Attachment—Additional Questions for the Record

Subcommittee on Health
Hearing on
"The Fiscal Year 2023 HHS Budget"
April 27, 2022

The Honorable Xavier Becerra, Secretary, U.S. Department of Health and Human Services

Questions from The Honorable G.K. Butterfield (D-NC)

1. Question:
COVID's impact to nursing home residents combined with continued staffing shortages have dramatically impacted care to this vulnerable population. Combine this impact with longstanding work Congress has tried to combat on antipsychotic usage and overall behavioral health support in nursing homes, we are seeing a growing and continued crisis for our elderly and mental health population.

During COVID, Federally Qualified Health Centers (FQHC) have been able to be responsive and innovative in meeting the behavioral health needs of the community through relaxed rules and resources provide. Do you feel it is warranted to learn from success that has taken place? Do you think it is possible to continue to enable FQHCs to pilot programs that have been a success during COVID to combat and support behavioral health needs in nursing homes and other community settings?

Response: Currently, approximately 97 percent of the nearly 1,400 HRSA-funded health centers provide mental health counseling and treatment. In 2020, HRSA-funded health centers provided nearly 1.7 million patient visits related to substance use disorder. In addition, HRSA has provided $540 million in ongoing investments annually, including $205 million to health centers in rural areas, to support and increase access to mental health and substance use disorder services for patients nationwide. Given the continuing need for behavioral health services and the recent success in delivering these services via telehealth and in the community, HRSA plans to continue supporting these effective strategies for reaching high-need populations.

2. Question:
As Chair of the Congressional Rare Disease Caucus, I wrote to the National Center for Health Statistics (NCHS) at the Centers for Disease Control and Prevention (CDC) to gain a better understanding of the process used to assign new International Classification Disease (ICD) diagnosis codes for rare diseases. The additional questions below seek further clarity and transparency into the current application process for rare disease stakeholders seeking assignment of a diagnosis code.

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a. What are the specific criteria for deciding whether the application is accepted to proceed, rejected, or deferred?

Response: Criteria for deciding on acceptance, rejection, or deferral of new codes depends on the following:

1. The proposal submission is complete and includes all information requested for consideration (https://www.cdc.gov/nchs/icd/icd10_maintenance.htm):
    a. A description of the code(s)/change(s) being requested including suggested placement within the ICD-10-CM classification structure.
    b. Rationale for why the new code/change is needed (including clinical relevancy).
    c. Supporting clinical references and literature
    d. Proposals (including clinical justification) should be no longer than two pages.
    e. Proposals should be consistent with the structure and conventions of the ICD-10-CM classification system.
    f. Proposals should indicate the name of persons or organization requesting the code changes as well as a designated primary point of contact with contact information.
    g. Proposals are submitted to nchsicd10cm@cdc.gov by the deadline provided on the upcoming meeting webpage: https://www.cdc.gov/nchs/icd/icd10cm_maintenance.htm
2. Proposal must be consistent with ICD-10-CM structure and conventions. The ICD-10-CM is based structurally on the World Health Organization (WHO) ICD-10, and maintenance and development of ICD-10-CM depend on agreement with WHO.
3. If a proposal cannot be presented at a public meeting due to time constraints for the meeting but meets all other criteria, the proposal will be placed on the agenda for the next public meeting.
4. Final decisions on code revisions are made through a clearance process with the Department of Health and Human Services.
5. Applicants are informed whether their proposal will be approved, approved with modifications, or will need to be presented again at a future meeting following the 60-day comment period post public meeting (or 30-day comment period for accelerated implementation when applicable).

b. Has CDC engaged with the rare disease community to help the community navigate these processes?

Response: CDC staff have engaged with several people in the rare disease community, including patient advocacy organizations that have sought new codes on how to work within the regular ICD-10-CM code proposal process. While several new proposals were made that will be implemented this coming Oct. 1, 2022, additional recent proposals are currently under

review. It is possible that these additional proposals will be implemented next year. Other new proposals are under review, and we anticipate them to be discussed at future meetings.

For example, the following new rare disease codes were implemented in 2021:

- A79.82, Anaplasmosis
- F78.A1, SYNGAP1-related intellectual disability
- F78.A9, Other genetic related intellectual disability
- G04.82, Acute flaccid myelitis
- Z91.014, Allergy to mammalian meats
- C84.7A, Anaplastic large cell lymphoma, ALK-negative, breast
- M31.11, Hematopoietic stem cell transplantation-associated thrombotic microangiopathy [HSCT-TMA]
- D89.44, Hereditary alpha tryptasemia
- M35.81, Multisystem inflammatory syndrome
- E75.244, Niemann-Pick disease type A/B
- D55.21, Anemia due to pyruvate kinase deficiency

Additionally, members of the Rare Disorders and Health Outcomes Team within CDC's National Center on Birth Defects and Developmental Disabilities have provided support to patient organizations and clinicians on proposals that were approved for specific ICD-10 codes for Duchenne and Becker muscular dystrophies, facioscapulohumeral muscular dystrophy, and limb-girdle muscular dystrophies.

c. NCHS states that applicants are informed whether their proposal will be approved, approved with modifications, or will need to be presented again at a future meeting following the 30-day comment period post public meeting. Stakeholders have commented that their experience with NCHS has differed from the process as outlined.

How does NCHS hold itself accountable to this process?

Response: NCHS has a tracking system in place to document all incoming proposals and follow them through the cycle of the proposal process. The tracking system is as follows:

1. NCHS receives new proposals at the following email address: nchsicd10cm@cdc.gov.
2. The proposal is documented in a tracking database with the date received and who is assigned the initial review of the proposal.
3. NCHS responds back to the submitter acknowledging receipt of the proposal and the next steps.
4. The assigned NCHS Point of Contact conducts a cursory review to determine whom else needs to review the proposal from the ICD-10 Coordination and Maintenance Committee.

5. After reviews are complete and input provided from the initial review, NCHS responds to the submitter on whether or not they will be able to present their proposal at the next Committee Meeting.
    a. If the proposal will be presented at the upcoming committee meeting, NCHS provides guidance on how to prepare for the meeting, including what materials are needed for clinical presentation.
    b. If the proposal is not selected for presentation, NCHS provides the reasoning, which can include:
        i. Did not provide all required materials in original submission.
        ii. Limited time due to other topics on the upcoming meeting agenda
        iii. Information insufficient to make a determination on relevancy of new code
        iv. Complexity and need for further subject matter expert input
    c. If the proposal is not selected to be presented at the next Committee Meeting, the submitter can address the reasoning provided by NCHS and re-submit for consideration at the next Committee Meeting.
    d. If a proposal is not considered only due to limited time for the agenda, it will be held for potential consideration at the next meeting, without need for resubmission.
6. All of these steps are documented in the tracking system, including the final determination on the proposal, if it is considered at a Committee Meeting.
7. The proposal is closed out in the tracking system upon final determination.

d. Many rare disease patients do not have accurate diagnoses in their health records – what role does NCHS have to address this disparity?

Response: NCHS works closely with the Centers for Medicare & Medicaid (CMS) to update and create diagnosis codes. NCHS and CMS publish guidance on how to use updated or new diagnosis codes through Coding Clinic, a subscriber-based system managed by the American Hospital Association. NCHS and CMS also work closely with AHA and the American Health Information Management Association to develop guidance and messaging on updated and new diagnosis codes.

There are many ways to represent diagnoses in addition to ICD codes. These can include simple text representation (free text in an electronic health record) as well as other systems such as SNOMED CT (a terminology that includes most rare diseases directly). As a clinical classification rather than a terminology, ICD is generally expected to group certain diseases and disorders into groups, particularly for rare diagnoses. To better support clinical usage, ICD-10-CM has added much more detail than what is included in the original WHO ICD-10, but there is still some grouping of disorders, particularly for very rare disorders. NCHS continues to seek expert input on how best to decide cutoff levels for prevalence when adding new codes and what types of exceptions can be reasonable. NCHS also considers additions of new ICD codes to directly represent rare diseases based on public input and comments.

Additionally, NCHS can help with measuring misclassification of diagnosis codes through the work of the National Hospital Care Survey.

3. Question:

As you know, the pandemic has exacerbated the persistent labor shortages experienced by providers across all health care sectors. With an even smaller labor pool that is in even higher demand, providers are experiencing significant increases in labor-related costs in the form of higher wages, benefits, and training expenses. These expenses come on top of others related to the pandemic, and there is no sign of abatement in the short term.

I appreciate that President Biden has recognized the need to address healthcare workforce issues by requesting additional funding for training programs overseen by the Department of Health and Human Services (HHS). These programs are an important component of the response. However, they will not address the workforce challenges that providers currently face. Although Congress and the Administration established programs to assist with these expenses, I believe additional relief is necessary to ensure that patients, particularly those from underserved communities and who need care for a chronic, life-threatening condition, such as end stage renal disease (ESRD), have good access to care.

Could you please share with the Committee what HHS has been hearing from providers about the impact of these higher labor and operational expenses and offer your insight on further steps that Congress and the Administration could take to help these providers overcome the challenges and ensure that patients have good access to care?

Response: HHS has heard concerns from providers, grant recipients, and stakeholders regarding increased labor costs, and we are committed to strengthening and expanding the health workforce and connecting skilled health care providers to communities in need. HRSA funds health professions training programs as well as critical nurse faculty programs that aim to increase the opportunities for more individuals to enter the health professions by building training programs' capacity to serve students. HHS offers several loan repayment and scholarship programs, including the National Health Service Corps and Nurse Corps programs, which make it easier for providers to gain qualified staff and address some of the issues associated with higher labor and operational expenses.

A critical tool in our health workforce efforts is the National Health Service Corps, which provides scholarships and loan repayment in return for a commitment to practice in high-need communities. Through additional congressional support through the CARES Act and the American Rescue Plan (ARP) Act, HRSA was able to expand the reach of this program and make more awards/fund more individuals than ever before. Moreover, the CARES Act provided additional flexibilities for NHSC clinicians who are currently serving in Health Professional Shortage Areas (HPSAs) and whose service obligations were negatively impacted by the pandemic.

We look forward to continuing to work with Congress to strengthen and support our health care workforce serving our communities of greatest need.

4. Question:

Rare kidney diseases are an overlooked and under-treated driver of chronic kidney disease (CKD) in America, and the resultant $81 billion per year of costs to Medicare. Moreover, most of the 200,000+ patients who suffer from these progressive genetic illnesses—including many children and young adults—end up facing dialysis, transplant, or death but thanks to 21st Century Cures passed by this Committee there is a wave of innovation taking place in this space.

I have introduced bipartisan legislation with Mr. Bilirakis, the New Era of Preventing End Stage Kidney Disease Act that would help their families face a myriad of struggles related to their rare kidney disease diagnosis, and ultimately help prevent dialysis and transplant costs.

What is the HHS' plan in the kidney space, does it include rare kidney diseases, and how are you working to address the challenges facing rare kidney disease families and exploring how this new era could save money and lives?

Response: CMS is committed to improving outcomes for our beneficiaries with kidney disease by making improvements to the organ transplantation system, enabling beneficiaries to make more informed decisions, and increasing access to innovative treatments. For example, the CMS Innovation Center is testing a model, the Kidney Care Choices Model, that provides strong financial incentives for health care providers to manage the care for Medicare beneficiaries with chronic kidney disease stages 4 and 5 and ESRD, to delay the onset of dialysis and to incentivize kidney transplantation. We look forward to continuing to work with Congress and stakeholders to make additional improvements in this space.

5. Question:

Every year, 800,000 people die of cardiovascular disease (CVD) in this country. We know screening is a top priority because you can't manage what you don't measure. The pandemic and lockdowns disrupted much of our lives and screening for cholesterol was on the top of that list. Cholesterol screenings were down a staggering 71 percent at one point during the pandemic and excess deaths—deaths over the annual average—were up more than 1 million. Almost 700,000 of those deaths were due to heart disease. Black Americans experienced approximately 20 percent increase in cardiovascular disease deaths during the pandemic, in contrast to non-Hispanic Whites, who experienced a two percent increase in deaths. Lack of awareness, diagnoses, and treatment of CVD is an undeniable obstacle for Black Americans in overall health management.

How can HHS improve increased access to screenings and better outcomes in CVD to close this healthy equity gap?

Response: Within HHS, the CDC works to improve the cardiovascular health of all Americans and recently adopted new health equity goals to make addressing disparities in CVD risk factors and outcomes a primary focus. For example, CDC aims to improve hypertension control rates among Black persons served by CDC-funded programs by five percent by December 31, 2024. The multiple factors associated with social determinants of health make this goal particularly challenging and will require extensive efforts, partnerships, and collaborations.

While all CDC-funded programs and initiatives work to reduce the burden of CVD among those disproportionately affected, there are several currently funded activities that are specifically focused on reducing the disparities that Black Americans face. For example, in the Mississippi Delta, one of the most medically underserved regions in the U.S., CDC funds the Mississippi State Department of Health's Delta Health Collaborative[1] to implement strategies to prevent and control hypertension and reduce disparities in an 18-county region. CDC also supports the American College of Preventive Medicine's (ACPM) Reducing Hypertension in Priority Populations project,[2] which uses clinical quality improvement practices to address uncontrolled high blood pressure in clinical settings with the highest level of uncontrolled hypertension among Black men aged 35 to 64 years, who the data indicate experience the greatest disparities in hypertension control.

Questions from The Honorable Kathy Castor (D-FL)

6. Question:
For years, I worked with my bipartisan, bicameral colleagues on the Advancing Care for Exceptional Kids (ACE Kids) Act, which was signed into law on April 18, 2019. The law creates a new state option to establish health homes tailored to "children with medically complex conditions," and includes six months of enhanced federal matching funds for health home services provided to eligible children enrolled in Medicaid. This law helps the Centers for Medicare and Medicaid Services (CMS) and state Medicaid programs align rules and reimbursement to improve health outcomes, reduce unnecessary hospitalizations, and provide better care coordination.

In this legislation, Congress included a national definition of children with medically complex conditions to enable better data collection related to this population. The list of chronic conditions in section (i)(2) of the ACE Kids Act refers to the definition of a child with medically complex conditions and is not meant to be a comprehensive list of conditions that would be included in the definition. This population of children often have multiple conditions that may not all be reflected in that list.

[1] www.msdh.ms.gov/msdhsite/_static/44,0,372.html

[2] https://members.acpm.org/page/reducinghypertension

While the statuary definition gives the Secretary some discretion, congressional intent did not support each state using its own definition. The foundational goals of the law—to improve health care and manage costs for this population—will only be achieved with consistent data.

Secretary Becerra: As CMS finalizes guidance to fully implement the ACE Kids Act, which is set to begin in October 2021, will HHS ensure a consistent national definition is used across states per congressional intent to enable collection of data needed for quality improvement for this population of children with very complex medical needs?

Response: At this time, CMS is working to finalize guidance to states on the new optional Medicaid state plan benefit for health homes for children with medically complex conditions under with section 1945A of the Social Security Act. States can begin covering this benefit on October 1, 2022. This guidance is expected to be released soon.

7. Question:

Under a final rule issued in August 2018, the Trump administration extended the short-term limited duration insurance (STLDI) plan duration limit from 90 days to up to 364 days, including an option to renew coverage for up to three years. STLDI plans do not have to comply with consumer protections included in the Affordable Care Act (ACA): they may opt not to cover all ten essential health benefits, include medical underwriting, deny coverage for pre-existing conditions, charge higher cost-sharing amounts, and impose lifetime limits. Additionally, expanding access to junk insurance negatively impacts the risk pool in the ACA-compliant market, thereby increasing premiums for everyone. According to an analysis by the Urban Institute, the number of people without minimum essential coverage is estimated to increase by 2.6 million in 2019 to 36.9 million, and premiums could increase by more than 18 percent thanks to Trump's junk insurance expansion coupled other sabotage efforts.

While STLDI plans serve a limited purpose for those who need temporary coverage, such as workers transitioning between jobs who do not elect COBRA, they are not comprehensive health care coverage, and constituents are suffering from the lack of proper guardrails on STLDI plans. Individuals looking for temporary health insurance are often enticed by the cheaper premiums these plans offer, only to find themselves with inadequate coverage when they need care. These junk plans return patients to the days when they would discover only upon illness that their plan imposes unreasonable limits on coverage and excludes vital benefits.

As we hopefully look towards the end of the COVID-19 pandemic and the public health emergency (PHE), it is critical that we roll back the previous administration's expansion of the STLDI plans. When the PHE ends, millions of Americans will need to find new health coverage, and having these expanded STLDI plans on the market as an option could have horrible consequences for individuals. President Biden has alluded to the harms of these plans in two Executive Orders, and it was included in the 2021 HHS rulemaking agenda. Unfortunately, no action has taken place.

Secretary Becerra: Can you please detail the Department's plans for taking action to address the inappropriately expanded definition of "short-term, limited duration insurance" and ensuring that this type of coverage does not undermine the Affordable Care Act? When do you plan to release a proposed rule as included in the 2021 rulemaking agenda?

Response: Making sure that all Americans have access to quality, affordable health care is one of the Biden-Harris Administration's top priorities. Patients and their families deserve the security of knowing that the insurance they buy will be there for them when they need it, and we need to make sure consumers are protected and understand the health insurance they are buying.

HHS has announced that it intends, along with the Departments of Labor and the Treasury, to propose regulatory policies regarding short-term limited duration insurance. This rule would propose amendments to the definition of 'short-term, limited-duration insurance' under section 2791(b)(5) of the Public Health Service Act. The rule's proposals would be designed to ensure this type of coverage does not undermine the Affordable Care Act, including its protections for people with pre-existing conditions, the Health Insurance Exchanges, or the individual, small group, or large group markets for health insurance in the United States.

8. Question:

CDC's ability to prevent and control disease relies on its access to quality and timely data to drive decision-making. Unfortunately, the federal government has almost no data authority, leaving them unable to access data to public health in a timely and coordinated way. The lack of standardization means that CDC must negotiate separate data agreements with every U.S. jurisdiction, leading to wide variations in how data are captured and incomplete reporting.
In the CARES Act, Congress gave the CDC temporary authority to acquire some public health data through the end of the PHE.

Secretary Becerra: Could the Department use any regulatory authorities to improve CDC's data collecting abilities once the PHE ends?

Response: Yes, the regulatory authority for the HHS Secretary, acting through the CDC Director, to compel healthcare providers and public health labs to submit data in the form, manner, and content most useful for public health purposes is essential to identify and respond to health threats. The lack of this authority is a significant barrier to timely and complete collection of data to inform public health action.

Currently CDC has no direct authority to compel what, when, and how data are reported for public health surveillance to CDC and to public health more broadly. Most reporting to CDC is voluntary, and, even in cases of emergency, CDC has very limited authority to require the reporting of data to public health.
The nation's communities must be ready to identify and respond to emerging health threats. Directed authority for CDC to compel the content, form, and manner of data reported for public health purposes will help standardize how data are reported, which means better data for federal, state, local, and tribal partners—and less burden on data providers. This step is essential to

ensure that our country is relying on more consistent and complete data for public health decision making.

9. Question:
Secretary Becerra: What are some current roadblocks or barriers to standing up a secure, standardized, and real-time national data platform?

Response: CDC is leading a national effort to modernize core data and surveillance infrastructure across the federal, state, and local public health landscape. CDC's Data Modernization Initiative (DMI) has already begun to move from siloed and brittle public health data systems to connected and response-ready systems that can help us solve problems before they happen. To most effectively leverage these investments in DMI, we must also modernize the way we collect public health data. Improved authority to securely collect and access data would modernize CDC's ability to coordinate timely reporting and standardize how data are reported, which will mean better data for states and the federal government and less burden on data providers.

Currently, data are not coordinated at the federal level, leaving CDC and their state and local partners with blind spots. Without data authority, CDC depends on a variety of inefficient approaches to get the public health data it needs this includes negotiating separate data agreements with every U.S. jurisdiction for every data system, including those needed for outbreaks. This lack of standardization creates significant variation in how data are captured and reported to public health, resulting in data that are slow, incomplete, lower quality, and more challenging to put together for decision-making. The nation needs a common streamlined approach to public health data to inform decision makers and provide a cohesive picture of what is happening nationwide.

9a. Question:
Secretary Becerra: What has worked well for CDC with their increased data authorities during the pandemic? What are areas for improvement as we look past the end of the PHE—what lessons have we learned?

Response: The COVID-19 pandemic highlighted CDC's lack of data authority for obtaining a variety of essential pandemic data – it took too long to access important data when COVID-19 struck. This critically impaired CDC's ability to have a clear national picture of how many people were sick, the severity of disease, and the capacity of the healthcare system. The declaration of a public health emergency temporarily created the authority that required some of these critical public health data to be reported to CDC. However, without additional data authorities, when the declaration of the public health emergency ends, many of these temporary federal data authorities will end. This expiration will result in the pre-pandemic state, lacking readiness and critical real time information to identify and respond to emerging public health threats.

Using the temporary authorities granted under the public health emergency, CDC has seen benefits in several areas – areas that will once again be at risk when the public health emergency ends without additional authorities.

10. Question:
Each year in the United States, 6 million women become pregnant and more than 3 million initiate breastfeeding. Almost 90 percent of American women will give birth during their lifetime. Despite how common it is, and how critical the pregnant and postpartum periods are for mothers and babies, there is very little information on the safety of therapeutics and vaccines in pregnancy, and even less on safety for the baby while breastfeeding.

We saw this failure most recently with the COVID-19 vaccine, where developers originally chose to exclude pregnant people from their trials, leading many pregnant people, who are at higher risk for severe illness or death, to forgo the protection of vaccines.

I was proud to sponsor legislation included in the 21st Century Cures Act that created the PRGLAC Taskforce, which issued 15 recommendations and a detailed Implementation Plan to ensure we protect pregnant and lactating people through research, not from it.

The first recommendation was to "include and integrate pregnant and lactating people in the clinical research agenda," including by harmonizing Food and Drug Administration (FDA) regulations with the "Common Rule" to remove pregnant women as a vulnerable population in research.

In January 2019, HHS and other federal agencies implemented these changes to the "Common Rule" regulations to protect human subjects in research, removing pregnant people as an example of a "vulnerable population" that requires additional ethical scrutiny prior to participating in research. But the FDA has yet to act.

It is critical that the FDA act swiftly to remove pregnant people as a vulnerable research population, like their fellow HHS agencies.

Secretary Becerra: Will the FDA take action to align its regulations with the "Common Rule"?

Response: Under section 3023 of the 21st Century Cures Act, HHS is required to harmonize differences between the Common Rule and FDA's human subject protection regulations to the extent practicable and consistent with other statutory provisions. We are actively engaging in this harmonization, which is a key priority for the Agency. The current Unified Agenda at https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202204&RIN=0910-AI07 and https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202204&RIN=0910-AI08 identify these efforts.

11. Question:
Many of the other PRGLAC recommendations focus on enhancing post-market surveillance for therapies and vaccines in pregnancy.

Secretary Becerra: Can you explain why current pregnant safety surveillance systems haven't produced robust data, and describe opportunities to strengthen pregnancy registries and other post-market studies in pregnant and lactating people?

Experts have advised we need focused research to assess the risks of medications to expectant mothers and babies.

Response: We acknowledge the need to increase the quality and quantity of information collected to support the safety of medications used by pregnant and lactating people. Currently, most drugs and biological products do not have any human safety or pharmacokinetic data collected for pregnant and lactating people prior to approval. Consequently, most of the information included in product labeling describing potential risks to pregnant and lactating people is derived from animal data alone. FDA is actively engaged to change this current situation. The Agency participated in the NICHD PRGLAC Task Force and has worked with stakeholders to implement many of the recommendations. For example, in the effort to advance data collection in pregnant and lactating individuals, FDA has published several draft guidances for industry:

- Postapproval Pregnancy Safety Studies, Draft Guidance (published May 2019), https://www.fda.gov/media/124746/download
- Clinical Lactation Studies: Considerations for Study Design, Draft Guidance (published May 2019) https://www.fda.gov/media/124749/download
- Pregnant Women: Scientific and Ethical Considerations for Inclusion in Clinical Trials, Draft Guidance, Revision 1 (published April 2018) https://www.fda.gov/media/112195/download

When final, these guidances will reflect FDA's current thinking on these topics.

Additionally, FDA has and will conduct and participate in public workshops to increase the quantity, quality, and timeliness of research involving products used by pregnant and lactating people:

- Scientific and Ethical Considerations for the Inclusion of Pregnant Women in Clinical Trials, February 2-3, 2021: https://www.fda.gov/drugs/news-events-human-drugs/scientific-and-ethical-considerations-inclusion-pregnant-women-clinical-trials-public-meeting
- Leveraging Real-World Data to Study Medication Use in Pregnancy and Lactation, May 9, 2022: https://www.jhsph.edu/research/centers-and-institutes/center-of-excellence-in-regulatory-science-and-innovation/news-and-events/
- Pharmacokinetic Evaluation in Pregnancy, May 16-17, 2022: https://www.fda.gov/drugs/news-events-human-drugs/pharmacokinetic-evaluation-pregnancy-virtual-public-workshop-05162022#:~:text=About%20this%20Virtual%20Workshop%3A,May%2016%2D17%2C%202022

- Inclusion of Pregnant and Lactating Persons in Clinical Trials, June 16-17, 2022: https://www.nationalacademies.org/event/06-16-2022/inclusion-of-pregnant-and-lactating-persons-in-clinical-trials-a-workshop

In addition, FDA funds research pertinent to pregnancy and lactation including research to expand our knowledge on medication use during pregnancy and breastfeeding (https://www.fda.gov/scienceresearch/specialtopics/womenshealthresearch/ucm256927.htm). FDA also maintains a list of pregnancy exposure registries as an online resource for providers and pregnant individuals who would like to volunteer for enrollment (https://www.fda.gov/science-research/womens-health-research/pregnancy-registries). We also agree that there are opportunities to strengthen the implementation and successful completion of pregnancy registries by raising awareness of the existence and availability of these studies. In addition, increasing the efficiency of the collection of data through multi-product disease-based registries could be successful. One example is the Antiretroviral Pregnancy Registry, which is supported by manufacturers of antiretroviral drugs and has generated data that have resulted in labeling changes regarding the safety of these drugs when used in pregnancy (http://www.apregistry.com/HCP.aspx). However, for multi-product registries to be successful, there is a need for industry collaboration.

In addition to consideration of multi-product registries, FDA is eager to work with stakeholders to overcome perceived challenges in conducting and completing pregnancy registry studies. FDA is also considering ways to encourage sponsors to conduct and successfully complete post-market studies in pregnant and lactating people.

12. Question:

Secretary Becerra: Will the FDA release guidance with more specific recommendations for trial sponsors on inclusion of these populations?

Response: To support the appropriate inclusion of pregnant people in clinical trials, among other activities, FDA has published draft guidance, *Pregnant Women: Scientific and Ethical Considerations for Inclusion in Clinical Trials*,[3] which describes appropriate circumstances for the enrollment of pregnant people in clinical trials.

FDA has also recently published several draft guidances related to therapeutics development during pregnancy and lactation, including *Postapproval Pregnancy Safety Studies, Draft Guidance for Industry;*[4] and *Clinical Lactation Studies: Considerations for Study Design, Draft Guidance for Industry*.[5] When final, these guidances will reflect FDA's current thinking on these topics. FDA also recently issued a final guidance, *Enhancing the Diversity of Clinical Trial*

[3] U.S. Food and Drug Administration, "Pregnant Women: Scientific and Ethical Considerations for Inclusion in Clinical Trials; Guidance for Industry," Revision 1, April 2018, available at https://www.fda.gov/media/112195/download.

[4] U.S. Food and Drug Administration, "Postapproval Pregnancy Safety Studies; Guidance for Industry," May 2019, available at https://www.fda.gov/media/124746/download.

[5] U.S. Food and Drug Administration, "Clinical Lactation Studies: Considerations for Study Design; Guidance for Industry," May 2019, available as https://www.fda.gov/media/124749/download.

Populations – Eligibility Criteria, Enrollment Practices, and Trial Designs, Guidance for Industry.[6]

Further, FDA has published guidance entitled *Considerations for Developmental Toxicity Studies for Preventive and Therapeutic Vaccines for Infectious Disease Indications*,[7] which sets forth recommendations for assessing the developmental toxicity potential of preventive and therapeutic vaccines for infectious diseases indicated for people of childbearing potential and pregnant people.

13. Question:

Last month, HHS's Office of the Inspector General (OIG) released a report (OEI-09-18-00260) saying that some Medicare Advantage (MA) organizations were denying prior authorization and payment requests that met Medicare coverage rules by using inappropriate clinical criteria, requesting unnecessary documentation, and making manual review errors and system errors. Among prior authorization requests that were denied, 13 percent met Medicare coverage rules, and among payment requests that were denied, 18 percent met Medicare coverage rules and MA billing rules. These denials delay or event prevent MA beneficiaries from receiving necessary care.

Secretary Becerra: How are you working with CMS to address the findings and recommendations in the HHS OIG report?

14. Question:

Secretary Becerra: How can Medicare increase oversight of MA plans and ensure that they are using appropriate clinical criteria for coverage determinations?

Response 13-14: HHS and CMS are committed to the oversight and enforcement of the requirements of the Medicare Advantage program. CMS uses several tools to oversee the Medicare Advantage program and help ensure enrollees have adequate access to health care services, such as annual audits of a sample of Medicare Advantage organizations (MAOs) to evaluate compliance with the terms of the MAOs' contracts with CMS; in particular, the requirements associated with access to medical services, drugs, and other enrollee protections required by Medicare. Per the recommendations by the OIG, CMS plans to issue clarifying guidance regarding appropriate use of clinical criteria in medical necessity reviews and update audit protocols as necessary. Additionally, CMS will direct MAOs to examine their manual review and system programming processes and address vulnerabilities that may result in inappropriate denials in keeping with updated clarifying guidance.

[6] U.S. Food and Drug Administration, "Enhancing the Diversity of Clinical Trial Populations – Eligibility Criteria, Enrollment Practices, and Trial Designs; Guidance for Industry," November 2020, available at https://www.fda.gov/media/127712/download.

[7] U.S. Food and Drug Administration, "Considerations for Developmental Toxicity Studies for Preventive and Therapeutic Vaccines for Infectious Disease Indications; Guidance for Industry," February 2006, available at https://www.fda.gov/media/73986/download.

15. Question:
I applaud the HHS work in helping vulnerable communities who bear the brunt of climate change, particularly with the August 2021 establishment of the Office of Climate Change and Health Equity (OCCHE).

Secretary Becerra: Can you speak to how additional funding for OCCHE would enable communities to receive assistance in addressing health equity issues related to climate change?

Response: OCCHE's responsibilities include fostering innovation in climate adaptation and resilience for disadvantaged communities and vulnerable populations and addressing health disparities exacerbated by climate impacts to enhance community health resilience. OCCHE works closely with Department of Health and Human Services operating divisions, including the Centers for Medicare & Medicaid Services and the Centers for Disease Control and Prevention to incorporate climate change resilience into the missions and programs of relevant offices. OCCHE also works across federal agencies, including co-chairing the Extreme Heat Interagency Working Group, to address the disproportionate and cumulative impacts of climate change on disadvantaged communities.

The Fiscal Year 2023 President's Budget includes a request for $3 million in funding for OCCHE. This funding will allow OCCHE to support fellowships for underrepresented minority students in climate change and health equity. It will also build on an initial mini- and microgrant program to stimulate innovation and build capacity for resilience in disadvantaged and at-risk communities. In addition, funds will be dedicated for staffing who will manage contracts, cooperative agreements, grant programs, and fellowship administration. Without appropriated funds, OCCHE has relied on details from other HHS operating divisions. This funding would allow the office to focus on medium and long-term goals such as developing climate resilience grant language and related training resources for use across operating divisions and federal agencies.

16. Question:
Secretary Becerra: What additional changes are needed to help disadvantaged and frontline communities access the funding they need?

Climate impacts, such as worsening heatwaves, storms, droughts, flooding, and disease outbreaks, are far reaching and impact many of the issues you mentioned in your testimony, including mental health, maternal health, and access to adequate health care.

Response: The environments where we live, work, and play influence our health and can also introduce health disparities. These disparities can make us more susceptible to the health threats of climate change. As the largest grant-making agency in the United States, the Department of Health and Human Services (HHS) has a significant impact on the health and well-being of Americans, especially disadvantaged populations, and an opportunity to improve the health resilience of at-risk communities and to address social determinants of health through climate mitigation and adaptation actions. Including climate equity language into grants demonstrates

HHS's commitment to addressing climate change and improving public health and this work must continue across HHS divisions. In addition to coordinating internally, HHS must work with other parts of the federal government and non-governmental stakeholders to make communities more resilient to a future of more frequent and severe climate events, such as heatwaves.

17. Question:
Secretary Becerra: How is HHS supporting the development of public health system resources and infrastructure to address the needs of all communities in a changing climate?

Response: The Department of Health and Human Services (HHS) is taking actions across all of its divisions to address climate change and health equity priorities. Programs to help the nation prepare for the health impacts of the climate crisis are ongoing in the Office of Climate Change and Health Equity (OCCHE), Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), and other HHS divisions. These programs fund and provide technical assistance to states, local, tribal, and territorial health departments, and community-based organizations; conduct research on the health implications of the climate crisis; develop climate and health communication products and information resources; and coordinate cross-government climate and health efforts.

For example, the CDC's Climate and Health Program supports state, tribal, local, and territorial public health agencies as they prepare for the health impacts of a changing climate. CDC's Climate-Ready States and Cities Initiative is now helping 11 grant recipients around the nation use the five-step Building Resilience Against Climate Effects (BRACE) framework to identify likely climate impacts in their communities, potential health effects associated with these impacts, and their most at-risk populations and locations. The BRACE framework then helps these jurisdictions develop and implement health adaptation plans and address gaps in critical public health functions and services. Additionally, the program has created a suite of communication products and guidance to help our grant recipients better communicate with local communities and partners about these climate and health impacts.

18. Question:
In your testimony, you discussed the importance of funding for mental health programs, emphasizing the need for prevention as "an investment in our future."

Secretary Becerra: What other programs might benefit from additional support to prioritize prevention efforts, particularly when addressing the worsening impacts of climate change?

Response: Health outcomes are inextricably linked to the environment, and safe and healthy environments promote healthier people and communities. Ensuring healthier environments is a key objective outlined in the President's Mental Health Strategy. By investing in prevention programs, we can minimize the burden of mental health and minimize risk of other poor health outcomes. The priority actions laid out in the 2021 HHS Climate Action Plan aim to enhance resilience and adaptation to climate change throughout the activities of HHS, including both the physical and mental health impacts of severe and repeated weather-related disasters.

The Fiscal Year 2023 budget includes a request to increased funding to support the Centers for Disease Control and Prevention's (CDC) environmental health activities. These resources will allow the CDC's Climate and Health Program to continue the program in all states and territories, identify potential health effects associated with climate change, and implement health adaptation plans. Additionally, funds will support states to pilot the provision of portable High Efficiency Particulate Air (HEPA) filtration systems in homes and communities most affected by exposure to wildfire smoke, and to better understand the feasibility and health impact of installing such systems.

As part of the Justice40 pilot, HHS plans to increase efforts to prevent energy shutoffs and increase support for households with young children and older people, households including people with disabilities, and households with high energy burdens. Since the Low Income Household Water Assistance Program (LIHWAP) expires at the end of 2023, the budget proposes to expand the Low Income Home Energy Assistance Program (LIHEAP) to advance the goals of both LIHEAP and LIHWAP. Specifically, the budget request increases LIHEAP funding and gives states the option to use a portion of their LIHEAP funds to provide water bill assistance to low-income households.

In addition, the budget requests funding for the Office of Climate Change and Health Equity (OCCHE) and implementation of Executive Order 14008, "Tackling the Climate Crisis at Home and Abroad," to pilot regional climate change and health equity collaboratives, expand fellowship programs to train scientists and health professional from underrepresented minorities, and expand technical assistance to communities. As the nation recovers from the COVID-19 pandemic, the negative and compounding effects of long existing health disparities and climate change are more apparent than ever. On June 1, 2022, the Assistant Secretary for Health announced the establishment of the Office of Environmental Justice in the Office of Climate Change and Health Equity. The Office works with HHS divisions to improve health in disadvantaged communities and vulnerable populations across the nation.

Questions from The Honorable Peter Welch (D-VT)

Strengthening value-based care is one of my top health care priorities. Over the past decade we have seen ACOs, and other alternative payment models (APMs), improve health outcomes and reduce the growth of Medicare spending. Notably, CMS is now integrating health equity mechanisms into its value-based care models, and we expect ACOs and other innovative models to be ready mechanisms for Medicare and other payers to institute measurable reforms in health equity.

That said, key incentives for providers are expiring this year, and I've been working to build support for my bipartisan legislation (the Value in Health Care Act) that extends MACRA's five percent Advanced APM incentive payment and maintains qualifying thresholds at current levels. These payments have been instrumental in encouraging participation in Advanced APMs. Unfortunately, uptake of these models has been much slower than envisioned by Congress and CMS. If Congress fails to act this year, roughly 290,000 providers could see a five percent cut in their reimbursements.

While it was encouraging to see that CMS outlined a proposal in the President's budget to move up MACRA's conversion factor updates up by one year, I've heard from many stakeholders expressing concern that this will simply not be enough of an incentive in the short-term to continue growing participation in APMs. The administration has set laudable goals of having all Medicare beneficiaries in an accountable care relationship by 2030.

19. Question:
Does the Administration support extending the 5 percent Advanced APM incentive payment, and will you commit to working with us to advance our bipartisan legislation that extends these critical incentive payments that help providers transition into value-based care?

Response: The Biden-Harris Administration is committed to protecting and strengthening Medicare so that Americans of every generation can count on it. The budget proposes investments in Medicare that incentivize physician participation in value-based payment models designed to help drive down overall health care costs and improve patient outcomes by rewarding value and quality of care versus volume of physician services. HHS looks forward to working with Congress and other stakeholders as we continue our efforts to incentivize value-based care.

20. Question:
CMS is taking steps to regulate "future medicals" under the Medicare Secondary Payer Act. The Medicare Secondary Payer Act makes Medicare the secondary payer to certain primary plans in an effort to shift costs from Medicare to the appropriate private sources of payment. And while the spirit of the Medicare Secondary Payer Act and saving money for the program is laudable; implementation can have far reaching negative impacts for beneficiaries who run the risk of losing their health insurance or having to pay exorbitant (non-Medicare) rates for services just because they were hurt and someone else's insurance might have some responsibility for their health care.

Some are concerned that CMS would take a regulatory path that doesn't appropriately balance the solvency of the program against the best interests of its beneficiaries. It is also concerning that almost all of the parties regulated under the Medicare Secondary Payer Act (including insurers, self-insureds, disability and beneficiary groups as well as both the plaintiff and defense bars) have uniformly seen the path the Agency is taking as harmful.

a. What steps is CMS taking to ensure that Medicare recipients continue to have consistent access to high quality healthcare and reasonable prices even when they need health care that is subject to the payment requirements under the Medicare Secondary Payer Act?

b. What steps has CMS taken to acknowledge that the Medicare Secondary Payer Act is an important program to keeping Medicare solvent, but if beneficiaries opt out of pursuing other reimbursement from other private sources of payment because the program is not efficient, user friendly and fair, Medicare will not get reimbursed?

Response: CMS' goals for Medicare are to advance health equity; expand access to affordable coverage and care; drive high quality, person-centered care; and promote affordability and the sustainability of the Medicare trust funds. CMS is committed to meeting these goals, including through efforts to fulfill Medicare Secondary Payer requirements.

Questions from The Honorable Tony Cárdenas (D-CA)

I am concerned that we are not doing enough to combat diabetes and its related comorbidities. In 2019, the CDC estimated that between 70 and 80 million Americans were pre-diabetic, before the COVID-19 PHE. That number, added to the number of Americans suffering from chronic kidney disease (CKD), is shocking.

21. Question:
How is HHS addressing the urgent needs of the diabetes and CKD communities?

Response: To address the growing epidemic of diabetes, CDC established the National Diabetes Prevention Program (National DPP), a public-private partnership working to build a nationwide system to deliver an affordable, evidence-based lifestyle change program to prevent or delay type 2 diabetes. CDC also funds public health efforts in all 50 States and the District of Columbia, as well as selected local governments and national organizations, to improve access to and uptake of the National DPP as well as diabetes management services for people with diabetes.

To raise awareness and help people with prediabetes know where they stand and how to prevent type 2 diabetes, CDC, in partnership with the American Medical Association and the Ad Council, recently launched the fourth phase of the national prediabetes awareness campaign, Do I Have Prediabetes? CDC also conducts surveillance and other research to ensure our diabetes prevention and treatment work is grounded in science.

To prevent and control risk factors for chronic kidney disease (CKD) and raise awareness of CKD and its complications, CDC established the CKD Initiative to provide public health strategies for promoting kidney health in 2006. Current activities of the CKD Initiative include collaboration with partners to support and enhance the CKD Surveillance System; public awareness of CKD, its risk factors and complications; promotion of early diagnosis and treatment of CKD; and surveillance, epidemiology, health outcomes, and economic studies in partnership with other offices at CDC, other government agencies, universities, and national organizations.

22. Question:
Secretary Becerra, on November 16th I joined some of my colleagues in sending a letter to you urging HHS to postpone the expansion of the Repetitive Scheduled Non-Emergent Ambulance Transport (RSNAT) model due to our concerns that Medicare patients in need of dialysis and diabetes-related wound care treatment would be left without alternative transportation, especially in rural areas. At a time where HHS is looking to improve equity in the healthcare system, I'm worried this lack of transportation could be particularly harmful for Black, Latino, and Native

American populations that tend to have disproportionately high rates of diabetes and kidney disease.

Will you commit to working with us to ensure the model includes adequate transportation options for vulnerable dual-eligible Medicare beneficiaries?

Response: CMS is dedicated to ensuring that all Medicare beneficiaries have access to the medical care they need and we remain committed to educating beneficiaries who do not meet Medicare's coverage requirements of other community transportation resources. In cases where the beneficiary's condition does not meet Medicare's coverage requirements, CMS provides the beneficiary with contact information for state and local agencies that may be able to assist with identifying alternative transportation arrangements, such as Eldercare or their State Health Insurance Assistance Program. CMS also encourages beneficiaries with Medicaid or Programs of All-inclusive Care for the Elderly to contact those programs to see if they qualify for help with transportation coverage.

23. Question:

In August 2021, I wrote to you to urge HHS to evaluate how shared savings models for biosimilars could be leveraged to reduce costs and build marketplace competition. In the interest of continuing efforts to improve access to low-cost alternatives, what can be done on the agency side to try to bolster access to biosimilars and support shared savings models?

Response: The Administration remains committed to lowering prescription drug costs for Americans and supports actions to address high and rising drug prices. President Biden's comprehensive Prescription Drug Pricing Plan[8] reiterates the important call to action to lower prescription drug prices, which is guided by the Administration's principles for equitable drug pricing reform through competition, innovation, and transparency. The Biden-Harris Administration is advancing a multi-pronged approach to improving competition in the prescription drug market, including supporting greater availability and use of biosimilar biological products and generic drugs in order to lower the prices Americans pay for prescription drugs. CMS stands ready to work with Congress on this issue.

24. Question:

Recent data suggests that the COVID-19 pandemic has caused significant declines in HIV testing, new diagnoses, and fewer patients living with HIV starting and continuing treatment, especially in historically underserved and minority communities.

Has HHS conducted an assessment of the impact of the COVID-19 pandemic on access to and utilization of HIV testing, prevention, treatment and care services, especially among minority populations? What resources are included in the FY 2023 Budget Request that will help communities of color equitably recover from these documented setbacks in HIV testing and care that were exacerbated by the COVID pandemic?

[8] https://aspe.hhs.gov/sites/default/files/2021-09/Drug_Pricing_Plan_9-9-2021.pdf

Response: The FY23 budget will be the fourth year of the Ending the HIV Epidemic in the U.S. (EHE) initiative. The first year of EHE was focused on planning, with the second year of implementation coinciding with the beginning of the COVID pandemic. President Biden's FY22 budget proposed to increase EHE funding by $266 million, but the final FY Omnibus only increased funding by $70 million. Increased funding is needed for HHS offices to ensure ongoing coordination and alignment of efforts to expand prevention, treatment and care services in communities that are disproportionately impacted.

CDC recently published data that showed a decrease in the number of CDC-funded HIV tests administered in health care and non-health-care settings (43% and 50%, respectively) from 2019 to 2020, thus indicating the impact of COVID-19 pandemic. These concerning drops were seen among groups disproportionately affected by HIV, highlighting the urgent need to scale up testing and reduce disparities among the people who could most benefit from HIV prevention and care.

When the pandemic disrupted HIV-prevention services and care, CDC and impacted entities capitalized on innovations to continue providing essential services and advance health equity. For example, HIV testing options and the availability of pre-exposure prophylaxis (PrEP) were expanded to include self-tests kits and make PrEP accessible to more people. CDC also encouraged the use of telemedicine for HIV services, which included expanding Pharmacy Data to Care to increase re-engagement in care and viral suppression. Finally, prevention efforts included strengthening the infrastructure of sexually transmitted disease (STD) clinics to offer HIV prevention services, including increased testing and the provision of PrEP, and expanding support for syringe services programs. CDC will continue to amplify efforts to ensure that health equity is prioritized, HIV self-testing options are expanded, syndemic collaborations are strengthened, and status neutral care models are employed.

Questions from The Honorable Raul Ruiz (D-CA)

I appreciate HHS efforts to advance health equity and for detailing those efforts in the recent "HHS Equity Action" plan. However, I noticed that FDA's role was absent. As you may know, I believe FDA will play a critical role in helping to advance clinical trial diversity and by prioritizing the review of applications for medications to treat diseases that have been historically ignored, such as sickle cell disease.

25. Question:
Can you comment on how your priority to improve health equity is being translated at the FDA?

Response: HHS is committed to encouraging diverse participation in and equal access to clinical trials used to support marketing applications for regulated medical products. With the proposed funding increases for Advancing Medical Product Safety, FDA will, among other actions, support the President's initiative to reignite the Cancer Moonshot^{SM} by strengthening FDA's programs that incorporate patient voice, real-world evidence, and collaborations with FDA's global partners to help facilitate faster patient access to innovative cancer therapies. FDA will

build on existing efforts to continue to facilitate and expand internal and external collaborations to expedite the development of oncology and malignant hematology products as well as increase diversity and speed progress against the most deadly and rare cancers, including childhood cancers, and foster the development of novel therapeutics for patients with ultra-rare cancers. Although progress has been made to increase the enrollment of diverse populations, there is still room for improvement.

One strategy that has not been scaled up in a sustainable way is engaging community clinicians and investigators in research. There is considerable evidence that clinician recommendations play an important role in helping patients consider participating in clinical investigations. Also, removing barriers to participation, such as bringing trials closer to where participants live, work, worship, and typically receive their healthcare, may also help achieve more diversity in both the workforce administering the trials and the participants taking part in clinical investigations.

In addition, FDA conducts outreach on this important topic through the FDA Office of Women's Health Diverse Women in Clinical Trials Initiative. This campaign was developed in collaboration with the NIH Office of Research on Women's Health to raise awareness about clinical trial participation by diverse women of different ages, races, ethnic backgrounds, disabilities, chronic illnesses, and health conditions and to share best practices.

In support of FDA's efforts, the FDA Office of Minority Health and Health Equity developed and continues to advance the Diversity in Clinical Trials Initiative, which includes an ongoing multimedia, public education, and outreach campaign to help address some of the barriers preventing diverse groups from participating in clinical trials through a variety of culturally and linguistically tailored strategies, tools, and resources. The initiative aims to combat myths, educate consumers about key issues, provide positive messaging reflecting diverse spokespersons who are representative of diverse communities, stimulate dialogue among peers and peer-to-provider groups, and tailor resources to be culturally and linguistically appropriate and translated into multiple languages.

Even before the pandemic, FDA supported, and sponsors were utilizing, decentralized clinical trials to bring the trial to patients and facilitate broader access to clinical research. Due to the restrictions on travel and other logistics to control the spread of disease, the COVID-19 pandemic increased the use of these trial designs, and we expect such use to continue after the pandemic ends. Decentralized clinical trials were not a temporary or interim measure employed solely for the purposes of the pandemic. When appropriately implemented in accordance with regulatory requirements applicable to all clinical trials, such trials have significant potential to broaden the availability of clinical research to historically underrepresented populations and we expect sponsors will continue to utilize them.

Questions from The Honorable Debbie Dingell (D-MI)

Secretary Becerra, our Committee has made significant efforts to improve medical and supply chain readiness to ensure our nation is ready to address a future PHE or pandemic.

Your testimony laid out some of the key investments that HHS is making across the Department in public health, climate, and research. For my questions, I would like to focus on preparedness and how our work in this Committee can continue to support a robust preparedness plan.

26. Question:
This Administration has made historic successes in the manufacturing and distribution of the vaccines during this pandemic. How does your budget continue to support this work and ensure areas, such as our Strategic National Stockpile, meet the needs of a future national pandemic response?

Response: As included in the Fiscal Year 2023 President's Budget request, $130M above FY22 levels was requested for the Strategic National Stockpile (SNS) to enhance capabilities. If appropriated, the funding would support the sustainment of current product lines and procurement of several products previously supported by the Biomedical Advanced Research and Development Authority (BARDA) that lack a significant commercial market. These items include procurement of sufficient quantities of a domestically manufactured, FDA approved, smallpox antiviral to treat an estimated 350,000 people during a smallpox incident, meeting the stockpiling requirement for this product. Additionally, SNS would be able to procure enough bandages to treat an estimated 14,000 people impacted by a radiological/nuclear incident, meeting the stockpiling requirement for this product. Finally, with remaining funding at this level, SNS would procure limited quantities of anthrax therapeutics. It is critical that funding be provided for these efforts to enhance national preparedness.

In addition to the funding request for the SNS, the FY 2023 budget request includes $40 billion over 5 years to fund the President's pandemic preparedness plan. Specific to ASPR, if funding is provided it will support: end-to-end advanced development of vaccines and therapeutics against high priority viral families ($12 billion); capital investments in vaccine production capacity and warm surge capacity for manufacturing vaccines, vials, and syringes/needles ($15 billion); technology and manufacturing for new vaccine administration tools ($1.5 billion); and, capital investments in active pharmaceutical ingredient (API) manufacturing and innovative manufacturing processes ($1.4 billion).

27. Question:
The FY 2023 budget request also proposes to bolster funding levels for the Biomedical Advanced Research and Development Authority (BARDA), the Strategic National Stockpile (SNS), and the National Disaster Medical System (NDMS). Can you list specific improvements or work that this increased funding will support?

Response: As included in the FY2023 President's Budget request, an additional $231,680,000 was requested to support Advanced Research and Development efforts within BARDA. The additional funds would support an expansion of BARDA's Broad Spectrum Antimicrobials Program to include next generation antibacterial candidates addressing the global threat of antimicrobial resistance and to continue its support of an Accelerator to support early stage development of novel antimicrobial therapies, and the Division of Research, Innovation, and Ventures (DRIVe) and its Medical Countermeasures Innovation Partner (MCIP), which will provide equity funding for research and development of innovative and disruptive healthcare technologies.

With the requested increase for the SNS, funding would support the sustainment of current product lines and procurement of several products previously supported by the Biomedical Advanced Research and Development Authority (BARDA) that lack a significant commercial market. These items include procurement of sufficient quantities of a domestically manufactured, FDA approved, smallpox antiviral to treat an estimated 350,000 people during a smallpox incident, meeting the stockpiling requirement for this product. Additionally, SNS would be able to procure enough bandages to treat an estimated 14,000 people impacted by a radiological/nuclear incident, meeting the stockpiling requirement for this product. Finally, with remaining funding at this level, SNS would procure limited quantities of anthrax therapeutics. It is critical that funding be provided for these efforts to enhance national preparedness.

Lastly, the additional $50 million requested for the National Disaster Medical System (NDMS) would support the recruitment and hiring of NDMS intermittent staff, as well as meet demands for additional individual and team training to ensure mission readiness, including additional hands-on and online training for new NDMS intermittent employees. Additionally, the President's Budget includes an additional $13 million to maintain NDMS caches and equipment. The budget continues to include $6 million for the Pediatric Disaster Care program. Lastly, there is a continued need for permanent direct hire authority to continually recruit and retain NDMS personnel. Congress continues to extend the direct hiring authority (currently extended through September 2023) but ensuring the authority is permanent would strengthen the overall program and ability to hire and retain critical personnel.

28. Question:

The FY 2023 budget request also establishes a mandatory pandemic preparedness fund, available over 5 years, to supplement appropriations for activities at the CDC, the National Institutes of Health (NIH), Assistant Secretary for Preparedness and Response (ASPR), and the Food and Drug Administration (FDA). Can you list what improvements in our nation's preparedness this fund will support?

Response: In addition to the funding request for the SNS, the FY 2023 budget request includes $40 billion over 5 years to fund the President's pandemic preparedness plan. Specific to the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR), if funding is provided it will support: end-to-end advanced development of vaccines and therapeutics against high priority viral families ($12 billion); capital investments in vaccine production capacity and warm surge capacity for manufacturing vaccines, vials, and syringes/needles ($15 billion); technology and manufacturing for new vaccine administration tools ($1.5 billion); and, capital investments in active pharmaceutical ingredient (API) manufacturing and innovative manufacturing processes ($1.4 billion).

29. Question:

Finally, the FY 2023 budget proposes $40 million for the ASPR to invest in our capability to rapidly respond and deliver countermeasures against future pandemics and other biological threats. Can you share some insight into how this funding will improve our development and

manufacturing of countermeasures for high priority threats, vaccines, therapeutics, diagnostics, and personal protective equipment (PPE)?

Response: In addition to the funding request for the SNS, the FY 2023 budget request includes $40 billion over 5 years to fund the President's pandemic preparedness plan. Specific to ASPR, if funding is provided it will support: end-to-end advanced development of vaccines and therapeutics against high priority viral families ($12 billion); capital investments in vaccine production capacity and warm surge capacity for manufacturing vaccines, vials, and syringes/needles ($15 billion); technology and manufacturing for new vaccine administration tools ($1.5 billion); and, capital investments in active pharmaceutical ingredient (API) manufacturing and innovative manufacturing processes ($1.4 billion).

Questions from The Honorable Lori Trahan (D-MA)

30. Question:
Mr. Secretary, as you and your team are well aware, based on the Provider Relief Fund formula, Lawrence General Hospital was deemed an "outlier" and therefore did not receive critically needed phase 3 funds, and received minimal phase 4 funds. While I'd like to think that LGH is in a particularly unique situation, I can't imagine it is the only safety-net hospital struggling to keep its doors open that was deemed ineligible to receive appropriate PRF funds. How many independent, community-based hospitals—like Lawrence General—are outliers? What is being done at the Department to identify these outliers?

Response: HHS recognizes the importance of Provider Relief Fund (PRF) payments for healthcare providers that have been on the frontlines fighting COVID-19. In processing PRF Phase 3 General Distribution applications, given available resources, HHS employed pre-payment risk mitigation and cost containment measures. As part of this effort, HHS used the provider's self-selected provider type in the calculation. Approximately 17 percent of the more than 117,000 PRF Phase 3 applications were adjusted through this process. More information about providers that were adjusted is available at https://www.hrsa.gov/sites/default/files/hrsa/provider-relief/phase-3-methodology-overview.pdf.

31. Question:
Mr. Secretary, hip fracture is the most devastating fracture that someone with osteoporosis can experience. In Massachusetts, there has been a 51 percent decline in DXA testing of Medicare women since 2008, resulting in almost 625 unnecessary and avoidable hip fracture-related deaths each year. Mr. Secretary, will you commit to working with me and improving access to osteoporosis testing by restoring adequate reimbursement for screenings in the physician's office?

Response: CMS is committed to ensuring that Medicare beneficiaries have access to the preventive services they need, including tests to help determine if they're at risk for broken bones. Medicare Part B covers bone mass measurements once every 24 months for eligible

beneficiaries, or more often if medically necessary, with no copayment, coinsurance, or deductible for the beneficiary. CMS looks forward to working with you and other stakeholders to determine how we can improve access to preventive services for Medicare beneficiaries.

Questions from The Honorable Brett Guthrie (R-KY)

32. Question:
Right now, we have millions of Americans who are enrolled in Medicaid who shouldn't necessarily be eligible for the program because of their incomes or other factors, because current COVID laws prevent states from disenrolling anyone until the end of the PHE is over. As a result, there are nearly 15 million more Americans enrolled in Medicaid than there were prior to the start of the pandemic. All the while, we found out last year that improper payments in Medicaid reached 21 percent or $98 billion in total improper claims. I'm worried that we have a bad situation that is only getting worse, with rates of fraud and waste rapidly increasing in Medicaid.

a. What, if anything, are you proposing to crack down on these high rates of improper payments?

b. Can you detail which of these are new initiatives or approaches that will actually help go after these rising improper payment rates?

c. Do you think Congress needs to authorize stronger enforcement mechanisms to go after fraud and waste?

Response: CMS uses the Payment Error Rate Measurement (PERM) program to measure improper payments and produce state and national improper payment rate estimates in Medicaid and the Children's Health Insurance Program (CHIP). As defined in statute, improper payments include payments when an agency cannot determine, due to lacking or insufficient documentation, whether a payment is proper or not. These improper payments are often related to routine administrative issues, such as incomplete documentation for someone who may be eligible for care or for a service that may have been appropriate. The improper payment rates are based on reviews of samples of the fee-for-service (FFS), managed care, and eligibility components of Medicaid in the year under review. CMS uses a 17-state cycle for PERM, which means that each state is reviewed once every three years. Detailed information on the PERM sampling and calculation process can be found in the PERM Manual located in the Downloads section at https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Improper-Payment-Measurement-Programs/PERM.

CMS recovers the federal share of the actual overpayments in the sample that are identified for the FFS and managed care components in a given year. With respect to Medicaid eligibility and enrollment, sampled overpayments identified through the PERM eligibility review are subject to requirements specified at section 1903(u) of the Social Security Act. For eligibility-related improper payments, section 1903(u) of the Social Security Act sets a 3 percent threshold for states' rates in any given PERM year and generally requires the Secretary to disallow payments

to states with respect to the extrapolated amount of improper payments that exceed the threshold. However, states may receive a "good faith effort" waiver from the disallowance if the state meets all PERM Corrective Action Plan (CAP) and Medicaid Eligibility Quality Control (MEQC) program requirements, despite having an eligibility-related improper payment rate above the 3 percent threshold. Potential disallowances under section 1903(u) of the Social Security Act may occur beginning in FY 2022 under a process specified in regulation that was finalized in 2017.

With respect to CMS's efforts on Medicaid improper payments, the agency has many successful improper payment reduction strategies in place to prevent and address improper payments in Medicaid. Several key corrective actions are listed below. Additional details and other corrective actions can be found in HHS Agency Financial Reports, available at https://www.hhs.gov/about/agencies/asfr/finance/financial-policy-library/agency-financial-reports/index.html.

Enhanced State PERM CAP Process: CMS continues to implement a robust state-specific PERM CAP process that provides enhanced technical assistance and guidance to states. CMS works with states to coordinate state development of CAPs to address each error and deficiency identified during the PERM cycle. After each state submits the corrective action plan, CMS monitors the state's progress in implementing effective corrective actions. Throughout the process, CMS also provides training opportunities to ensure compliance with federal policies.

Enhanced Assistance on State Medicaid Provider Screening and Enrollment: CMS provides ongoing guidance, education, and outreach to states on federal requirements for Medicaid provider screening and enrollment. For example, CMS regularly updates the Medicaid Provider Enrollment Compendium, most recently in March 2021, to provide additional subregulatory guidance to assist states in applying the regulatory requirements. CMS also assesses provider screening and enrollment compliance, provides technical assistance, and offers states the opportunity to leverage Medicare screening and enrollment activities.

State Medicaid Provider Screening and Enrollment Data and Tools: CMS shares Medicare data to assist states and territories with meeting Medicaid screening and enrollment requirements. Specifically, CMS shares the Medicare provider enrollment record via the Provider, Enrollment, Chain and Ownership System (PECOS) administrative interface and data extracts from the PECOS system and OIG exclusion data. CMS offers a data compare service allowing states and territories to rely on Medicare's screening in lieu of conducting a state screening, particularly during revalidation. This allows states and territories to remove dually-enrolled providers from the revalidation workload and focus resources in areas such as strengthening overall processes to prevent future improper payments. CMS also returns information on providers with deactivated National Provider Identifiers, or who are deceased, excluded by the Department of Health and Human Services Office of Inspector General (OIG), revoked by Medicare or terminated for cause by a State Medicaid Agency (thus allowing the state or territory to take deactivation or termination action against the provider when applicable). Additionally, CMS offers states the ability to screen their Medicaid-only provider population via the same screening system Medicare uses to screen Medicare providers. The Advanced Provider Screening tool screens Medicaid-only providers against the Department of Treasury's Do Not Pay list, and monitors for criminal and licensure alerts.

Medicaid Eligibility Quality Control (MEQC) Program: Under the MEQC program, states design and conduct pilots to evaluate the processes that determine an individual's eligibility for Medicaid benefits. States have flexibility in designing pilots to focus on vulnerable or error-prone areas identified by the PERM program and state. The MEQC program also reviews eligibility determinations that are not reviewed under the PERM program, such as denials and terminations. MEQC pilots are conducted during the 2-year intervals that occur between states' triennial PERM review years, allowing states to implement prospective improvements in eligibility determination processes prior to their next PERM review.

33. Question:
Mr. Secretary, you've previously voiced support for telehealth services across state lines, as my bill the TREAT Act does. Would you please expand further as to why you believe this legislation is needed for Americans?

34. Question:
As we approach hopefully the end of the PHE, do you believe that temporary license reciprocity would be an appropriate course of action and useful tool for any future PHE?

Response: Telehealth has been critical for providing health care services during the pandemic, and demonstrates the long-term potential of telehealth to increase access to critical health care and behavioral health services. HHS is committed to continuing to work within the confines of the law to strengthen the health care workforce and connect skilled providers with communities in need including through the use of telehealth.

35. Question:
Secretary Becerra, during the PHE the expanded use of telehealth provided patients with innovative solutions to access to healthcare and interface with healthcare providers. Innovations which allow health care providers to provide care remotely through monitoring, programming and video are a few examples of the immense clinical value telehealth can have to transform the delivery of care. Today, we have a great opportunity for Congress and the Administration to partner to ensure our nation continues to improve and expand utilization of telehealth and healthcare innovations as we move towards the end of the pandemic.

a. As the PHE ends, how is CMS working to utilize the lessons learned from the PHE and ensure innovative care like remote monitoring and remote programming, which in many instances have become the 'new standard of care', will continue?

b. Does CMS intend to continue all flexibilities granted during the PHE during the 151-day extension granted through the FY 2022 omnibus legislation, or will some flexibilities end upon expiration of the PHE?

c. Has CMS developed plans on how the 151-day extension will be implemented, as well as how the post-PHE transition will be handled?

Response: Throughout the COVID-19 public health emergency, telehealth has been a reliable resource, allowing providers to reach patients directly in their homes to ensure access to care and continuity of services. The Biden-Harris Administration is committed to supporting a temporary extension of broader telehealth coverage under Medicare beyond the declared COVID-19 Public Health Emergency in order to study its impact on utilization of services and access to care. Telehealth, including audio-only telehealth, can greatly expand access to services for individuals who may not have access to broadband or technology to support 2-way audio-video. This is particularly true in rural and underserved areas, and among older populations.

The Administration is also expanding access to mental health and beneficiary-centered care under Medicare through greater use of telehealth and other telecommunications technologies to provide behavioral health care, among other services. Medicare beneficiaries can access care directly in their homes thanks to recent regulations, including CMS's CY 2022 Physician Fee Schedule final rule, that allow for certain behavioral health services via audio-only telephone calls. In addition, the President's FY 2023 Budget includes a proposal to remove statutory limits on the list of providers that are authorized to receive direct Medicare payment for their mental health services, which would expand access to mental health services in Medicare, especially in rural and underserved areas with fewer mental health professionals or in communities more likely to receive care from the referenced practitioners.

36. Question:

Mr. Secretary, do you anticipate the PHE for COVID-19 ending this year?

a. In your Budget for this upcoming fiscal year, it appears that you anticipate a decline in the number of enrolled Medicaid beneficiaries. Under current law, states cannot disenroll anyone, regardless of their eligibility status, until the end of the PHE. The only way we could expect to see a decline like this would be a change in law or the end of the PHE. With that in mind, what do you anticipate occurring to lead to this change?

Response: The Biden-Harris Administration has worked to ensure that every eligible person can access the coverage and care to which they are entitled, and is committed to working with states to make sure they have the tools and resources they need to prepare for the end of the public health emergency. It is a top priority at CMS to ensure, when the PHE eventually ends and states resume routine operations, including terminations of Medicaid eligibility, that renewals of eligibility and transitions between coverage programs occur in an orderly process that minimizes beneficiary burden and promotes continuity of coverage.

CMS is dedicated to supporting states in this process, known as "unwinding." CMS has taken many steps to promote continuity of coverage, including planning tools to support state decision-making and advance planning, issuing updated guidance to state Medicaid directors, state reporting requirements and templates, communications tools to help states with consumer outreach, and providing ongoing technical assistance and resources.

CMS has launched a landing page—Medicaid.gov/unwinding—dedicated to providing resources to supporting states and other stakeholders during the unwinding process, and continues to provide updated guidance to states. CMS has already conducted calls with every state to discuss

and support them in developing their unwinding plans, and continues to be available to provide technical assistance. CMS also will monitor states' progress in meeting the timelines and completing required eligibility and enrollment actions described in guidance.

CMS also has highlighted the policy options available to states to ensure continuity of coverage for families when they need it most. For example, in April 2021, CMS approved Illinois' section 1115 Medicaid demonstration, allowing the state to receive federal matching funds to provide 12 months of continuous postpartum coverage for Medicaid and Children's Health Insurance Program (CHIP) enrollees. As many as 720,000 pregnant and postpartum individuals across the United States could be guaranteed Medicaid and CHIP coverage for 12 months after pregnancy thanks to the American Rescue Plan.

In addition, during the COVID-19 public health emergency, telehealth has been a reliable resource, allowing health care providers to reach patients directly in their homes to ensure access to care and continuity of services. The Biden-Harris Administration is committed to supporting a temporary extension of broader telehealth access under Medicare beyond the declared COVID-19 Public Health Emergency (PHE) in order to study its impact on utilization of services and access to care. Telehealth, including audio-only telehealth, can greatly expand access to services for individuals who may not have access to broadband or technology to support 2-way audio-video. This is particularly true in rural and underserved areas, and among older populations.

I look forward to working with Congress and partners across the federal government to expand on this important work and connect eligible children, parents, and pregnant individuals to health care coverage through Medicaid and CHIP.

b. Do you think that it's appropriate to give us a budget without a means to justify how your Department is claiming to find certain savings?

Response: The Department's goal is to always provide context and transparency to Congress when we share our budget submissions. We think that we have done that here, but if there are questions about specific savings, please have your staff contact us so that we can provide additional details.

37. Question:

Secretary Becerra, I would like to ask you about a tool at FDA called change control plans. FDA has proposed the use of such plans in the artificial intelligence space, but there is interest in making this novel concept more widely available across FDA as part of the user fee legislative package. To give just one example, right now the developer of a regulated app must frequently make two submissions for the same app to FDA to provide the app through both the iOS and Android platforms. Using a change control plan, and with FDA's approval, medical device manufacturers could maintain high standards for safety and efficacy, and also make an updated digital product available to the end user more quickly.

Will you work with Congress and FDA to expand access to change control plans beyond the AI/ML space, to unlock the potential of this transformative tool for digital health?

Response: PCCPs may be used to help ensure that FDA's statutory standards are met for approval or clearance of devices. Because device changes made in accordance with a PCCP likely do not require additional FDA premarket review before the change is deployed, PCCPs can allow patients to have more timely access to innovative devices and also to have the benefits of updates to devices more quickly. The PCCP, by including the types of anticipated modifications to implement changes and associated methodology to implement those changes in a controlled manner, will allow FDA the oversight to enable responsible enhancements in a manner that manages risks to patients. FDA notes that it is critical for these plans to be evaluated as part of the premarket submission for an individual device or in connection to a specific device. FDA considers a PCCP to be part of the technological characteristics of the device. Evaluating the PCCP outside of a premarket application, therefore, would be akin to evaluating part, but not all, of a device's technological characteristics with no context. We appreciate the potential of this tool for medical devices and are willing to work with Congress on this moving forward.

38. Question:

Secretary Becerra, as we enter a new phase of the pandemic, we must continue to utilize all of the tools available to us in the fight against COVID-19, including serology tests. There are important uses of these tests, even while we await the results of ongoing studies into "correlates of immunity." For example, elderly persons and other high-risk populations could benefit from knowing whether they have any antibody response to SARS-CoV-2 using qualitative antibody tests. This could be particularly important for individuals in nursing homes and assisted living facilities and could allow staff to cohort patients or otherwise provide care with that important piece of information in hand. What efforts are underway at HHS to advance research in this space, and ensure that guidance and other recommendations ensure utilization of these tests to their full potential at this time and as the research continues to evolve?

Response: The National Institutes of Health (NIH) is committed to advancing our understanding and the promise of serology tests, particularly with regard to high-risk populations. In October 2020, the National Cancer Institute (NCI), in collaboration with the National Institute of Allergy and Infectious Diseases (NIAID), established the Serological Sciences Network (SeroNet), which aims to understand all aspects of the immune response associated with the SARS-CoV-2 viral infection and vaccination.

This research is conducted through an extensive research network that was established using funds from the Paycheck Protection Program and Health Care Enhancement Act which included a supplemental appropriation of $306 million for NCI "to develop, validate, improve, and implement serological testing and associated technologies." The SeroNet research sites include the Frederick National Laboratory for Cancer Research (FNLCR) Serology lab.[9] SeroNet supports the development and ongoing dissemination of the National SARS-CoV-2 serology standard[10] through FNLCR and works across the serology community to promote assay standardization and validation to advance the clinical utility of serology tests.

[9] frederick.cancer.gov/research/vaccine-immunity-and-cancer-directorate/covid-19-serology-laboratory

[10] frederick.cancer.gov/initiatives/seronet/serology-standard

The FNLCR Serology Lab has conducted independent evaluations of commercially available antibody test kits in partnership with the U.S. Food and Drug Administration (FDA) to ensure that antibody tests available to the public are accurate and reliable. The lab serves as the SeroNet coordinating center, which fosters coordination and collaboration across all research sites. In addition, SeroNet includes four Serological Sciences Capacity Building Centers at research universities across the country to develop tests for novel coronavirus antibodies and conduct serosurveillance studies; eight Serological Sciences Centers of Excellence to conduct research characterizing the immune responses to coronavirus infection and learn about what drives immune response, disease progression, and protection against future infection; and thirteen Research Projects investigating basic and applied serological research.[11]

Research projects supported by SeroNet span diverse and high-risk populations as they seek to provide insight into the immune response to SARS-CoV-2 infection as well as vaccine induced immunity. One of the key objectives of the program is to identify serological correlates of protection[12] from infection and severe disease, especially in high-risk populations including the elderly and individuals with cancer, autoimmune disease, and transplant recipients. Identifying these correlates requires longitudinal studies of these risk groups in which blood samples are collected at multiple timepoints and assayed for antibody levels and other immune markers to look for association with protection from initial infections, breakthrough infections, and severe disease. SeroNet supports serosurveillance studies on a variety of these at-risk populations.[13]

SeroNet research has shown reduced antibody levels and function in at-risk populations following primary vaccination that in some cases is improved with booster doses. Researchers at Case Western Research University have shown that elderly individuals mount a weakened immune response to the COVID-19 vaccines. Post-vaccination antibody levels were measured and compared in a cohort of 149 nursing home residents and 110 healthcare workers. Nursing home residents' median antibody neutralization titers were found to be one-quarter that of matched healthcare workers.[14]

Studies conducted by Emory University and Cedars-Sinai Medical Center focusing on cancer patients have shown that patients with hematological malignancies and those receiving some immunosuppressive therapies, have low and in some cases, undetectable, SARS-CoV-2 antibody levels after two doses of the mRNA vaccines. A third dose has been shown to increase antibody levels in some, but not all individuals.[15] Differences in antibody responses were partly explained by differences in treatment regimens, timing between vaccination and treatment, mRNA vaccine

[11] www.cancer.gov/research/key-initiatives/covid-19/coronavirus-research-initiatives/serological-sciences-network

[12] Serological correlates of protection are measurements of immune response, such as the presence and levels of antibodies and/or immune cells, that can be used as a marker of likely protection against infection or symptomatic disease.

[13] academic.oup.com/ofid/advance-article/doi/10.1093/ofid/ofac171/6575098?guestAccessKey=ecbb9c4d-899b-4f4a-bbd1-383f493d56f6

[14] academic.oup.com/cid/article/73/11/2112/6276391?login=true

[15] ascopubs.org/doi/full/10.1200/JCO.22.00088

type, age, and ethnicity.[16] This work will help inform evidence-based guidance for timing of vaccine boosters in the future.

Research supported by the NCI and across NIH is ongoing to elucidate the complexities of immune response to SARS-CoV-2 infection and vaccination. One critical question is whether a definitive SARS-CoV-2 antibody level, or cutoff, can be established to determine if someone is likely to be protected from infection or severe disease. Continued research is needed to establish such measures for clinical utility. The ability to reliably identify individuals with low antibody levels and function, who are at higher risk of poor outcomes from COVID-19, requires availability of validated serology assays and measurements reported in standard units.

Validated serology tests and standardized reporting are also a critical tool for evaluating vaccine efficacy against emergent variants of concern. The current authorized or approved COVID-19 vaccines were developed against the ancestral strain of SARS-CoV-2, raising questions of efficacy against viral variants. Recent studies supported by the NCI[17] have shown that serum from individuals immunized with the primary vaccination series has reduced function against the delta and omicron variants relative to the ancestral strain, however protection can be significantly improved with boosting.

NCI will continue to support research into these vulnerable populations and disseminate the serology standard so that ultimately serology tests can be used clinically, and in particular to benefit those at most risk of poor outcomes from SARS-CoV-2.

39. Question:

At your Appropriations Committee hearing, you suggested that we ought to listen to the "experts in the medical field" for the protection of the American people when it comes to nationwide vaccination mandates in our public health programs.

a. Which experts are you referring to specifically?

b. Please explain how you and those experts weighed the public health tradeoffs involving unemployment or staffing shortages at critical facilities.

c. What should I tell a constituent who is struggling to pay for her children's food or her rent because she got fired for refusing the vaccination?

d. How should I respond to the nursing home administrators who tell me they're not sure they can keep their residents safe and healthy because these vaccine mandates are forcing them to fire their staff who were keeping their residents safe?

[16] aacrjournals.org/cancerres/article/81/24/6273/674815/Longitudinal-SARS-CoV-2-mRNA-Vaccine-Induced

[17] www.nejm.org/doi/10.1056/NEJMc2206725?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed; https://www.thelancet.com/journals/ebiom/article/PIIS2352-3964(22)00247-X/fulltext

Response: Implementation of the rule that requires health care facilities to ensure that their workers are vaccinated will undoubtedly save lives. This is an important requirement to protect patients. Health care workers are giving their all, every day, to battle this pandemic and save lives, and the rule helps ensure that our hospitals and health care facilities are safer environments. CMS believes that the vaccination rule helps to stabilize the health care system and eliminate potential incentives for staff to migrate to different care settings or across state lines. This will also ensure that a significant number of health care staff are vaccinated across settings, reducing staff quarantines and improving safety no matter where patients seek care. Early research indicates that many COVID-19 vaccine mandates have already been successfully initiated in a variety of health care settings, systems, and states, with few resignations among staff. As cited within a recent White House Report, two large health systems in Texas (Houston Methodist) and Michigan (Henry Ford Health System) instituted a vaccine mandate and both reported a 98 percent vaccination rate among staff. Similar evidence exists in North Carolina, New York, Maine, and Kentucky.

40. Question:

I was shocked to receive a response from SAMHSA that they have not participated in other agency's efforts to or analyzed any mental health impacts of any state or local COVID-19 prevention measures instituted by states and local communities during the pandemic. Why hasn't SAMHSA participated in such an analysis given the short- and long-term mental health impacts that some of these measures have had on Americans?

a. Is this something SAMHSA plans to do so policy makers are more aware of the mental health consequences of any prevention efforts that may be considered in the future?

b. Can you commit to making sure mental health impacts are considered as we prepare for future pandemics?

Response: Addressing our nation's mental health crisis is a priority of the Biden-Harris Administration. In March, President Biden announced a comprehensive national mental health strategy to strengthen system capacity, connect more Americans to care, and create a continuum of support –transforming our health and social services infrastructure to address mental health holistically and equitably. The President's fiscal year (FY) 2023 budget is proposing over $27 billion in discretionary funding and another $100 billion in mandatory funding over 10 years to implement his national strategy and transform behavioral health services for all Americans.

SAMHSA has issued guidance and resources to assist individuals, providers, communities, and states deal with the challenges posed by COVID-19 and is part of the cross-agency work on long COVID. Additionally, in April President Biden directed HHS to issue a report outlining services and supports across federal agencies to assist people experiencing long COVID, individuals who are dealing with a COVID-related loss and people who are experiencing mental health and substance use related issues related to the pandemic. SAMHSA is helping to lead the development of this report and is also collaborating with stakeholders to advance our understanding of the mental health effects of COVID-19 and promoting high-quality mental and behavioral health care services for those who need it.

41. Question:
I was similarly shocked to receive a response from SAMHSA that they did not provide input to CDC in the development of CDC's Guidance for COVID-19 Prevention in K-12 schools that was released in February 2021, nor did SAMHSA provide input to CDC in the development of CDC's additional guidance for COVID-19 prevention in K-12 schools, including masking.

a. Why wasn't SAMHSA involved or able to provide input in the development of such guidance, particularly given the mental health implications for children and adolescents?

Response: CDC shared the K-12 guidance with HHS, and HHS shared it with its Operating Divisions and other Departments for a comprehensive review.

b. Do you believe it is important for SAMHSA to be involved in the development of such policies moving forward?

Response: HHS works with its Operating Divisions, such as CDC and SAMHSA, to make determinations about appropriate development and clearance processes to ensure a comprehensive review.

c. When was SAMHSA's involvement in the vaccine roll out in Phase I?

Response: During the rollout of COVID-19 vaccines, five federal agencies provided direct vaccination for their employees and persons under their care. These agencies are Indian Health Service (IHS), Department of Defense (DoD), Veterans Health Administration (VHA), Bureau of Prisons (BOP), and Department of State (DoS). Each federal entity received a pro-rata allocation for distribution to their administration sites based on the estimated population they will be serving. The allocations for federal entities were separate from the state/jurisdictional allocation and federal entities are treated as a separate jurisdiction. Federal entity populations are not deducted from the state population. Federal entity populations are added to the total U.S. adult population, which is used as the denominator for determining allocations, and pro-rata distribution is then determined for each jurisdiction. SAMHSA was not determined to be a federal entity with a direct allocation and therefore, had limited involvement in the COVID vaccine rollout.

42. Question:
Of the $7.6 billion that SAMHSA has awarded to respond to mental health impacts of COVID-19, how much do states have left of the mental health money provided through the block grants?

a. It looks like SAMHSA retained about $600 million. How is that being spent?

Response: Details about SAMHSA's COVID-19-related awards, including funds provided through the Community Mental Health Services Block Grant, are available at following SAMHSA websites:

https://www.samhsa.gov/sites/default/files/covid19-programs-funded-samhsa-fy21.pdf
https://www.samhsa.gov/sites/default/files/fy21-american-rescue-plan.pdf

43. Question:
Can you explain the decision for SAMHSA to study the mental health effects of long COVID, but not the effects of mitigation efforts that affected both those who contracted COVID and those who did not?

Response: On April 5, 2022, President Joe Biden issued a Memorandum on Addressing the Long-Term Effects of COVID-19, which called for the creation of two reports. Within 120 days, the U.S. Department of Health and Human Services (HHS), leading a whole-of-government response, will develop two reports that together, pave an actionable path forward to address long COVID and associated conditions.

SAMHSA is committed to working across HHS and collaborating with stakeholders to advance understanding of the mental health effects of COVID-19 and promoting high-quality behavioral health care services for those who need it. Long COVID is a complex condition that we are still learning more about. SAMHSA is working with its HHS partners to issue a report outlining services and supports across federal agencies to assist people experiencing long COVID, individuals who are dealing with a COVID-related loss, and people who are experiencing mental health and substance use issues related to the pandemic. Throughout the pandemic, SAMHSA has recognized the challenges posed by COVID-19 and has provided guidance and resources to assist individuals, providers, communities, and states.

44. Question:
Telehealth has been touted for mental health, but according to SAMSHA's response to my letter, there is less evidence for its use for conditions like schizophrenia. As we in Congress, states, and private insurers look at what telehealth access to make permanent, how are you making those aware of the need for in person availability for some mental health services?

a. Do you have concerns that some mental health professionals will switch to telehealth-only, leaving those patients with schizophrenia even less able to find a doctor to help them?

Response*:* Telehealth is an important modality to help address the mental health treatment gap by making treatment services more accessible and convenient, improving health outcomes, and reducing health disparities. Prior to the pandemic, telehealth usage was increasing each year across the country, especially for people living with schizophrenia in rural areas. For example, between 2010 and 2017 among Medicare beneficiaries, people living with schizophrenia or bipolar disorder in rural areas were more likely to use telehealth for mental health care than those with any other mental illness or those living in urban areas.[18]

[18] Patel, S. Y., Huskamp, H. A., Busch, A. B., & Mehrotra, A. (2020). Telemental health and US rural–urban differences in specialty mental health use, 2010–2017. American Journal of Public Health, 110(9), 1308-1314. https://doi.org/10.2105/ AJPH.2020.305657

Since telehealth is still relatively new to the field of mental health, particularly for its usage for individuals with serious mental illness, research is still in its early phases. However, the existing research has found ongoing case management interventions via telehealth are effective for people with schizophrenia.[19]

While there may be some challenges with telehealth when a person is in an acute phase of psychosis, this is transient and does not mean that person would not benefit from telehealth after the acute phase subsides. Telehealth can be feasible and effective for the majority of individuals with schizophrenia. It is important that telehealth be aligned with appropriate clinical approaches for all disorders and any symptomology.

45. Question:

Interagency Working Group on College Mental Health doesn't appear to have been funded, started, and SAMHSA doesn't feel need to participate. Secretary Becerra, how are you coordinating with Dept of Education on college mental health and why did you not feel that this was necessary since you've taken over at HHS?

Response*:* The Department of Health and Human Services and the Department of Education coordinate on many pressing issues facing Americans, including mental health. For example, in March 2022, HHS and the Department of Education announced a joint effort to develop and share resources to ensure that children have access to school-based health services. Additionally, in 2021 the Department of Education released a report *Supporting Child and Student Social, Emotional, Behavioral and Mental Health,* which highlights many of SAMHSA's programs, resources, and recommendations. The Department of Education is also part of the SAMHSA-led Interdepartmental Serious Mental Illness Coordinating Committee (ISMICC).

46. Question:

Secretary Becerra, given all the lessons learned from the Pandemic - for example, not to rely of global supply chains for critical items like PPE – please elaborate on your strategy to increase U.S. production of domestic PPE manufacturers and small businesses as we refill the national stockpile.

Response: HHS contributed to the development of a 100-day report released June 2021 on supply chains as part of EO14001. Within that report is a section specific to the pharmaceutical supply chain including a focus on mapping the supply chain, risk assessment, global footprint, and recommendations.

More generally, HHS has supported efforts to strengthen the overall domestic manufacturing base to ensure we are better positioned and prepared for whatever comes next. Within HHS, ASPR is supporting efforts to institutionalize domestic manufacturing efforts. Specifically,

[19] Kasckow, J., Zickmund, S., Gurklis, J., Luther, J., Fox, L., Taylor, M., Richmond, I., & Haas, G. L. (2016). Using telehealth to augment an intensive case monitoring program in veterans with schizophrenia and suicidal ideation: A pilot trial. Psychiatry Research, 239, 111-116. https://doi.org/10.1016/j. psychres.2016.02.049

ASPR is integrating and organizing supply chain situational awareness and industrial analysis, domestic industrial base expansion, and supply chain logistics. Bringing these pieces together will strengthen our industry partnerships and support our work to establish and maintain resilient supply chains.

47. Question:
Can you speak to the government's capacity to distribute and deliver medical supplies to healthcare providers on short notice? What role does the private sector play?

Response: The Strategic National Stockpile (SNS) is not structured to provide medical material directly to healthcare providers. Rather the SNS, which is part of the federal medical response infrastructure, is structured to rapidly deploy medical material to states, local, tribal, and territorial (SLTT) governments during public health emergencies. Accordingly, SLTT jurisdictions can request supplies, medicines, and devices for lifesaving care contained in the stockpile to use as a short-term, stopgap buffer when the immediate supply of these materials may not be available or sufficient. Once SLTT jurisdictions receive material from SNS they are responsible for distributing the medical material as needed when requested to support public health and medical emergencies. Medical countermeasures, material and other supplies held within the SNS is determined using Material Threat Determinations (set by the US Department of Homeland Security for assets procured through Project BioShield) and informed by modeling and perceived needs and impacts. When an event occurs, states can request additional support from the SNS to aid in response operations.

48. Question:
How does the government work with the private sector to fully understand the capacity of the commercial supply chain and how they can support the government to meet supply and demand during public health emergencies? What additional action is needed to strengthen the partnership?

Response: As you are aware, the pandemic severely strained our public health and medical supply chains. The medical supply chain ecosystem is complex, with different private sector players and market dynamics across multiple domains of medical equipment and supplies. The Office of the Assistant Secretary for Preparedness and Response (ASPR) has been focused on revitalizing and rebuilding our nation's domestic manufacturing capacity.

In addition, HHS/ASPR contributed to the development of a 100-day report released June 2021 on supply chains as part of EO14001. Within that report is a section specific to the pharmaceutical supply chain including a focus on mapping the supply chain, risk assessment, global footprint, and recommendations.

More generally, HHS has supported efforts to strengthen the overall domestic manufacturing base to ensure we are better positioned and prepared for whatever comes next. Within HHS, ASPR is supporting efforts to institutionalize domestic manufacturing efforts. Specifically, ASPR is integrating and organizing supply chain situational awareness and industrial analysis,

domestic industrial base expansion, and supply chain logistics. Bringing these pieces together will strengthen our industry partnerships and support our work to establish and maintain resilient supply chains.

49. Question:
The budget proposes $2.1 billion in mandatory spending on a Vaccines for Adults Program. The "317 vaccine program" currently exists as a partnership with states and can be used for uninsured or underinsured adults. Why create a new program, funded by mandatory money, when there is an existing discretionary program?

Response: Modeled after the highly successful Vaccines for Children (VFC) program, the proposed Vaccines for Adults (VFA) program would build on the investments made in response to the COVID-19 pandemic and provide a crucial – and missing – component of the public health infrastructure toward achieving vaccinations across the lifespan. CDC has proposed $2.1B in mandatory funding in FY2023 and a total of $25 billion over 10 years.

While CDC has authority under section 317(j)(1) of the Public Health Service Act (42 U.S.C. 247b(j)(1)) to provide grants for "preventive health service programs to immunize without charge children, adolescents, and adults against vaccine-preventable diseases," this is an annually appropriated program that is limited to serving only those as its funding allows. At current levels, this discretionary funding has been used to vaccinate a small proportion of the uninsured adult population and facilitates rapid vaccination response in outbreak settings; however, these efforts represent a small portion of discretionary immunization activities. There has been no dedicated program to ensure vaccination of uninsured adults.

The VFA program will provide uninsured adults access to recommended routine and outbreak vaccines at no cost. The creation of this new mandatory program will be a significant step toward filling existing gaps in vaccine coverage among US adults and provide sustained support for immunizations from year to year. CDC will also work with jurisdictions to leverage base immunization funding ("317") and other resources to support associated program operations costs, vaccine confidence and vaccine equity activities, including communications, partnerships, education, and technical assistance.

50. Question:
Secretary Becerra, do you plan to declare a PHE on climate change?

Response: At this time, I do not have plans to declare a public health emergency (PHE) on climate change. However, there have already been PHEs for climate change-related events. On May 9, 2022, I declared that a public health emergency exists and has existed since April 5, 2022, in the State of New Mexico as a result of the consequences of wildfires and straight-line winds. In 2021, I declared public health emergencies in the states of Louisiana, Mississippi, New York, and New Jersey as a result of the consequences of Hurricane Ida and a PHE in Texas as a result of the consequences of a winter storm.

51. Question:
If so, can you elaborate on any plans or actions that you have explored in declaring this PHE, such as whether or not to facilitate a public comment period on the PHE or how you will involve Congress in the process?

Response: I appreciate Congress' collaboration and input as we work toward our shared goal of improving the health of the American people. In accordance with section 319 of the Public Health Service Act, no later than 48 hours after making a determination of a public health emergency (including a renewal), I shall submit to Congress written notification of the determination.

52. Question:
The Office of Climate Change and Health Equity (OCCHE) was established in August 2021 pursuant to Executive Order 14008 (EO14008). To understand the office's statutory authority, objectives, and activities, Republican Leader Rodgers and Ranking Member Griffith on the Oversight and Investigations subcommittee sent a letter to you requesting a briefing on this new HHS office last December. In January, Committee staff received a briefing on the new office. From this briefing, the office seemed to be in its early stages of development with no full-time staff hired and no clear benchmarks for its operations. A recent Politico article states that currently the National Institute of Environmental Health Sciences adviser John Balbus and Arsenio Mataka are meeting with federal agencies to form the office's goals and stitch together the scope of the problem.

a. Secretary Becerra, can you provide any updates on the progress this office has made in completing the tasks outlined in EO 14008?

b. In your office's meetings with other federal agencies, how do you establish benchmarks under your statutory authority to avoid pursuing actions outside your department's jurisdiction?

c. Can you explain the recent nature and frequency of the interactions between the EPA and the HHS Office of Climate Change and Health Equity? Considering the expertise of the EPA on climate change, how closely is this office working with the EPA?

Response: The Office of Climate Change and Health Equity (OCCHE) was created by Executive Order 14008 to address the impact of climate change on the health of the American people. In working to achieve that goal, OCCHE meets regularly with the leadership of other HHS agencies such as the Centers for Disease Control & Prevention (CDC) and the National Integrated Heat Health Information System (NIHHIS) to assist in coordination of HHS climate change and health initiatives. OCCHE also meets regularly with senior Environmental Protection Agency (EPA), Federal Emergency Management Agency (FEMA) and National Oceanic and Atmospheric Administration (NOAA) staff to coordinate action. One of OCCHE's strengths is leveraging expertise and data from different agencies to support HHS' mission of protecting the health of the American people.

OCCHE's recent accomplishments include collaborating with NOAA and NIHHIS on a Climate and Health Outlook offering information on potential climate-related health risks for Americans and relevant mitigation approaches; launching the Extreme Heat Interagency Working Group; and leading HHS involvement in Justice40, an initiative to deliver at least 40 percent of the overall benefits from Federal investments in climate and clean energy to disadvantaged communities. OCCHE also launched a webinar series on health sector decarbonization and resilience in partnership with several federal agencies, including the EPA. Consistent with Executive Order 14008, all of OCCHE's actions are in service of protecting Americans from the health effects of climate change.

Under Title XVII of the Public Health Service Act, the Secretary of HHS has authority to engage in health information and health promotion activities, including authority to determine and study environmental factors, which affect and determine health, and ascertain programs and areas for which educational and preventive measures could be implemented to improve health as it is affected by such factors. Further, the Secretary has authority under Title XVII to develop and disseminate reports and information related to environmental factors to improve and safeguard individuals' health. The Secretary has delegated these Title XVII authorities to the Assistant Secretary of Health (ASH) and the ASH has assigned OCCHE to carry out these health information and health promotion activities, on behalf of the ASH, to the extent they relate to OCCHE's mission.

53. Question:

Your department is currently facing some of the most significant crises since its existence, including the COVID-19 pandemic, the mental health crisis, and the substance use disorder (SUD) crisis. These national crises continue to heighten risks factors that are threatening the health of vulnerable Americans, especially the youth. Considering your renewal of the PHE existing for the COVID-19 pandemic, can you describe how HHS will prioritize and devote resources to these existing crises as well as the impacts of climate change on health?

Response: COVID-19 remains a public health emergency. While we have made substantial progress since the beginning of the pandemic, much more work remains to be done. We aim to work together to learn more about and prevent future infections of this devastating disease. Based on the level of COVID-19 cases in communities across the nation, among other factors, in consultation with federal public health officials, I made the decision to renew the PHE on April 12, 2022. The determination to renew the PHE, in conjunction with other emergency authorities, ensures response efforts can continue at the level needed to address the ongoing impact of the virus. The PHE declaration offers a variety of important flexibilities that allowed the Department to ensure it is best equipped to assist state, local, territorial, and Tribal partners in responding to COVID-19 in their communities. The PHE determination provides for the ability to streamline and increase the accessibility of healthcare, such as the practice of telemedicine. It allows under section 1135 of the Social Security Act, in conjunction with a Presidential Declaration under the National Emergencies Act or Stafford Act, the Secretary to waive or modify certain Medicare, Medicaid, Children's Health Insurance Program (CHIP), and Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule requirements. The goal is to ensure to the maximum extent feasible that, in an emergency area during an emergency period, sufficient health care

items and services are available to meet the needs of individuals receiving Medicare, Medicaid, and CHIP and that providers that furnish such items and services can be reimbursed for them and exempt from sanctions, absent fraud or abuse. It is important to note that the PHE determination for COVID-19 does not and will not detract from the other serious health crises you mention in your question. This determination rather supports efforts to mitigate the ongoing health consequences of COVID-19 directly.

Investing in children's mental health programs, including essential school-based supports to ensure our nation's schools provide a positive and safe learning environment for America's youth, continues to be a key priority for HHS. The President's Fiscal Year 2023 budget proposes historic investments for youth mental health, including $244 million for Project AWARE to support training for teachers, first responders, and other adults who interact with youth to recognize and respond to the signs of behavioral health issues; $64 million for the Mental Health Awareness Training program to train school personnel, emergency first responders, law enforcement, and other professionals how to recognize the signs and symptoms of mental illness; $61.4 million for Healthy Transitions to improve access to mental illness treatment and related support services for young people aged 16 to 25; $150 million in the National Child Traumatic Stress Network to target funding to trauma-informed services and interventions for children; $35.4 million for Project Launch to promote the wellness of young children, from birth to eight years of age; $225 million for Children's Mental Health Services, an increase of $100 million, to provide "systems of care" (SOC) for children and youth with serious emotional disturbances and to help prevent the development of psychosis for youth and young adults; $47.9 million for Garrett Lee Smith Youth Suicide Prevention State/Tribal and Campus to implement youth suicide prevention and early intervention strategies within communities and at college campuses; $23.2 million for Tribal Behavioral Health Grants to addresses the high incidence of substance use and suicide among American Indian/Alaska Native youth; and $38 million for Infant and Early Childhood Mental Health, an increase of $30 million, to improve outcomes for children from birth to 12 years of age. Additionally, the Mental Health Block Grant budget request creates a new 10% set-aside to support evidence-based programs that address early intervention and prevention of mental disorders for at-risk youth and adults.

HHS continues to work to protect and promote human health in the face of climate change. While most Americans experience some exposures to health threats being made worse by climate change, the burden of impacts is not equally shared. Some people are more likely to suffer harm than others, and those most at risk from climate change are also bearing the health burdens of other hazards, from COVID-19 to air pollution. The Office of Climate Change and Health Equity is committed to building the resilience of communities to the health impacts of climate change, especially those communities experiencing a larger share of the climate change burden. The Office is collaborating with HHS and other federal agencies to guide climate change investments in ways that reduce these health disparities and reduce people's risks to health threats.

54. Question:

Mr. Secretary, it's my belief that a hallmark of our Medicaid program is the ability for it to be flexible and meet the needs of states and beneficiaries. 1115 waivers are a key demonstration of these flexibilities. Can you name some flexibilities from 1115 waivers that you support?

a. In my view, this Administration did not start off on the right foot when it came to 1115 waivers. A number of waivers from the previous Administration were rescinded, and it's my hope that we can work more constructively together on these things going forward. Are you willing to commit to working with States that still have pending 1115 waivers in order to meet their goals rather than just unilaterally rescinding waivers?

b. Mr. Secretary, do you think it's appropriate for the Federal Government to dictate reimbursement rates in Medicaid?

c. As you know, States currently have the authority to set their rates as part of their State Budgets. In a Request For Information on Access to Coverage and Care in Medicaid and CHIP, CMS asked for comment on establishing access rules that set payment floors. I'm deeply troubled by this idea. If Washington is setting rates in Medicaid, that will have profound impacts on State Budgets. The consequences of it will mean, as States balance their budgets, that services are cut and waitlists grow. To me, this seems like the opposite of increasing access. Will you commit not finalizing any rule that will set payment rate floors in Medicaid and undermine access to care for Medicaid beneficiaries?

Response: Medicaid is an important source of coverage for many American families. The partnership between states and the federal government is central to Medicaid, and this Administration is committed to working with states to strengthen this vital program. To this end, it is important that states' Medicaid section 1115 demonstrations promote the objectives of the Medicaid program. While HHS is committed to supporting state innovation and states' ability to test different models that meet the unique needs of their residents, CMS considers each waiver application on its merits to make sure we are encouraging innovation while also protecting beneficiaries and following the law.

Ensuring access to care is critically important for Medicaid and CHIP beneficiaries. The Medicaid statute requires that payments are "consistent with efficiency, economy, and quality and are sufficient to enlist enough providers so that care and services are available under the [state] plan at least to the extent that such care and services are available to the general population in the geographic area." The Social Security Act provides additional standards related to Medicaid managed care payments. Under CHIP, child health assistance must be provided in "an effective and efficient manner." Aligned with the objectives under Medicaid and CHIP, this Administration is committed to working with states on approaches for payment regulation and compliance that serve to ensure adequate access for Medicaid and CHIP beneficiaries and that are aligned across the Medicaid and CHIP programs regardless of the delivery systems or services and benefits being accessed. CMS also aims to increase provider participation rates among provider types with historically low participation in Medicaid and CHIP, such as behavioral health and dental providers. CMS is committed to working with states on actions that

will help reduce administrative burdens that discourage participation in Medicaid and CHIP while protecting program integrity.

55. Question:

Mr. Secretary, I'm appreciative that you've chosen to continue the Trump Administration's goal of ending the HIV epidemic in our country by 2030. A key means to getting this done is by making sure that those at high-risk of getting HIV are taking "pre-exposure prophylaxis" or "PrEP". The Trump Administration recognized this with its "Ready, Set, PrEP" program which sought to provide free doses of PrEP to those in need. Your budget is calling for nearly $10 billion in new, mandatory spending to provide access for PrEP, with a large bulk of these costs coming from requiring Medicaid to cover PrEP. However, Medicaid already covers PrEP and HIV testing free of charge to beneficiaries, and as I mentioned, we already have programs like "Ready, Set, PrEP" and our "FQHCs" and "Ryan White Clinics" which can offer free PrEP and testing for HIV to those in need. What exactly are you proposing to spend this new money on and does it materially differ from what we already do to provide free PrEP to our most vulnerable?

Response: We are extremely encouraged to see that the President's budget request includes $9.8 billion over the next ten years for a "PrEP Delivery Program to End the HIV Epidemic in the United States." While much progress has been made in expanding PrEP, there is still much to be done. Only 9% of Black people and 16% of Latino people who could benefit from PrEP have received a prescription. These populations are already disproportionately impacted by HIV, yet racial and social health barriers prevent these populations from accessing PrEP.

The PrEP Delivery Program is designed to advance equitable access to HIV prevention by addressing many of the systemic barriers. The program will provide access to PrEP at no cost; eliminate costs for essential associated services; and establish a network of providers in underserved communities that provide culturally and linguistically appropriate services.

Additionally, the PrEP Delivery Program will establish and support PrEP programs for state, tribal, and local public health departments, community-based organizations, and health care facilities that serve the highest risk populations such as community health centers, Title X clinics, etc. to implement education campaigns, medication support services, and provide outreach and education. It also expands access to PrEP under Medicaid by covering the drug and associated services without cost sharing, while removing utilization management practices that may limit access.

56. Question:

Secretary Becerra, New UNOS heart transplant selection criteria went into effect in 2018 which were aimed at shortening the transplant wait list. Does HHS know what impact the new guidelines have had on clinical outcomes for patients over the four years since the new criteria were implemented?

a. Do you have data on post-transplant survival rates and/or quality of life over these four years? Please share any data related to clinical outcomes and any plans to study long-term the impact on clinical outcomes.

Response: In October 2018, the Organ Procurement and Transplantation Network implemented a revised adult heart allocation policy. The changes included revised medical urgency categories, and allocation changes based on the new medical urgency categories and the distance of transplant candidates from the donor hospital. The OPTN issued a report titled, One-Year Monitoring of Heart Allocation Proposal to Modify the Heart Allocation System, in February 2020, which found broader geographic distribution of donor hearts, and a reduction in the median time spent waiting for a heart transplant, especially for the most medically urgent candidates. While transplant rates increased for the most medically urgent candidates, the rate of death on the waiting list and post-transplant clinical outcomes (e.g., patient death, and graft failure one-year post transplant) remained constant. The report did not identify any substantial effects on the number of wait list registrations, transplants performed, or the number of donor hearts used.

57. Question:

While Artificial Intelligence (AI) continues to prove effective in many sectors, including healthcare, how does the Department of Health and Human Services (HHS) plan to incorporate AI into your agency's goals of improving health outcomes for all Americans?

a. Is HHS considering incentives to encourage health care providers and payors to use AI?

b. What other ways are you envisioning AI being used to improve patient engagement and streamline processes?

c. What plans do you have for AI for program integrity uses, in particular within CMS programs such as Medicaid and Medicare?

d. Please elaborate on your plans for AI payment within the relevant payment rules and policies and some of the ways you are thinking about how public programs should compensate providers for the various AI products.

Response: Rapid advances in innovative technology are having a profound effect on every facet of the economy, including in the delivery of health care. CMS is routinely reviewing applications for new technologies, including those using artificial intelligence, consistent with our statute and regulations to determine whether they meet the criteria for additional Medicare payments or for pricing under the standard payment methodologies. However, Medicare fee-for-service coverage and payment are governed by statutory limitations, known as benefit categories. There is no separate benefit category for AI, and coverage for AI technologies does not always fit under an existing covered category.

CMS has been engaging with stakeholders and associations on how to approach and categorize AI devices as well as developing categories for AI devices for coding purposes. As healthcare delivery evolves to include innovative technologies, we are also aware that the information we use to set payment for physician services must also change to account for the cost of these new technologies appropriately. We continue to solicit feedback to help us better understand the resource costs for services involving the use of innovative technologies.

In the area of program integrity, new advancements in predictive modeling and artificial intelligence will allow CMS to enhance existing efforts to reduce improper payments, prevent fraud, and target bad actors, while limiting burden. For example, CMS is exploring methods of using machine learning to conduct more rapid review of chart documentation to improve payment accuracy.

58. Question:

Secretary Becerra, the standard monthly premium for Medicare Part B enrollees skyrocketed to $170.10 in 2022 from $148.50 last year, marking the largest dollar increase in the program's history. The historic increase in premiums seniors now pay are compounded by the effects of this Administration's inflationary agenda and its deliberate choice to ignore—and its intent potentially to exacerbate via the so-called Build Back Better Act—the looming insolvency of the Medicare program. Your agency, CMS, attributed roughly half of this increase to a "contingency reserve" to help defray the costs of the new Alzheimer's drug, Aduhelm. Last December the drug manufacturer Biogen dropped its price in half and CMS a few weeks later issued an unprecedentedly restrictive proposed coverage determination focused on Aduhelm.

a. Mr. Secretary, on March 17th you said that "Once we have that determination, we'll be able to fully assess what impact Aduhelm may have had on premiums for seniors." Now that the final coverage determination was released on April 7th when can we expect a public release of this assessment and a plan to correct your premium-setting error?

b. What do you expect the spending impact of this drug will be on the Medicare Part B program in 2022 compared with your original projections?

c. What does this mean for Medicare beneficiaries' living on fixed budgets and their premiums?

d. We knew that no matter what that NCD looked like—including the company's own pricing data and the Aduhelm take-up rate from hospitals—that dramatically fewer people would be taking this drug this year than what CMS estimated last year. It didn't take any inside information to know that your Department's estimates were wildly off base. How are you planning to correct your mistake and ensure it doesn't happen again?

Response: The 2022 Part B premium amount was announced in November 2021 and is based on rising prices and utilization of health care, prior Congressional action that limited the 2021 Medicare Part B monthly premium increase, and the CMS Office of the Actuary's estimates of

potential spending for the Alzheimer's disease drug Aduhelm, to ensure that the Part B Trust Fund has sufficient revenues to pay claims consistent with statutory requirements. On December 20, 2021, after the Part B premium amount for 2022 was announced, Biogen reduced the price of Aduhelm by one-half, from approximately $56,000 per year for each Medicare beneficiary covered on a maintenance dose, to $28,000 per year. CMS is examining the Part B premium and the effect that the price drop of Aduhelm, as well as the final national coverage determination, may have on its amount.

In addition, individuals may be eligible for immediate assistance from their states through Medicare Savings Programs, which can pay Medicare Part B premiums, copayments and deductibles for qualifying beneficiaries.

59. Question:

Mr. Secretary, I'm gravely concerned by your Department's refusal to embrace medical innovation and science that has delivered promising medical treatments to our seniors in the Medicare program. Your health care bureaucracy continues to stand in the way of patients and their doctors from accessing treatments despite ample scientific evidence and clear Congressional intent that they should. The latest example is your Department's unprecedented coverage limitations on an entire class of FDA-approved drugs treating Alzheimer's Disease. Medicare patients won't be able to access any of these treatments unless they are enrolled in a CMS-approved clinical trial which means that many of our most vulnerable friends and neighbors, especially those in underrepresented communities including rural parts of the country, racial minorities, and those with other neurological diseases like Down Syndrome, will be unable to access FDA-approved drugs for Alzheimer's unless they are successfully enrolled in a very limited trial. And as you well know, gaining entry into and successfully accessing a limited number of trials for a disease that affects more than 6 million families is quite challenging.

a. What specific and concrete actions will your Department be taking to ensure that those with Down Syndrome and other neurological diseases will be able to access FDA-approved Alzheimer's treatments in consultation with their doctors?

b. Can you explain why your Department has taken the approach that a drug approved under FDA's accelerated approval framework should be held to a different and higher standard for coverage than a drug approved under the traditional framework, despite Congressional intent and statute instructing you otherwise?

c. The prospect of a Medicare beneficiary—who currently may only access these drugs through a CMS-approved trial—will be required to pay some form of cost-sharing for a placebo of an FDA-approved drug is troubling. Can you explain in detail how the placebo cost-sharing requirements will work in concert with accepted clinical trial protocols for Medicare patients?

d. Can you explain the difference between the FDA's "safe and effective" requirements for approval and CMS's "reasonable and necessary" requirements for coverage?

e. Considering the confusion among patient organizations, manufacturers, and the general public about the difference in these respective FDA and CMS standards, what specific actions will you be taking to clarify these definitions to mitigate future confusion?

f. Can you elaborate as to how a drug which is targeted at an older population of Alzheimer's patients that the FDA has determined safe and effective for said population would not be "reasonable and necessary" for the Medicare population?

g. Who has the ultimate say over safety and effectiveness for drugs and devices potentially in use by Medicare beneficiaries: is it the FDA or CMS?

Response: Ensuring the availability of innovative interventions is a shared priority for both CMS and the FDA. HHS recognizes the important and related – but different – roles of these respective agencies and know that CMS and FDA decisions have an outsized impact on the U.S. health care system, as well as implications for the rest of the world. Underpinning both agencies' work is the unwavering commitment to use reliable data to ensure that effective treatments are made available to patients. The FDA's decision to approve a new medical product is based on a careful evaluation of the available data and a determination that the medical product is safe and effective for its intended use. In some instances, the FDA has the authority to require additional studies after approval to provide additional information (for example additional information regarding the anticipated clinical benefit of a medical product).
CMS works to ensure that all beneficiaries have access to needed care as rapidly as possible, with items and services based on accurate, reliable information that demonstrates a clear clinical benefit. In developing this National Coverage Determination (NCD), CMS followed a long-standing process developed by Congress to determine whether an item is reasonable and necessary for the diagnosis or treatment of an illness or injury.

Under the final NCD, Food and Drug Administration approved monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease (AD) are covered under Medicare when furnished in accordance with certain coverage criteria under coverage with evidence development for patients who have a clinical diagnosis of mild cognitive impairment due to AD or mild AD dementia, both with confirmed presence of amyloid beta pathology consistent with AD.

CMS received over 10,000 comments on the proposed NCD and in response to those comments and the evidence, changed the final NCD. The final decision creates two coverage pathways. For monoclonal antibodies approved through the accelerated approval process for the treatment of Alzheimer's disease, CMS no longer requires a CMS-approved randomized controlled trial. Instead, we are supporting any Food and Drug Administration (FDA) or National Institutes of Health (NIH) trial. What this means is CMS will cover antiamyloid monoclonal antibodies in an FDA investigational new drug application or other NIH trial. CMS does not need to review/see or approve these trials.

The proposed NCD included criteria that would have excluded some key patient subpopulations (e.g., Down syndrome patients). Based on public comment, CMS did not finalize the patient exclusion criteria to allow appropriate access to patient subpopulations that may need treatment

based on ongoing research. FDA and NIH have said they will make efforts to ensure there is diverse participation and access to their trials.

For antiamyloid monoclonal antibodies that have been approved by FDA through the traditional approval process for the treatment of Alzheimer's disease, the final decision allows for flexibility in a less rigorous study design. Such drugs would be eligible for coverage under prospective comparative studies to answer the coverage with evidence development questions specified in the NCD. For example, registry data could be used to assess whether outcomes seen in carefully controlled clinical trials are reproduced in real-world use and in a broader range of patient groups.

Promising medicines and technologies that treat devasting conditions will continue to be developed in the coming years, and it is important to make sure that patients have access to effective treatments that will not cause harm.

60. Question:

As you now know firsthand through leading HHS during the COVID pandemic, while the US made historic investments through Operation Warp Speed, there were also countless companies large and small that invested their own resources without any federal dollars in order to bring treatments and vaccines to market. I would like to hear more from you about the role of private sector investment which ultimately brings drugs and devices to the American people—and specifically the barriers that exist to getting these to our seniors in the Medicare program. As you may be aware, the gap between FDA approval and CMS coverage was eight years for a new cutting-edge approach to treating brain tumors, a treatment that came to market with data from large randomized controlled trials. There was a similar extended time gap for devices that allow for continuous monitoring of blood glucose levels, something that can substantially reduce hospitalization rates for the elderly with type two diabetes. Medicare patients' opportunity to receive expedite coverage and access to innovative FDA-approved devices was upended by your Department's decision to rescind that rule. While we are encouraged that the agency is working to address the issues raised in the MCIT rule, we are concerned about further delays to a policy that would provide clarity and stability for innovators.

a. Will you work with us to ensure a robust and meaningful rule is put forward by CMS this year, ideally prior to the holiday season in order to become active in 2023, that does not duplicate the role of FDA but rather ensures that there is a clear coverage pathway without moving goalposts?

b. As Secretary of HHS you oversee both CMS and FDA. Are there currently duplicative or burdensome requirements from FDA approval to CMS coverage that we should look to streamline or coordinate in order to expedite investment in and access to innovative devices?

c. Do you believe that earlier interactions between the FDA and CMS could ensure more certainty for innovators and expedite access for Medicare beneficiaries to life-saving medical devices upon FDA approval or clearance?

d. Does any meaningful pathway for such communication exists today between the FDA and CMS? Between the device manufacturer, CMS and FDA?

61. Question:
Can you elaborate on the principles behind the "Transitional Coverage for Emerging Technologies" and how this differs from the MCIT rule? If the goals are similar, why was it necessary to repeal the rule entirely and delay coverage for at least a year or more, as opposed to working with the structure of that rule?

Response 60-61: CMS remains committed to expanding access to health care coverage and services, including new, innovative treatments when they are safe and appropriate. CMS rescinded the Medicare Coverage of Innovative Technology and Definition of "Reasonable and Necessary" final rule because of concerns that the provisions in the final rule may not have been sufficient to protect Medicare patients. By rescinding this rule, CMS will take action to better address those safety concerns in the future.

Improving and modernizing the Medicare coverage process continues to be a priority for HHS and we remain committed to providing stakeholders with more transparent and predictable coverage pathways. CMS is exploring coverage process improvements that will enhance access to innovative and beneficial medical devices in a way that will better suit the health care needs of people with Medicare. This will also help to establish a process in which the Medicare program covers new technologies on the basis of scientifically sound clinical evidence, with appropriate health and safety protections in place for the Medicare population. CMS is working as quickly as possible to advance multiple coverage process improvements that provide an appropriate balance of access to new technologies with necessary patient protections. As part of this effort, CMS conducted several listening sessions to learn about stakeholders' most pressing challenges and to receive feedback from stakeholders about which coverage process improvements would be most valuable. HHS looks forward to hearing your feedback as we move forward with our efforts.

62. Question:
How many warning letters have you sent to hospitals regarding their compliance with the hospital price transparency rule?

63. Question:
How many full-time staff do you have working on compliance with the hospital price transparency rule and how many complaints, on average, can they review in a given period of time such as one day, one week, or a month?

64. Question:
Is it true that if a hospital were to come into compliance with the rule after some combination of warning letters, corrective action plans or other educational or disciplinary actions and then subsequently fall out of compliance with the rule at any point in time—e.g. days or weeks later—the "compliance clock" would start over completely?

a. Meaning, if a hospital comes into compliance over a period of time and then intentionally or not falls out of compliance with the rule, it would begin the compliance process completely anew. If this is true, would this in any way provide an incentive for hospitals to come into compliance at one point and then fall out of compliance shortly thereafter?

b. Is there anything in your process that would prevent a hospital from endlessly restarting this process to avoid financial penalties?

Response 62-64: Increasing access to affordable health care is a top priority for the Biden-Harris Administration. That's why HHS is committed to ensuring that consumers have the information they need to make fully informed decisions regarding their health care.

Hospital price transparency helps people know what a hospital charges for the items and services it provides. Under CMS regulations, hospitals must post on their website a machine-readable file containing a list of all standard charges for the items and services they provide, as well as a consumer-friendly list of standard charges for at least 300 shoppable services. CMS expects hospitals to comply with these requirements, and is enforcing them to ensure people know what a hospital charges for items and services.

The enforcement process is established in the Hospital Price Transparency regulations and occurs in a phased manner. The process typically involves a comprehensive compliance review in response to CMS audit or a complaint received through the Hospital Price Transparency website. If CMS concludes a hospital is noncompliant with one or more of the requirements to make public standard changes, CMS may take any of the following actions, which generally, but not necessarily, will occur in the following order:

- Provide a written warning notice to the hospital of the specific violation(s)
- Request a Corrective Action Plan (CAP) if noncompliance constitutes a material violation of one or more requirements
- Impose a civil monetary penalty

In January 2021, CMS began proactive audits of hospital websites as well as review of complaints submitted to CMS via the hospital price transparency website. In April 2021, CMS issued the first set of warning letters to noncompliant hospitals. These letters list specific areas of deficiencies identified through CMS compliance review and request hospital action to remedy the deficiencies. Hospitals that fail to submit a corrective action plan or comply with the requirements of a corrective action plan will be subject to a civil monetary penalty. In the event CMS issues a civil monetary penalty, CMS will identify the hospital and display the hospital's name on a CMS website.

In the Calendar Year (CY) 2022 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems Final Rule (86 Fed. Reg. 63,458), CMS finalized modifications to the hospital price transparency regulations to increase compliance. The modifications became effective January 1, 2022 and include the use of a scaling factor to increase the amount of the civil money penalties based on hospital bed count.

HHS looks forward to working with its partners across the federal government, along with Congress and other stakeholders, to examine additional ways to increase price transparency across the health care industry and improve access to affordable coverage and services.

65. Question:
Medicare payment policy encourages ever greater consolidation among providers, in particular as it relates to the differential in payment among outpatient sites of care such as the hospital department, ambulatory surgery center, and physician office. Numerous government watchdog organizations such as GAO, the HHS OIG, MedPAC and other policy organizations spread out across the political spectrum have long advocated for site neutral payment policies in the Medicare program. Can you elaborate on which specific site neutral payment policies you support or do not support?

Response: CMS seeks to continue to promote site neutrality, where possible, between the hospital outpatient department, ambulatory surgical center (ASC), and physician office settings. CMS strives to balance the goals of increasing physician and patient choice, and expanding site neutral options with patient safety considerations. For example, there is a longstanding policy that designates as ''office-based'' those procedures that are added to the ASC Covered Procedures List that we determine are furnished predominantly (more than 50 percent of the time) in physicians' offices based on consideration of the most recent available volume and utilization data for each individual procedure code and/or, if appropriate, the clinical characteristics, utilization, and volume of related codes. The ASC payments for these procedures would be the lesser of the rate that would otherwise apply under the ASC payment system or an amount calculated based on the Physician Fee Schedule. This office-based policy is meant to achieve payment parity between the ASC and physician office settings.

66. Question:
According to MedPAC, in 2012 Hospital Outpatient Departments accounted for approximately 35% of chemotherapy administration. By 2019 that figure passed 50%.

a. Do you think that the trend of chemotherapy administration migrating to hospital outpatient departments from less expensive sites of care (and studies demonstrate comparable or even improved quality of care) for both the Medicare program and Medicare patients is at least partly a result of the Medicare payment differential among sites of care?

b. If so, what are you planning to do to throttle this trend in line with the President's Executive Order on Promoting Competition in the American Economy that seeks to address hospital consolidation?

c. If not, what else explains this trend?

Response: Americans are paying too much for prescription drugs and health care services — far more than the prices paid in other countries. Hospital consolidation has left many areas, particularly rural communities, with inadequate or more expensive health care options. The patent system also affects prescription drug prices, and the Biden-Harris Administration supports

action to ensure that drug manufacturers cannot unfairly use the patent system to discourage competition.

CMS recently released data publicly -- for the first time -- on mergers, acquisitions, consolidations, and changes of ownership from 2016-2022 for hospitals and nursing homes enrolled in Medicare. The data can help researchers, enforcers, and the public analyze trends and issues in health care markets, and more specifically, provide insight into how the ownership of health care providers impacts costs and outcomes of consumers.

CMS expects to release updated change of ownership data on a quarterly basis. The hospital change of ownership data is available at: https://data.cms.gov/provider-characteristics/hospitals-and-other-facilities/hospital-change-of-ownership; and the skilled nursing facility change of ownership data is available at: https://data.cms.gov/provider-characteristics/hospitals-and-other-facilities/skilled-nursing-facility-change-of-ownership.

HHS's Office of the Assistant Secretary for Planning and Evaluation (ASPE) also released a report examining the new CMS change in ownership data. The ASPE report is available at: https://aspe.hhs.gov/reports/changes-ownership-hospital-skilled-nursing-facilities.

In addition, as authorized in the Bipartisan Budget Act of 2015, CMS has implemented amended policies related to treatment of off-campus outpatient department(s) of a provider services. Since January 1, 2017, hospital providers have been required to correctly identify off-campus outpatient department(s) of provider services that fall under this provision. This requirement helps ensure that only facilities that meet provider-based requirements are receiving higher payments allowed by the provider-based designation.

67. Question:

The COVID-19 response has brought to light several shortcomings in our healthcare system, including in critical settings like nursing homes for our nation's most vulnerable. I am hopeful we can continue to work on greater accountability and oversight and bipartisan reforms to ensure we never repeat what led to the tragic COVID nursing home deaths. In his State of the Union address, President Biden stated that HHS through CMS would be working to improve nursing homes' quality and safety, including through more transparency on the ownership interests in nursing homes. On April 20th CMS released nursing home data on ownership with the stated goal of better understanding consolidation and competition.

a. Has CMS digitized all submitted ownership information for nursing homes covered under sections 1819 and 1919 of the Social Security Act?

b. Does CMS have all the resources necessary to ensure they can access this information to make it public as appropriate?

c. Are there non-CMS datasets (e.g., SEC filings, records of incorporation, real estate records etc.) that HHS/CMS believes they do not currently have the authority to utilize when investigating and adjudicating applications to participate in the Medicare and/or Medicaid programs that would greatly assist CMS in preventing fraud and ensuring high quality care in nursing homes?

d. Does HHS/CMS have sufficient data systems to capture, investigate and adjudicate new participation requests, changes in ownership and tracking of ownership chains in an efficient and data driven manner? If yes, why has CMS not alerted the public to the issues surrounding private equity or other ownership interests in nursing homes until now?

Response: Ownership information for currently active nursing homes enrolled in Medicare is available at: https://data.cms.gov/provider-data/dataset/y2hd-n93e. This includes detailed information about individuals and organizations that have direct or indirect ownership of, a partnership interest in, and/or managing control of the nursing homes.

In April 2022, HHS announced new actions to promote competition and transparency in our nation's health care system that can improve the safety and quality of nursing homes and hospitals. For the first time, CMS publicly released data on mergers, acquisitions, consolidations, and changes of ownership from 2016-2022 for hospitals and nursing homes enrolled in Medicare. This data, available on data.cms.gov, is a powerful new tool for researchers, state and federal enforcement agencies, and the public to better understand the impacts of consolidation on health care prices and quality of care. CMS expects to release updated change of ownership data on a quarterly basis. The CMS data will enhance transparency for hospitals and nursing homes patients, potential patients and their loved ones, as well as for policymakers and the communities where these facilities are located.

68. Question:

Mr. Secretary, according to CDC's National Center for Health Statistics there was an estimated 100,000 drug overdose deaths in the United States during the 12-month period ending in April 2021—an increase of almost 30 percent from the same time period the previous year. We know a large majority of opioid diversion comes from the surgical setting. HHS recognized the need to reduce opioids in the surgical setting and recommended removing restrictive barriers to allow patients access to new, non-opioid therapies. CMS followed suit by unbundling certain therapeutics in the Ambulatory Surgery Center setting to spur further adoption. Recently, I have heard from a number of physician organizations with concerns over coverage policies that restrict physicians' ability to utilize an FDA-cleared technology that treats chronic pain without requiring opioids. Specifically, the Sprint PNS is a pain-relieving device used by nearly 1000 interventional pain management physicians across approximately 10,000 patients that employs electrical impulses to reduce chronic and acute pain. There are more than 30 peer-reviewed publications that support its use and it is currently covered by a National Coverage Determination (NCD) set forth by CMS, making it eligible for use under all Medicare plans across the entire US. However, I understand that at least one Medicare Administrative Contractor, Noridian, has issued a more restrictive Local Coverage Determination (LCD) that appears to be at odds with the coverage granted by CMS's NCD. Despite Congressional inquiries to raise this issue with CMS, Noridian continues to override the existing national coverage policy—which may be a violation of existing law. During a time with unprecedented opioid use, addiction and even death, it is all the more important that we champion and enforce policies to address these regressive policies such as the one being instituted by Noridian only serve to exacerbate the growing opioid epidemic in the United States.

a. Can you provide us an update on this situation and your interactions with the relevant MACs and indicate when we can expect this conflicting LCD policy to be withdrawn? If it is not withdrawn, what can you do to help clear up the confusion for providers and patients?

Response: Addressing the opioid epidemic is a top priority for HHS, and CMS remains committed to ongoing examination of its payment and coverage policies to ensure that health care providers can execute best practices with respect to pain management and treatment of substance use disorder. As part of our efforts, CMS will continue exploring policy options that could facilitate the use of non-opioid treatments when appropriate.

With respect to the Sprint PNS device in particular, where a National Coverage Determination (NCD) or regulation has not opined on a coverage issue, Medicare Administrative Contractors (MACs) are able to make reasonable and necessary decisions in accordance with section 1862(a)(1)(A) of the Social Security Act. NCD 160.7 identifies broad criteria for coverage for electrical nerve stimulators. The NCD does not identify specific medical conditions where electrical nerve stimulators are or are not indicated, instead giving guidance such as that patients must have undergone careful screening, evaluation and diagnosis by a multidisciplinary team prior to implantation. Within their Local Coverage Determination (LCD), the MAC has identified certain conditions for which it believes peripheral nerve stimulation is not supported by the scientific literature and has referenced the appropriate NCD. As this matter is under the purview of the MAC, HHS's role is to ensure the MAC follows the appropriate LCD development process and we believe that they have in this instance. Stakeholders may request a reconsideration of an LCD following the instructions in section 13.3 of Chapter 13 of the Medicare Program Integrity Manual: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c13.pdf.

69. Question:

Ground ambulance service providers have played a pivotal role during the COVID-19 pandemic. These vital medical service providers and their paramedics and EMTs have been on the frontline of providing medical care, transportation, testing and vaccinations during the PHE. They are experiencing higher operational costs and dealing with a chronic severe shortage of paramedics and EMTs exacerbated by the pandemic response. They are struggling like other health care providers but do so while still providing communities with 9-1-1 emergency and non-emergency ambulance services 24 hours a day 7 days a week. We need to ensure that our EMS systems have the resources including training for paramedics and EMTS necessary for future health emergencies.

a. What HHS programs are available currently to both governmental and nongovernmental ground ambulance service providers for training of paramedics and EMTs?

Response: HHS does not operate any federal grant programs specifically for the entry level education of paramedics and EMTs for either governmental or nongovernment ground ambulance providers.

70. Question:

Numerous estimates indicate that office-based physician specialties like cardiology, vascular surgery, and radiology have seen cuts of 20 percent, 40 percent, and even 60 percent in some cases since 2006. Under the 2022 Physician Fee Schedule and the clinical labor cuts that are now being phased in through 2025, these same specialties will see additional cuts of upwards of 20 percent in some cases. These cuts are driving health system consolidation, exacerbating provider shortages and access issues, and hurting our health system's responsiveness and capabilities for future pandemics.

a. Please speak to how your Department's policies are affecting office-based specialties and the need for fundamental Physician Fee Schedule reform to mitigate these harms.

b. Please name one or more specific policies that you commit to working with us on that would mitigate the consolidation occurring among office-based specialists. If you don't have any particular policies in mind for office-based specialists, are there any specific policies that you will commit to working with us on to stem the tide of broader provider consolidation?

c. Can you commit to us that the 2023 Physician Fee Schedule won't include another large payment reduction, e.g. reductions to the indirect practice expenses, to physicians in an office setting?

Response: The Biden-Harris Administration is committed to protecting and strengthening Medicare so that Americans of every generation can count on it, and ensuring providers receive appropriate payments is a critical part of our efforts. Ensuring adequate payment rates for physicians and other health care professionals is essential in maintaining patients' ability to access high-quality and affordable health care. CMS is required to base payments for services under the physician fee schedule on the relative resource costs involved in furnishing a service, and the fee schedule is subject to statutory budget-neutrality requirements. CMS does not have the legal authority to implement increases in payment outside of budget neutrality without additional action taken by Congress. As always, HHS appreciates the opportunity to provide technical assistance to Congress on important health care issues.

71. Question:
Recently, the bodies of five aborted babies were found in Washington, D.C. They appear to have been viable human beings that were possibly aborted illegally. A neonatal specialist who looked at the babies said, "I can say with confidence that [four of] these babies died at an age when they were viable, premature people."
Are you aware of the Live Action article that reported about these babies?

72. Question:
At what point does human life begin and at what point is that life deserving of care?

73. Question:
As Secretary of Health and Human Services, do you have a direct role in ensuring that the 14th Amendment, which says that no State shall "deprive any person of life", is carried out in our nation?

74. Question:
What is the Department of Health and Human Services doing to protect the lives of infants in and out of the womb?

75. Question:
Do you recognize that euphemisms such as "family planning" and "reproductive rights" oftentimes refer to abortion and the killing of babies before they are born?

Response 71-75: I support access to reproductive care, which includes safe and legal abortion care. Medical decisions are between a patient and their doctor. The Department will continue to enforce the law.

76. Question:
The ongoing nationwide shortage of infant formula is the latest failure of the Food and Drug Administration and its Center for Food Safety and Applied Nutrition (CFSAN) in conducting sufficient oversight and regulation over food safety and nutrition. Americans have been facing disruptions in the availability of infant formula since the beginning of the COVID-19 PHE in March of 2020, which has only been further exacerbated by historic inflation rates caused by Biden Administration policies. It is our understanding that you have been aware of this issue since last year. Energy and Commerce's Subcommittee on Oversight and Investigations have announced a hearing to examine the current infant formula shortage.

a. Are you aware that as of today, May 17, 2022, FDA Commissioner Califf has not made himself available to testify before the Subcommittee on Oversight and Investigations' May 25, 2022, hearing, "Formula Safety and Supply: Protecting the Health of America's Babies?"

b. Do you agree with Energy and Commerce Republicans that it is imperative we hear directly from Commissioner Califf on this emergent public health crisis and what steps the Biden Administrations is planning to improve supply of infant and specialty formula products?

Response: The HHS response to Questions for the Record reflects the date of the hearing, April 27, 2022. Should you have questions pertaining to events after the date of the hearing, HHS is available to assist. Please have your staff contact the Office of the Assistant Secretary for Legislation at (202) 690-7627.

77. Question:
In late April, a 34-page whistleblower document that was sent to FDA officials in October 2021 was made public. In the document the former employee at Abbott's Sturgis plant flagged concerns about food safety violations, including falsification of records, releasing untested infant formula, efforts by to keep FDA auditors from learning about certain events during a 2019 FDA audit, and issues associated with the traceability of its products, among other things. It is unclear how FDA is presently working through the allegations included in this document. It does seem clear, however, that the Biden Administration has had nearly two years to address worsening

disruptions to our infant formula supply chains and has only recently announced steps to mitigate the present crisis once national news media began covering it.

a. Can you share what actions have been taken between April 2022—when national news ramped up coverage of the infant formula crisis—and March 2020, when disruptions to our national supply and distribution chains first became critical?

Response: The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall began on February 17, 2022. Abbott Nutrition's voluntary recall and subsequent voluntary cessation of operations at its Sturgis plant in February further destabilized the infant formula supply chain. Prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition facility in Sturgis, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Our efforts to help support an all-of-government supply chain response included regular engagement with the Infant Nutrition Council of America and its members to identify challenges they were facing. Beginning immediately after the recall in February, this work greatly intensified, and the Agency has been working extensively with Abbott Nutrition and other manufacturers to increase production and to bring safe and nutritionally adequate products to the U.S. market as quickly as possible.

FDA established an intra-agency working group, including experts from the Office of Food Policy and Response (OFPR) and the Center for Food Safety and Applied Nutrition (CFSAN). They began evaluating infant formula supply chain implications prior to the recall, met with USDA, and ensured that U.S. government supply chain partners were engaged at the highest levels. FDA and USDA, as co-leads for Food and Agriculture Sector Risk Management, provided regular updates to the White House regarding overall supply chain concerns, including information about infant formula. FDA has worked tirelessly with U.S. government partners to mitigate the supply chain disruption for both regular and specialty formulas.

FDA has continued taking key steps to help increase the supply of infant formula in the United States. As of the date of the hearing, FDA was leveraging all tools at our disposal to support the supply of infant formula products by:

- Meeting regularly with major infant formula manufacturers to better understand and maximize their capacity to increase production of various types of infant formulas and certain medical foods. The infant formula industry is already working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.

- Monitoring the status of the infant formula supply by using the Agency's 21Forward food supply chain continuity system, combined with external data. Originally designed to address the broader food supply during the pandemic, FDA has adapted

21Forward to monitor and support infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales.

- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Implementing a new process to temporarily exercise enforcement discretion, on a case-by-case basis, for certain requirements that apply to infant formula. These flexibilities, applicable to both imported and domestically produced infant formula, will augment supply volume while still allowing FDA the opportunity to review vital information relating to the safety and nutritional sufficiency of the products. Within a week of implementing the program, FDA informed two foreign manufacturers that they could use this pathway to import their infant formula, and we are evaluating multiple other promising requests. We continuously update the status of these efforts on our website.[20]
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
- Exercising enforcement discretion with respect to minor labeling issues to help increase volume of product available as quickly as possible.
- Continuing outreach to retailer stakeholder groups to request that their members consider placing purchase limits on some products to protect infant formula inventories for all consumers.

b. Given the urgency and public health threat posed by these shortages, can you explain why FDA and CFSAN continue to work remotely and why they are not conducting daily, in-person meetings to address this crisis?

Response: FDA employees have continuously been completing their work. Employees work onsite depending on their position requirements. For instance, those who work in the laboratories have worked onsite throughout the pandemic. On the other hand, people with positions dealing with data and administrative functions, who do not need to be present in person, have the option to work remotely. FDA employees have been particularly productive working remotely in addressing the usual tasks in addition to pandemic and infant formula related-activities. FDA is currently undergoing a pilot program to analyze the hybrid environment studying specific jobs and their functions. The decision to return to onsite work going forward will be based on the most productive method for employees and the Agency.

[20] U.S. Food and Drug Administration, "Enforcement Discretion to Increase Infant Formula Supplies," updated August 10, 2022, available at https://www.fda.gov/food/infant-formula-guidance-documents-regulatory-information/enforcement-discretion-manufacturers-increase-infant-formula-supplies.

78. Question:
On the CDC's website is a list of "preferred terms" for its "Gateway to Health Communication" initiative.

a. Who did the CDC consult in making this list?

Response: CDC developed these guiding principles using a consensus method of review among many internal and external subject matter experts, including receiving feedback from members of the communities of focus included in the guiding principles.

b. What does this list have to do with health care?

Response: The Health Equity Guiding Principles suggestions for using inclusive language are anchored by the 10 Essential Public Health Services. These services provide a framework for public health to protect and promote the health of all people in all communities. To achieve equity, the Essential Public Health Services promote policies, systems, and overall community conditions that facilitate the achievement of optimal health for all. Beyond language choices, these guiding principles are intended to provide public health professionals with ways to address communities in a manner that may advance efforts for all Americans to benefit from a fair and just opportunity to achieve optimal health and well-being.

c. Why is this under the purview of the CDC, whose mission is to "protect people from health threats"?

Response: Disparities in deaths and illness, use of health care, behavioral risk factors for disease, environmental hazards, and social determinants of health drive many health threats in the United States. Part of CDC's mission is therefore to address these gaps and to better assist Americans disproportionately impacted by the burden of poor health, including interventions that will allow all Americans to live healthier and more productive lives.

CDC encourages all public health professionals and partners at the federal, state, and local levels to apply the Health Equity Guiding Principles for Inclusive Communication across their public health communication work, including when creating information resources and presentations, when engaging with partners, and/or when developing and reviewing external or internal communication materials, in order to address health disparities and to further health equity.

79. Question:
On the list it says, "instead of 'prisoner', try this… 'people/persons who are incarcerated or detained'."

a. Can you explain why using the definition of the word "prisoner" instead of using the word "prisoner" is helpful to the American people?

Response: CDC's Health Equity Guiding Principles for Inclusive Communication is not meant to be prescriptive or exhaustive, but rather to provide resources and specific suggestions on a variety of topics to help inform an inclusive approach to public health communications. CDC recommends describing people as having a condition or circumstance, not being a condition – also known as person-first language. Using person-first language humanizes those referred to by using people or persons and this is one example of its use.

b. Was an expert in the English language consulted when making this list of preferred terms?

Response: Yes, CDC developed these guiding principles using a consensus method of review among many internal and external subject matter experts, including many health communication specialists as well as members of the communities referenced. These guiding principles reflect best practices for health communication at CDC. As culture and language evolve, these resources will be reevaluated and updated to reflect needed changes.

80. Question:

Also on the list, the CDC suggests using the term "assigned male/female at birth". For the largest government sponsor of science and health, this is anti-biology, anti-science, and anti-truth.

a. Do you believe that this term denies commonly known biology that humans are not "assigned" sexes, but they are born male or female?

Response: The United States Core Data for Interoperability is a standardized set of health data classes and constituent data elements for nationwide, interoperable health information exchange. This standard sets a foundation for broader sharing of electronic health information to support patient care in electronic health records and is widely used and recognized in healthcare practice in the United States. Medical professionals assign gender at birth as a matter of course, and this is based on a number of observable factors such as anatomical and physiological traits (sex traits) such as external genitalia, secondary sex characteristics, gonads, chromosomes, and hormones.

b. Do you view this strange list as a way for the CDC and HHS to influence speech and thereby influence culture?

Response: The Health Equity Guiding Principles for Inclusive Communication is primarily intended for (but not limited to) public health communicators both at CDC and in the health communication field.[21] The Guiding Principles are anchored by the 10 Essential Public Health Services. These services provide a framework for public health to

[21] https://www.cdc.gov/healthcommunication/Health_Equity.html

protect and promote the health of all people in all communities. CDC's Health Equity Guiding Principles for Inclusive Communication contains suggestions for best practices. These suggestions are to consider the context and intended audience for communications and choose words carefully, inclusively, and appropriately for a specific use and audience.

Language in communication products should reflect and speak to the needs of people in the audience of focus. The preferred terms are given as examples for select population groups. CDC suggests considering using these or other inclusive terms for select population groups while recognizing that there is not always agreement on which terms are best.

81. Question:

Recently, HHS's Office for Civil Rights put out notice and guidance on "Gender Affirming Care, Civil Rights, and Patient Privacy", which expressed your fervent support for children seeking - gender changes.

a. How many federal tax dollars do you plan to use to support gender transitions?

b. How much of that money will be for minors specifically?

Response to a-b: HHS is committed to ensuring equal access to all federally-assisted and -conducted health and human service programs. As you may be aware, the HHS Office for Civil Rights (OCR) is responsible for enforcing prohibitions against discrimination on the basis of sex, pursuant to Section 1557 of the Affordable Care Act and Title IX of the Education Amendments of 1972. On May 10, 2021, HHS notified the public that the Department will interpret and enforce Section 1557's prohibition on sex discrimination to include sexual orientation and gender identity discrimination. OCR's policies protect all Americans from unlawful discrimination by ensuring equal access to health and human services.

c. Do you agree with scientists that the human brain is not yet fully developed until the age of 25?

d. Do you believe that children as young as 6, 7, or 8 have the decision-making capacity to decide to switch genders?

Response to c-d: HHS would recommend consulting with medical associations regarding standards of care. Generally speaking, care is between a patient, their family and their health care provider.

HHS is committed to ensuring equal access to all federally-assisted and federally-conducted health and human service programs, including for minors. HHS OCR's *Notice and Guidance on Gender Affirming Care, Civil Rights, and Patient Privacy* details OCR's policies regarding how federal civil rights laws apply to children.

e. Do you believe that it is ever appropriate for a parent to be cut out of their child's health care?

Response: The Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule generally treats a parent as the minor's "personal representative" when state or other applicable law gives the parent authority to make decisions related to health care on behalf of their unemancipated minor child. As a personal representative, the parent can exercise Privacy Rule rights on the minor's behalf, including the right to access the minor's protected health information (PHI), and can authorize uses and disclosures of PHI on behalf of the minor. *See* 45 CFR 164.502(g).

However, the Privacy Rule does not recognize a parent as an unemancipated minor's personal representative in three circumstances: 1) when a minor consents to care and the consent of the parent is not required under applicable law; 2) when the minor obtains care at the direction of a court or a person appointed by the court; and 3) when, and to the extent that, the parent agrees that the minor and the health care provider may have a confidential relationship. In addition, if a licensed health care provider has determined, in the exercise of professional judgment, that the provision of access to the parent (or any personal representative) is reasonably likely to cause substantial harm to the minor, the Privacy Rule permits the licensed health care provider to deny the parent access to the minor's records. *See* 45 CFR 164.502(g) and 45 CFR 164.524.

f. Do you believe that parents who desire to affirm their child's birth sex and help them to overcome confusion and gender dysphoria and love themselves as God made them should be removed from their child's life for not giving into their desire to switch genders?

Response: HHS would recommend consulting with medical associations regarding standards of care. Generally speaking, care is between a patient, their family and their health care provider. OCR will enforce civil rights laws over programs with removal authority consistent with HIPAA and OCR's guidance referenced in response to parts c-d of this question.

Research demonstrates that gender-affirming care improves the mental health and overall well-being of gender diverse children and adolescents. Gender-affirming care encompasses many facets of healthcare needs and support and has been shown to increase positive outcomes for transgender and nonbinary children and adolescents. Gender-affirming care is patient-centered and treats individuals holistically, aligning their outward, physical traits with their gender identity.

82. Question:

HHS manages several facilities to house unaccompanied migrant children that come across our southern border illegally. As Biden's crisis on the border continues and worsens, the number of border apprehensions is skyrocketing. This March, CBP apprehended 221,303 illegal immigrants. That's more than 7,000 per day. Recent reports state that HHS is preparing staff to

accept "temporary deployments" to the border to help manage the surge of unaccompanied children.

a. Is this because the Biden Administration has recklessly decided to terminate Title 42?

Response: Unaccompanied children have been exempted from Title 42 since January 2021. ORR's primary mission is to safely care for the unaccompanied children referred by DHS until they are either placed with a vetted sponsor or leave ORR's custody upon turning the age of 18. The numbers of children referred by DHS in ORR care can fluctuate, and ORR continuously reviews capacity needs throughout the year. Capacity estimates are based on historic data and DHS predictions and consider several factors such as UC referral numbers, trends, projections, and COVID-19 infection rates and impact on staffing and bed availability.

b. What happens to the work that HHS employees were hired to do while they are diverted to the border?

Response: HHS's priority is the safe and timely placement of unaccompanied children with their vetted sponsor, usually a parent, legal guardian, or other relative. Federal staff were initially deployed to help ORR accomplish two missions: UC mission at emergency intake sites (EIS) that had to be set up very quickly, serving in a variety of roles, including case management, records management, and youth care worker roles while EIS locations stabilized operations under contractor providers; and Operation Allies Welcome (OAW) mission serving in a variety of roles, including case management, health enrollment, health related support and activities, and youth care workers.

Since August 20, 2021, HHS has adopted a more targeted and limited approach to staffing its UC programs and OAW locations with federal detailees, based on specific skillsets needed at the sites and ACF Headquarters. Prior to deployment, detailees and their home agencies work with other staff to disperse regular duties and workload to ensure the completion of tasks.

c. How has the drastic increase in illegal border crossings impacted HHS migrant children's facilities?

Response: The COVID-19 pandemic and high number of referrals from the Department of Homeland Security (DHS) in the early part of calendar year 2021 placed significant demands on the state-licensed bed capacity of ORR's Unaccompanied Children's (UC) Program. Pursuant to the William Wilberforce Trafficking Victims Protection Reauthorization Act of 2008, absent exceptional circumstances, any federal department or agency that has an unaccompanied child in its custody must transfer the custody of such child to ORR care within 72 hours of determining that such child is a UC. At the height of the influx in April 2021, over 4,000 UC were in CBP custody awaiting placement.

ORR activated Influx Care Facilities (ICF) and Emergency Intake Sites (EIS) to provide immediate temporary bed capacity in short term DHS border facilities and ensure the safe and prompt placement of children into ORR care and custody. ORR does not consider EIS to be a long-term placement option and continues to review capacity needs based on all available indicators. Of the 14 EIS that were brought online, 12 were closed and two are being converted to ICFs: Pecos ICF in Pecos, Texas, and the ORR ICF at Fort Bliss in El Paso, Texas.

d. When a child is released from HHS facilities, what processes and protocols are in place to ensure that they are not released into the hands of a trafficker, sex offender, or other predator?

Response: ORR is dedicated to ensuring the safety of children from the moment they enter ORR care to when they are safely placed with a vetted sponsor who has undergone a robust screening process. Throughout ORR's sponsor screening process there are numerous risk-assessments completed for both the UC and the potential sponsor so that any red flags or derogatory information can be brought to light in terms of release determinations. This includes sponsor interviews, background checks, fingerprinting, and home studies.

ORR follows up by phone with both the sponsor and child after the child is released from ORR care to help continue and facilitate a child's successful transition into their community and encourage permanency. The purpose of the call is to determine if the child is still residing with the sponsor, is enrolled or attending school, is aware of any upcoming court dates, and is safe, and to see if they would benefit from additional support or services

Additionally, UC who may benefit from additional resources identified as part of this follow up call are referred to ORR's National Call Center where they can access resources within their local community appropriate for their needs. All children released from ORR care are given the number to the National Call Center, which is available 24 hours a day and provides a mechanism to report any concern a child has about their placement.

ORR funds post-release services (PRS) during the pendency of removal proceedings for all UCs for whom a home study was conducted, and in other cases where it assesses that the UC would benefit from ongoing assistance from a social welfare agency. PRS include assistance in connecting children and their sponsors to community-based resources suitable to their needs, and are authorized under statute to protect UCs from traffickers and other persons seeking to victimize or otherwise engage such children in criminal, harmful, or exploitative activity. Children who are released from ORR care have access to the following services:

- **ORR National Call Center (ORRNCC)**: This is a helpline that fields calls from released children and families and links them to the appropriate resources in the

community. In addition, all legal services providers, child advocates, and other members of the community can report concerns to the ORRNCC.

- **UC Sexual Abuse Hotline**: Although primarily designed as a hotline for children in ORR custody, released children, including their families, sponsor or legal service providers continue to have access to this line, and can report any suspected incidents of sexual abuse or sexual harassment that occurred at an ORR care provider facility that may not have been previously reported while the unaccompanied child was in ORR care. Incidents are reported to law enforcements and child protective services (CPS) as appropriate.
- **Notification of Concern**: This is a line that ORR grantees and contractors use to notify ORR of any perceived or actual danger to a released child's safety and well-being. This may include suspicion that the child is at risk for becoming a victim of human trafficking, being involved with a gang, running away, or suffering abuse. ORR reviews the matter to determine what, if any, additional action should be taken, including but not limited to: reporting the matter to local law enforcement; CPS, or state or child welfare licensing authorities. ORR may also consider at that time to provide post-release services to the released child and his or her sponsor.
- **National Human Trafficking Hotline**: This is a 24-hour helpline that coordinates with the ORRNCC and provides information, emergency assistance, and service referrals for individuals experiencing human trafficking.
- **Trafficking Victim Assistance Program**: HHS's Office of Trafficking in Persons coordinates with ORR to provide direct referrals for grant-funded comprehensive case management services for unaccompanied children who may have or have experienced human trafficking after discharge from ORR care (up to 12 months with possibility for extension).

Questions from The Honorable Michael C. Burgess, M.D. (R-TX)

83. Question:

As you know, the ACA created the quality bonus program for MA plans and the benchmark system. Unfortunately, despite over 80% of MA beneficiaries being enrolled in 4- and 5-Star plans, almost half of all counties in the country are impacted and not receiving a full quality bonus. Every year, more and more seniors in Texas and across the country are losing out on benefits. According to CMS data, more than 132,000 Texas seniors in 4 to 5 Star MA plans are not receiving all the benefits that Texas seniors in other counties are receiving.

a. To help my colleagues understand the importance of addressing this issue, can you please explain how providing financial incentives for innovation and quality makes MA markets fairer and more competitive?

b. How would seniors in Texas and across the country benefit from benchmark cap relief?

c. Do you support Congress enacting a benchmark cap relief?

Response: HHS is committed to providing affordable, high-quality, equitable coverage to all beneficiaries. Our goals for Medicare Advantage mirror our vision for CMS programs as a whole, which include advancing health equity; driving comprehensive, person-centered care; and promoting affordability and sustainability of our programs.

CMS continually seeks to refine the Star Ratings approach, and in the Advance Notice of Methodological Changes for Calendar Year 2023 MA Capitation Rates and Part C and Part D Payment Policies (CY 2023 Advance Notice) CMS requested input on how to improve Medicare Advantage and Part D Star Ratings. Substantive changes to the Star Ratings are adopted through the rulemaking process, which provides an opportunity for public notice and comment before CMS finalizes policy changes for the Star Ratings program.

CMS looks forward to working with you to improve the Medicare Advantage and Part D Star Ratings system and to find other ways to ensure beneficiaries in these plans are receiving high-quality, affordable coverage.

84. Question:

Hip fracture is the most devastating fracture that someone with osteoporosis can experience. In Texas, there has been a 55 percent decline in DXA testing of Medicare women since 2008, resulting in over 1,200 avoidable hip fracture-related deaths each year. These numbers are staggering for my state and completely preventable if more women could receive testing in an in-office setting.

a. Will you commit to working with me to improve access to osteoporosis testing by restoring adequate reimbursement for screenings in the physician office?

Response: CMS is committed to ensuring that Medicare beneficiaries have access to the preventive services they need, including tests to help determine if they're at risk for broken bones. Medicare Part B covers bone mass measurements once every 24 months for eligible beneficiaries, or more often if medically necessary, with no copayment, coinsurance, or deductible for the beneficiary. CMS looks forward to working with you and other stakeholders to determine how we can improve access to preventive services for Medicare beneficiaries.

85. Question:

Congress worked for several years to put together bipartisan legislation to protect consumers from surprise medical bills. The culmination of that work was the No Surprises Act and HHS is among the agencies that have been tasked with implementing the rules for this legislation. One of the elements of the bill is an independent dispute resolution process that allows for negotiations between insurance companies and providers regarding reimbursement for out-of-network services. This process is currently subject to litigation regarding the Agencies' direction to arbiters to begin with the presumption that the health insurance company's median in-network rate is an appropriate payment for out-of-network care under dispute, rather than equal consideration of all of the factors that were listed in the statute. In February, the United States

District Court for the Eastern District of Texas ruled that this portion of the Agencies' regulations implementing the No Surprises Act was unlawful.

a. Can you confirm that HHS will follow that decision in its forthcoming final rule and, as the Court held, respect Congress's intent to create a balanced arbitration process where ALL of the statutory factors are weighed equally?

Response: HHS—together with our colleagues at the Department of Labor, Department of the Treasury, and Office of Personnel Management—has been working to implement the No Surprises Act and ensure that consumers receive the benefits of the protections included in the law by Congress.

As you may know, on February 23, 2022, the United States District Court for the Eastern District of Texas, in the case of Texas Medical Ass'n, et al. v. United States Department of Health and Human Services, et al., Case No. 6:21-cv-425 (E.D. Tex.), invalidated portions of an interim final rule, Requirements Related to Surprise Billing; Part II, 86 Fed. Reg. 55,980 (Oct. 7, 2021) (the "Rule"), issued by the Departments of Health and Human Services, Labor, and the Treasury (the "Departments") governing aspects of the federal independent dispute resolution (IDR) process under the No Surprises Act. This court's order did not affect any of the Departments' other rulemaking under the No Surprises Act. Thus, consumers continue to be protected from surprise bills for out-of-network emergency services, out-of-network air ambulance services, and certain out-of-network services received at in-network facilities. The Departments are reviewing the court's decision and will respond as appropriate.

86. Question:

Given that the SNS has been run by the ASPR and given all the lessons we've learned during the pandemic - for example, we can't rely on global supply chains for critical items like PPE.

a. Are there changes that need to be made in the law that would allow ASPR to give preference to domestic PPE manufacturers and small businesses here in the US as you refill the stockpile?

Response: HHS is evaluating whether additional authority is necessary to support implementation. Currently, legislative authority is not needed for ASPR and the SNS to procure domestic PPE and other supplies for the Stockpile. In addition, the requirement for SNS to procure domestically manufactured PPE already exists under the Make PPE in America provision of the Infrastructure Investment and Jobs Act (IIJA)which requires SNS to procure PPE from domestic manufacturers. Should additional authority be required, HHS will inform Congress. The limiting factor for SNS is that it will be unable to procure additional domestically manufactured PPE based on availability of funding. Unless additional funds are made available for this purpose SNS is unlikely to make significant investments in PPE.

87. Question:

Through the pandemic, so many here in this country have stood up to help in many different ways; medical professionals, first responders, industry professionals, and small business. There were a lot of individuals and entrepreneurs who stood up new lines to make masks, N95s, face shields and other PPE to respond.

a. When the Administration made the decision to give out 400 million N95 masks to the American people for free can you share with us your plan to mitigate the damage done to small and medium sized manufacturers whose customer base has been eviscerated by this decision?

Response: The Biden Administration announced an initiative in January 2022 to provide masks, at no costs, to those who needed them. The intention was to create equity and availability for all.

b. Will there be a preference towards these companies when it comes time to refill the stockpile?

Response: As of April 2022, the SNS holds more than 400M N95 American made N95 respirators, meeting the COVID-19 target for N95 respirators. When and where possible the SNS seeks to procure domestically manufactured PPE. As the SNS continues to enhance domestic PPE stockpiles, the SNS will continue to utilize domestic manufacturers, when and where possible. SNS will comply with the IIJA requirement to procure PPE from domestic manufacturers.

Questions from The Honorable H. Morgan Griffith (R-VA)

Last month, FDA released new data showing the median time it takes the FDA to grant a generic drug application tentative approval is now in excess of 30 months.

88. Question:
Do any of the legislative proposals in the HHS FY 2023 budget request seek to address the speed at which generic drugs can obtain tentative or final approval?

Response: Yes. The goal of the HHS FY 23 budget's legislative proposal to "Amend the 180-Day Exclusivity Provisions to Encourage Timely Marketing of First Generics" is to increase the likelihood that generic versions of patent-protected drugs will come into the market in a timely fashion and that multiple versions of generic products will be approved quickly.[22]

89. Question:

[22] U.S. Food and Drug Administration, "Executive Summary of FY 2023 Legislative Proposals," available at https://fda.report/media/157194/FY+2023+FDA+Legislative+Proposals_FINAL.pdf.

Currently, how often does a first generic applicant that is entitled to 180-day exclusivity receive final approval within 30 months?

Response: FDA does not track time to approval for this specific subset of applications, but we have information available on mean and median time to approval and tentative approval for generic drug applications on our GDUFA II Quarterly Performance web page, available at https://www.fda.gov/industry/generic-drug-user-fee-amendments/activities-report-generic-drugs-program-gdufa-ii-quarterly-performance.

90. Question:
Is patent litigation the primary reason generic drug companies do not receive final approval within 30 months? How often does patent litigation take longer than 30 months to conclude?

Response: FDA does not track how often patent litigation takes longer than 30 months to conclude, but notes that, as reflected in FDA's November 2021 study on "Marketing of First Generic Drugs Approved by U.S. FDA from January 2010 to June 2017," available at https://www.fda.gov/media/154101/download, the vast majority of patent challenges are settled following confidential agreements between the companies rather than being decided by the courts on the merits.

91. Question:
Is the goal of FDA's FY 2023 budget request to increase the number of approvals or is the goal of the proposal to increase the number of generic products that are actually launched?

Response: The proposal is intended to address the problem of excessive periods of delay that can occur between when the first generic version of certain drugs could receive final approval and be made available to consumers versus when the drugs are actually marketed due to issues related to how Hatch-Waxman 180-day generic drug exclusivity is operating under current law. It is expected to provide first applicants a stronger incentive than they have under current law to begin marketing their product as soon as possible to realize the benefits of exclusivity.

In addition, if the proposal was enacted, approval of subsequent applicants' ANDAs would only be blocked once a first applicant begins commercial marketing and that block would terminate 180 days later, which is expected to result in more timely approvals of subsequent applicants' ANDAs for first generic products than occurs under current law, and to address the parking of 180-day exclusivity that can occur before or after final approval of a first applicant's ANDA under current law.

Questions from The Honorable Billy Long (R-MO)

92. Question:
One of the biggest changes CMS proposed for the Part D program in its rule for 2023 makes changes to pharmacy direct and indirect remuneration (DIR) fees or adjustments so they are recognized at the point of sale, in part, by changing the definition of negotiated price.

a. Given the complexity of this change, what—if any—steps has CMS taken to begin implementing this change? Will this require significant changes to CMS's internal systems for managing the part D program? If so, does your budget request additional discretionary funding to support these changes? Are you confident that CMS can implement this change for plan year 2023 without disrupting the bid process or negatively impacting beneficiaries' access or pharmacy costs for plan year 2023?

93. Question:

In CMS's proposed rule for Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs, one of the biggest changes CMS proposed for the Part D program is to have pharmacy direct and indirect remuneration (DIR) fees or adjustments be recognized at the point of sale. In the rule, CMS's non-partisan independent actuary estimated beneficiary premium increases of 5 percent on average per year and a total cost to the federal government of $40 billion over 10 years.

a. Can you please tell me whether this $40 billion increase in mandatory spending is reflected in your baseline for the budget?

b. There are significant operational changes associated with implementing this rule for 2023. How does your budget account for implementation costs? Will additional funds be needed to communicate with beneficiaries so they are aware of changes to their part D coverage or so they can make informed decisions at the next open enrollment?

Response 92-93: CMS issued the "Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs" final rule (CMS-4192-F), which went on display for public inspection on April 29, 2022, where CMS finalized a policy that requires Part D plans to apply all price concessions they receive from network pharmacies to the negotiated price at the point of sale, so that beneficiaries also can share in the savings. Specifically, CMS redefined the negotiated price as the baseline, or lowest possible, payment to a pharmacy, effective January 1, 2024. This policy will reduce beneficiary out-of-pocket costs and improve price transparency and market competition in the Part D program. CMS routinely takes operational considerations into account when assessing its budget needs each year.

94. Question:

It's my understanding that last year there were more than a dozen temporary intake facilities stood up to handle the surge at our southern border, at a cost of billions of taxpayer dollars, only to have most of them stood down during the winter slowdown. Now that summer is approaching, we're already seeing another surge, but what is the plan to deal with this? Specifically, HHS handles unaccompanied children, how are you planning to handle another rapid increase? Are we looking at billions more for temporary facilities or are you looking at more permanent options? If so, what kind of processing facilities are you considering?

Response: ORR continues to evaluate capacity needs by closely monitoring and reviewing several variables: UC referral numbers, projections and trends; DHS referral and ORR initial placement timelines; COVID-19 infection rates and impact on staffing and bed capacity; and

total operational bed capacity, including state licensed capacity. ORR activated Influx Care Facilities (ICF) and Emergency Intake Sites (EIS) to provide immediate temporary bed capacity from temporary DHS border facilities to ensure the safe and prompt placement of children into ORR care and custody. EIS provide immediate temporary bed capacity from temporary DHS border facilities and ensure the safe and prompt placement of children into ORR care and custody. ORR does not consider EIS to be a long-term placement option and continues to review capacity needs based on all available indicators. Of the 14 EIS that were brought online, 12 were closed and two are being converted to ICFs: Pecos ICF in Pecos, Texas, and the ORR ICF at Fort Bliss in El Paso, Texas.

ORR ensures that conditions on the ground guide decision-making processes. Given DHS projections of referral increases as well as the potential for capacity needs that can accommodate COVID-positive UC, ORR has determined that extending the use of the Pecos ICF in Pecos, Texas, and the ORR ICF at Fort Bliss in El Paso, Texas is necessary to ensure UC safety and well-being.

ORR's preference is to place UC into state-licensed care provider facilities, including transitional foster care (TFC) placements, while sponsorship suitability determinations proceed. Thus, ORR consistently works on expanding its network of standard beds by awarding funding to existing and new grantees. For example, ORR published two Notices of Funding Opportunity (NOFOs) for licensed shelters and transitional foster care beds on December 6, 2021 and April 7, 2022, with award dates targeted for July and November 2022, respectively. With these awards, additional capacity estimates are targeted at 4,240 beds.

ORR is committed to growing its licensed capacity and continues to expand its standard beds capacity by ensuring beds that were previously unavailable due to COVID-19 are brought back online.

Questions from The Honorable Richard Hudson (R-NC)

95. Question:

As evidenced by several public comments from this Administration, the U.S. intelligence community appears to believe there is a growing risk of Russia deploying chemical weapons in Ukraine. This should serve as a reminder of the unprecedented threat posed by chemical, biological, radiological, and nuclear (CBRN) weapons. While ASPR's main focus has assumedly been our COVID-19 response, ASPR's primary mission has always been to protect Americans from these kinds of deliberate threats.

a. Given the threat posed by CBRN weapons, please explain what actions ASPR is currently taking to re-double efforts to ensure Americans are protected against these threats in the future.

   Response: BARDA, within HHS/ASPR continues to develop innovative medical countermeasures (MCMs) for the detection, prevention and treatment of chemical, biological, radiological and nuclear (CBRN) threats. The overarching strategy that drives

the development of MCMs for many of these threats is to "treat the injury, not the agent." This is accomplished by providing treatment options for first responders and clinicians, irrespective of the cause of injury.

BARDA, in partnership with industry, has built a robust and formidable pipeline of MCMs in advanced development. These efforts focus on countering the medical consequences of 20 CBRN threats as identified by the Department of Homeland Security (DHS) that represent threats to U.S. national health security, such as anthrax, smallpox, Ebola Zaire, nerve agents, sulfur mustard gas, and nuclear and radiological weapons, among many other threats. These advanced development programs have supported 30 products that have transitioned to support under Project Bioshield (PBS), 22 of which have been procured for the Strategic National Stockpile or as vendor managed inventory. BARDA's efforts have led to 63 FDA licensures, approvals, or clearances of MCMs since 2008, 28 of which focus on countering CBRN threats. Additionally, BARDA's Division of Research, Innovation, and Ventures provides investments in novel technologies that may provide protection against multiple threats and make it easier to manufacture and deliver MCMs to diverse populations.

b. Given the threat posed by CBRN weapons, please explain what actions HHS is currently taking to ensure ASPR is re-doubling efforts to ensure Americans are protected against these threats in the future.

Response: While SNS has devoted significant time and resources (as appropriated by Congress in supplemental appropriations) to responding to COVID-19 over the last few years, SNS's annual appropriations have continued to support procurement of medical countermeasures (MCMs) necessary to respond to CBRN threats. Specifically with additional funds requested in FY 2023, SNS would procure MCMs necessary to respond to smallpox, radiological/nuclear, and anthrax incidents.

c. What actions is HHS taking to ensure ASPR is prioritizing America's stockpile of critical CBRN vaccines, treatments, and PPE, as well as ensuring they are well-maintained?

Response: Over the last decade, the Office of the Assistant Secretary for Preparedness and Response's (ASPR) Biomedical Advanced Research and Development Authority (BARDA) has advanced medical countermeasure (MCM) research and development, enhanced partnerships with industry, and sustained investments in potential products made possible under Project BioShield (PBS). This has resulted in the support of 30 products that are critical to the nation's preparedness and response to these threats. Twenty-two of these MCMs have been delivered to the Strategic National Stockpile (SNS) or procured as vendor managed inventory, with additional products to be delivered in FY 2023 and FY 2024. As of December 2021, 28 MCMs to detect, prevent, or treat CBRN threats have achieved FDA approval, licensure, or clearance with additional approvals anticipated in FY 2022 and FY 2023.

PBS allows BARDA to purchase and maintain in the SNS promising products that are sufficiently mature for use under an Emergency Use Authorization (EUA) issued by the FDA while continuing to support the late-stage development of these product candidates towards FDA approval. PBS funding is also utilized to replenish expiring CBRN MCMs in the SNS prior to FDA approval and, in some instances, post-approval (e.g., Raxibacumab anthrax antitoxin and anthrax vaccine) depending on availability of funding. BARDA and the SNS work closely to align resources and timelines for transition of products. The most significant challenge remains the difficult decisions of what to stockpile within available resources. This challenge has increased with the increasing number of regulatory approvals and subsequent products eligible for stockpiling.

With the requested increase for the SNS of $130M above FY 22 levels that was included in the FY23 President's budget, funding would support the sustainment of current product lines and procurement of several products previously supported by the Biomedical Advanced Research and Development Authority (BARDA) that lack a significant commercial market. These items include procurement of sufficient quantities of a domestically manufactured, FDA approved, smallpox antiviral to treat an estimated 350,000 people during a smallpox incident, meeting the stockpiling requirement for this product. Additionally, SNS would be able to procure enough bandages to treat an estimated 14,000 people impacted by a radiological/nuclear incident, meeting the stockpiling requirement for this product. Finally, with remaining funding at this level, SNS would procure limited quantities of anthrax therapeutics. It is critical that funding be provided for these efforts to enhance national preparedness.

d. Is HHS working with BARDA to re-engage with private sector partners to ensure there is no disruption in the availability of these supplies?

Response: During BARDA's COVID-19 response, BARDA maintained engagement with the private sector and executed on its strategy to accelerate the development and delivery of novel MCMs for non-COVID-19 related CBRN threats. Since the World Health Organization declared COVID-19 a Public Health Emergency of International Concern in January 2020, 14 BARDA supported products for threats such as Ebola, Zika, anthrax, smallpox and monkeypox, pandemic influenza, radiological injuries and nuclear blasts have been approved, licensed or cleared by the FDA. These accomplishments are the direct result of the investments made in these products and partnerships made between BARDA and the companies that discovered and developed them many years ago. BARDA continues to invest in new technologies and programs that deliver new products to the U.S. public to address existing and future threats to national health security. BARDA does this by identifying new technologies and new partners that will help us meet this critical mission. The ability of SNS and ASPR to maintain availability of supplies, particularly when there is no commercial market, is driven primarily by funding constraints, and not by any lack of engagement caused by COVID-19 response efforts.

e. What, if any, additional resources do HHS and/or ASPR need from Congress to ramp up its stockpile security?

Response: Enacting the funding level requested in the FY23 President's budget is critical to ensuring HHS and ASPR can continue to support the life-saving responsibilities outlined in supporting missions without diminishing capabilities.

96. Question:

Given Russia's aggression in Ukraine, there has been a notable increase in concern from national security experts on the growing risk and deployment of chemical and biological weapons, particularly on the use of illegal biological weapons.

a. What would be the consequences of a biological weapon attack, such as anthrax or smallpox, on human health in Ukraine?

Response: There would almost certainly be severe negative consequences to human health in Ukraine if a biological weapon attack occurred. The harm that would occur would depends on many criteria including but not limited to the agent used; the delivery mode; the magnitude of the attack; weather conditions; the degree to which infrastructure, institutions, and human resources have been undermined in the area attacked; whether there is active fighting in the area; whether combatants are willing to cooperate on mitigating the effects of an attack; and the capability to distribute available medical countermeasures for the specific biological agent. The degree of impact would also be affected by the type of biological weapon used because different biological agents possess different properties; some agents are highly transmissible and selective for humans and others are persistent agents which would create long-term contamination hazards and consequently long-term health risks for humans and animals. Individuals residing in areas damaged from recent bombings or areas experiencing resources shortages related to war-time conditions may be more susceptible to infection due to inadequate diets and environmental stress, and have delays or difficulty accessing healthcare, medical supplies, and medical countermeasures. Infection control measures may be difficult or impossible to instigate in the region and especially in areas experiencing active combat due to a limited number of healthcare workers and first responders who can provide immediate care, the availability of medical countermeasures, and other supply chain constraints.

In recent months, Russia has inflicted significant damage to Ukrainian infrastructure that is likely to impede Ukraine's ability to enact a swift and effective response to a biological weapon attack. The World Health Organization recorded over 160 incidents of Russian attacks on health care services in Ukraine, including attacks on health facilities, medical transport, health care personnel, patients, supplies, and supply warehouses. Russia's brutal war has also limited Ukraine's ability to recover from war damage and rebuild. Under these conditions, a biological weapon attack would be disastrous.

b. Given the unprecedented nature of these threats, what is HHS doing to ensure ASPR re-prioritizes the U.S. stockpile of drugs and vaccines that protect against CBRN weapons?

Response: While SNS has devoted significant time and resources (as appropriated by Congress in supplemental appropriations) to responding to COVID-19 over the last few years, SNS's annual appropriations have continued to support procurement of medical countermeasures (MCMs) necessary to respond to CBRN threats. Specifically, with additional funds requested in FY 2023, SNS would procure MCMs necessary to respond to smallpox, radiological and nuclear, and anthrax incidents.

c. What specific actions is HHS taking to ensure ASPR remains focused on the very real threat posed by CBRN weapons?

Response: The Biomedical Advanced Research and Development Authority (BARDA) within the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR) continues to develop innovative medical countermeasures (MCM) for the detection, prevention and treatment of non-infectious disease threats including chemical, radiological and nuclear (CRN) threats. The overarching strategy that drives development of MCMs for these threats is to "treat the injury, not the agent" and provides options for first responders and clinicians to treat the injuries they can easily see without regard to what specifically caused the injury.

97. Question:

The National Academies of Sciences, Engineering, and Medicine (NASEM) released a report in November 2021, *Ensuring an Effective Public Health Emergency Medical Countermeasures Enterprise*. The report provides recommendations for a re-envisioned Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). Four priority areas of improvement emerged, including collaborating more effectively with external public and private partners. One of the recommendations to achieve this priority area was to establish an advisory committee of nonfederal and private-sector partners and stakeholders.

a. Please describe HHS' plan, including the specific actions you plan to take, to work with ASPR to create and implement this PHEMCE advisory committee.

Response: ASPR recently relaunched the PHEMCE, with the first meeting of the newly reconstituted PHEMCE on February 24, 2022. The strategy has been to lead with the relaunch of the PHEMCE, which allows us to build connection, coordination, and momentum among the federal interagency on timely and relevant issues as we continue to build out the supporting elements of the PHEMCE, including engagement with key industry partners. We are pleased to see strong PHEMCE engagement and participation and look forward to continuing to drive progress through this forum.

b. Will the advisory committee's input be considered in all major decisions and actions by PHEMCE regarding the development and delivery of medical countermeasures?

Response: The PHEMCE exists to provide the HHS Secretary with recommendations and advice on key issues of medical countermeasures preparedness. We plan to continue leveraging their experience, expertise, and diverse perspectives on key issues. We also will engage individuals from their respective organizations, getting input and feedback from a variety of leadership levels.

d. Will the advisory committee assist with PHEMCE's strategic planning and decision making around stockpile needs and requirements, as well as interactions with other government agencies?

Response: Yes, the PHEMCE will be asked to engage on a number of issues impacting the Strategic National Stockpile's current and future holdings.

98. Question:

There remains concern around the threat of and the nation's preparedness to combat pandemic influenza. In addition to vaccines, antivirals are a critical medical countermeasure. Currently, the SNS includes only one type of influenza antiviral. HHS has previously recognized the gaps in influenza pandemic readiness, including the lack of supply and diversification of antivirals.

a. Does HHS and ASPR remain concerned about the supply and diversification of the antiviral stockpile for pandemic influenza?

Response: The United States Government has and continues to support preparedness for a flu pandemic. Specific to holdings in the Strategic National Stockpile (SNS), original products were purchased using funds provided in 2005 under a pandemic influenza supplemental. Historically, influenza antivirals were originally purchased by SNS using funds provided in 2005 under a pandemic influenza supplemental. In the absence of funds necessary to replenish influenza antivirals procured with supplemental funding, SNS has worked closely with the Food and Drug Administration (FDA) to extend the expiration dates of many of the influenza antivirals held by the SNS. The most recent extension of expiration dates for influenza antivirals held by SNS was granted in April 2022.

SNS plans to procure a limited quantity of influenza antivirals in FY 2022 using appropriated funding. These planned procurements will support the following recommendations included in the FY 2021 SNS Annual Review:

- Procure additional quantities of oral antivirals, including oral suspensions, for treatment in all populations to meet the requirements of 54,000,000 for adults, and 31,000,000 for pediatrics.
- Procure additional quantities of parenteral antivirals for treatment in hospital or ICU settings to meet the requirement of 1,200,000.HHS recognizes the threat posed by antiviral resistance and remains concerned about supply and diversification of antivirals to respond to pandemic influenza held by SNS.

b. If so, please describe how HHS plans to ensure ASPR addresses this lack of supply and diversification pandemic influenza antivirals.

Response: SNS currently holds two antivirals necessary to respond to respond to pandemic influenza. In accordance with a recommendation from the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), pending availability of funding in FY 2023, the SNS plans to expand its holdings of antivirals necessary to treat pandemic influenza by procuring a third antiviral not currently stockpiled by SNS.

As mentioned in the previous response, SNS plans to procure a limited quantity of influenza antivirals in FY 2022 using appropriated funding. These planned procurements will support the following recommendations included in the FY 2021 SNS Annual Review:

- Procure additional quantities of oral antivirals, including oral suspensions, for treatment in all populations to meet the requirements of 54,000,000 for adults, and 31,000,000 for pediatrics.
- Procure additional quantities of parenteral antivirals for treatment in hospital or ICU settings to meet the requirement of 1,200,000.

The FY 2023 President's Budget request includes $347 million in no-year funding and $35 million in annual funding for pandemic influenza. Based on lessons learned from the COVID-19 response, the requested $95 million in additional funding will support the advanced development of non-egg-based influenza vaccines and associated technologies by investing in: synthetic vaccine platforms; efforts to transfer technologies to public-private partnerships to improve pandemic response; and alternative vaccine delivery systems. Funds will be used to sustain previous investments in critical domestic influenza vaccine manufacturing facility infrastructure, and support development of improved vaccines. In addition to lessons learned from COVID-19, this strategy aligns with the Presidential Executive Order 13887 Modernizing Influenza Vaccines in the United States to Promote National Security and Public Health and the HHS Pandemic Influenza Plan Update.

99. Question:

The House of Representatives has now twice approved H.R. 3635, *Strengthening America's Strategic National Stockpile Act*, that includes a new grant program for states to establish state strategic stockpiles. The Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act (PREVENT Pandemics Act), introduced in the Senate as S. 3799, includes similar language.

a. Does HHS support the establishment of state strategic stockpiles?

b. If so, will HHS work with Congress to quickly establish state strategic stockpile guidelines and regulations to ensure these policies are implemented efficiently and effectively?

Response a-b: The HHS Secretary is aware of legislative proposals that seek to support states, territories, and large localities in the development of strategic stockpiles. Should Congress establish a grant program to establish state stockpiles, HHS will work to implement as required. There are several existing mechanisms that could help facilitate such an initiative, including the Centers for Disease Control and Prevention's (CDC) Public Health Emergency Preparedness (PHEP) program and Cities Readiness Initiative. Since 2002, the PHEP program has provided funding and guidance to all 50 states, four large metropolitan areas, and eight U.S. territories and freely associated states to build and strengthen their preparedness and response capabilities, such as medical countermeasure distribution and dispensing/administration. In addition, all 50 states and eight territories currently participate in the Cities Readiness Initiative, which is designed to enhance preparedness in the nation's largest population centers, to effectively respond to large public health emergencies needing life-saving medicines and medical supplies. If there is an effort to establish more robust medical stockpiles, it would be beneficial to review if current programs can be expanded to fulfill the objectives of future initiatives to minimize burden across jurisdictions and avoid duplication.

100. Question:

The Pandemic and All-Hazards Preparedness and Advancing Innovation Act (PAHPAIA) of 2019 established a framework to support public private partnerships, with the goal of capitalizing on the experience and efficiency of the private sector to improve the ability of the Strategic National Stockpile (SNS) to respond to public health emergencies and national security threats. Building on this success, H.R. 3635, *Strengthening America's Strategic National Stockpile Act of 2021*, included a provision establishing a pilot program that would work with manufacturers and distributors of medical supplies to manage domestic reserves of such critical supplies.

a. How can the SNS best leverage its relationships with private sector companies and associations to improve its ability to respond to the next PHE?

Response: ASPR has long worked through BARDA and SNS to engage manufacturers and supply chain partners both directly and through trade associations. The focus of this work has been to identify and address supply chain security and stability concerns identified as vulnerabilities or opportunities for improvement of access to critical MCMs during public health emergencies.

ASPR will continue to engage private sector partners in these discussions, and include them in initiatives such as the Supply Chain Control Tower. Access to private sector data, capabilities, guidance and participation are critical to successful government engagement on supply chain challenges, to include deployment of stockpiled resources, strategic investment in production capacity, or coordinated allocation of scarce resources during shortages or supply chain disruptions.

While pro-active communication and coordination is key to enhancing supply chain stability, HHS must also be prepared to invest in and support private sector partners in these initiatives

to invest in and fund sustainment of capabilities developed beyond established commercial market demand.

b. Under the current framework, does HHS have a similar or adequate capacity as the private sector to rapidly distribute and deliver medical supplies to healthcare providers?

Response: Under current operations, the SNS is designed to provide requested material or countermeasures to the State for dissemination. The SNS does not provide material directly to healthcare providers. In order to deliver medical supplies to healthcare providers during the COVID-19 response, SNS put several distributor working model contracts into place with private sector companies to enhance distribution capacity.

c. What is HHS' current understanding of the capacity of the commercial supply chain and how it can support the government to meet supply demand during public health emergencies?

Response: The pandemic severely strained our public health and medical supply chains. The medical supply chain ecosystem is complex, with different private sector players and market dynamics across multiple domains of medical equipment and supplies. HHS/ASPR has been focused on revitalizing and rebuilding our nation's domestic manufacturing capacity. HHS/ASPR contributed to the development of a 100-day report released June 2021 on supply chains as part of EO14001. This Report examined the supply chain and included a focus on mapping the supply chain, risk assessment of the overall system, a review of the global footprint, and included recommendations to strengthen current capabilities and enhance preparedness for public health emergencies.

In addition to supporting the development and implementation of actions associated with this report, HHS has supported efforts to strengthen the overall domestic manufacturing base to ensure we are better positioned and prepared for public health emergencies. Within HHS, ASPR is supporting efforts to institutionalize domestic manufacturing efforts. Specifically, ASPR is integrating and organizing supply chain situational awareness and industrial analysis, domestic industrial base expansion, and supply chain logistics. Bringing these pieces together will strengthen our industry partnerships and support our work to establish and maintain resilient supply chains.

d. If there is a lack of understanding, what additional action is needed by Congress or otherwise to strengthen these partnerships?

Response: HHS has strong and robust partnerships with the private sector. While the Department would be more than willing to provide technical assistance on legislation, there is no specific action or requirement that is requested of Congress at this time respective to these authorities.

e. What is HHS' position on establishing a vendor managed inventory framework for critical products, such as personal protective equipment or testing supplies, particularly in the context of ensuring non-expired product be made rapidly available to the government?

Response: The SNS uses VMI contracts when appropriate. The COVID-19 response has significantly increased SNS's use of VMI to assist with surge capacity. Currently SNS is using VMI contracts for maintenance and management of medical ventilators; material management and kitting support for ancillary kits used to support vaccination efforts; and storage and management of personal protective equipment, pharmaceuticals, and other medical material procured to support the COVID-19 response.

While SNS's use of VMI has expanded during the COVID-19 response, allowing the SNS to rapidly increase capacity, contracts using VMI account for approximately 10% of SNS contracts. Traditionally, VMI contracts work best when there is a commercial market for the product and when the inventory is continually refreshed. They do not work well for products that have limited commercial market support, such as products for specific CBRN needs.

Notable limitations to the VMI approach include:

- Lack of 24/7 access to VMI facilities for immediate deployment, and limited geographic distribution of VMI facilities with potentially one facility shipping to all destinations (both of which could hinder provision of the countermeasures in a clinically relevant time frame);
- Large SNS requirements that exceed the rotational capability of vendors; and,
- Added costs associated with exercising VMI partners' rotational and deployment capability and including options for packaging and delivery specifications into contracts.

Currently, 10 percent of SNS contracts utilize vendor managed inventory. The SNS had an increase in VMI contracts for Covid when there were significant purchases of PPE since PPE is commercially available product and sees great product use and rotation on the commercial market. VMI works well for commercially available products that have high use and rotation.

101. Question:

Sustained, reliable, and robust funding is critical to the country's ability to prepare for, respond to, and recover from public health emergencies. Lack of long-term, designated funding for these efforts has led to a pattern of borrowing from the previous disaster to pay for the next (i.e. the Zika response was largely paid for with funding originally intended for the Ebola crisis). What resources does HHS need from Congress to ensure HHS is not only able to continue to respond to and recover from the COVID-19 pandemic, but also ensure we are adequately prepared for the PHE?

Response: The Administration's supplemental request, which OMB submitted in a formal request to Congress on March 2, 2022, is $22.5 billion for the COVID-19 response, of which $18.25 billion is for the U.S. Department of Health and Human Services (HHS). This request will cover immediate needs for tests, treatments and vaccines, investments in research and

development of next-generation vaccines, and responding globally, including getting more shots in arms around the world.

The COVID-19 response has illuminated both longstanding and newly discovered limitations in our local, national, and international health systems and health security capabilities. It has also resulted in an unparalleled, multisectoral, whole-of-society response, which has galvanized breakthrough innovation. HHS has made great progress in combatting COVID-19 and building better health security to protect against future pandemics and other health emergencies. However, much more is needed to prevent future biological catastrophes.

The FY 2023 President's Budget includes $88.2 billion in mandatory funding over five years, of which $81.7 billion is requested across the Office of the Assistant Secretary for Preparedness and Response (ASPR), Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH), and Food and Drug Administration (FDA) to support President Biden's plan to transform U.S. capabilities to prepare for and respond rapidly and effectively to future pandemics and other high consequence biological threats. This investment will fund transformative improvements in our capabilities to prevent, detect, and respond to emerging biological catastrophes. We recognize the additional $6.5 billion in mandatory funding, requested for State and USAID, will also help the United States and the world be better prepared to prevent, detect, and respond to infectious disease threats, including by supporting the new Financial Intermediary Fund for Pandemic Prevention, Preparedness, and Response *(Pandemic Fund)* at the World Bank.

The additional funding requested in the Budget for HHS will help transform our capability to rapidly produce and deliver countermeasures against pandemics and other biological threats; strengthen our public health infrastructure and early warning capabilities; invest in basic research to enable an effective response to novel pandemics and biological threats; modernize and streamline our regulatory infrastructure; and, advance biosafety and biosecurity in the United States and globally to prevent biological incidents.

102. Question:

The Administration's Budget includes $40 billon for ASPR, a portion of which is designated for fill/finish capabilities, domestic manufacturing of raw materials and needles/syringes, and large-scale vaccine platform technology manufacturing capacity. Please describe the current status and progress of ASPR's Program Office for Innovation and Industrial Base Expansion, as well as any identified gaps to which this funding was intended.

Response: As you are aware, the pandemic severely strained our public health and medical supply chains. The medical supply chain ecosystem is complex, with different private sector players and market dynamics across multiple domains of medical equipment and supplies. The Office of the Assistant Secretary for Preparedness and Response (ASPR) has been focused on revitalizing and rebuilding our nation's domestic manufacturing capacity.

ASPR is examining ways to strengthen the nation's supply chain to ensure a robust and resilient public health supply chain is in place to support any national response to public health

emergencies. Specifically, ASPR has established an Industrial Base Management and Supply Chain Office with focus on building the nation's capacity to manufacture personal protective equipment (PPE), essential medicines/chemicals, diagnostic tests and vaccines, and to bring these critical capacities back to American shores. The Office also includes a support division focused exclusively on the applicability and, when appropriate, the use of Defense Production Act authorities to advance U.S. interests in this space. The Office is also supported by a "Supply Chain Control Tower" that utilizes new data management and analytical teams to generate real time insights into issues impacting these areas within the public health supply chain, and helps ASPR anticipate challenges and identify opportunities for investments that will bolster the public health supply chain and better prepare the country for future public health emergencies.

103. Question:

Doctors of Osteopathic Medicine (DOs) are trained and licensed to provide osteopathic manipulative treatment (OMT), a form of manipulation that can be used to treat structural and functional issues in the bones, joints, tissues, and muscles of the body. Osteopathic medical students receive training in the musculoskeletal system and learn the value of OMT as a non-pharmacological alternative to pain medication. This advanced training provides DOs with an understanding of how the body's systems are interconnected and can be used as a powerful tool for individual healing and performance. Please describe any HHS programs or initiatives that explore the benefits of OMT.

Response: As you've noted, osteopathic medicine is a fast-growing area of the medical field that makes up a significant portion of primary care providers in the U.S. The osteopathic medical education community and DOs serve an integral role in the HHS Initiative to Strengthen Primary Health Care – the guiding principles of which are equity, access, and health outcomes.

The HHS Initiative to Strengthen Primary Health Care (the Initiative) aims to improve the health of individuals, families and communities and improve health equity by strengthening the foundation of our health care system, primary health care. This means equitable access for all to primary health care that is comprehensive, coordinated across health care settings and sectors, including human services providers, and delivered by interprofessional teams.

Osteopathic medical schools and graduate medical education programs are important for educating and training our next generation of primary health care professionals and have demonstrated success in placing physicians in rural and underserved communities. The Office of the Assistant Secretary for Health, which is coordinating the Initiative, met with the American Association of Colleges of Osteopathic Medicine (AACOM) in April 2022 to discuss the Initiative and the important role of osteopathic medicine providers. The Initiative alerted AACOM to the forthcoming Request for Information to inform the HHS plan for strengthening primary health care. The Initiative envisions ongoing community and stakeholder engagement in the implementation of actions to strengthen primary health.

DOs play a substantial role in making up interprofessional teams and supporting and receiving interprofessional training in community-based, primary care practice environments in Fiscal Year (FY) 2022 and beyond. Many of HRSA's programs focus on supporting interprofessional

training, integrating traditional primary care providers with interprofessional teams, and/or aligning the workforce with the unique communities they serve. These programs include:

- the Primary Care Training Enhancement (PCTE): Integrating Behavioral Health and Primary Care Program (active through FY 2024),
- the Teaching Health Center Graduate Medical Education Program (active through FY 2024),
- the Opioid Workforce Expansion Program (OWEP) Professionals (active through FY 2022),
- the Addiction Medicine Fellowship Program (active through FY 2025), and
- the Behavioral Health Workforce Education and Training Program for Professionals (active through FY 2025).

HHS is hopeful that DOs and the osteopathic medical education community will continue to have an active role in expanding access to primary care via community-based settings, especially those in areas of greatest need.

Questions from The Honorable Neal P. Dunn, M.D. (R-FL)

104. Question:

It's come to my attention that HHS' Children's Bureau (CB) is withholding Title IV-E funds for Florida to subgrant to the Statewide Guardian ad Litem Office (GAL) over questions about GAL ability to provide independent legal representation. This appears to be contrary to the operation of the Florida Statewide GAL and recent policy announcements by the CB recognizing the Florida model.

Can you provide me with an explanation of why the Title IV-E funds are being withheld?

Response: In recognition of the evidence of the positive benefits of high quality legal representation for children and parents and its essential role in supporting a well-functioning child welfare system, CB issued revised and new policies in 2019 that allow title IV-E agencies to claim federal financial participation (FFP) at a rate of 50 percent for administrative costs of independent legal representation provided by attorneys representing children in title IV-E foster care, children who are candidates for title IV-E foster care, and their parents for "preparation for and participation in judicial determinations" in all stages of foster care legal proceedings. Previous policy prohibited the agency from claiming title IV-E administrative costs for legal services provided by an attorney representing a child or parent.

To claim legal representation costs, a title IV-E agency must submit for approval an amendment to its cost allocation plan, identifying procedures and methodologies for ensuring that costs claimed under title IV-E are only for allowable costs of independent legal representation provided to eligible children in foster care or who are candidates for IV-E foster care. Florida has submitted a cost allocation plan amendment which was reviewed by program and financial staff in the Administration for Children and Families and CB who provided comments and questions for response by the state. Responses to a number of questions are still pending with

the State. As of March 2022, the Florida Department of Children and Families indicated that it was working with the office of the Guardian Ad Litem to respond to some of the questions.

We in HHS appreciate the partnership that we share with Florida. We are committed to supporting Florida and all states in providing high quality, independent legal representation to children and parents involved with the child welfare system. In partnership, we will continue to work with the state to support them in being able to access federal resources to support legal representation, consistent with federal requirements and guidelines.

105. Question:

With each new variant that emerges, there is a lack of population-level data on how our immune systems respond—not just antibodies but also T-cells. This is limiting our ability to inform public health policy decisions. Last week a letter was sent by to you a number of experts in the field of cellular immunity urging the FDA in its guidance to vaccine developers to include a recommendation for T-cell assessment in COVID-19 vaccine clinical trials to more comprehensively measure immune response.

a. Given the need to understand the efficacy of COVID-19 vaccines and boosters that can only be answered by understanding both T-cells AND antibodies, can you share what steps FDA is taking to guide manufacturers to generate this data?

Response: FDA agrees that greater understanding of the role of T-cell response in protection against COVID-19 could be useful to the scientific and public health community. As noted in FDA's guidance document, "Development and Licensure of Vaccines to Prevent COVID-19," (https://www.fda.gov/media/139638/download), understanding of SARS-CoV2 immunology and vaccine immune responses that might predict protection is limited and evolving. The guidance also states that "once additional understanding of … vaccine immune responses that might be reasonably likely to predict protection … is acquired," it may be possible to approve a COVID-19 vaccine under accelerated approval, if an applicant provides sufficient data and information to satisfy the applicable requirements. In addition, one of the references that the authors of the letter cite, an article published in *Science Immunology*, states that "a comprehensive understanding of the adaptive immune response to SARS-CoV-2 infection is imperative." The article also notes that "[d]efining what constitutes a protective versus harmful T cell response [to SARS-CoV-2] warrants further investigation."[23] Basic scientific research is necessary to assess the contribution of T-cell responses to protection.

b. How can on-going and new cellular immunity research with respect to COVID-19 being conducted at the NIH support efforts to integrate T-cell data into vaccine, booster, and other public health decisions at FDA and the federal government at large?

Response: NIAID investigators will continue to integrate T cell data into vaccine and booster research, including in clinical studies and pre-clinical challenge studies for COVID-19 vaccine

[23] S. Vardhana, L. Baldo, W. G. Moriceii, and E. J. Wherry, "Understanding T Cell Responses to COVID-19 Is Essential for Informing Public Health Strategies," *Science Immunology*, 7:71 (March 24, 2022): available at https://www.science.org/doi/10.1126/sciimmunol.abo1303.

candidates. For example, NIAID is supporting a Phase 1 clinical trial in healthy adults to assess the safety and immunogenicity of COVID-19 vaccine candidates developed by Gritstone Oncology, Inc., that utilize a strategy aimed at inducing both neutralizing antibodies and T cell responses to elicit a broad immune response against conserved viral antigens. In addition, the NIAID Vaccine Research Center (VRC) has established the Pandemic Response Repository through Microbial/Immune Surveillance and Epidemiology (PREMISE) program. The program will use data from the measurement of T and B cell immune responses to inform the discovery and development of diagnostic, prophylactic, and therapeutic countermeasures and accelerate the global response to pandemic threats. NIAID anticipates the research conducted by PREMISE will advance our knowledge of immune responses to vaccination and infection and help inform the response to future pandemic threats.

NIAID also is leading a study in fully vaccinated individuals to assess the safety and immune responses (including T cell responses) following boosting with a COVID-19 vaccine different than the one used for the initial vaccination ("mix and match"). NIAID released early data from this trial demonstrating that administering the Pfizer, Moderna, or Johnson & Johnson/Janssen COVID-19 vaccines at least 12 weeks after individuals received a different vaccine regimen effectively enhanced the immune response to SARS-CoV-2. The results of this trial were made available to the U.S. Food and Drug Administration (FDA) during FDA's decision-making process to authorize the use of heterologous, or "mix and match," booster dosing in eligible individuals following completion of primary vaccination with a different available COVID-19 vaccine for persons 18 years of age and older. NIAID-supported scientists shared results of the "mix and match" study with the FDA Vaccines and Related Biological Products Advisory Committee during its public meeting on October 15, 2021, and with the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices during its public meeting on October 21, 2021.

As noted above, research that yields informative and practical means to measure relevant immune responses could be helpful in both developing COVID-19 vaccines and boosters, and informing FDA's evaluation of vaccine safety and effectiveness.

106. Question:

A recent paper in *Science Immunology* [*Understanding T-cell responses to COVID-19 is essential for informing public health strategies*] discusses the need to understand the complete immune response to COVID-19 to inform public health policies and interventions.

a. How can immune response data, including both Abs and cellular immunity, be used by the FDA or other public health entities to measure the U.S.' progress towards herd immunity and inform future public health guidance as additional variants emerge?

Response: There is no known threshold of population antibody seroprevalence which, when achieved, will stop community transmission of SARS-CoV-2. Both infection-induced and vaccination-induced protection against infection are not 100%, and protection wanes over time. Coronaviruses, the family of viruses to which SARS-CoV-2 belongs, typically do not induce long-term sterilizing immunity and reinfection throughout our lifetimes is common. Primary infection usually results in developing memory T and B cell responses – and these provide a

memory immune response that likely protects from severe disease and shorten the duration of disease.

More research is needed to understand the role of SARS-CoV-2 T-cell testing and serology testing in evaluating a person's immunity or protection against COVID-19. Antibody levels associated with protection against SARS-CoV-2, known as a correlate of protection, have not been established. Furthermore, at present there is an incomplete understanding by the scientific community of the nature of COVID-19 herd immunity or how measurements might be useful. In certain cases, FDA considers neutralizing antibody titers (a functional measure of the vaccine immune response against SARS-CoV-2) to be clinically relevant to infer effectiveness of COVID-19 vaccines. Because no specific neutralizing antibody titer has been established to predict protection against COVID-19, two immunogenicity endpoints (Geometric Mean Titer and Seroresponse rate) are considered appropriate for comparing the range of neutralizing antibody responses elicited by the vaccine.

b. How has technology to measure T cells changed in the last decade? Can you explain recent advances that might enable vaccine manufacturers to provide this information at scale?

Response: Within the U.S. Department of Health and Human Services (HHS), the NIAID, a component of the NIH, conducts and supports research to improve understanding of the role of T cells in protection against infectious diseases and their involvement in allergic and immunologic diseases. Over the last decade, the ability for scientists to assay T cell responses in a high throughput manner has improved the speed and efficiency of research in this area. In addition, advances in sequencing technology, sampling protocols, and molecular and structural biology techniques facilitated new approaches that allow for the use of easier and more relevant sample preparation and the generation of more robust T cell data.

NIAID researchers published multiple assays that can be used to define T cell responses to vaccinations using blood samples from vaccinees. These assays utilize flow cytometry to detect the specificity, types and functions of T cells, which can lead to deeper insights into immune responses, and their durability, against pathogens or immune pathologies. NIAID-funded researchers also have developed an assay for T cell function, called the Activation Induced Marker (AIM) assay. This protocol stimulates T cells *in vitro* using pathogen specific peptides and then measures activation markers by flow cytometry. The AIM assay can provide a broader view of the total antigen-specific T cell response to enable a more comprehensive evaluation of vaccine immunogenicity and, unlike other techniques, allows for the isolation and preservation of live cells.

NIAID also supported research that utilized rapid gene sequencing and bioinformatics to enable direct analysis of T cell receptors (TCR), the molecular structures that determine what T cells recognize. NIAID-funded investigators used advanced computational techniques to identify the antigens that the T cells could detect and respond to. This technique is similar to that used by the T Detect COVID Test developed by Adaptive Biotechnologies, which received emergency use authorization from FDA for identifying individuals with an adaptive T cell immune response to SARS-CoV-2, indicating recent or prior infection.

When performed on longitudinal samples, TCR sequencing also can be used to assess changes in the T cell response over time. Sequencing has the advantage that it can be performed on blood samples with minimal handling in the lab. Development of single cell nucleic acid sequencing allows researchers to reconstruct and examine the highly variable TCR with an unprecedented level of detail. Using these techniques, analysis of the repertoire of TCRs in clinical samples is currently being performed in NIAID-funded longitudinal Covid-19 Prevention Network (CoVPN) studies of the immune response to SARS-CoV-2 infection.

The NIAID-supported HIV Vaccine Trials Network (HVTN) uses state-of-the-art functional T cell assays to assess novel HIV vaccine candidates. Advances in flow cytometry, like the ones described above, and sampling techniques, including fine-needle aspirates of lymph nodes, have enabled improved analysis of T cell function within these vaccine trials. Fine-needle aspiration of lymph nodes, where the cell-to-cell interactions necessary for protective immune memory (T cell, B cell, and antibody responses) occur, enables more accurate evaluations of vaccine responses.

These advanced techniques are powerful tools to uncover and understand T cell responses. T cell assays often are more difficult to perform at scale and tend to be overlooked in favor of antibody assays. However, basic and clinical researchers in the public and private sectors are rigorously studying the critical role of T cells and developing new techniques that continue to progress this critical field forward. HHS is committed to continuing to fund research in this important area and to working together with vaccine developers to leverage the newest technologies for public health.

107. Question:

Congress included language in our FY22 appropriations bill encouraging NIH to conduct additional research around cellular immunity for COVID-19 and requesting an HHS-wide assessment of the department's efforts to incorporate cell-mediated immunity measures.

a. How might this kind of data assist FDA in assessing the effectiveness of vaccines, boosters, and therapeutics?

Response: The mission of FDA is to protect and promote the public health, in part by ensuring the safety and effectiveness of the products we regulate. In keeping with that mission, FDA uses every tool available to help patients access promising medical products while facilitating research to evaluate their safety and effectiveness as well as manufacturing efforts. Research that yields informative and practical means to measure relevant immune responses will be very helpful in both developing COVID-19 vaccines and informing FDA's evaluation of vaccine safety and effectiveness.

Throughout the pandemic, as the virus that causes COVID-19 has continuously evolved, the need for FDA to quickly adapt has meant using the best available science to make informed decisions with the health and safety of the American public in mind.

b. How can FDA work with CDC and outside stakeholders to make this sort of data collection a reality?

Response: All of the Agency's COVID-19 response efforts are in close coordination and collaboration with our partners, both within the Department of Health and Human Services (HHS) and across the federal government, to help ensure the development and availability of critical, safe, and effective medical products to address the COVID-19 public health emergency.

108. Question:

Congress also required a report within 60 days of enactment "on the efforts of the Department to incorporate cell-mediated immunity measures into the Department's COVID-19 surveillance and research strategy."

a. The President signed the omnibus on March 15, meaning that report is due to Congress in less than three weeks. Will that report be delivered to Congress by the deadline?

Response: The Department is aware of the request for this report and is working to provide it to the subcommittee.

Questions from The Honorable Dan Crenshaw (R-TX)

109. Question:

Fentanyl is the number one killer of Americans between 18 and 45. In 2020 fentanyl killed more Americans than car crashes, suicides, cancer, gun violence, and COVID-19. But, in your written testimony, you didn't mention fentanyl once.

a. Secretary Becerra, do you consider the fentanyl epidemic a PHE?

b. You have pursued an approach of "harm reduction"—like fentanyl test strips to help users identify contaminated drugs. What is your view of preventative policies, rather than harm management policies, to reduce access to fentanyl?

Response*:* As a result of the continued consequences of the opioid crisis affecting our nation, on April 1 I renewed the determination that an opioid public health emergency exists nationwide.

Both primary prevention and harm reduction activities are two of the four pillars of the Overdose Prevention Strategy. In acknowledging that fentanyl (and other synthetic opioids) were responsible for the spike in the nation's opioid overdose epidemic, we directed that SAMHSA, through some of its grant programs, make fentanyl strips available to their constituencies (i.e., people who use drugs, their caretakers, and those with whom they have contact.) SAMHSA grant programs such as the First Responder Training for Opioid Overdose-Related Drugs and the Harm Reduction grant program are now allowing fentanyl test strips to be used with grant funds. A significant aim of harm reduction is to keep people who use drugs alive, for longer periods of time, which often results in connecting these individuals to treatment and helping them achieve and sustain recovery. This approach meets people where they are to prevent various levels of drug misuse, harmful health indicia consequent to drug use, and overdose deaths.

110. Question:

HHS, in partnership with the White House, is issuing a call to action for health care stakeholders to commit to tackling the climate crisis through a new initiative aimed at reducing emissions across the health care sector. United States hospitals, health systems, suppliers, pharmaceutical companies and other industry stakeholders are invited to submit pledges to reduce greenhouse gas emissions and increase their climate resilience.

a. You say this pledge is "voluntary," however you are stating that we need "all players on the field confronting the climate crisis" and "sitting on the sidelines is not an option." When a company regulated by HHS hears this, even if you say it is voluntary, how can they possibly believe that this is actually voluntary and that there will be no backlash if they do not participate in this program?

b. This is a federal agency circumventing the authority that Congress gave them by establishing a "voluntary program" that is not linked to a single statutory authority that exists under HHS. This creates a chilling atmosphere that discourages companies from building and investing in the United States. It is also concerning that the SEC is working on a rulemaking that significantly overlaps with this "voluntary" initiative that is currently out for public comment. It seems that HHS is trying to influence an independent agencies rulemaking or scare companies from commenting on that rulemaking.

c. Based on all of this, can you explain and provide what analysis HHS did before issuing this clearly not voluntary initiative on their regulated companies? Specifically, what statutory authority do you believe you have to start this initiative? What are the economic or public health impacts from this initiative? What internal HHS resources are being devoted to this program and how was it authorized?

Response a-c: The Health Care Sector Pledge invited organizations to commit to lowering their greenhouse gas emissions and building more climate resilient infrastructure. As noted on the Department of Health and Human Services (HHS) website, the pledges made are voluntary, and the organizations that signed this pledge are not obligated to report data on their progress to the federal government in association with this pledge. It is our understanding that several health systems are already reporting data on their emissions for state and federal requirements. HHS created the Office of Climate Change and Health Equity in response to the requirement to do so from Section 222(d) of Executive Order 14008, Tackling the Climate Crisis at Home and Abroad. Under Title XVII of the Public Health Service Act, the Secretary of HHS has authority to engage in health information and health promotion activities, including authority to determine and study environmental factors which affect and determine health and ascertain programs and areas for which educational and preventive measures could be implemented to improve health as it is affected by such factors. The Fiscal Year 2023 President's Budget includes a request for $3 million in funding for OCCHE.

111. Question:

While the moonshot is led out of the White House, I am curious to better understand the role that you and the many relevant agencies at HHS will play in the reignited Cancer Moonshot? Can

you provide additional context as to your role and how you will effectively ensue that HHS and its many divisions are effectively collaborating with the Cancer Moonshot, other agencies, and amongst themselves?

a. The Cancer Moonshot's initial priorities were to "to accelerate scientific discovery in cancer, foster greater collaboration, and improve the sharing of data"—yet as seen with colorectal cancer and too many other cancers, more still needs to be done along these parameters to ensure that we can accomplish the reignited Cancer Moonshot's goals of "to reduce the death rate from cancer by at least 50 percent over the next 25 years and improve the experience of people and their families living with and surviving cancer—and, by doing these and more, to end cancer as we know it today". Can you please elaborate on how HHS will help the reignited Cancer Moonshot address the original priorities? Please provide a special emphasis on collaboration among agencies alongside researchers, the patient advocacy community, and other stakeholders, as well as how data sharing will be improved.

b. Too often, patient leaders cite experiences in which officials at research agencies do not take seriously their concerns or meaningfully engage with patients, so I would particularly like to hear about how the Administration will ensure things will be different with the reignited Cancer Moonshot. The Cancer Moonshot should have a mechanism to ensure meaningful patient engagement in project selection and development. Could you talk about what form that mechanism could take? How will you ensure patient voices will be heard beyond listening sessions?

Response: President Biden announced the reignited Cancer Moonshot [SM] initiative would take a renewed, whole-of-government approach to tackle new goals aimed at ending cancer as we know it. HHS and its relevant component agencies are key participants in the government-wide Cancer Cabinet established as part of the reignited initiative. Participation in the Cabinet by representatives across departments and agencies enables collaborative involvement in planning and coordination, while ensuring that new efforts will build on the original Moonshot's previous investments and health advances. For example, NCI, part of the NIH, leads a major research effort as part of the original Cancer Moonshot launched in 2016, and as a key participant in the Cancer Cabinet, NCI will continue to play an important role in the reignited Cancer Moonshot.

NCI recognizes that sharing genomic, epidemiologic, and clinical data is essential to advancing progress for cancer patients. In supporting the goals of the initial Cancer Moonshot, NCI is developing a National Cancer Data Ecosystem to enable and encourage all participants across the cancer research and care continuum to share, access, combine, and analyze diverse data sets. Elements of this cloud-based ecosystem already in place include the NCI Genomic Data Commons, the Proteomic Data Commons, the Data Commons Framework, and NCI Cloud Resources. To enhance the Cancer Research Data Commons, NCI is also developing the Imaging Data Commons, the Cancer Immunologic Data Commons Network, the Center for Cancer Data Harmonization, and the Cancer Data Aggregator.[24] NCI will continue to utilize these data sharing resources to support research activities of the reignited Cancer Moonshot, and

[24] www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative/implementation/data-ecosystem

data sharing will remain a top priority, both for the Moonshot, and across other NCI-supported research efforts, including the complementary Childhood Cancer Data Initiative.[25]

CDC is involved in multiple initiatives to advance various priorities set out in the Cancer Moonshot. CDC is one of 8 federal partners that is contributing to a larger HRSA initiative, the Federal Cervical Cancer Collaborative (FCCC) to accelerate federal and safety net settings of care patient engagement for prevention, screening and treatment of cervical cancer and other cancers. As part of this initiative, agencies are working to develop patient engagement materials to support the goal of accelerated cervical cancer prevention and control within HRSA-supported and safety-net settings of care. CDC is also supporting the moonshot commitment to cancer prevention and control by accelerating efforts to eliminate cervical cancer through CDC's National Breast and Cervical Cancer Early Detection Program (NBCCEDP) which helps women with low incomes who are uninsured or underinsured get breast and cervical cancer screening and diagnostic services.

CDC's National Program of Cancer Registries (NPCR) and the National Cancer Institute's (NCI's) Surveillance, Epidemiology, and End Results (SEER) Program are also working to improve cancer surveillance for the nation. CDC funds cancer registries in 46 states, the District of Columbia, and territorial jurisdictions to collect data on cancer occurrence, the type of initial treatment, and outcomes.

Input across a diverse array of perspectives will be essential to the success of the reignited Cancer Moonshot. In May, federal departments and agencies that are part of the Cancer Cabinet – including HHS and several of its component agencies – will host a series of virtual roundtable discussions to inform and advance Cancer Moonshot priorities. These "Cancer Moonshot Community Conversations,"[26] addressing topics such as cancer and environment, diversity and equity, clinical trials accrual, tobacco cessation, and rural health settings, among others, are one way we have provided venues for all Americans to join the mission of reducing the deadly impact of cancer and improving patient experiences.

As the renewed Cancer Moonshot initiative embarks on planning activities over the next year, it will be imperative that representatives of the entire cancer community are involved. Toward this goal, in conjunction with the announcement of the next phase of the Cancer Moonshot, the White House created a special web page, www.whitehouse.gov/cancermoonshot/, where interested parties can submit stories of personal experiences, ideas, and proposed actions to help deliver on this bold mission.

Within HHS, the incorporation of cancer advocacy community perspectives has long been critical to the Department's work. The NCI Office of Advocacy Relations manages the NCI Council of Research Advocates (NCRA), a federal advisory committee comprised solely of advocate leaders who represent the broad cancer patient community. The NCRA regularly convenes to discuss cancer research issues – including those relevant to the Cancer Moonshot – and provides the NCI Director with strategic insights.

[25] www.cancer.gov/research/areas/childhood/childhood-cancer-data-initiative

[26] www.whitehouse.gov/cancermoonshot/events-and-webinars/past-events/

Additionally, patient advocates and members of the broader cancer community continue to engage directly in Cancer Moonshot activities. From its inception in 2016, the Cancer Moonshot has included patient advocates in its planning process, including through service on the Cancer Moonshot Blue Ribbon Panel,[27] and over time through the Moonshot's continued research efforts to establish a network for direct patient engagement.[28] To date the Cancer Moonshot is supporting several initiatives to engage a diverse set of patients in cancer research to ensure that research and clinical trials can benefit people from all communities. These networks and programs include the Cancer Moonshot Biobank,[29] the NCI Comprehensive Oncology Network Evaluating Rare CNS Tumors (NCI-CONNECT),[30] My Pediatric and Adult Rare Tumor Network (MyPART),[31] and the Participant Engagement and Cancer Genome Sequencing (PE-CGS) Network.[32]

As President Biden reignites the Cancer Moonshot with participation across the Department and across the Administration, patient engagement remains a central focus at NCI, HHS, and for all of our federal partners.

112. Question:

In a recent request for information, the Health Resources and Services Administration (HRSA) raised questions to improve the performance of the Organ Procurement and Transplantation Network, specifically related to contracting and operations. I believe it is critical to allow a more competitive process to improve the performance of the procurement and donation system. We need expertise beyond the United Network and Transplantation Network to help improve the function and official work of the OPTN.

a. What additional steps and timelines is the Department considering to advance these goals?

Response: HHS will leverage feedback from the 2022 Request for Information (RFI) to gauge the interest and capabilities of vendors to handle the entirety of the Organ Procurement and Transplantation Network (OPTN) operational functions, to include the technology, oversight, and policy development responsibilities. The RFI will support HRSA's efforts to increase accountability in OPTN operations, modernize performance of the OPTN IT system and related tools, and improve engagement with donors and patients. It specifically focuses on opportunities to strengthen equity, access, and transparency in the organ donation, allocation, procurement, and transplantation process in the contract arrangement that results from the forthcoming Request for Proposal. In addition to seeking feedback on the governance, finance, IT, data collection, policy, and operational components of the OPTN contract more broadly, this RFI

[27] www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative/blue-ribbon-panel/members

[28] www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative/implementation/patient-engagement

[29] moonshotbiobank.cancer.gov/

[30] www.cancer.gov/rare-brain-spine-tumor/

[31] www.cancer.gov/research/cancer-research-partners/research-studies/mypart-study

[32] epi.grants.cancer.gov/events/pe-cgs/

specifically solicits feedback on ways to incorporate the findings and recommendations of the February 2022 National Academies of Science, Engineering, and Medicine report titled Realizing the Promise of Equity in the Organ Transplantation System, as well as the lessons learned from HRSA's 2019 market research, conducted in partnership with the U.S. Digital Service, on ways the OPTN IT system should leverage modern IT architecture. HRSA plans to utilize the responses and comments to strengthen the Performance Work Statement for the upcoming OPTN contract solicitation scheduled for later this year.

113. Question:
In the past you have had some difficulty acknowledging the existence of the Partial-Birth Abortion Ban, which is a federal law barring an abortion procedure that involves partially delivery a child, cutting a hole in the baby's neck and crushing their skull by suctioning the brain (see 18 USC 1531). Federal law also defines a baby who is born alive – even after an abortion – as a person. Despite your difficulty acknowledging federal protections for the unborn, you often say you will uphold the law. Recently the remains of five unborn children who died in an abortion clinic have been made available to the District of Columbia Medical Examiner, and he has refused to conduct an autopsy. This is alarming since there is substantial evidence that these babies may have died as a result of an illegal partial-birth abortion or even died after being born alive.

a. Will you call on the DC Medical Examiner to conduct an autopsy?

114. Question:
Do you think a child who survives an abortion should be given health care? YES OR NO. Is it ok if a baby born in an abortion clinic is killed after birth? Is there any circumstance in which you think a baby who dies in an abortion facility should be investigated?

Response 113-114: The Department will continue to enforce the law.

115. Question:
Is it accurate to say that Alzheimer's patients will have to join government-approved studies, such as patient registries or clinical trials, to gain access to FDA-approved treatments? Do you support policies that, effectively, tell seniors they must agree to give the government their health data, and be part of an experiment, in order to gain access to a treatment the FDA has deemed safe and effective?

116. Question:
Historically, CMS has deferred to the judgement of physicians when it comes to deciding what FDA-approved Medicare Part B drugs are best for their patients; why doesn't CMS trust physician judgement in this instance?

117. Question:
I'm concerned that, in its final coverage decision for Alzheimer's medicines, CMS is using "coverage with evidence development" to restrict access to these treatments. As I understand it, when CMS has set CED policies in the past, they have continued for an average of 11 years. Is

that correct? Since Alzheimer's patients' life expectancy is between 4 and 8 years from the time of diagnosis, doesn't this mean they could die or see their disease progress significantly before having the chance to access the treatment?

118. Question:
I'm very concerned about CMS' lack of timeliness in concluding coverage policies that involve Coverage with Evidence Development. How many other CED policies have involved part B drugs, and how long have they been in place?

119. Question:
The final NCD treats medicines approved via the accelerated approval pathway and the traditional approval pathway differently—it places access restrictions on both, but patients will have much more difficulty accessing those approved via accelerated approval. Doesn't this contravene the intent of the AA pathway, which is to get safe and effective medicines to patients more quickly?

120. Question:
CMS made only minor tweaks to the NCD to address concerns around health equity. Many of those who commented on the proposed decision memo thought that it would be difficult for vulnerable populations to access the treatment through randomized clinical trials, which is still a requirement for patients to access treatments approved based on a surrogate endpoint. How do you explain the failure of CMS to address these concerns around health equity?

121. Question:
Decisions about whether or not drugs are safe and effective have historically been left to the FDA, which is the gold standard in terms of science-based, rigorous drug review. In both the proposed and final coverage decisions, CMS appears to question the FDA's judgement regarding whether these drugs are safe effective. Are you concerned how this NCD could undermine the FDA in the eyes of the public?

122. Question:
In the final decision memo, CMS makes clear that Alzheimer's treatments will be subject to the same, significant restrictions for beneficiaries dually eligible for Medicaid and Medicare. Given their lack of resources, it appears particularly unlikely this population will be able to find enroll in a randomized clinical trial for one of the treatments approved via the accelerated approval pathway. Doesn't this NCD have the potential to worsen health disparities?

123. Question:
In the final NCD, CMS restricts access to treatments approved via the accelerated approval pathway to randomized clinical trials. Given that RCT sites tend to be fairly limited, what impact do you think this will have on access for rural populations?

124. Question:
In the final NCD, CMS failed to revise the coverage policy for beta amyloid PET scans, an important diagnostic tool for patients who have Alzheimer's. In the listening sessions CMS conducted prior to finalizing the NCD, many stakeholders noted this was important to

appropriately targeting treatments. Why didn't CMS revise this policy so that Alzheimer's patients can be accurately diagnosed and treated?

Response 115-124: CMS works to ensure that all beneficiaries have access to needed care as rapidly as possible, with items and services based on accurate, reliable information that demonstrates a clear clinical benefit. In developing this National Coverage Determination (NCD), CMS followed a long-standing process developed by Congress to determine whether an item is reasonable and necessary for the diagnosis or treatment of an illness or injury.

FDA is committed to using expedited programs to bring medicines to underserved populations with serious conditions and unmet medical need when the science supports the decision within the statutory authorities given to FDA by Congress. FDA's decision regarding Aduhelm exemplifies that commitment. It is important to distinguish between FDA's and CMS' roles. The standard for Medicare coverage is not the same as the standards for FDA approval of a drug. FDA's role is to determine if the drug is safe and effective for its intended use. FDA continues to see sponsors pursue accelerated approval.

Under the final NCD, the Food and Drug Administration approved monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease (AD) are covered under Medicare when furnished in accordance with certain coverage criteria under coverage with evidence development for patients who have a clinical diagnosis of mild cognitive impairment due to AD or mild AD dementia, both with confirmed presence of amyloid beta pathology consistent with AD.

CMS received over 10,000 comments on the proposed NCD and in response to those comments and the evidence, changed the final NCD. The final decision creates two coverage pathways. For monoclonal antibodies approved through the accelerated approval process for the treatment of Alzheimer's disease, CMS no longer requires a CMS-approved randomized controlled trial. Instead, we are supporting any Food and Drug Administration (FDA) or National Institutes of Health (NIH) trial. What this means is CMS will cover antiamyloid monoclonal antibodies in an FDA investigational new drug application or other NIH trial. CMS does not need to review/see or approve these trials. FDA and NIH have said they will make efforts to ensure there is diverse participation and access to their trials.

For antiamyloid monoclonal antibodies that have been approved by FDA through the traditional approval process for the treatment of Alzheimer's disease, the final decision allows for flexibility in a less rigorous study design. Such drugs would be eligible for coverage under prospective comparative studies to answer the coverage with evidence development questions specified in the NCD. For example, registry data could be used to assess whether outcomes seen in carefully controlled clinical trials are reproduced in real-world use and in a broader range of patient groups.

Promising medicines and technologies that treat devasting conditions will continue to be developed in the coming years, and it is important to make sure that patients have access to effective treatments that will not cause harm.