." It would also enable a significant investment in CDC's Social Determinants of Health (SDOH) program, which seeks to work with communities to identify and remedy SDOH.

To better envision what CDC would be capable of achieving with a consistent increase in funding, it is beneficial to consider examples of the feats that CDC has already managed to accomplish with its current levels of funding.

EXAMPLE: Tobacco Use is Leading Driver of Chronic Disease and Death

One of CDC's most successful efforts to date in preventing and managing chronic disease is its work on tobacco. According to the U.S. Surgeon General, more than 16 million Americans are currently living with cancer, heart disease, chronic obstructive pulmonary disease (COPD) and other diseases caused by tobacco use. Tobacco use kills more than 480,000 individuals in the United States each year. Nearly one in three heart disease deaths and cancer deaths and nearly eight in 10 chronic obstructive pulmonary

⁴⁵ American Cancer Society. *Cancer Facts & Figures 2022*. Atlanta: American Cancer Society; 2022.

⁴⁶ Livingston, G., Huntley, J., Sommerlad, A., et al. (2020). Dementia Prevention, Intervention, and Care: 2020 report of the Lancet Commission. The Lancet, 396(10248), 413–446. <u>https://doi.org/10.1016/s0140-6736(20)30367-6</u>

disease (COPD) deaths are caused by tobacco use. Further, tobacco use is responsible for an estimated \$226 billion in annual health care costs. ⁴⁷

It is undeniable that addressing tobacco use must be a central aspect of any effort to tackle chronic disease. Thankfully, CDC has more than acknowledged as much. CDC's "Tips from Former Smokers" (Tips) media campaign has proven to be highly effective in aiding individuals to quit smoking. From 2012 to 2018, CDC estimates that more than 16.4 million people who smoke attempted to quit and approximately one million quit for good because of the Tips campaign.⁴⁸ Additionally, CDC has made great progress through its support of tobacco prevention and cessation programs in states and territories. States and territories are able to use funds from CDC's Office on Smoking and Health (OSH) to help individuals quit smoking, prevent youth tobacco use, reduce secondhand smoke exposure, and reduce disparities associated with tobacco use. With every \$1 spent on their tobacco control programs, states can secure a \$55 return on investment. As just one example, during the 2020 Tips campaign, North Carolina saw 13,037 calls come into its state quitline, an increase of 20 percent.⁴⁹

CDC is already doing phenomenal work to address tobacco use, yet it could achieve so much more with additional funding. Currently, the Tips campaign is only able to run for part of the year. With additional funding, the Tips campaign could run throughout the entire year and encourage more individuals to make quit attempts. A 2020 study that estimated the budgetary impact of a national year-long antitobacco media campaign found that running a sustained media campaign like Tips would reduce Medicaid spending by \$3.6 billion, Medicare spending by \$1.37 billion, and private insurer spending by \$180 million over 10 years.⁵⁰ With additional funds, CDC could also enhance efforts to end youth and young adult tobacco use, including e-cigarette use.

Youth continue to use e-cigarettes at alarming levels. CDC and the FDA's most recent National Youth Tobacco Survey showed that more than 2 million middle and high school students reported using ecigarettes in the first half of 2021, even when many schools were closed because of the COVID-19 pandemic.⁵¹ With more resources, CDC could better equip states to address this epidemic; could educate youth, parents, health professionals, communities, and others about tobacco products and the harms associated with their use; and could identify evidence-based strategies to protect youth and young adults from initiating tobacco use. Finally, with more funding, CDC could better advance health equity by strengthening efforts to assist groups who are disproportionately harmed by tobacco products, including by designing and implementing prevention and cessation programs that are tailored to address their specific needs. While the nation's adult smoking rate has decreased from 21.6 percent in 2003 to 14 percent in 2019, reductions in smoking have been uneven and certain populations continue to use commercial tobacco products at much higher rates than the national rate.⁵² For example, smoking remains particularly high among Indigenous Peoples (Native Americans and Alaskan Natives) at 20.9

⁴⁷ U.S. Department of Health and Human Services. The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014. Printed with corrections, January 2014.

⁴⁸ Murphy-Hoefer R, Davis KC, King BA, Beistle D, Rodes R, Graffunder C. <u>Association between the *Tips From Former Smokers* Campaign and Smoking Cessation Among Adults, United States, 2012–2018</u>. Preventing Chronic Disease 2020;17:200052.

 ⁴⁹ Centers for Disease Control and Prevention. <u>Extinguishing the Tobacco Epidemic in North Carolina</u>. 2021.
 ⁵⁰ Maciosek, Michael V., et al., "Budgetary impact from multiple perspectives of sustained antitobacco national media

campaigns to reduce the arms of cigarette smoking," Tobacco Control, April, 2020.

⁵¹ Park-Lee E, Ren C, Sawdey MD, et al. *Notes from the Field:* E-Cigarette Use Among Middle and High School Students — National Youth Tobacco Survey, United States, 2021. MMWR Morb Mortal Wkly Rep 2021;70:1387–1389. DOI: <u>http://dx.doi.org/10.15585/mmwr.mm7039a4external icon</u>

⁵² Centers for Disease Control and Prevention. National Health Interview Survey. Various years.

percent and LGB adults at 19.2 percent.⁵³ Targeted efforts from CDC could enable the agency to meet unique needs and tackle disparities.

EXAMPLE: Prevention and Early Detection of Cancer

Another example of important work that CDC is engaged in to prevent disease that could benefit from additional resources is the Division of Cancer Prevention and Control (DCPC) under NCCDPHP. Cancer death rates have decreased by nearly 30 percent in the past two decades, yet, despite this progress, cancer was still the nation's second leading cause of death in 2019.⁵⁴ The DCPC spearheads the federal government's efforts to prevent and control cancer and, in doing so, furthers essential work to lower the risk of cancer and cancer death for individuals in the United States.

The DCPC facilitates data collection through the administration of the National Program of Cancer Registries (NPCR). The NPCR supports and collects cancer incidence and death data in 46 states, DC and 3 territories, encompassing 97 percent of the population. Additional funding can help modernize the current data system to allow larger studies monitoring the burden of disease, disparities, prevention strategies, and treatment efficacy to further improve cancer care, prevention, and early detection.

Cancer screening is a key element of secondary prevention and management as it helps to identify disease early enough to allow for optimal intervention. One instance of the benefits of screening can be seen with lung cancer. Detecting lung cancer in early stages versus late stage is often the difference between life and death. Low-dose computed tomography screening among those at high risk for lung cancer can help detect this disease earlier and has been shown to reduce the lung cancer death rate by up to 20 percent.⁵⁵ Unfortunately, in 2020, only 5.7 percent of those eligible for screening were ultimately screened for lung cancer.⁵⁶ The CDC's National Comprehensive Cancer Control Program (NCCCP) works to reduce the burden of cancer across the entire country, including by working with grantees to coordinate early detection and treatment interventions. Increased CDC funding would allow the NCCCP to help more states implement programs that help to improve access to and utilization of screening, thereby saving lives.

For 30 years the National Breast and Cervical Cancer Early Detection Program (NBCCEDP) has decreased disparities in breast and cervical cancer deaths. Through cooperative agreements with states, tribes, and territories, the program provides breast and cervical cancer screenings, diagnostic tests, and treatment referral services to low-income communities. The NBCCEDP is the only nationally organized cancer screening program for breast and cervical cancer for underserved people in the United States, yet the program does not have adequate funding to serve all eligible individuals. Adequate funding for the NBCCEDP will preserve a critical safety net for those who continue to lack access to lifesaving screening, diagnostic, and treatment services and is an important step toward reducing disparities and advancing health equity in breast and cervical cancer.

Colorectal cancer screening is the most effective way of preventing cancer before it starts and finding it early when it is most treatable. During the screening process, non-cancerous polyps can be removed, preventing them from becoming cancerous. Cancers that are found at an early stage can be treated more easily, leading to greater survival. The Colorectal Cancer Control Program (CRCCP) provides grant funding to 20 state health departments, eight universities, and two tribal organizations over a five-year period to help prevent colorectal cancer. The goal of the CRCCP grant work is to increase colorectal cancer screening rates among high-need groups. Without a continued, dedicated federal investment in colorectal

⁵³ Cornelius ME, Wang TW, Jamal A, Loretan CG, Neff LJ. Tobacco Product Use Among Adults — United States, 2019. MMWR Morb Mortal Wkly Rep 2020;69:1736–1742

⁵⁴ Centers for Disease Control and Prevention. An Update on Cancer Deaths in the United States. 2021.

⁵⁵ American Lung Association. State of Lung Cancer: Lung Cancer Key Findings. 2021. <u>https://www.lung.org/research/state-of-lung-cancer/key-findings</u>

⁵⁶ American Lung Association. State of Lung Cancer: Lung Cancer Key Findings. 2021. <u>https://www.lung.org/research/state-of-lung-cancer/key-findings</u>

cancer prevention and early detection, the United States could experience a reduction in screening leading to increases in preventable colorectal cancer cases and deaths.

EXAMPLE: Addressing Obesity, Physical Education and Diabetes Education

For most Americans who do not use tobacco, the most important cancer risk factors that can be changed are body weight, diet, and physical activity. At least 18 percent of all cancers diagnosed in the United States are related to excess body weight, physical inactivity, excess alcohol consumption, and/or poor nutrition, and thus could be prevented. Although healthy choices are made by individuals, they can be promoted or hindered by the social, physical, or economic environment in which people live (social determinants of health). Lower income individuals, certain racial and ethnic groups, persons with disabilities, and those residing in rural communities frequently face additional environmental barriers to the adoption of cancer-preventive behaviors. Community efforts – such as increased access to affordable, healthy foods and the availability of safe, accessible opportunities for physical activity – are needed to create an environment that makes it easier for individuals to make healthy choices.

Secondary prevention – i.e., preventing cancer recurrence, exacerbation of symptoms during treatment, or treatment complications – is also extremely important in improving health outcomes and reducing costs. Counseling and programs for weight management, physical activity and nutrition can not only prevent cancer, but can also prevent cancer recurrence and help cancer patients currently in treatment manage their symptoms.

CDC has supported the Y's Healthy Weight and Your Child Program, an evidence-based program that empowers 7-to-13-year-olds and their families to live a healthier lifestyle. Since its launch, the program has been delivered in nearly 100 Ys in 37 states across the country. The program's curriculum is adapted from the most widely disseminated and evaluated child weight management program in the world, where research showed a statistically significant reduction in body mass index, waist circumference, sedentary activities and improvements in physical activity and self-esteem at six and 12 months. The family-centered program emphasizes three elements: healthy eating, regular physical activity and behavior change to elicit a positive life-long lifestyle transformation. We must take these life-saving interventions to scale more rapidly. That takes resources, cross agency collaboration, and an understanding of how community-based organizations work and adapt our models to understand how these programs and providers are different than the formal health system.

Serious Chronic Conditions Not Able to be Addressed at CDC

In addition to gaining the ability to expand existing activities, CDC's NCCDPHP could also benefit from obtaining funding for new efforts to address chronic conditions, including performing basic surveillance and public health intervention needs. For example, despite being one of the leading causes of death and disability in the United States, COPD does not have a standalone program at CDC. Thus, There are still many facets of chronic disease that CDC has yet to have been able to address due to a lack of resources.

With further resources, CDC could create additional disease-specific programs, of which it has many successful examples, or it could also utilize a cross-cutting approach that allows for greater flexibility as well as the ability to account for the overlapping nature of many diseases and their root causes. Both approaches, disease-specific and disease-agnostic, have unique value and purpose. An example of a recent effort to launch a disease-agnostic program that stands to benefit many suffering from chronic disease, and that could help several more with additional funding, is the CDEA program. As a competitive grant program, the CDEA enables stakeholders across the entire chronic disease community, particularly those representing diseases that do not have a standalone program, a fair chance to apply for funding of efforts to increase education and awareness of their diseases. The program just began, yet it already has more qualified applications than it does funding. With additional

resources, CDC could greatly expand its ability to support education and awareness activities across the chronic disease community.

Chronic disease presents a vast challenge to the health of individuals in the United States and the sustainability of the nation's health care system. CDC does incredible work already to stem the tide, but more is desperately needed. To better address conditions that lead to chronic illness and promote prevention strategies, CDC needs a robust and sustained level of funding that it can count on in the years to come. Only then will CDC be able to execute the type of public health effort that is necessary at the level that is necessary to effectively prevent and address chronic disease.

Question #14

The social determinants of health (SDOH) are the conditions in which people are born, grow, live, work, and age that can influence their health status over time. According to the World Health Organization, these circumstances are shaped by the distribution of money, power, and resources at global, national, and local levels. Unequal distribution of these resources leads to health inequities, which denotes a difference or disparity in health outcomes that is systematic, avoidable, and unjust.

We urge Congress to fund innovative models that allow for cross-sector collaboration (e.g., food, housing, employment, childcare, health and wellness, education, environmental protection, etc.) to improve upstream factors influencing health. A number of our organizations support bills like the Social Determinants of Health Accelerator Act (H.R.2503) and the Improving Social Determinants of Health Act (H.R.379/S.104), as well as funding for CDC in the annual appropriations bills to build these cross-sector solutions, that are important advancements to address this barrier. State and local public health departments and community-based organizations that address health and social needs must play a large role in these cross-sector efforts. State and local health departments can play an important role as a convener of multiple sectors, and community-based organizations, who are often built and led by community members and volunteers, have a unique lens into the challenges and opportunities in their community.

Additionally, many of our organizations contend that Congress must provide health system coverage for the lifestyle health and social services contributing to improved health. A lack of access to or payment for evidence-based lifestyle health programs and social services that address the drivers of health outcomes such as food, transportation, childcare, mental health/social connectedness, education, housing and more will only place more pressure on an overburden social safety net. State and local health departments and community-based organizations do not have the resources (administrative, technology, financial) that the health care system does, but are a critical, trusted, reliable and local resource for community needs. Congress can help provide resources for better coordination, communication, referral, and payment between the health system and SDOH providers.

Question #15

Public health officials hold a crucial responsibility to effectively communicate public health information so that it may be understood appropriately by a range of communities and populations, including the general public and nonscientific audiences. The COVID-19 pandemic has called attention to distrust by some populations of public health departments.

A key element and best practice to support bolster public trust and confidence in public health agencies and departments includes the need to provide reliable, sustainable, predictable, consistent, and

sufficient funding to improve the country's segmented public health infrastructure and communications platforms.

Further, the need for transparent, clear, concise, consistent, and simple vocabulary should be used to communicate such plans with the public. Decisions and communications plans should include patient advocates throughout the entirety of the process to design appropriate language and tools most beneficial to the public, not purely during a public comment period. In addition, it is important to achieve positive relationships between political leaders and scientists particularly in a public health emergency. Congress should consider policies to permit career expert scientists to communicate directly with the public in regular briefings with representatives from relevant health agencies to improve effectiveness of public messaging and answer questions in a timely manner.

Question #16

Vaccinations are one of the best public health tools created in the past century to reduce the burden of contagious disease and maintain health. Through use of vaccines, smallpox has officially been eradicated and wild polio virus nearly eliminated. Vaccines remain our best defense against infectious diseases, while acknowledging that no vaccine or prevention method is 100 percent safe or effective for everyone. Each individual may respond differently, and now in 2022 we may not have heard of or know anyone who experienced the dangers of conditions like diphtheria or tetanus thanks to vaccines. Before use in the general population, vaccines go through a rigorous series of clinical trials and reviews before, during, and after approval for market use to evaluate safety, efficacy, and effectiveness conducted by the CDC and the FDA along with their independent federal advisory bodies. As we continue to seek new methods to prevent disease and improve public health, vaccines will continue to be the most effective tool.

The best way for the federal government to support vaccination against preventable diseases is to increase reliable, sustainable, predictable, consistent, and sufficient funding for public health agencies, especially CDC. Such funding should contribute to increased research and funding for effective public messaging. Further, full funding for immunization-related activities at HHS, and especially within CDC's National Center for Immunization and Respiratory Diseases (NCIRD), should provide funds for state and local health departments to carry out activities to mitigate vaccine-preventable conditions. These activities include disease surveillance, safety and effectiveness studies, effective education and public outreach, and appropriate community-based programs especially for underserved and/or high-risk communities. Funds may also be useful to diversify communication methods, particularly while considering differences for high-risk populations and access to reliable broadband internet.

The federal government can better support state and local partners in educating by investing resources to diversify communication methods, particularly while considering differences for high-risk populations and access to reliable broadband internet. In addition, the federal government should invest in resources to facilitate better collection of state-level demographic data to ensure supplies are equitably administered. There is a need for a centralized immunization information system that patients and providers and health departments may use across the country to consolidate complete patient immunization history; at minimum, the systems should consider interoperability. Many of our organizations are supportive of legislation to help modernize and enhance Immunization Information Systems (IIS) across the country. Specifically, many of our organizations have been supportive of the Immunization Information Modernization Act (H.R.550). This bipartisan legislation has thankfully already passed through the House and is now awaiting further action in the Senate. If enacted, this legislation

could advance efforts to provide guidance and resources with the aim of achieving much needed improvements.

Financial barriers are a primary concern for most patients when seeking treatments or prevention for their health. Some vaccines are covered under Medicare Part B, such as influenza and pneumonia, and are available at zero cost to the beneficiary. However, other vaccines are covered under Medicare Part D, like shingles, tetanus, Tdap, and others which result in a cost-sharing component for the patient. Many of our organizations urge the federal government to eliminate or waive such cost-sharing for Part D vaccinations and align copay/coinsurance policies for both Part B and Part D. Eliminating such costsharing will result in fewer reasons for adults to hesitate to get vaccinated, resulting in higher rates of vaccination thus changing the practice of prevention from being an outlier to the norm. Additionally, such elimination of cost-sharing and shifting Part B and Part D coverage should address physician administrative burden given an unclear method for billing Part D vaccines, thereby reducing the likelihood that clinicians will be deterred from purchasing and offering vaccines to their patients. In a recent Avalere study, "savings associated with improved disease prevention largely offset costs from expanded beneficiary access and improved uptake of recommended vaccines." ⁵⁷ To address the harmful discrepancy between Part B and Part D, many of our organizations have supported the Protecting Seniors Through Immunization Act of 2021 (H.R.1978/S.912). If enacted, this legislation would remove the cost barriers to vaccines covered under Part D that are recommended by the CDC's Advisory Committee on Immunization Practices (ACIP).

In addition to the cost barriers that exist for Medicare beneficiaries, there are also barriers that must be eliminated for beneficiaries of traditional Medicaid. While beneficiaries covered under Medicaid expansion have access to all vaccines recommended by ACIP with no cost-sharing, beneficiaries under traditional Medicaid do not have the same guarantee. Not all vaccines are required to be covered for this population and cost-sharing is permitted. Those on traditional Medicaid are some of the nation's most vulnerable individuals, individuals for whom any cost-sharing may truly be an insurmountable obstacle. It is critical this barrier be removed so that all individuals can benefit from the added health security that is achieved through vaccination. To this end, many of our organizations have supported the Helping Adults Protect Immunity (HAPI) Act (H.R.2170/S.581), which would eliminate this barrier and ensure access to ACIP-recommended vaccines at no cost for all Medicaid beneficiaries.

Further, Congress should consider flexible incentives for Medicaid plans to reach vaccination targets for populations they serve, such as performance or quality measures, and provide supplemental funding to encourage quality improvements. Additional considerations may include evaluating timeline and data transparency criteria for new vaccine candidates and allowing the Vaccines and Related Biological Products Advisory Committee (VRBPAC) and ACIP recommendations to deliberate publicly on how and when products should be given to the public and thus respected by the federal government agencies in plans to gather information and next steps.

Finally, a number of our organizations support Congress considering insurance requirements to allow for the development of alternative routes of vaccine administration, such as self-injectable vaccinations as appropriate, which could be easily ordered, received, administered, and disposed of safely and effectively.

⁵⁷ Avalere. Impact of Removing Part D Vaccine Cost-Sharing on the Federal Government. 2021.

Question #18

Addressing Alzheimer's Disease and Related Dementias (ADRD) is an urgent health equity challenge: without appropriate interventions, our nation will see the number of individuals living with Alzheimer's and related dementias increase from nearly 6 million to 12.7 million by 2050, and Hispanic/Latino and Black individuals will see the largest increases in ADRD between 2015 and 2060.⁵⁸ Black individuals are about twice as likely to have Alzheimer's or other dementias as white individuals, and Hispanic/Latino individuals are about one and one-half times more likely. In addition, 65 percent of people living with Alzheimer's are women.⁵⁹

Challenges to appropriately addressing, preventing, and treating Alzheimer's are very much tied to social determinants of health. Examples include:

- Lack of tailored resources for dementia diagnosis and care is a key reason why Black and Hispanic/Latino individuals with dementia are less likely than white individuals with dementia to have a formal diagnosis and are more advanced in their disease when they are diagnosed.⁶⁰
- The lack of diversity in ADRD research is stark: Black and Hispanic/Latino individuals make up less than 10 percent of all clinical trial participants in federally funded ADRD research.⁶¹ This disparity tracks with the significant imbalance of minority representation in clinical research: while Black individuals make up 13.4 percent of the United States population, they only account for 5 percent of all clinical trial participants; Hispanic/Latino individuals represent less than 1 percent of trial participants, while they make up 18.1 percent of the population.⁶²
- Data from two NIH studies show a 60 percent lower Alzheimer's risk among those with the highest number of healthy behaviors, such as regular physical activity, not smoking, light-to-moderate alcohol consumption, a high-quality diet, and frequent cognitive activities.⁶³ Further, strengthening educational pathways and school quality may also improve cognitive health and help reduce brain health disparities.⁶⁴
- Primary care providers who practice in communities with a greater presence of Black and Hispanic/Latino individuals (as compared to those with a greater presence of white individuals) have fewer community resources to refer patients to specialists.⁶⁵

⁶⁰ Lines, Lisa M. & Weiner, Joshua M. (2014). *Racial and Ethnic Disparities in Alzheimer's Disease: A Literature Review*. Report prepared for Office of Disability, Aging and Long-Term Care Policy, Office of the Assistance Secretary for Planning and Evaluation, U.S. Department of Health and Human Services.

https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//138596/RacEthDis.pdf

⁵⁸ Alzheimer's Association. 2021 Alzheimer's Disease Facts and Figures. <u>https://www.alz.org/alzheimers-dementia/facts-figures</u>

⁵⁹ Alzheimer's Association. 2021 Alzheimer's Disease Facts and Figures. <u>https://www.alz.org/alzheimers-dementia/facts-figures</u>

⁶¹ National Alzheimer's Coordinating Center (n.d). Retrieved July 20, 2020, from www.naccdata.org

⁶² Association of Clinical Research Professionals. (2020, August 11). *Representation in clinical trials: A review on reaching underrepresented populations in research*. ACRP. Retrieved January 27, 2022, from

https://acrpnet.org/2020/08/10/representation-in-clinical-trials-a-review-on-reaching-underrepresented-populations-in-research/

⁶³ Dhana K, et al. Healthy lifestyle and risk of Alzheimer's dementia: Findings from two longitudinal studies. Neurology. 2020;95:1-10.

⁶⁴ Sisco, S et al. The Role of Early-Life Educational Quality and Literacy in Explaining Racial Disparities in Cognition in Late Life, The Journals of Gerontology: Series B, Volume 70, Issue 4, July 2015, 557–567, <u>https://doi.org/10.1093/geronb/gbt133</u>

⁶⁵ VanderWielen LM, Gilchrist EC, Nowels MA, Petterson SM, Rust G, Miller BF. Not Near Enough: Racial and Ethnic Disparities in Access to Nearby Behavioral Health Care and Primary Care. J Health Care Poor Underserved. 2015;26(3):1032-1047. doi:10.1353/hpu.2015.0083

- One of the surest ways to increase early detection of ADRD is to ensure that Medicare recipients receive a cognitive assessment using a screening tool during their Medicare Annual Wellness Visit (AWV). CMS currently allows clinicians to use their "direct observation," an unscientific method, to determine whether a patient is experiencing mild cognitive impairment. Legislation currently before Congress, the CHANGE Act of 2021, (H.R.3354/S.1692) would require use of an evidence-based cognitive screening test, as identified by the National Institute on Aging, during the AWV.
- Alzheimer's is not an inevitable part of aging and recent studies show that up to 40 percent of dementia cases may be slowed or prevented by the management of 12 modifiable risk factors, including smoking, excess alcohol consumption, lack of sleep, diabetes, hypertension, and others.⁶⁶

There are several efforts that Congress and the federal government can do to better support evidencebased prevention activities.

- Public and private payers (e.g., Medicare, Veterans Health Administration, Indian Health Service, state Medicaid programs, etc.) should identify a comprehensive set of actions to assess and reduce dementia risk, delay the onset of dementia, and improve early intervention, ensuring equitable reach and impact of interventions for historically marginalized populations. This should include:
 - Identifying opportunities to reduce the risk of mild cognitive impairment and dementia by addressing known risk factors and support early intervention for ADRD, including but not limited to beneficiary education; offering reimbursement incentives; providing payments for prevention and care delivery models that incorporate brain health being affected by other conditions and organ systems; and implementing quality measures.
 - Identifying existing benefits related to factors that can potentially help reduce dementia risk, as well as coverage gaps and inequities that, if addressed, could potentially reduce known risk factors associated with ADRD (e.g., nutrition support; physical activity prescriptions; diabetes management and treatment; audiology assessments and screenings, hearing rehabilitation, appropriate hearing technology; and screening and treatment for depression and unhealthy alcohol use).
- To truly reduce the number of people impacted by Alzheimer's, our nation must strengthen its public health infrastructure in communities across the country, particularly in underserved communities. The Alzheimers organizations recommend funding the CDC's Alzheimer's Disease and Healthy Aging Program at \$60 million to enable CDC to coordinate a stronger public health response to Alzheimer's.
- On December 2021, HHS Secretary Becerra prioritized dementia risk reduction by establishing a national prevention goal as part of the National Alzheimer's Plan. Congress should do everything in its power to ensure that HHS has the tools necessary to meet the recommended 15 percent

⁶⁶ Livingston, G., Huntley, J., Sommerlad, A., et al. (2020). Dementia Prevention, Intervention, and Care: 2020 report of the Lancet Commission. The Lancet, 396(10248), 413–446. <u>https://doi.org/10.1016/s0140-6736(20)30367-6</u>

prevalence reduction of 10 key risk factors by 2030. Since many of these risk factors (depression, diabetes, hearing loss, mid-life hypertension, physical inactivity, poor diet quality and obesity, poor sleep quality and sleep disorders, tobacco use, traumatic brain injury, and unhealthy alcohol use) are related to chronic disease, we cannot make effectively achieve this goal without robustly supporting CDC's NCCDPHP.

 The National Institute of Aging should report the recruitment and retention levels of underrepresented communities across federally funded ADRD research trials and sites, releasing disaggregated recruitment data in real time. Funding decisions should consider the plans of each applicant to engage, recruit, and retain underrepresented communities that reflect the diversity of the site's local community.

While the number of people living with Alzheimer's is projected to balloon in the next few decades, the United States lacks a support safety net to provide appropriate and necessary care. In 2017 alone, 16.1 million family caregivers in the United States provided an estimated 18.4 billion hours of unpaid care for people with Alzheimer's and other dementias.⁶⁷ Additionally, just over a quarter of employed caregivers (27 percent) and 40 percent of employed millennial caregivers, reported going into debt caring for their loved one.⁶⁸

Paid medical and family leave has a significant positive impact for employed adult caregivers of people living with Alzheimer's disease and related dementias. A number of our organizations believe that Congress must prioritize efforts to provide paid medical and family leave immediately if we ever stand a chance to appropriately meet the growing need of care in the United States. The Paid Leave Alliance for Dementia Caregivers created policy principles for paid medical and family leave policy:⁶⁹

- All employed individuals with the right to job-protected leave benefits that support workers who need time to care for themselves or their loved ones living with a serious chronic health condition like Alzheimer's and related dementias;
- Relief, such as tax deductions and credits, for at-home caregivers who have sacrificed income potential to care for their loved ones at home;
- Meaningful wage replacement benefits of a sufficient size and duration to caregivers to enable them to make a real choice about how care is provided; and
- Flexible workplace policies to enable employed caregivers to accompany their loved ones with serious medical conditions to medical visits including visits related to clinical research and trials.

Question #19

Nearly 10 million people living in the United States identify as American Indian and Alaska Native (AI/AN) based on the 2020 US Census.⁷⁰ It is important to draw attention to the fact that over 42

⁶⁸ Vega, W. A., Aranda, M. P., & Rodriguez, F. A. (2017). *Millennials and Dementia Caregiving in the United States*. YouthAgainstAlzheimer's and University of South California Edward R. Roybal Institute on Aging. Retrieved January 26, 2022, from <u>https://www.usagainstalzheimers.org/sites/default/files/Dementia%20Caregiver%20Report_Final.pdf</u>.

⁶⁷ Alzheimer's Association. 2017 Alzheimer's Disease Facts and Figures.

⁶⁹ Paid Leave Alliance for Dementia Caregivers Convened by UsAgainstAlzheimer's. Retrieved from:

https://www.usagainstalzheimers.org/sites/default/files/Paid%20Leave%20Alliance%204%20Dementia%20Care_Overview.pdf ⁷⁰ United States Census Bureau. Intergovernmental Affairs: Tribal Affairs — American Indian and Alaska Native (AIAN). 2021.

percent of AI/AN individuals rely on Medicaid or public health insurance coverage, while nearly 15 percent have no health insurance coverage.⁷¹ Health equity for these populations is key to improving overall health outcomes.

A number of our organizations advocate for Congress to increase and enact mandatory appropriations and support for the Federal Indian Health Service, which aims to care for and educate many populations, including American Indian tribes and Alaska Natives. This would align federal responsibility and trust among these peoples. Congress should enact legislation to fund a best practices survey to identify the next steps and appropriate recommendations.

Similarly, many of our organizations support a number of other policies aimed at improving health equity for this population, including:

- Increasing federal funding to a 100 percent federal medical assistance percentage (FMAP) for Medicaid and ensuring that Medicaid provides access to health coverage that meets the unique needs of the Indian Health Service. Congress should clarify the federal law that state Medicaid programs are permitted to implement policies specifically for AI/AN health providers through waivers. Providing full federal funding coverage for Medicaid for these populations will increase access, reduce patient out-of-pocket costs and therefore potential hesitancy to seek treatment, and deliver on the government's treaties and promise to provide health coverage and services for American Indian tribes and Alaska Native peoples.
- Revise FMAP eligibility to include AI/AN individuals who live on reservations in addition to those
 who are living in urban and other settings. Current eligibility criteria require AI/AN individuals to
 access health care services through the Indian Health Service or tribal health care facilities. The
 FMAP should be a benefit for all AI/AN individuals regardless of where they live or where they
 access health services. The current COVID-related flexibilities for accessing care allows for some
 federal funding to flow to states.
- Fund the establishment and continuity of Medical-Legal Partnerships (MLP) to meet the complex health needs of AI/AN people living in urban settings through the 41 Urban Indian Organizations (UIOs) and provide support for training of AI/AN legal professionals to serve in MLP roles.
- Strengthen and diversify the physician and clinician pipeline. Consider student loan repayment program for clinicians who choose to work in underserved communities.
- Prioritize supply chain support. Often, individuals may have to travel hundreds of miles or hours to seek medical care.
- Increase funding to ensure access to Broadband internet connection, thus reducing a barrier to
 communication and registration for health services among certain populations without reliable
 or consistent access or technology proficiency. A primary barrier to achieving reliable internet
 access is the lack of funding to adequately support health information technology infrastructure,
 including electronic medical records, resources for training and data/business application.

⁷¹ Health and Human Services. <u>Profile: American Indian/Alaskan Native</u>. 2022.

Congress should consider requiring the Indian Health Service to collaborate with the Veterans Administration on electronic health record upgrades.

The federal government should consider cultural competency and respect for various populations of people. There are numerous native languages spoken other than English at home, and many believe in local tribal or native remedies. As stated in a CDC Morbidity and Mortality Weekly Report (MMWR) from 2018, "culturally tailored public health approaches to reducing risk factors and chronic diseases among AI/AN are needed, including improved surveillance to identify priorities and implement interventions."⁷²

Question #21

The United States has the highest maternal mortality rates among developed countries, and cardiovascular disease is the leading cause, accounting for 1 in 3 pregnancy-related deaths.⁷³ Despite steep declines in global maternal mortality rates over the past two decades, United States maternal mortality rates have more than doubled to an estimated 700 deaths a year in the United States since data collection began in 1987.⁷⁴ An estimated two out of three pregnancy deaths are preventable, emphasizing that the best models of care must be put in place to save lives.⁷⁵ Pregnancy-related mortality rates for non-Hispanic Black and Indigenous women are nearly two to three times that of white women, and these disparities persist independent of socioeconomic variables.⁷⁶

There is compelling evidence for the critical role of access to health care in maternal outcomes. Health insurance status is an important dimension of access to care, and studies have documented disparities in health insurance coverage among poor, young, and racial and ethnic minority populations,⁷⁷ as well as adverse maternal and infant outcomes among uninsured and Medicaid-covered women.⁷⁸ Preexisting chronic health conditions also increase health risks for pregnant individuals, making access to preventive health care before pregnancy highly important.

Overall, individuals with cardiovascular risk factors should be actively managed both during and after pregnancy. Even beyond the conventional postpartum period, there is a need for ongoing individualized care across the lifespan. A systemic and critical exploration of the causes and contributors to maternal morbidity and mortality is critical, including the identification of health care, economic, legal, social, and cultural barriers that could be reduced and the implementation of recommendations, education programs, and policy changes to prevent future deaths and complications.

⁷² Adakai M, Sandoval-Rosario M, Xu F, et al. Health Disparities Among American Indians/Alaska Natives — Arizona, 2017. MMWR Morb Mortal Wkly Rep 2018;67:1314–1318. DOI: http://dx.doi.org/10.15585/mmwr.mm6747a4

⁷³ Centers for Disease Control and Prevention. <u>Reproductive health</u>. 2020.

⁷⁴ Call to Action: Maternal Health and Saving Mothers: A Policy Statement From the American Heart Association, September 8, 2021, https://www.ahajournals.org/doi/full/10.1161/CIR.000000000000000000

⁷⁵ Davis NL, Smoots AN, Goodman DA. Pregnancy-related deaths: data from 14 U.S. Maternal Mortality Review Committees, 2008-2017. Centers for Disease Control and Prevention, US Department of Health and Human Services; 2019. Accessed November 1, 2020. <u>https://opqic.org/wp-content/uploads/2019/06/MMR-Data-Brief_June-2019.pdf</u>

⁷⁶ Petersen EE, Davis NL, Goodman D, Cox S, Syverson C, Seed K, Shapiro-Mendoza C, Callaghan WM, Barfield W. Racial/ethnic disparities in pregnancy-related deaths—United States, 2007-2016.MMWR Morb Mortal Wkly Rep. 2019; 68:762–765

⁷⁷ Riley WJ. Health disparities: gaps in access, quality and affordability of medical care. Trans Am Clin ClimatolAssoc. 2012; 123:167–172.

⁷⁸ Wang E, Glazer KB, Howell EA, Janevic TM. Social determinants of pregnancy-related mortality and morbidity in the United States: a systematic review. Obstet Gynecol. 2020; 135:896–915.

Many of our organizations attest that maternal health equity is achievable through a three-pronged approach focused on patients, providers, and systems of care:

Addressing Disparities and Inequities

- **Provider Education**: Mitigate bias and unequal treatment in care by integrating cultural and structural competency training into medical education for all health care providers.
- **Better Reporting**: Improve quality reporting of maternal outcomes, as well as surveillance systems to better monitor key maternal and infant health indicators.
- **Funding Care & Research**: Address systemic inequities by expanding Medicaid in states that have yet to take that step, funding rural hospitals and researching intersections of determinants of health with sex, gender identity, sexual orientation, race and ethnicity.
- **Prevention Education**: Support public awareness and education campaigns for smoking cessation, physical activity, and heart healthy prevention from prenatal to postpartum.

Modernizing Maternal Health Care Delivery

- Preconception Counseling: Improve awareness of preconception counseling to increase adoption of healthy behaviors before, during and after pregnancy, and awareness of potential medical complications.
- **Postpartum Coverage Expansion**: Expand postpartum care for Medicaid participants to the first year after delivery.
- Payment Model Innovation: Transform provider payment in a way that prioritizes quality improvement and the provision of historically underutilized, high-value services and deprioritizes unnecessary services.

Updating Technology & Systems

- Invest in Under-Resourced Communities: Modernize the public health infrastructure through investments in community health workforce, health care facilities and digital perinatal services that serve under-resourced communities such as Text4Baby to support mothers and their newborns.
- Close Gaps in Rural Health: Enhance coordination of care across the cardio-obstetric team and improve access to telemedicine and remote patient monitoring through at-home technology.

The original questions posed by the Healthy Future Task Force are appended below.

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 <u>molly.brimmer@mail.house.gov</u> (Rep. Hudson) Andrew Keyes at <u>andrew.keyes@mail.house.gov</u> (Rep. Banks) Shane Hand at <u>shane.hand@mail.house.gov</u> (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

- 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.