DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 2021

TUESDAY, FEBRUARY 25, 2020

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 10:34 a.m. in room SD–124, Dirksen Senate Office Building, Hon. Roy Blunt (chairman) presiding. Present: Senators Blunt, Shelby, Alexander, Kennedy, Hyde-Smith, Rubio, Murray, Durbin, Shaheen, Merkley, Schatz, Baldwin, Murphy, and Leahy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF THE SECRETARY

STATEMENT OF HON. ALEX AZAR, SECRETARY

OPENING STATEMENT OF SENATOR ROY BLUNT

Senator BLUNT. The Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies will come to order.

Thank you, Secretary Azar, for being here. It has turned out to be a more eventful day and week than we might have anticipated when we set this hearing up. But we are grateful that you have shown up as we asked you to at the time we asked you to.

The budget you suggested requests many of the same kinds of cuts that occurred in fiscal year 2020 and I am sure we will have questions about that.

It is not unexpected and I think you will recall when I called you with the final budget numbers from the 2020 budget my first comment was that the good news is you did not get what you asked for and, hopefully, that will be the case again this time.

But you propose a 10 percent cut, similar cuts that you proposed in the past in programs that I think we would be very reluctant to do, especially in the healthcare workforce programs, the medical research programs, the preparedness programs, all of which have been talked about even earlier today at the members briefing on COVID–19. Home energy, rural health care—these programs are unlikely to be cut.

I, frankly, hope some of the cuts you suggested we can look at and decide that there are areas where we can reprioritize because
we are going to need a little more money this year, in my view, than the top line number is likely to give us.

I do appreciate that in this budget, unlike some in the past, the administration has actually tried to focus on priorities where we would increase spending. Ending the HIV Epidemic, the effort to do that, the effort to improve maternal health, to fight the opioid epidemic, also to maintain some of the other investments we have made.

But the budget request also looks at high-quality child care, Head Start, and child care development block grants and really suggests that they appreciate what they have been allowed in budgets in the past to happen there.

Many of the increases in this budget request were financed, again, let me say, by unrealistic cuts, cuts that we do not want to make, in my opinion, and cuts that at the end of the day you probably would not really want us to make like eliminating children’s hospitals graduate medical education.

That is not going to happen. Eliminating LIHEAP (Low Income Home Energy Assistance Program)—highly unlikely to happen. It slashes healthcare research, an area the subcommittee has prioritized the last 5 years that I have chaired this committee. And this is an area Senator Murray and I have worked together on.

We are not likely to cut healthcare research and I hope we can continue our pattern of increasing healthcare research at this incredible time.

I think we are making a difference. We have seen life expectancy numbers go up and quality of life efforts for Americans go up because of what is happening with the real innovative opportunity in healthcare.

Americans’ life expectancy rose for the first time since 2014. Last year cancer death declined. They first declined in a long time on opioid overdose deaths were part of that.

New treatments, screening tools, vaccines all make a difference and this is such an incredible time to move forward in all of those areas based on what we know now and what we think is out there in the future with CRISPR technology and other things.

I know you had to make difficult decisions with the budget number you had and we will have to do the same thing. Hopefully, we can work together to identify priorities and find common ground and, hopefully, our committee will be able to work together, as I think we have made a real effort to do for several years now.

Two years ago, this subcommittee created an Infectious Disease Fund to provide flexibility funding for the department for immediate response. You have used that money as intended. That first $105 million lets you respond to the coronavirus in ways that you would not have been able to respond otherwise.

However, you know, responding to this particular effort not only takes a rapid response, but if we are going to be your partners in this, it takes a lot of sharing of information and I encourage you to continue to do that.

We gave you broad authority, for instance, in the Infectious Disease Fund. But broad authority also includes broad responsibility to be forthcoming with information. When we give you this kind of authority to spend money, I think everyone on this committee
would like a similar kind of treatment in your response to how that money is being spent.

We have asked virtually every day for the department to give us specifics on spending money with the proposal that came out last night that you and I had a chance to talk about yesterday. I think we have a better sense of the path forward than we would have had before.

But whether it is your department or OMB (Office of Management and Budget) that makes it hard for you to share information, I would just encourage you once again that this is going to work better if we have the kind of sharing that allows you to have then the kind of flexibility that you would like to have.

One of those things comes with, in my sense, an obligation for the other thing, the sharing of information, to be part of that flexibility that we have given you.

We are going to talk a lot today, I suspect, or at least I am this morning about the virus, about the supplemental, the time that you think that supplemental fills the gap and what the backup plan would be if it is not adequate.

I appreciate, Mr. Secretary, your strong leadership at both CDC (Centers for Disease Control and Prevention) and NIH (National Institutes of Health) as well as overall at HHS (Department of Health and Human Services). I look forward to your testimony today. We have both the Chairman and the Vice Chairman of the Full Committee with us and I know that Senator Murray and I are glad to have both of them there. I think they will have some comments to make.

[The statement follows:]

PREPARED STATEMENT OF SENATOR ROY BLUNT

Good morning. Thank you, Secretary Azar, for appearing before the Subcommittee today to discuss the Department of Health and Human Services’ fiscal year 2021 budget request. We look forward to your testimony.

The fiscal year 2021 budget request mirrors the fiscal year 2020 budget request in many ways—which isn’t unexpected.

It proposes a $9.7 billion, or 10 percent, cut to the Department. Similar cuts that you have proposed before—to healthcare workforce programs, medical research, preparedness programs, home energy assistance, and rural healthcare—are once again part of this year’s request.

I do appreciate that this budget, unlike many in the past, reflects specific priorities from the Administration.

The budget builds off investments this Subcommittee has made to support the “Ending the HIV Epidemic” initiative, improve maternal health outcomes, and prioritize resources to fight the opioid epidemic. The budget also maintains the significant recent investments this Subcommittee has made in other areas, like supporting high-quality child care for working families, including through Head Start and the Child Care and Development Block Grant.

However, many of the increases in this budget request are financed by unrealistic cuts. Cuts we cannot take and ones that you would not want us to take—like eliminating Children’s Hospitals Graduate Medical Education or LIHEAP.

And we know by this point in my chairmanship that I will never write a bill that slashes the investment in medical research as the budget proposes.

It is clear that National Institutes of Health-funded research has raised life expectancy and vastly improved the quality of life for all Americans.

This fact was reinforced by a recently released report from the Centers for Disease Control and Prevention that announced that Americans’ life expectancy rose for the first time since 2014.

Smart investments in medical research have brought about new treatments, screening tools, and vaccines, particularly in cancer, leading to the largest 1 year decline in cancer deaths ever reported.
But your budget strategy, like many Secretaries before you, puts pressure on the Subcommittee to find savings in real ways to try to reflect some of your priorities because we simply will not cut the programs you did.

I understand you had to make difficult decisions under a tight fiscal year 2021 budget number. We will have to do the same. And my goal for fiscal year 2021 remains the same as it has been during my 5 years as chairman—for us to work together to identify priorities and find common ground while responsibly allocating taxpayers' resources.

Before I finish, I want to touch on the Department's response to the coronavirus.

Two years ago, this Subcommittee created an Infectious Disease Fund to provide flexible funding for the Department to immediately respond to an infectious disease outbreak. For the ongoing coronavirus response, you have used this money as intended.

I support your efforts to act quickly to contain the effects in the United States. However, responding to a potential epidemic like this not only takes effective communication between agencies, but a recognition that Congress is an important partner throughout the response.

This Committee has provided necessary flexibility to you and your Department, but what gives me pause about the Infectious Disease Fund in particular, and these flexible pots of funding in general, relates to both the broad authority the Department has to use them and the lack of accountability that seems to accompany them.

Since we were initially notified of the use of the Infectious Disease Fund on January 25, 1 month ago, the Subcommittee has asked, virtually every day, how fast the Department is spending money from the Fund and what, specifically, you're spending it on. I know the response is rapidly changing and that obligations have a lag time, but I am not asking difficult questions or questions that this Subcommittee should not receive complete and timely answers to.

We need transparency into what you are spending now and a recognition that the funding flexibility we provide comes with an expectation of open communication even during an ongoing response.

Yesterday evening, the Office of Management and Budget transmitted a supplemental request for the coronavirus. This Committee will take that request seriously and I hope will quickly act upon it.

As we work to assess whether the request provides the resources needed for a complete response, I hope you will work to provide timely answers.

I want to make sure funding is not a limitation to the response. I want to ensure that State and local communities have the resources they need.

And I want to make certain that we are looking at our response capabilities for the long game—and not, as we seem to do, leaping from one disease outbreak to the next.

I appreciate your strong leadership, along with the expertise CDC and NIH bring to this response. We must continue to work together as we protect the homeland.

Mr. Secretary, I look forward to hearing your testimony today and appreciate your dialogue with us about these important issues. Thank you.

Senator Blunt. Senator Murray, let us go to you for your opening comments.

STATEMENT OF SENATOR PATTY MURRAY

Senator Murray. Well, thank you very much, Chairman Blunt. Secretary Azar, welcome. Thank you for being here.

Mr. Secretary, let me just say at the top that I am alarmed by the recent developments that we have seen in the Office of Refugee Resettlement and how it has handled children in its care following President Trump’s inhumane family separation policy.

I have raised questions with you about that before. I hope we can continue that conversation today as well as we review this administration's budget proposal and I hope today, we can get a straightforward answer on many of the other healthcare issues that I am hearing about from my constituents in Washington State.

Because when it comes to helping families across the country who are struggling today to afford healthcare, this administration has continually said one thing and done the opposite, and at the
end of the day none of the president's empty promises say as much about his healthcare priorities, frankly, as his decision to champion a partisan lawsuit that could be catastrophic for families.

Because if Republicans get their way in court they will strike down protections for preexisting conditions, strip away healthcare families that got their healthcare through exchanges and Medicaid expansion and give power back to the insurance companies to offer low-quality coverage and leave patients, of course, with higher healthcare costs.

And much like that partisan lawsuit, President Trump's partisan budget exposes the truth behind that spin. Despite his promise to the contrary, this budget would slash $500 billion from Medicare and nearly a trillion from Medicaid, threatening millions of families' access to high-quality affordable care.

In fact, on seemingly every page this budget proposes taking huge steps backward on our Nation's most urgent challenges including the ones that the administration says they care about.

It proposes a small step forward with additional investments to fight HIV transmissions. But it takes an enormous leap backwards with the cuts to Medicaid which, by the way, covers more than two-fifths of the patients with HIV care, not to mention slashing investments in combating HIV overseas.

These Medicaid cuts would take us in the wrong direction when it comes to addressing mental and behavioral health challenges like the ongoing drug overdose crisis or the increasing suicide rate by making it harder for people to get the care they need.

In some States that have expanded Medicaid the program covers four out of five people receiving treatment for opioid addiction. To make matters worse, for behavioral health the budget eliminates funding for the new suicide prevention initiative at the Centers for Disease Control and Prevention, which Congress included last year in our bipartisan spending bill.

And then there is the maternal mortality rate, which is worse here in the United States than in any developed country in the world. Each year 700 women in our country die from pregnancy-related issues. Those deaths are mostly preventable and the impacted women are disproportionately black and Native American.

Instead of treating this like the emergency that it is, this budget actually offers a sleight of hand. It proposes expanding the maternal mortality initiative Congress created in 2018 by $75 million and I appreciate that.

But, unfortunately, that pales in comparison to the proposal to cut over a hundred times that amount from Medicaid, which actually pays for nearly half the births in this country.

And if that were not bad enough news for women and families, this budget continues the Trump/Pence administration's harmful trend of putting ideology over evidence and patient health by excluding Planned Parenthood from Federal funding and eliminating the teen pregnancy prevention program.

At a time when our Nation is facing a health professional shortage, this budget proposes cutting nearly $800 million from programs that support tuition assistance, loan forgiveness, and training for several hundred thousand health professionals annually.
And at a time when too many families are already forced to choose between paying for healthcare or other basic needs, this budget seems to go out of its way to make things worse for people living on the brink of poverty.

It eliminates safety net programs and critical assistance to millions of people like the Low-Income Home Energy Assistance Program which, as we know, helps families afford heating and cooling, and the community services block grant, which gives states resources to address the challenge of poverty.

It eliminates the social service block grant and greatly reduces programs, which help families facing adversity from keeping their heads above water. And as it continues the strong bipartisan investments in child care and Head Start Congress secured in our last spending bill, this budget eliminates funding for preschool development grants, which provide high-quality preschool to tens of thousands of families.

Finally, Mr. Secretary, as you know, I have been in close contact with health experts dealing with the 2019 novel coronavirus outbreak, which you declared a public health emergency last month.

As we work to bring hundreds of Americans from China’s Hubei Province and affected cruise ships safely back home and quarantine them for 2 weeks at a cost of, roughly, $6 million per flight, I have been pressing for more information on what resources are needed.

I sent a letter to you and the Office of Management and Budget Director Mick Mulvaney earlier this month expressing my deep concerns about this.

Now, you finally sent an emergency supplemental request last night, like I have been urging, and I am very concerned this request is not enough to ensure that we are putting all the necessary resources towards this emerging threat including making sure our States and local public health departments have what they need to respond to this crisis and being reimbursed for those costs.

And I am very concerned about how thin the details on that are because, despite what this budget proposes, not a single public health expert has told me the thing we really need to do right now is cut the CDC’s program by 9 percent or cut critical global health programs by $80 million or cut the Infectious Disease Rapid Response Reserve Fund by $35 million or cut public health preparedness and response programs by $120 million.

This is not going to help us deal with this. So while I recognize the efforts happening across your department to contain this virus, I have to say this is unacceptable. It is important that we stay ahead of this crisis and we are ready when additional cases are detected in the U.S., meaning we cannot plan on the cheap or at the last minute.

I have always said a budget is a reflection of our values and that applies here. While President Trump may not always tell the truth about his values, this budget speaks volumes to all of us.

It leaves no doubt that the president is not serious about fighting for women’s or for families’ healthcare or addressing national crises like drug addiction, maternal mortality, or suicide.

He is serious about cutting Medicaid and Medicare and cutting critical public health programs and safety net programs and healthcare workforce programs, and more.
Families across the country should know that we, as Democrats, have no intention of letting those cuts happen. We are going to continue to fight for patients and against these attacks.

Senator Blunt. Thank you, Senator.

Chairman Shelby.

STATEMENT OF SENATOR RICHARD C. SHELBY

Senator Shelby. Thank you. Thank you, Senator Blunt.

Dr. Azar, you bring a lot of experience at the right time in your job. I thank you for your service. I would like to focus on the current crisis that we have that face us in the world and could be here and how you are going to deal with it and so forth.

To many people—I think the American people are very concerned and should be. I am concerned. This is a serious, serious disease that if it keeps spreading nobody knows better than you what it could do here. It could be an existential threat to many people in this country.

This is not politics. This is doing our job for the American people. I know the requests you made, the supplemental $1.25 billion and some others. But money should not be an object. We should be trying to contain and eradicate as much as we can this in the U.S. Make sure it does not spread in the U.S. but help our friends all over the world because it is to our advantage.

Some people believe this is a lowball number here. I do not know. But I would like to hear from you on this because this is not the time to try to shortchange the American people on anything or say OMB has done this and that, whoever it is or whatever administration it is, Democrat or Republican.

This is the time to step up. I think you know this probably better than I do. But there is a lot of concern in America today and will be is this going to spread. You know, we brought some people into this country. Where is it going to go? How are we going to contain it?

I am looking forward to your testimony. I am sure you do not have all the answers but you have probably got more than a lot of people.

Thank you for your service again.

Senator Blunt. All right. Well, thank you, Chairman.

And, Senator Leahy, do you want to wait for your question time or do you have an opening?

Senator Leahy. I have a—I do have a question on a proposal made most recently, which is vague at best, on the coronavirus.

Senator Blunt. All right. Well, let us go ahead and, Secretary Azar, again, we are glad you are here. We are glad you are here and look forward to your opening statement and maybe you can answer some of these questions even in that statement.

SUMMARY STATEMENT OF HON. ALEX AZAR

Secretary Azar. Great. Thank you very much, Chairman Blunt, Ranking Member Murray, and Chairman Shelby and Ranking Member Leahy—Vice Chairman Leahy.

Thank you very much for having me and inviting me to discuss the president’s budget for fiscal year 2021. I am honored to appear before this committee for budget testimony as HHS secretary for
the third time, especially after the remarkable year of results that the HHS team has produced.

With support from this committee, this past year we saw the number of drug overdose deaths decline for the first time in decades, another record year of generic drug approvals from FDA, and historic drops in Medicare Advantage, Medicare Part D, and Affordable Care Act exchange premiums.

The president's budget aims to move toward a future where HHS programs work better for the people we serve, where Human Services programs put people at the center and where America's healthcare system is affordable, personalized, puts patients in control, treats you like a human being, not like a number.

HHS has the largest discretionary budget of any non-Defense Department, which means the difficult decisions must be made to put discretionary spending on a sustainable path. This committee has made important investments over the years in some of the HHS's large discretionary programs including at the National Institutes of Health and we are grateful for that work.

The president's budget proposes to protect what works in our healthcare system and make it better. I will mention two ways that we do that. First, facilitating patient-centered markets and, second, tackling key impactable healthcare challenges.

The budget's healthcare reforms aim to put the patient at the center. It would for instance, eliminate cost sharing for colonoscopies, a lifesaving preventive service. We would reduce patients' costs and promote competition by paying the same for certain services regardless of setting, and the budget endorses bipartisan bicameral drug pricing legislation.

These combined reforms will improve Medicare and extend the life of the Hospital Insurance Fund by at least 25 years. We propose investing $116 million in HHS's initiative to reduce maternal mortality and morbidity and we propose reforms to tackle America's rural health crisis including telehealth expansions and new flexibility for rural hospitals.

The budget increases investments to combat the opioid epidemic including SAMHSA's (Substance Abuse and Mental Health Services Administration) State Opioid Response Program and we appreciate this committee's work with us to give States flexibility in that program to address stimulants like methamphetamines.

We request $716 million for the president's initiative to end the HIV epidemic in America by using effective evidence-based tools. Thanks to funding appropriated by this committee, we have already begun implementing this initiative.

The budget reflects how seriously we take the threat of other infectious diseases such as the China coronavirus by prioritizing funding for CDC's infectious disease programs and maintaining investments in hospital preparedness.

We now have 14 cases of the China coronavirus detected in the United States involving travel to China or close contacts with those travelers, three cases among Americans repatriated from Wuhan and 40 cases among American passengers repatriated from the Diamond Princess.

While the immediate risks to individual members of the American public remains low, there is now community transmission in
a number of countries including outside of Asia, which is deeply concerning. We are working closely with State, local, and private sector partners to prepare for mitigating the virus’s potential spread in the United States, as we will likely see more cases here.

Today, NIH will announce the launch of the first U.S. clinical trial for an investigational antiviral at the University of Nebraska Medical Center.

Yesterday, OMB sent a request to make $2.5 billion in funding available for preparedness and response including for therapeutics, the vaccines, personal protective equipment, State and local support, and surveillance, and I look forward to working closely with Congress on that.

Lastly, when it comes to human services the budget cuts back on programs that lack proven results while reforming programs like TANF (Temporary Assistance for Needy Families) to drive State investments and supporting work and the benefits it brings for well-being.

We continue the fiscal year 2020 investments Congress made in Head Start and childcare programs, which promote children’s well-being and adults’ independence.

This year’s budget aims to protect and enhance Americans’ well-being and deliver Americans a more affordable personalized healthcare system that works better rather than just spends more.

I look forward to working with this committee to make that common sense goal a reality.

Thank you, Mr. Chairman.

[The statement follows:]

PREPARED STATEMENT OF HON. ALEX AZAR

The President's Fiscal Year 2021 Budget (Budget) is built around a vision for HHS and a vision for American healthcare. We are building toward a future where HHS's programs work better for the people we serve; where America’s healthcare system is affordable, personalized, and puts patients in control; and where our human services programs put people at the center.

The Budget reflects the Administration’s commitments to delivering on this vision and other important themes of HHS’s work: advancing a patient-centered healthcare system, protecting the lives of the American people, promoting independence, and making HHS the healthiest organization it can be.

Over the past year, under President Trump’s leadership, the men and women of HHS have delivered remarkable results. Beginning in 2018 and through 2019, the number of drug overdose deaths in America began to decline for the first time in nearly two decades, thanks to huge expansions, assisted by HHS, in access to evidence-based addiction treatment. The Food and Drug Administration (FDA) approved a record number of generic drugs and biosimilars in fiscal year 2019. We launched new payment models in Medicare that pay for health and outcomes, rather than sickness and procedures. We finalized a requirement, effective January 2021, that hospitals provide patients with useful price information, and proposed measures to give patients control over their own health data through interoperability. We launched President Trump’s initiative to end the HIV epidemic in America within 10 years, and worked with Congress to secure funding for it. The Department played a vital role in responding to an Ebola outbreak in the eastern Democratic Republic of the Congo and the humanitarian crisis in Latin America. We took unprecedented steps to expand access to treatment for Americans with serious mental illness and worked to help seniors remain in their homes. The latest data from the Administration for Children and Families shows a record number of adoptions with child-welfare-agency involvement, and reductions in the number of children entering foster care. The Budget proposes to continue work on these priorities, while also identifying new areas for action, such as maternal and rural health.

The Budget proposes $94.5 billion in discretionary budget authority and $1.3 trillion in mandatory funding. Within our discretionary programs, it prioritizes funding
for programs that have demonstrated effectiveness, proposes to end programs that have not, and focuses on direct services provided to the American people. On mandatory spending, the Budget proposes commonsense reforms that will pave a path to fiscal sustainability and make these important programs work better for the people they serve.

**FACILITATE PATIENT-CENTERED CARE**

**Providing Price and Quality Transparency**

President Trump’s Executive Order on Improving Price and Quality Transparency in American Healthcare to Put Patients First directs HHS to make healthcare prices transparent, laying the foundation for a patient-driven and value-based health system. HHS has acted swiftly to require hospitals to publish the prices they negotiate with insurers and is working to do the same for issuers, so patients can understand their own out-of-pocket costs. CMS has also required Part D prescription drug plans to develop tools that allow beneficiaries to determine plan benefits and formularies.

The Executive Order calls for the development of a Health Quality Roadmap that aligns and improves reporting on data and quality measures across Medicare, Medicaid, the Children’s Health Insurance Program, and other Federal health programs. The Roadmap will include a strategy for establishing, adopting, and publishing common quality measures; aligning hospital inpatient and hospital outpatient measures; and eliminating low-value or counterproductive measures.

HHS legislative proposals increase price and quality transparency in Medicare. For instance, the Budget would eliminate coinsurance or copayments for a screening colonoscopy when a polyp is found, saving lives and supporting the President’s policy to reduce out-of-pocket costs for this common procedure.

The Budget also invests funding in programs that promote transparency. The Budget requests $51 million for the Office of the National Coordinator for Health IT, which includes funding to develop, promote, and adopt common standards to integrate health information and product transparency while protecting privacy. In addition, the new National Institute for Research on Safety and Quality within the National Institutes of Health (NIH) supports the Administration’s efforts to move healthcare organizations from volume to value by focusing on improving outcomes, reducing cost, and expanding choices for consumers. Research investments will focus on developing knowledge, tools, and data needed to improve the healthcare system.

**Lowering the Cost of Prescription Drugs**

The United States is first in the world in biopharmaceutical investment and innovation. But too often, this system has not put American patients first. We have access to the greatest medicines in the world, but access is meaningless without affordability. The Budget supports quick Congressional action to pass comprehensive legislation to address these flaws in our current drug pricing system and provide needed relief to the American people.

The Budget delivers on President Trump’s promise to bring down the high cost of drugs and reduce out-of-pocket costs for American consumers by pursuing policies that align with the four pillars of the President’s American Patients First Blueprint: increased competition, better negotiation, incentives for lower list prices, and lowering out-of-pocket costs.

The Budget includes an allowance for bipartisan drug pricing proposals. The Administration supports legislative efforts to improve the Medicare Part D benefit by establishing an out-of-pocket maximum and reducing out-of-pocket costs for seniors. The Administration also supports changes to bring lower cost generic and biosimilar drugs to patients. These efforts would increase competition, reduce drug prices, and lower out of pocket costs for patients at the pharmacy counter.

The Budget includes an allowance for savings of $135 billion over 10 years to support the President’s commitment to lower the cost of prescription drugs.

**Protecting and Improving Medicare for our Nation’s Seniors**

Over 60 million American seniors are in the Medicare program, and they are overwhelmingly satisfied with the care they receive through traditional Medicare and Medicare Advantage. The President is continuing to strengthen and improve these programs.

The Budget continues to implement the President’s Executive Order on Protecting and Improving Medicare for Our Nation’s Seniors, building on those aspects of the program that work well, while also introducing market-based approaches to Medicare reimbursement. The Administration seeks to protect and reform Medicare with proposals that strengthen fiscal sustainability and deliver value to patients. To drive reform, the Centers for Medicare & Medicaid Services (CMS) is modernizing the Medicare Advantage program, unleashing innovation, expanding telehealth op-
tions, and driving competition to improve quality among private Medicare health and drug plans. The Administration is expanding flexibility for these Medicare Advantage plans to maximize choices for seniors, and taking action to ensure fee-for-service Medicare is not promoted over Medicare Advantage.

President's Health Reform Vision Allowance

While Americans have the best healthcare options in the world, rising healthcare costs continue to be a top financial concern for many Americans. President Trump's Health Reform Vision will protect the most vulnerable, especially those with pre-existing conditions, and provide the affordability, choice, and control Americans want and the high-quality care that all Americans deserve.

The President's Health Reform Vision would build on efforts outlined in the Executive Order, "Improving Price and Quality Transparency in American Healthcare To Put Patients First" to provide greater transparency of healthcare costs and enshrine the right of a patient to know the cost of care before it is delivered. It focuses on lowering the price of medicine, ending surprise medical bills, breaking down barriers to choice and competition, and reducing unnecessary regulatory burdens. The Health Reform Vision will also prioritize Federal resources for the most vulnerable and provide assistance for low-income individuals. Medicaid reform will restore balance, flexibility, integrity, and accountability to the State-Federal partnership. Medicaid spending will grow at a more sustainable rate by ending the financial bias that currently favors able-bodied working-age adults over the truly vulnerable.

The Budget includes savings of $844 billion over 10 years for the President's Health Reform Vision Allowance.

Paying for Outcomes

The Administration is committed to advancing a personalized and affordable healthcare system that puts the patient at the center by ensuring Federal health programs produce quality outcomes and results at the lowest possible cost. In part, this will be achieved by our continued focus on paying for outcomes rather than procedures. For instance, the Budget seeks to improve Medicare primary care services by ensuring payments more accurately reflect clinician time, resources, and outcomes. The Budget also implements a value-based purchasing program for hospital outpatient departments, ambulatory surgical centers, and post-acute care facilities, offering incentives to improve quality and health outcomes. Finally, the Budget proposes a set of reforms that improve the physician experience and participation in the Quality Payment Program by eliminating reporting burdens for clinicians participating in the Merit-Based Incentive Payment System, CMS's largest value-based care payment program.

The Administration issued proposed rules to modernize key regulations that advance the movement to value-based care and paying for outcomes. Specifically, the Administration proposed reforms to the Anti-Kickback Statute, the Physician Self-Referral regulations (Stark Law), and 42 CFR Part 2. These proposed rules are part of HHS's Regulatory Sprint to Coordinated Care, which aims to reduce regulatory barriers and accelerate the transformation of the healthcare system into one that better pays for value and promotes care coordination. These proposed rules reduce unnecessary regulatory burden on physicians and other healthcare providers while reinforcing their statutory intents of protecting patients from unnecessary services, and limiting fraud waste and abuse. This includes adding flexibilities with respect to outcomes-based payments and part-time arrangements. These rules would allow physicians and other healthcare providers and suppliers to design and enter into value-based arrangements that improve quality outcomes, produce health system efficiencies, and lower costs. The CMS Center for Medicare and Medicaid Innovation (Innovation Center) launched a number of innovative payment and service delivery models to test ideas to shift our healthcare system toward payment for outcomes and health rather than sickness and procedures. This effort includes Direct Contracting and Primary Care First, a new suite of payment model options that will transform primary care to deliver better value for patients throughout the healthcare system. In addition, the Emergency Triage, Treat, and Transport Model provides greater flexibility to ambulance care teams to address emergency healthcare needs of Medicare beneficiaries following a 911 call, rather than delivering them to the hospital or emergency department for an unnecessary and expensive visit.

PROTECT LIFE AND LIVES

Combating the Opioid and Methamphetamine Crisis

In 2018, drug overdose deaths declined for the first time since 1990. A reduction in deaths from prescription opioid painkillers is almost entirely responsible for this
To maintain and build on this progress, HHS continues to advance the department’s five-point strategy to:

— Improve access to prevention, treatment, and recovery services, including the full range of medication-assisted treatments;
— Better target the availability of overdose-reversing drugs;
— Strengthen our understanding of the crisis through better public health data and reporting;
— Provide support for cutting edge research on pain and addiction; and
— Improve pain management practices.

The Budget requests $5.2 billion to address the opioid overdose epidemic and methamphetamine use, including $169 million in new resources. Funding expands State Opioid Response grants in the Substance Abuse and Mental Health Services Administration (SAMHSA) to provide treatment, recovery support services, and relapse prevention. The Budget provides funding to the Health Resources and Services Administration (HRSA) for Addiction Medicine Fellowships to support approximately 60 fellows annually in underserved, community-based settings that integrate primary care with mental health and substance use disorder prevention and treatment services.

While opioids have been at the forefront of the drug landscape, the crisis continues to evolve and many public health experts believe we are entering into the fourth wave of the crisis, which is underscored by increases in overdose deaths involving cocaine and methamphetamine.

HHS is leveraging current efforts to address the opioid epidemic to combat the rising mortality and morbidity associated with methamphetamines and other stimulants. To allow flexibility to most effectively combat substance use in whatever form it takes, SAMHSA’s State Opioid Response grant program has the flexibility to also address stimulants. HHS would direct $50 million within NIH for research to develop medication-assisted treatment and evidence-based psychosocial treatment for methamphetamines and other stimulants.

Ending the HIV Epidemic: A Plan for America

In the 2019 State of the Union, President Trump announced a bold new initiative to reduce new HIV infections by 75 percent in the next 5 years and by 90 percent in the next 10 years, averted more than 400,000 HIV infections in that time period. This initiative focuses on four key strategies:

— Diagnose all individuals with HIV as early as possible after infection;
— Treat the infection rapidly and effectively after diagnosis, achieving sustained viral suppression;
— Protect individuals at risk for HIV using proven prevention approaches; and
— Respond rapidly to detect and respond to growing HIV clusters and prevent new HIV infections.

The Budget invests $716 million in dedicated funding for the second year of the Ending the HIV Epidemic: A Plan for America initiative, an increase of $450 million from fiscal year 2020. This funding expands activities in the 57 target jurisdictions to increase HIV testing and access to prevention and treatment services.

With $371 million, the Centers for Disease Control and Prevention (CDC) transitions from planning to implementation and intensifies work begun in fiscal year 2020 in the 57 target jurisdictions. CDC grants to affected communities will drive additional testing with the goal in the second year of doubling the number of new HIV diagnoses rapidly treated with antiretroviral therapy to maintain health and prevent additional HIV transmissions. Funded jurisdictions will use pharmacy data, telehealth, mobile testing, and new science-based networks to ensure individuals enter and adhere to care.

With $302 million, HRSA expands HIV prevention services to all community health centers in the targeted initiative areas and serves 28,000 additional HIV positive people through the Ryan White Program. HHS also requests $27 million for the Indian Health Service (IHS) to enhance HIV testing and linkages to care for American Indians and Alaska Natives.

NIH directs $16 million to leverage pilot data from 17 Centers for AIDS Research to design and evaluate effective, sustainable systems to implement HIV prevention and treatment interventions and rapidly implement strategies at scale that will be most effective.

These investments build on ongoing HIV activities supported across the Department and an announcement in 2019 to make pre-exposure prophylaxis medication available free of charge for up to 200,000 uninsured individuals each year for up to 11 years. The donation by Gilead Sciences, in partnership with HHS, will help reduce the risk of HIV infections, particularly for individuals that may be at the highest risk.
Improving Maternal Health

Approximately 700 women die each year in the United States from pregnancy-related complications and more than 60 percent of these deaths are preventable. In fact, women in the United States have higher rates of maternal mortality and morbidity than in any other industrialized nation—and the rates are rising. In addition to rising mortality rates, severe maternal morbidity affects more than 50,000 women and adds significant costs to the healthcare system.

Cardiovascular disease is now the leading cause of death in pregnancy and the postpartum period, constituting nearly 30 percent of pregnancy-related deaths. Chronic hypertension—which is diagnosed or present before pregnancy or before 20 weeks gestation—may result in significant maternal, fetal, and neonatal morbidity and mortality. The rate of chronic hypertension increased by 67 percent from 2000 to 2009, with the largest increase (87 percent) among African American women. CDC points to hypertensive disorders, cerebrovascular accidents, and other cardiovascular conditions as some of the leading causes of maternal deaths, all potentially preventable and imperative to identify risk factors prior to pregnancy in order to prevent poor pregnancy and postpartum outcomes.

HHS’s Improving Maternal Health in America initiative is addressing this significant public health problem. This initiative focuses on four strategic goals:

— Achieve healthy outcomes for all women of reproductive age by improving prevention and treatment;
— Achieve healthy pregnancies and births by prioritizing quality improvement;
— Achieve healthy futures by optimizing postpartum health; and
— Improve data and bolster research to inform future interventions.

The Budget provides a total of $116 million for this initiative across the National Institute for Research on Safety and Quality (NIRSQ), CDC, HRSA, and IHS. This includes $7 million for NIRSQ to improve service data, advance data evaluation, and expand medical expenditure surveys to ensure policy makers have timely and accurate data. The Budget also invests $24 million in CDC to expand the Maternal Mortality Review Committees to all 50 States and D.C. to ensure every case of pregnancy-related death is examined. The Budget provides $80 million in HRSA to improve the quality of maternal health services, expand access to care, and reduce disparities in care. The Budget invests $5 million in IHS to help improve health outcomes by standardizing care, increasing cultural awareness, and improving care for pregnant women.

Advancing American Kidney Health

Today’s status quo in kidney care carries a tremendous financial cost. In 2016, Medicare fee-for-service spent approximately $114 billion to cover people with kidney disease, representing more than one in five dollars spent by the traditional Medicare program. In July 2019, the President signed an Executive Order launching an initiative to transform care for the estimated 37 million Americans with kidney disease. The Advancing American Kidney Health initiative tackles the challenges people living with kidney disease face across the stages of kidney disease, while also improving the lives of patients, their caregivers, and family members.

The Budget includes $39 million across multiple HHS agencies and requests new legislative authority in support of the initiative’s three goals:

— Reduce the number of Americans developing End-Stage Renal Disease (ESRD) by 25 percent by 2030.
— Have 80 percent of new ESRD patients in 2025 receive dialysis at home or a transplant.
— Double the number of kidneys available for transplant by 2030.

This funding also supports transplantation activities for other organs. New and pioneering payment models are also being developed to increase both value and quality of care for the patient.

The Budget also targets new funding towards HRSA’s Organ Transplantation Program to remove financial disincentives for living organ donors. The Budget invests $31 million in HRSA for the Organ Transplantation program, including $18.3 million for the Organ Procurement Transplantation Network, Scientific Registry of Transplant Recipients, and public and professional education efforts to increase public awareness about the need for organ donation. In addition, the proposed rule to increase accountability and availability of the organ supply—announced in December 2019—would improve the donation and transplantation rate measures, incentivize Organ Procurement Organizations (OPOs) to ensure all viable organs are
transplanted, and hold OPOs to greater oversight, transparency, and accountability while driving higher OPO performance.

HHS is working to accelerate innovation in the prevention, diagnosis, and treatment of kidney disease through the Kidney Innovation Accelerator (KidneyX), a public-private partnership between HHS and the American Society of Nephrology. The HHS Office of the Chief Technology Officer will continue the KidneyX competition in fiscal year 2021 by challenging individuals, teams, and companies to build and test prototype solutions, or components of solutions, that can replicate normal kidney functions or improve dialysis access.

The Budget proposes to establish a new program within the Office of the Assistant Secretary for Preparedness and Response (ASPR) that will advance kidney health. The Preparedness and Response Innovation program will support advanced research and development, prototyping and procurement of revolutionary health security products, technologies and other innovations. The program’s first project will focus on portable dialysis equipment for emergency response. This will ensure that individuals with kidney failure have access to dialysis during a disaster.

The Budget also advances legislative proposals to revolutionize the way patients with chronic kidney disease and kidney failure are diagnosed, treated, and supported. This effort includes extensions of both the NIH Special Diabetes Program and IHS Special Diabetes Program for Indians to address chronic conditions, such as diabetes, that can lead to kidney disease.

For patients who lose Medicare coverage at 36 months post-transplant and who do not have another source of healthcare coverage, the costs of continuing immunosuppressive drug therapy may be prohibitive. Without these drugs, the patient’s body rejects the transplant, reverts to kidney failure, and requires dialysis. To prevent transplant rejection and reversion to dialysis, the Budget proposes to establish a new Federal program that provides lifetime coverage of immunosuppressive drugs for certain kidney transplant recipients until they are otherwise eligible for Medicare coverage. The Budget also proposes to increase competition among, and oversight over, Organ Procurement Organizations to improve performance and increase the supply of organs for transplant. In addition, the Budget advances new innovative kidney care payment models to encourage home dialysis, increase access to kidney transplants, and incentivize clinicians to better manage care for patients with kidney disease.

Transforming Rural Health

There are 57 million Americans living in rural communities. Rural Americans face many unique health challenges, including hospitals that are closing or in danger of closing; difficulty recruiting and retaining physicians, nurses, and other providers; and increased likelihood of dying from many leading causes of avoidable death such as cancer and heart disease.

HHS’s 4–Point Strategy to Transform Rural Health builds on current HHS initiatives in the following areas:

—Build a Sustainable Health Model for Rural Communities;
—Leverage Technology and Innovation;
—Focus on Preventing Disease and Mortality; and
—Increase Rural Access to Healthcare.

The Budget supports rural communities through programs such as the Rural Communities Opioids Response Program and the Telehealth Network Grant Program at HRSA, which supports substance use prevention, treatment, and recovery services, and promotes telehealth technologies for healthcare delivery in rural communities. Project AWARE (Advancing Wellness and Resiliency in Education) will increase mental health awareness training in rural communities. In response to American Indian and Alaska Native communities’ demand for telebehavioral services, IHS expands the Telebehavioral Health Center of Excellence with funding for new space, updated equipment, and additional behavioral health providers.

Telehealth services strive to make rural health programs more effective, increase the quality of healthcare, and improve health outcomes. The Budget seeks to remove barriers to telehealth services in rural and underserved areas through a proposal to expand telehealth services in

Medicare fee-for-service advanced payments models with more than nominal financial risk. This proposal broadens beneficiary access to Medicare telehealth services and addresses longstanding stakeholder concerns that the current statutory restrictions hinder beneficiary access. The proposal expands the telehealth benefit in Medicare Fee-for-Service and provides authority for Rural Health Clinics and federally Qualified Health Centers to be distant site providers for Medicare telehealth services. It also permits IHS and tribal facilities to be originating and distant site providers, even if the facility does not meet the requirements for being located in
certain rural or shortage areas, and allows for coverage across State lines. The Budget also proposes to modernize payments to Rural Health Clinics to ensure equitable payment for these health clinics and help rural communities maintain access to these crucial services. Finally, the Budget proposes to allow Critical Access Hospitals to voluntarily convert to an emergency hospital that does not maintain inpatient beds.

**Addressing Tick-borne Diseases**

Tick-borne diseases, of which Lyme Disease is the most common, account for 80 percent of all reported vector-borne disease cases each year and represent an important emerging public health threat in the United States. With 59,349 reported cases in 2017, the annual number of reported cases has more than tripled over the last 20 years; due to under-reporting, this number substantially under-represents actual disease occurrence. The geographic ranges of ticks are also expanding, which leads to increased risk for human exposure to the bites of infected ticks. Most humans are infected through bites from very small young ticks, hosted by deer or mice.

To address critical gaps in knowledge, diagnostics, and preventive measures for tick-borne diseases, HHS is proposing an action plan that will prioritize and advance the most promising candidates and technologies for diagnosing and preventing Lyme and other tick-borne diseases. This plan, led by the Office of the Assistant Secretary for Health in partnership with NIH, CDC, and FDA, will address four primary areas: innovations in diagnosis and advanced detection, developing vaccine-based prevention, ensuring robust domestic surveillance of vector borne diseases, and providing additional knowledge to advance the best treatment and prevention options. These efforts will improve outcomes for those affected by Lyme Disease symptoms. This plan builds on the Kay Hagan Tick Act, enacted through the Consolidated Appropriations Act for 2020, to improve research, prevention, diagnostics, and treatment for tick-borne diseases.

The Budget requests $189 million, an increase of $58 million, to address tick-borne diseases. This amount includes $115 million for NIH to expand its research on of tick-borne disease, including in the prevention, diagnosis, and treatment; and $66 million for CDC to address vector-borne diseases, focusing on tick-borne diseases, including tick surveillance, insecticide resistance activities, and development of improved diagnostics. FDA will ensure the safety and efficacy of products developed to prevent, diagnose, and treat vector-borne diseases.

**Focusing on Influenza**

Influenza is a serious disease that can lead to hospitalization and sometimes death, even among healthy people. In the United States, millions of people are sickened, hundreds of thousands are hospitalized, and tens of thousands die from influenza every year. In September 2019, the President signed Executive Order 13887, Modernizing Influenza Vaccines in the United States to Promote National Security and Public Health. The Executive Order recognized influenza as a public health threat and national security priority, and directed HHS to prepare and protect the Nation.

The Budget invests $998 million to continue on-going influenza activities as well as targeted increases to support this directive. This amount includes $306 million for ASPR to modernize influenza vaccine manufacturing infrastructure and advance medical countermeasure research and development. Activities include additional clinical studies on licensure of pre-pandemic recombinant-based influenza vaccine and the advanced development of novel diagnostics, respiratory protective devices, and alternative vaccine delivery technology. The Budget also funds the Office of Global Affairs to support U.S. leadership of international efforts on pandemic influenza preparedness.

The Executive Order also calls for the development of novel technologies to speed seed vaccine development, targeted development of vaccines that protect against multiple types of virus for multiple years, and to improve adjuvants. In support of this goal, the Budget includes $49 million for FDA to support regulatory science research and clinical assessments to promote development and access to safe and ef-
Effective influenza vaccines, and $423 million for NIH to accelerate influenza research, including universal flu vaccine development.

Emergency Preparedness

HHS plays a key role in supporting domestic and international preparedness and response to ensure our Nation’s safety. The Budget invests $2.6 billion in ASPR to expand efforts to prevent, prepare for, respond to, and recover from, the adverse health effects of public health emergencies. This amount includes $562 million for the Biomedical Advanced Research and Development Authority to maintain a robust pipeline of innovative medical countermeasures that mitigate health effects of infectious diseases and chemical, biological, radiological, and nuclear agents. It also includes $535 million for Project BioShield to support procurement of medical countermeasures against these threats, and $705 million for the Strategic National Stockpile to sustain and increase inventory of high-priority countermeasures such as antibiotics to treat anthrax exposure and vaccine to prevent smallpox. These investments will help HHS advance progress towards national preparedness goals.

NIH supports a robust research portfolio to develop vaccines and therapeutics that enable rapid response to public health threats including emerging microbial threats, such as extensively drug-resistant tuberculosis, emerging viral strains such as Zika, and hemorrhagic fevers such as Ebola. The Budget continues investments in NIH in scientific research on these new threats, and invests $120 million in FDA to facilitate medical countermeasure development and availability to respond in the event of a microbial or other public health threat.

Strengthening the Indian Health Service

The Administration is committed to improving the health and well-being of American Indians and Alaska Natives. This population continues to experience significant health disparities, and the Budget includes key investments to ensure quality of care. The Budget invests $6.2 billion in IHS, which includes $125 million for electronic health record modernization, provides funding to support IHS Services, Ending the HIV Epidemic, and Maternal Health, and includes $125 million for high-priority healthcare facilities construction projects. The Budget proposes a new, indefinite discretionary appropriation and reforms for IHS to address Indian Self-Determination and Education Assistance Act section 105(l) lease costs.

Reforming Oversight of Tobacco Products

The Budget proposes to move the Center for Tobacco Products out of FDA and create a new agency within HHS to focus on tobacco regulation. A new agency with a mission focused on tobacco and its impact on public health would have greater capacity to respond rapidly to the growing complexity of new tobacco products. Additionally, this reorganization will allow the FDA Commissioner to focus on its traditional mission of ensuring the safety of our Nation’s drug, food, and medical products supply.

Providing Shelter and Services for Unaccompanied Alien Children

The Administration for Children and Families (ACF) provides shelter, care, and support for unaccompanied alien children apprehended by the Department of Homeland Security or other Federal Government department or agency. The number of unaccompanied alien children requiring care is inherently unpredictable. In fiscal year 2019, ACF cared for 69,488 children, the highest number in the program’s history. In fiscal year 2021, the Budget requests a total of $2 billion in discretionary funds to support capacity of 16,000 licensed permanent beds, depending on operational needs, and includes a mandatory contingency fund to provide up to $2 billion in additional resources if needed.

Promoting Upward Mobility

In the human services work at HHS, the overarching goal is to promote personal responsibility, independence, and self-sufficiency—to help Americans lead flourishing, fulfilling, independent lives. HHS programs for low-income Americans achieve this goal by supporting work, marriage, and family life. HHS seeks to better align our social safety net programs with the booming economy, and focus on work as the means to lift families out of poverty.

Many Americans are joining the workforce as the Administration’s policies continue to strengthen the economy and produce historically low unemployment rates. The Administration supports working families by investing in child care, an important work support that helps families achieve independence and self-sufficiency. The
Administration is working to implement policies that increase access to high-quality, affordable child care.

The Budget proposes to improve the Temporary Assistance for Needy Families (TANF) program by restoring its focus on employment and work preparation, and by targeting funds to low-income families. The proposal fundamentally changes the way the program measures success by moving to measures that focus on employment outcomes, phasing out the ineffective work participation rate. In addition, the Budget establishes Opportunity and Economic Mobility Demonstrations that allow for the streamlining of funding from multiple safety net programs to deliver coordinated and effective services. The Budget also seeks to improve consistency between work requirements in TANF and Medicaid by requiring that able-bodied individuals participate in work activities at least 20 hours per week in order to receive welfare benefits.

Supporting Child Care

Child care is an investment in both present and future generations of the workforce. However, it is also one of the biggest expenses for families and can be a barrier to work. Funding plays a critical role in helping families achieve self-sufficiency by providing parents access to a range of child care options. In fiscal year 2018, the most recent year for which preliminary data are available, over 1.3 million children from about 813,000 low-income families received a monthly child care subsidy from the Child Care and Development Fund. The Budget provides $5.8 billion for the Child Care and Development Block Grant and $4.2 billion in mandatory child care funding for a total investment of $10.0 billion in child care. The mandatory funding includes a one-time $1 billion fund for competitive grants to States to increase child care access for underserved populations and stimulate employer investment in child care. The Budget will serve 1.9 million children.

Promoting Adoption

Adoption gives children stability and love during their childhood, and also a safe and stable environment in which to grow into responsible adults who flourish. Approximately 20,000 youth exit “age out” of foster care each year without the safety net of a forever family, and their outcomes are often concerning. A longitudinal study found that only 58 percent graduated from high school, and only half found employment by age 24. More than a third of youth in one study had experienced homelessness at least once by age 26. Children and young adults in foster care cannot be expected to achieve the independence they need to thrive and flourish on their own—but finding them a loving forever family could change all that.

According to ACF, the number of children adopted with help from public child welfare agencies rose from 59,000 in fiscal year 2017 to more than 63,000 in fiscal year 2018. To sustain this momentum, ACF has launched a Call to Action for States and other stakeholders, which aims to develop and sustain key partnerships across public and private groups, including faith-based groups, with the goal of reducing the number of children in foster care and increasing the number of children who find a forever family, through adoption or otherwise.

The Adoption Assistance and Guardianship Assistance programs will provide $4.1 billion in fiscal year 2021 in mandatory funding to provide monthly support payments to families adopting sibling groups or other children with special needs. Under existing law, Adoption Assistance funding will keep pace with the number of qualifying children adopted each year.

HHS promotes adoption through administrative actions and funding incentives to promote adoption, and to identify and address barriers to adoption. Initiatives include family-finding programs, focusing on identifying the barriers that exist in the recruitment and development of foster and adoptive families, and the development and dissemination of court-related practice improvements addressing barriers to timely adoptions.

Supporting Families and Preventing the Need for Foster Care

Helping families receive the care and services they need before the involvement of a child welfare agency can help prevent a child from entering foster care. The Administration has focused on primary prevention, as well as adoption, and we are starting to see better results. HHS is implementing the Family First Prevention Services Act (Family First Act), which supports services to prevent child maltreatment and the need for foster care. This groundbreaking new legislation provides the opportunity for substantial improvements in outcomes for children and families. The Budget proposes to streamline the process for evaluating evidence-based prevention services programs under the Family First Act to give States and Tribes access to more programs that help prevent the need for foster care and assist kinship caregivers.
The Budget invests $510 million for discretionary child welfare activities in ACF, including services that allow children to remain safely with their families and education and training vouchers for youth aging out of foster care. In collaboration with CMS, the Budget proposes that Qualified Residential Treatment Programs (QRTPs) be exempted from the institution for mental diseases (IMD) payment exclusion allowing children in foster care to have Medicaid coverage in these placements even if a QRTP qualifies as an IMD.

The Budget provides $197 million to ACF for child abuse prevention grants. These grants support increased use of evidence-based prevention programs, allowing States to explore new research opportunities and to adapt more rigorous evaluations of existing programs; demonstration projects to test the effectiveness of partnerships that strengthen family capacity and prevent child abuse through the co-location of services; and State plans for safe care of infants affected by substance use disorders.

The Budget also proposes to expand the Regional Partnership Grant program by $40 million each year, which will increase funding for grants that help courts, child welfare agencies, and other government and community entities work together and improve practices to address the impact of substance abuse, including opioids, on child welfare. The Budget proposes an increase of $30 million each year for the Court Improvement Program to help courts improve practices and comply with new mandates in the Family First Act.

Strengthening Efforts to Treat Serious Mental Illness and Serious Emotional Disturbances In 2018, more than 11 million adults in the U.S. were living with a serious mental illness. More than 7 million children and youth experienced a serious emotional disturbance. They faced a greater risk of suicide and life expectancy 10 years shorter than the general population.

The Budget provides $1.1 billion to SAMHSA for serious mental illness and serious emotional disturbances, which includes funding to support Assertive Community Treatment for Individuals with Serious Mental Illness, Community Mental Health Services Block Grant, and Children’s Mental Health Services. These programs provide comprehensive and coordinated mental health services for some of the Nation’s most vulnerable populations and increases access to mental health services in schools. The Budget will also provide targeted flexibility for States to provide inpatient mental health services to Medicaid beneficiaries with serious mental illness.

The Budget also invests in programs that address the Nation’s alarming rates of suicide. Suicide is the 10th leading cause of death in the United States—responsible for more than 47,000 deaths in 2017—and suicide rates have increased steadily for individuals of all ages. The Budget provides $93 million for suicide prevention activities, including additional funding to expand Zero Suicide initiatives to focus on adult suicide prevention and allow communities and States to tailor strategies to prevent suicide in their local jurisdictions.

Supporting Independence for Older Adults and People with Disabilities

The Administration prioritizes community living for older adults and people with disabilities to ensure that they can maintain independence and live fully integrated in their communities. The Budget invests $1.5 billion in the Administration for Community Living for critical direct services that enable seniors and people with disabilities to live independently, such as senior meals, in-home chore assistance, independent living skills training, employment training, and information and referral services. These programs empower older adults and people with disabilities to live independently and make critical choices about their own lives.

PROMOTE EFFECTIVE AND EFFICIENT MANAGEMENT AND STEWARDSHIP

HHS is responsible for more than one-quarter of total Federal outlays. The Department administers more grant dollars than all other Federal agencies combined. HHS is committed to responsible stewardship of taxpayer dollars, and the Budget continues to support key reforms that improve the efficiency of Departmental operations.

Advancing Fiscal Stewardship

The Administration recognizes its immense responsibility to manage taxpayer dollars wisely. HHS ensures the integrity of all its financial transactions by leveraging financial management expertise, implementing strong business processes, and effectively managing risk.

As the Department overseeing Medicare and Medicaid, HHS is committed to exercising proper oversight of these programs to protect the millions of impacted beneficiaries and the taxpayers in general. In accordance with the direction in the Executive Order on Improving and Protecting
Medicare, HHS is investing in the newest technological advancements, such as Artificial Intelligence, to enhance our ability to detect and prevent fraud, waste, and abuse.

The Department is committed to reducing improper payments in Medicare, Medicaid, and Children’s Health Insurance Program (CHIP). HHS continues to enhance existing program integrity tools to address improper payments and prevent fraud, including provider screening, prior authorization, and auditing providers and plans. New methods and technologies will allow HHS oversight to reduce improper payments and adapt to the changes in healthcare as we shift from a fee-for-service to a value-based healthcare payment system.

The Budget advances new legislative and administrative proposals to strengthen the Department’s ability to address weaknesses in Medicaid beneficiary eligibility determination processes, while providing tools to facilitate the recovery of overpayments made by States. HHS also continues to support updates to Medicaid information systems that offer critical support to program integrity efforts, including the Transformed Medicaid Statistical Information System (T-MISIS) and a new Medicaid drug rebate system. In addition, HHS includes proposals that enhance oversight of Medicare Advantage and Part D plans, increase the period of enhanced oversight on new providers, and expand Medicare fee-for-service prior authorization.

Implementing ReImagine HHS

HHS supports the President’s Management Agenda through ReImagine HHS, the Department’s robust reform and transformation effort, organized around core goals to streamline processes, reduce burden, and realize cost savings. The effort takes an enterprise approach, affecting activities across the Department. For example, the Buy Smarter initiative plans to use new and emerging technologies to leverage the enormous purchasing power of HHS and streamline the end-to-end procurement process. The Maximize Talent initiative addresses modern-day human capital management and human resources operational challenges, resulting in key achievements: HHS’s simplified recruitment process resulted in a significant increase in the number of new hires on-boarded since implementation, and HHS was rated the “Best Place to Work in the Federal Government” out of all executive departments in 2019. As a result, 48 States and territories participate in the Produce Safety Implementation Cooperative Agreement Program, which increased State large farm inspections over 400 percent in fiscal year 2019.

ReImagine HHS efforts are also making HHS more innovative and responsive. Under the Optimizing Regional Performance initiative, HHS developed a Regional Facilities Utilization Model with $150 million in potential savings and a footprint reduction of more than 62 percent within 10 years. For the first time since 1974, HHS completed a comprehensive assessment of regions to better align with Administration priorities and improve HHS’s ability to serve Americans across the country. In addition, under the Optimize Coordination Across HHS initiative, HHS configured a new cloud environment for an administrative data hub to provide dashboarding capabilities for Operating Divisions, bringing together human resources, travel, and facilities data to inform better decisionmaking across the enterprise.

In fiscal year 2021, all ReImagine HHS projects will reside in their permanent offices within HHS. This ensures that their work can sustainably continue going forward.

Grants Management

HHS continues to drive change for grants management government-wide. Leveraging the efforts and success of the HHS ReImagine Grants Management initiative, the Office of Management and Budget pre-designated HHS as the Grants Quality Services Management Office (QSMO) to create and manage a marketplace of solutions for grants management; govern its long-term sustainability; institute a customer engagement model; and drive the implementation of standards and solutions to modernize grants management processes and systems. Guided by a government-wide governance board, QSMOs are tasked with offering solutions that, over time, will improve quality of service and customer satisfaction; modernize and automate processes and supporting technology; standardize processes and data; and achieve efficiencies in government-wide operations and maintenance.

In fiscal year 2018, the government awarded over $750 billion in grants to approximately 40,000 recipients across more than 1,500 programs.
Full designation as the Grants QSMO is contingent upon approval of a 5-Year Implementation Plan and budget estimate in alignment with the published QSMO Long-term Designation Criteria. HHS is developing a vision and strategy to inform the Grants QSMO 5-Year Implementation Plan, with significant engagement with stakeholders to ensure the Grants QSMO can meet their diverse needs.

**Regulatory Reduction**

HHS is committed to streamlining the regulatory process and evaluating necessary steps to eliminate or change regulations that impose unnecessary burden. Burdensome regulations can drive up costs of healthcare, while poorly designed regulations can come between doctors and patients, reducing the quality of care and the essential trust to that relationship. From fiscal year 2017 to fiscal year 2019, HHS succeeded in cutting the economic burden of its regulations by $25.7 billion through 46 deregulatory actions. HHS had the largest deregulatory impact of any Cabinet agency during this time period.

HHS is using the power of new cognitive technologies for greater operational effectiveness and research insights, including regulatory reduction. HHS used an Artificial Intelligence-driven regulation analysis tool and expert insight to analyze the Code of Federal Regulations, seeking potential opportunities to modernize regulations. HHS since launched a Department-wide Regulatory Clean-Up Initiative to implement changes based on these findings, by reviewing and—where a change is warranted—addressing incorrect citations and eliminating the submission of triplicate or quadruplicate of the same citation.

HHS is working to implement the provisions of the Executive Order on Promoting the Rule of Law through Improved Agency Guidance Documents. This Executive Order will accomplish important policy goals that will improve HHS guidance practices in the long term. Prior to the issuance of this Executive Order, several Federal agencies issued internal memoranda regarding the appropriate use of guidance. The Executive Order requires agencies to now go a step further and codify certain good guidance practices and policies into Federal regulations. By August 27, 2020, each agency must finalize regulations to set forth processes and procedures for issuing guidance documents. In addition, by February 28, 2020, Federal agencies must establish a single, searchable database on its website that contains, or links to, all of the agency’s guidance documents currently in effect. Any guidance document not included in the guidance website is deemed rescinded. HHS is committed to meeting the President’s timelines.

Senator BLUNT. Thank you, Mr. Secretary.

I will say for the members that there are votes scheduled at 11:30 and we will try to keep the hearing going through at least the first two of those votes, and so there will be some effort made for members to leave and take the first vote and come back and we will see if we cannot make that work.

**LIVER ALLOCATION POLICY**

Glad to have you. Glad to have your time. I want to ask two questions. One is on the liver allocation policy. Senator Moran and I sent you a letter on January 21st urging that you step in to prevent what we thought was a shortsighted and ill-thought-out policy.

Roughly, 40 percent of the country will be harmed by the new process, which goes from a regional allocation to a nationwide allocation.

We have already seen, Mr. Secretary, increased cost per transplant, increased waste in what was already a complex system and organs that were discarded because people had to travel too far to get the organs to bring back to the recipient.

Even the Federal judge in the litigation referred to what would be a regional bias here. The government contractor on this effort provides no information to the committee on how the decision was made.
They overruled experts in their own Liver and Intestine Committee. Now they want to continue to have all the evidence in the litigation under seal.

So, my question to you is, one, what made you determine after our January letter that you could not do anything, and two, are you willing to do something to work to get the evidence and what supposedly should have been available to this outside contractor to make that evidence public?

Secretary AZAR. So, Chairman, I share your concerns and frustrations, and HHS has actually requested OPTN (Organ Procurement Transplant Network) to reconsider their decision to ensure a full consideration of the comments that they received from Kansas and Missouri.

As you know, HHS does not make decisions on organ allocation policy. The Organ Procurement Transplant Network is responsible for organ allocation policy, and while we are charged with oversight of OPTN, those decisions by statute are delegated to the OPTN and I do not have the ability to change those decisions.

We continue to look for authorities that might do that and we certainly look forward to working with you if there were legislative proposals that might give me authority. But those have actually been walled off from the secretary.

Of course, the number-one thing we can do is increase the number of livers available and that is why we are working to reform our organ procurement policies and our oversight policies and practices regarding the organ procurement organizations in the country so that we can dramatically increase the number of organs available in this country.

But I am happy to keep working with you on this liver issue but my degrees of freedom are limited, quite frankly, by Congress in my ability to influence the OPTN.

Senator BLUNT. Well, let us continue to see if we cannot find ways to help you have more ability in that oversight process to have oversight.

CORONAVIRUS SUPPLEMENTAL REQUEST

Let us go to the supplemental request, the emergency supplemental. I understand it to be $2.5 billion. About half of that would be counted as emergency spending and the other half would be paid for in various ways like the $105 million that you will soon have gone through.

The fund I mentioned earlier today, the Infectious Disease Response Fund—the infectious disease reaction ability you did not have before—talk to us a little about putting that together, your thoughts for internal transfers.

We are always concerned, as we should be, about big amounts of money being transferred under the secretary’s authority in different ways than this committee and with the president’s signature decided that money should be spent.

Secretary AZAR. Yes. So, first, let me be clear. We would like to focus on the top line of the $2.5 billion in terms of the key strategic needs. We have, of course, put forward a supplemental that would allow offsets and transfers to pay for about half of that.
But, of course, that is Congress's decision and we look forward to working with you if those choices make sense to you or if there are other sources or offsets or approaches that you would like to take.

In terms of the top line, that $2.5 billion, I focused my energies here in five key critical success factors. The first is we need to expand our surveillance system in the United States for the China coronavirus to be comparable to our flu surveillance system. This is the backbone of our effective public health response at the State, local, and Federal level to have that surveillance.

Second, we need support for State and local governments. While we provide almost half of the funding of State and local public health departments and $675 million a year for emergency preparedness by those departments, we do believe we need more money to support contract tracing, communications with impacted individuals, and laboratory test work, and we have that in here.

Third, we have to take advantage of telehealth and other innovation. And fourth, we need to support the research, development, and procurement of vaccines and therapeutics, and so there is money in there to support both of those.

Then, finally, we need to support the acquisition of personal protective equipment, especially masks, into the Strategic National Stockpile. So those five key areas are where the funding is directed.

Senator BLUNT. Thank you, Mr. Secretary.

Based on, again, the other challenges we are facing this morning, I am going to keep my questions to 5 minutes and hope everybody will do their best to keep theirs, and if there is time for a second round and people want to stay for that we will have that. But be sure everybody gives everybody else the ability to have a first round.

Senator Murray.

CORONAVIRUS PREPAREDNESS

Senator MURRAY. Thank you, Mr. Chairman.

At the administration's briefing this morning on the coronavirus, we were told by the experts at NIH and CDC that there is a very strong chance of an extremely serious outbreak of the coronavirus here in the United States.

So I want to talk about the preparations of this administration and what you have been doing. You have had more than a month now to prepare for this increasing likelihood and I want to ask you is our country ready?

Secretary AZAR. So our country is preparing every day and the effective aggressive containment measures that we have taken at our borders as well as working with our public health departments.

Senator MURRAY. I meant——

Secretary AZAR. So I bought us time to continue preparedness. One is always advancing preparedness. Every day one advances those activities and the emergency supplement would help that.

Senator MURRAY. Okay. Mr. Secretary, I only have a few minutes. Let me be really clear, because you sent over a supplemental that was not clear to me at all. You just mentioned a number of
things from tracing, State and local governments needing their health cares and hospitals ready for this.

You have talked about protective masks. You talked about surveillance system. I did not see anything in that request that specifically says how much each of those are going to cost. And we know—we have seen this outbreak in China now. We know it is going to other countries.

It quickly overwhelms a healthcare system. It puts patients who do not have the virus at risk, who suffer from other conditions. We know that medications become very difficult.

Did you stockpile any of these critical supplies that we are told we need—masks, protective suits, ventilators, anything? Is that stockpiled and ready?

Secretary Azar. So we do have in the Strategic National Stockpile ventilators. We have masks. We have all the appropriate——

Senator Murray. Enough?

Secretary Azar. Well, of course not or we would not be asking for a supplemental to seek more money to procure more of that for this circumstance. This is a very—this is an unprecedented potential severe health challenge globally and will require these additional measures.

Senator Murray. Okay. Well, I did not see any numbers in your request.

Secretary Azar. We will be briefing committee staff and members. This just came over last night and we will be briefing you on those details and supporting you with technical assistance.

LONG-TERM COSTS OF RESPONSE

Senator Murray. You just gave us a very long list of things that are needed, most of which we do not have, which you cannot just buy tomorrow. And I am very concerned that this is not only inadequate in terms of numbers but in terms of specifics of what we are going to need and we need to know that from your experts.

You know, health experts including your own tell us that this outbreak could be very long lasting and this is a very vague request for supplemental money and I just think it is a Band-Aid and I want to know why.

We know this is coming. We have been watching in China. Everybody has been telling this. What are the long-term costs of a sustained response? Do we know that? Including the manufacturing, by the way, of diagnostics that we know we are not ready for right now.

Secretary Azar. Well, we have the details. We will be providing them to the committee and the committee staff and we want to work with you on this to ensure that it is an effective supplemental that meets your needs.

This funding request is for 2020 money only at this point. It would have a permission for carryover into 2021 spend. But then we would work with the Congress, the appropriators, on adjusting any 2021 needs as we learn.

We are really learning day by day and week-by-week here of the contours of this disease as well as the spread of the disease and its potential impact and that will help inform those 2021 discus-
sessions that we would, of course, have with this committee, going for-
ward, in the next couple of months.

Senator MURRAY. Well, I just have to say I am very concerned
about this administration's attitude towards this.

If a pandemic is coming and we are disregarding scientific evi-
deence and relying on tweets and an emergency supplemental with-
out details and we are not stockpiling those things right now that
we know we might possibly need for this or for any future pan-
demic. I am deeply concerned that we are way behind the eight ball
on this.

Secretary AZAR. Well, we actually have been aggressively mov-
ing. It has been a month and a half since this situation arose and
we have enacted the most aggressive containment measures in the
history of our country in terms of our borders.

I have used the first Federal quarantine authority in 50 years of
an HHS secretary. We have worked with our State and local part-
ners——

Senator MURRAY. Can you assure every single American today
that if this pandemic hits our shores that we have everything avail-
able and we have stockpiled it and we are ready to go?

Secretary AZAR. That is precisely why we need to work with Con-
gress for additional appropriations to enable procurement. But
right now—and we have been very clear. Dr. Fauci has told you
just this morning we do not have a vaccine. One cannot have a vac-
cine for—one cannot——

DIAGNOSTIC TESTS

Senator MURRAY. No, I am not asking about—I am asking about
diagnostics and testing, which we are not—we do not have enough
currently.

Secretary AZAR. Well, one—well, yes, we have a diagnostic. CDC
invented a diagnostic in historic time, within one week of the se-
quence arriving.

Senator MURRAY. But it is not available to the 137 CDC——

Secretary AZAR. It is available now at CDC and then 12 sites
have been able to validate it. We are working with—CDC and FDA
(Food and Drug Administration) are working together on a modi-
fied version of the test that would enable qualified control at the
third reagent stage or elimination of that if possible to enable fur-
ther spread of the diagnostic.

Senator MURRAY. Mr. Secretary, I am out of time. But I am told
that the diagnostic does not work.

Secretary AZAR. That is incorrect. That is simply flatly incorrect.
The diagnostic works at CDC and at 12 sites it has been validated.
At other sites, we are working to get them validated.

This is a working diagnostic. In the areas of the 170 labs where
it was sent, there was a problem in the third reagent stage of it
that led to inconclusive results against control.

We are assessing right now with FDA whether that actual step
is needed in the process and we have 70 private sector diagnostic
manufacturers who are working to bring forward diagnostics and
we will work with those on emergency use authorization.

Senator MURRAY. Working to bring forward. But we are not there
yet.
Secretary AZAR. We are now, what, 50 days into it. This is historic. No administration, no CDC in American history, has delivered like this.

Senator MURRAY. I do not question that at all but I do question our ability with a very small unspecified supplemental and the lack of preparedness that we have to be ready for this.

Thank you, Mr. Chairman.

Senator BLUNT. Senator Shelby.

CORONAVIRUS SUPPLEMENTAL REQUEST

Senator SHELBY. Mr. Secretary, I want to follow up on what Senator Murray was talking about.

One, it seems to me at the outset that this request for the money, the supplemental, is low-balling it possibly and you cannot afford to do that. I hope the—we want to help the administration. We want to help you do your job. But if you low-ball something like this you will pay for it later. But you are not only dealing with the crisis. You are dealing with the perception and the concern of the American people, right. Both, at the same time.

I know you cannot develop a vaccine and immunize everybody in America from something that has just fallen on us all at once, and the world, really, coming at you. But what are you specifically doing—what are your guidelines and this administration to contain this in America?

We do not want this to spread. If it spreads, it is going to be hard to contain. What are you doing and what do you propose to do?

Secretary AZAR. So we are taking——

Senator SHELBY. And what is your message to the American people that may be watching this hearing?

Secretary AZAR. So the steps that the president has taken are the most aggressive containment measures ever in history in terms of travel restrictions at our borders, funneling passengers, restricting foreigners from coming into our country if they have been in China, travel restrictions and advisories to countries, in addition to, of course, the solid State and local public health response which actually identified all but one of the 14 cases here in the United States. One of them was identified through our aggressive screening measures at the 11 funneling airports.

So that is part of it. But then the aggressive measures we need now are we have a historic opportunity with the vaccine. We have developed a vaccine candidate. That should—Dr. Fauci talked about that in the Wall Street Journal today going to clinical trials we hope within 3 months from development.

That would be a historic development of a product. We are supporting and working with manufacturers on potential therapeutics that could be cures or mitigation for individuals who contract this.

So we work to contain as much as possible but at some point if there is sustained human-to-human transmission we also work to mitigate through our traditional public health tools and those are the steps that we would take.

I was very clear when we enacted our containment measures at the border. We cannot hermetically seal off the United States to a virus.

Senator SHELBY. No, I know.
Secretary AZAR. And we need to be realistic about that. And so this virus we will have——

Senator SHELBY. Life goes on in some form.

Secretary AZAR. It does, and we will have more cases in the United States and we have been very transparent about that and we will then work to mitigate the impact of those.

Senator SHELBY. And when does it get to the point in the U.S.—you say we will have more cases and I think that is logical—where we are over concerned? We are really concerned. Is it because it is spread city to city?

Secretary AZAR. Well, we always look for sustained human-to-human transmission——

Senator SHELBY. But you have got to have these models and——

Secretary AZAR. We do. We do. So what we look for is sustained human-to-human transmission especially that is unidentified.

That is what is particularly concerning about Iran and Italy right now is we have apparently sustained human-to-human transmission with no identifiable connection to existing cases. That is very, very concerning to see that in other countries and that is what we would certainly look for here.

Right now, it is important to remember the 14 cases that we have that are in the U.S. as well as the 40 from the repatriated individuals from China and Japan, in every single instance we know why that person has the novel coronavirus. We know. That is a product of the world’s finest public health system, which allows us to have that level of knowledge on this rapidly developing situation.

CORONAVIRUS TREATMENTS

Senator SHELBY. Well, what is the treatment for it?

Secretary AZAR. Right now, one has to simply—because there is no treatment, one treats the symptoms as one does for other therapies.

There are some experimental products and clinical trials. One is a Gilead product known as remdesivir that some individuals have been treated under an IND (Investigational New Drug) protocol for a clinical trial.

We have—that product is being tested in two trials in China, two 500-person arm trials in China as well as now, as I mentioned this morning, in the University of Nebraska and I believe also in Japan.

Senator SHELBY. Mr. Secretary, I believe that this committee—Senator Leahy is here, Senator Blunt and Senator Murray are the leaders of this subcommittee. I believe that we will be able to mindset to fund this crisis, not to underfund it in any way, and I hope the administration will look at this as something that they cannot afford to let get out of hand, period, or the perception that it is getting out of hand.

Secretary AZAR. Well, Chairman, I want to assure you that I am fully supportive of this $2.5 billion request. I was part of architecting it. It is what I believe we need for 2020.

But, of course, if Congress differs with the power of the purse, we will work with you, provide technical assistance to try to make sure it meets what you view as the needs are.

Senator SHELBY. Whatever. Thank you, Mr. Chair.
Senator Blunt. Thank you, Chairman.

Senator Leahy.

Senator Leahy. Thank you, Mr. Chairman, and welcome, Secretary.

FISCAL YEAR 2021 BUDGET REQUEST

Like so many others up here, both Republicans and Democrats, I am concerned with the budget the administration has put forward for the Department of Health and Human Services.

Obviously, you were involved with it but it seems to have been drafted to hit an arbitrary target to slash funding without any realization of real-world impact of the proposed cuts.

In fact, a move that is completely confounding in the midst of the novel coronavirus outbreak you wanted to slash funding in fiscal year 2021 to varied programs to help us combat dangerous infectious diseases.

And while we might talk about having a vaccination for the virus that is still about 2 years away, it has spread to 30 countries. It has infected more than 79,000 people. It has caused at least 2,600 deaths.

Hundreds of Americans are restricted to U.S. military bases under a Federal government quarantine, and that is the first time in 50 years.

But you proposed to cut $3.1 billion from the National Institute of Health, nearly $700 million from Centers for Disease Control and Prevention programs, roughly, $100 million from public health preparedness and response programs. These are the very programs we are going to have to rely on to combat coronavirus and other infectious diseases.

If Congress went along and made the cuts that you and the administration has asked for, you would not be able to keep the public safe when the next threat emerges, and one will. So why would you propose such cuts? How does it make any sense?

Secretary Azar. Well, Vice Chairman, as you know, we have a tight budget environment but we prioritized actually the infectious disease preparedness and emergency response. So, for instance, at CDC those three activities were prioritized and actually increased the propose funding by $135 million in the 2021 budget.

Now, of course——

INFECTIOUS DISEASE RAPID RESPONSE FUND

Senator Leahy. Well, the CDC’s Infectious Disease Rapid Response Reserve Fund, which we had created to help you, is running out of money, including the number—and now we see an increased number of infectious people, 53 in the U.S.

Secretary Azar. We estimate——

Senator Leahy. How is that being careful with these—and this has been going on for months and last night we get this somewhat vague request for emergency funding. If I was cynical, and Vermonter never are, I might think it was rushed over just in time for your appearance before this committee this morning and that is why it is vague enough.
Secretary AZAR. So the Infectious Disease Rapid Response Fund at CDC was funded by Congress in 2020 as well as 2019 and so it is current year money.

We are running out of that money, which is why we have sent over that we plan to do transfer and reprogramming using the existing authorities for 2020 appropriations and precisely why we are asking for an emergency supplemental.

CORONAVIRUS SUPPLEMENTAL REQUEST

Senator LEAHY. But you would take a half a billion dollars out of the money appropriated for the Ebola threat.

Secretary AZAR. Those would be proposed offsets or trade offs for the emergency supplemental. If the appropriators do not want to do that—that is just an option for the appropriators for the——

Senator LEAHY. Did you have any of your requests for supplemental funds, any requests that you made to OMB, were there any of them that were denied by OMB?

Secretary AZAR. Well, I am not going to discuss internal deliberations.

Senator LEAHY. Why not?

Secretary AZAR. That is not proper to discuss internal deliberations.

Senator LEAHY. Why is it not proper? I have heard that question asked by—during Democratic administrations and Republican administrations over my 40 year on this committee and it has been answered.

Secretary AZAR. I would never answer internal deliberations with the White House. But I will tell you I am completely supportive of the $2.5 billion request. It does exactly what I want, which is to focus on those five critical to success factor areas.

Senator LEAHY. Okay. So what you want is a proposal that would divert $135 million from other important programs including $37 million from LIHEAP, millions from substance abuse, $7 million from Medicare and Medicaid programs.

So I will not ask you deliberation but you just want to cut a whole lot of things that we rely on.

Secretary AZAR. Well, those are options for funding half of the cost of the emergency supplemental. But if Congress makes a different choice Congress makes a different choice. These are the top line.

Senator LEAHY. Where does the other half come from?

Secretary AZAR. That would be emergency supplemental. New money that you would have to come up with.

Senator LEAHY. Okay. So the things you want—some of the NIH funding, the Ebola funding—your recommendation, and you are the expert in this, is to cut that out.

Secretary AZAR. It is a proposal of how to fund half of the cost of the total response.

Senator LEAHY. It is your proposal.

Secretary AZAR. That is our proposal. But if Congress disagrees with other approaches there are other ways to get there.

Senator BLUNT. Thank you, Senator Leahy.

Senator Alexander.

Senator ALEXANDER. Thank you, Mr. Chairman.
Mr. Secretary, welcome. Before I ask—get into coronavirus I want to congratulate Senator Blunt and Senator Murray and Senator Durbin and Leahy and Shelby and members of the subcommittee for the last 5 years of funding for the National Institutes of Health.

Over that 5 years, discretionary spending, which is about a third of our budget that the Federal Government spends, has gone up 20 percent.

But funding for the National Institutes of Health has gone up 39 percent and, I might add, the subcommittee that deals with the Office of Science in the Department of Energy that Senator Feinstein and I work on has gone up 38 percent. So one of the best kept secrets in Washington is the big increase in funding for biomedical research and science and I want to congratulate this committee for its part of it.

CORONAVIRUS

I think one of our responsibilities as members of the Senate is to help the American people get a fair view of exactly how threatening to them individually the coronavirus is.

Looking around the world, there is reason for alarm. Ten days ago, for example, there were 49,000 confirmed cases in the world. Ten years ago in China there were 48,000 confirmed cases.

Today in China there are 79,000 confirmed cases in the world and there are 77,000 in China, and we read about problems and popping up in Italy, which could get across their borders, and in Iran and other places, South Korea.

And not only do we have the problem of a rapidly spreading virus, which could jump into our country. We have to think about what items manufactured in those countries could mean for us with 13 percent of our prescription drugs—our drugs being manufactured in China, for example.

Are we going to have shortages? And even beyond that with a quarter or so of everything that we use in this country being made in China will we have supplies for our automobiles and our other things that we make in this country and what will it do to our economy.

So looking around the world, there is a reason to be alarmed. But, now, looking at home, let me go through what the facts are at home. We have known about this for about 2 months, right, about 50 days.

Secretary AZAR. Yes, about 50 days.

Senator ALEXANDER. And 10 days ago, if I am right, we had detected 14 cases in the United States.

Secretary AZAR. I believe that is correct, yes.

Senator ALEXANDER. And today we have detected 14 cases in the United States——

Secretary AZAR. That is correct.

Senator ALEXANDER [continuing]. In addition to the 39 cases of Americans who have been brought home from overseas and isolated in this country because they might have been infected there.

Secretary AZAR. Exactly. The imported cases.
Senator ALEXANDER. And during that time, you have begun to develop a vaccine, which will not be ready for a year or longer but you are doing that more rapidly than any other time in the history of our country.

Secretary AZAR. That is correct.

Senator ALEXANDER. And my question is going to be with this alarming situation in the world, what have you been doing right at home that caused us to see a situation where this huge country of ours we only have 14 cases a year ago—a mean, 10 days ago and 14 today?

My guess is, is 20 years of preparation by Democrats and Republicans on this committee and Democrats and Republican presidents to be ready for pandemics, number one. Number two, it is the extraordinary health system we have in this country, State and local, doing their job.

And number three, it is the first and most aggressive quarantine requirements that you have done in 50 years.

So if we are alarmed about what has gone on around the world, what can we learn about the last 50 days in this country that you have been doing right that makes us be able to say 10 days ago there were 14 cases and today there are 14 cases at a time when around the world cases are going up?

Secretary AZAR. So we are bearing the fruits, actually, of our pandemic flu preparedness activities, which I was one of the architects of in the Bush administration and that Congress funded.

We are seeing the public health infrastructure from that that is coming to fore. One of the most important things we did as soon as alerted to this and as soon as we had a genetic sequence and understood the nature of the symptoms of this disease was to alert our State and local public health partners and our health professionals, and that is why 13 of those 14 cases were identified by healthcare professionals, astutely seeing that these were individuals who had been in Hubei Province and presented with flu-like symptoms, got into the system and took advantage of that one-week-developed CDC test to confirm results.

So that is the—that kind of public health infrastructure, the world's best, is the backbone of our response activities here.

In addition, we worked on aggressive border containment measures and we have worked with China to try to get transparency and get information. We still do not have, unfortunately, solid information to take to the bank on severity, on transmissibility, on incubation period, on asymptomatic transmission.

Senator ALEXANDER. I am out of time. But I think what I am hearing you say you would do more of what you have already done, properly funded?

Secretary AZAR. Yes.

Senator BLUNT. Thank you, Senator Alexander.

Senator Schatz.

Senator SCHATZ. Thank you, Mr. Chairman.

FISCAL YEAR 2021 BUDGET REQUEST FOR PREPAREDNESS PROGRAMS

Thank you, Secretary, for being here. This committee has a long tradition of bipartisanship and I know Secretary, you and I have had a couple of disagreements in private and in public. So I want
to kind of see whether we can find some common ground in fighting the coronavirus.

The president’s budget cuts the Infectious Disease Rapid Response Reserve Fund, the Public Health Preparedness and Response Fund, Hospital Preparedness Program, and the Epidemiology and Laboratory Capacity Program.

So given everything that has happened over the last 50 days I want to give you an opportunity, and given the context here, which is last night you proposed a $2.5 billion supplemental, do you want to rescind those cuts to the base budget of your agencies that deal with this problem?

Secretary AZAR. Well, it is a good question, Senator. As I mentioned to Chairman Blunt, this is a request focused on 2020 money, so money to be spent——

Senator SCHATZ. Not—hold on.

Secretary AZAR. Hold——

Senator SCHATZ. Hold on. I am not asking you about the supplemental. I am asking you about the president’s budget, which cuts all those programs which I described, and the question is a simple one, because I have a couple of other questions I would like to get to.

Will you rescind those cuts? Will you ask us to restore those programs or will you not?

Secretary AZAR. So as I said to Chairman Blunt, we will work with you over the coming months as we learn more about this disease on whether to modify the 2021 appropriation request in light of that. We do increase by $135 million CDC’s budget around preparedness, emergency response, infectious disease, and global health security.

Senator SCHATZ. I am not going to get too much into the weeds there but I will just offer that actually is a shell game. There are four key programs that deal with this problem. They are being cut.

The CDC overall is being cut by 9 percent. And so you may have increased a line item or two but that is a talking point. That is not the fact of the matter.

And this committee will very likely reject these cuts. But it is absurd to me that you are proposing cuts at the same time that you are proposing a supplemental on the same topic.

MASKS IN STOCKPILE

So moving on, how many masks do we need in our strategic stockpile and how much will that cost?

Secretary AZAR. So we would need to determine through procurement what the cost would be of additional masks. I know that this morning in the briefing there was a reference to possibly as many as 300 million masks needed in the U.S. for healthcare workers.

We want to define that better through procurement criteria. We have to, frankly, establish supply here in the United States, ability to manufacture as well as to find sourcing of active ingredients such as the filtration, even the nickel and copper nose joints that go on the N95 masks.

Senator SCHATZ. I got it. So for the——

Secretary AZAR. So if we get—if we get the money we can actually make that market and get capacity built here in the U.S.

Senator SCHATZ. Understood.
Secretary AZAR. We want to work with you on——

Senator SCHATZ. But for the $2.5 billion, the masks and the strategic stockpile, the test kits, all of your five lines of effort, it seems to me you do not quite know how much each line of effort is going to cost. Is that accurate?

Secretary AZAR. We would have to do procurements to find out exactly what we would—our per unit cost would be on the masks——

Senator SCHATZ. So that is a yes?

Secretary AZAR [continuing]. Because, again, we would be scaling up domestic production that does not fully exist right now. So one does not know until one actually procures those.

CORONAVIRUS SUPPLEMENTAL

Senator SCHATZ. So how do you get to $2.5 billion not knowing how to compile—you have five lines of effort. You do not know how much the—the first one I am asking about you say you have to go through procurement.

You have to build a market. I understand all that. So then how do you get to $2.5 billion with any degree of specificity or reliability? Is $2.5 billion sort of pulled out of a hat?

Secretary AZAR. No, not at all. The $2.5 billion actually reflects——

Senator SCHATZ. Well, then but one of the major cost items you do not know how much it is going to cost.

Secretary AZAR. You do not know the precise per unit cost but in the range of the hundreds of millions of dollars we are dealing with that, clearly, would be sufficient.

I think right now acquisition costs for N95 masks tends to be under a dollar. So that gives you a rough approximation. But we have to scale up domestic production. That might be——

Senator SCHATZ. So do you have that—do you have back of the envelope numbers that you have not yet provided to the committee?

Secretary AZAR. Yes, because I have——

Senator SCHATZ. Because it sounds like you have—well, but it sounds like you have ballpark numbers. I was told by a staff person that the supp—now, I have not gone through it with a fine-tooth comb yet but I have been told that this is the least detailed supplemental that they have ever seen.

Secretary AZAR. Well, you have—yes.

Senator SCHATZ. And so should we just consider this a marker and you will get us the details later?

Secretary AZAR. Not in the least. There is a letter that went up last night which has the number—the basic numbers in it and, as I have told both the chairman and the vice chairwoman, we will work with your staffs to get you the details behind that. There is detail behind that. Just last night you got the initial letter.

DIAGNOSTIC TEST KITS

Senator SCHATZ. Okay. Final question on test kits. They were deployed into a bunch of locations. They did not function properly. Why in the world do we have test kits—do we have tests that operate in Atlanta but cannot be—and the country of Japan has test kits that are reliable.
Other places—first of all, other States but also other countries have operating test kits. And given all of the preparedness work that you say you have been doing and all of the extraordinary work of all of our agencies, why cannot we deploy test kits that function and why does it have to be mid-March before States and especially ports of entry have functioning test kits?

Secretary AZAR. So as I mentioned before, the CDC test was developed with historic speed. It has three reagent phases on it. The third one, it is unclear whether it is actually necessary.

But what we do whenever it deploys out into the field or at CDC one has to do the quality control and validate those results. That validation failed at the third stage not for false positive or false negative but simply for inconclusive results against control in one of the 92 reagent slots. We are now—

Senator SCHATZ. Thank you, and my—I am sorry—

Secretary AZAR [continuing]. Working on streamlining that process with FDA. So we hope to get those revised ones out very quickly.

Senator SCHATZ. Thank you.
Senator BLUNT. Thank you, Senator Schatz.
Senator Kennedy.
Senator KENNEDY. Thank you, Mr. Chairman.
Thank you, Mr. Secretary, for being here.

CORONAVIRUS

We have 14 active cases now, excluding the 39 that were imported.

Secretary AZAR. That is correct. We have 14 and then we, at the moment, are at a total of 43 imported. Forty from the Diamond Princess, three from Wuhan. Yes.

Senator KENNEDY. How did the 14 contract the virus?

Secretary AZAR. The 14 contracted the virus. Twelve of them contracted it by travel in Wuhan, China, and the other two were spouses of infected—of those 12.

Senator KENNEDY. How is the virus transmitted?

Secretary AZAR. I do not want to play doctor on this. It is transmitted generally by respiratory symptoms. But I would like to defer, if I could. We will be happy to get you, from scientists, the best assessment of transmissibility of the disease.

Senator KENNEDY. Can it be transmitted through food?

Secretary AZAR. We do not believe that there would be fomite transmission through food. But we still are trying to learn of the sustainability of the virus on surfaces. That is what we call fomite transmission is, and Dr. Fauci has said he does not believe that there is a reason to believe it should survive more than a couple of hours on hard surfaces.

Senator KENNEDY. So it can survive a couple of hours outside the body?

Secretary AZAR. That is what Dr. Fauci has said is the working assumption. But, of course, we do not have firm trial data on that yet. That is one of the things we are hoping to learn from the WHO (World Health Organization) team in China.

Senator KENNEDY. How is severity determined?
Senator AZAR. Severity is determined usually by fatality rate against the number of people infected.

Senator KENNEDY. Right, obviously. Let me rephrase that. That was not a very artful question. Some people get really sick. Others do not.

Secretary AZAR. Right.

Senator KENNEDY. Why the difference?

Secretary AZAR. Well, we do not know. That will depend on the nature of this disease. For instance, with the 1918 flu, the so-called Spanish flu, it was interestingly your healthier young middle-aged adult males that seemed to have the worst reaction and greatest severity.

Senator KENNEDY. Let me stop you, Doctor.

Secretary AZAR. Yes.

Senator KENNEDY. I do not want to get too far afield here. The short answer is we do not know, right?

Secretary AZAR. We do not know right now, no.

MASKS IN STOCKPILE

Senator KENNEDY. Okay. How many face masks do we have?

Secretary AZAR. We currently have 30 million N95 respirators in the Strategic National Stockpile.

[The information follows:]
Senator KENNEDY. How many do we need?
Secretary AZAR. Dr. Kadlec mentioned to the Senate this morning needing approximately 300 million for healthcare workers.
Senator KENNEDY. We have 300 million healthcare workers in America, do we?
Secretary AZAR. No, that would be assuming the need to swap out used ones.

CORONAVIRUS CASE MODELING

Senator KENNEDY. Okay. What do your models show about how many cases we are anticipating?
Secretary AZAR. Well, we do not know because we do not know the full attack rate in China. So, for instance, we have seen a high of 30 percent infection on the Diamond Princess, approximately, which was, frankly, seemed to be an incubator.
In Wuhan, China, it is very hard to know what the total accurate number of cases are.
Senator KENNEDY. We do not know then?
Secretary AZAR. We do not know.
Senator KENNEDY. Okay. Do you have models to try to answer this question?
Secretary AZAR. Well, we can only extrapolate based on the data we get from China at this——

Senator KENNEDY. Is China telling you the truth?

Secretary AZAR. We are getting data from China, as the world is. But whether that information is full and transparent we just do not know.

MORTALITY RATES

Senator KENNEDY. What is the mortality rate of the coronavirus?

Secretary AZAR. It is showing right now anywhere between 1 and 2 percent. But, again, that is based on a denominator. There may be many, many more cases in China that are low symptomatic or have not secured treatment and, hence, are not in the Chinese reported cases.

Senator KENNEDY. What is the mortality rate of influenza?

Secretary AZAR. Seasonal influenza tends to be .1 percent mortality.

Senator KENNEDY. Okay. So we are talking about a substantially higher mortality rate?

Secretary AZAR. It could be, again, dependent on what that denominator is. That is why we need to use great caution in making predictions about the severity of this.

CORONAVIRUS VACCINE

Senator KENNEDY. How soon will we have a vaccine?

Secretary AZAR. Well, as I mentioned, Dr. Fauci in the Wall Street Journal today talked about this going into clinical trial, amazingly, within 3 months after discovery. We could, within a year, have a vaccine.

But we want to, through the supplemental, put multiple vaccine candidates out there. We have a billion dollars of proposed investment in vaccine through the supplemental.

Senator KENNEDY. The secretary of the Department of Homeland Security, which is charged with keeping us safe, just testified about 10 minutes ago a month and a half. Which is it?

Secretary AZAR. One could not develop a vaccine in a month and a half. That would—that has never happened in human history.

Senator KENNEDY. Maybe you ought to talk to the secretary of Homeland Security before he spreads that too far.

Are we getting the cooperation that we need from countries other than China and, obviously, Iran?

[Laughter.]

Secretary AZAR. Well, obviously, not Iran. But for other countries, yes, we believe so.

Senator KENNEDY. That is all I had, Mr. Chairman.

Senator BLUNT. Thank you, Senator.

Senator Baldwin.

Senator BALDWIN. Thank you, Mr. Chairman.

DRUG PRICING

Secretary Azar, I want to tell you about a couple of constituents. Mary from Franklin, Wisconsin, attended a roundtable I had over the President’s Recess Week on the price of medications, and she
worked for Kenosha County for over 20 years, retiring as a child support caseworker. She has diabetes and the cost of her medications including insulin are over $1,500 a month.

She said to me, I am just one of millions of people that have this problem. There are people who are not getting their medication who are dying because they cannot get their medication who are deciding on food or medication or paying mortgages.

At that same roundtable, I met a father whose son—young son had a severe allergic reaction. He was treated at the hospital and then the physician prescribed epinephrine. Because of the child’s tender age and weight, an EpiPen was not appropriate because it would contain too high of a dose, and when he went to fill the alternate prescription that had the right dose, the out-of-pocket cost would have been $5,000.

Now, my—I was in disbelief when I heard that. He explained a little bit more, and what he ended up doing was buying an EpiPen and praying that his son will gain at least seven pounds before he next has any type of allergic reaction. But how frightening.

So in December, the House of Representatives passed a comprehensive prescription drug pricing bill that included my bipartisan Fair Drug Pricing Act. The Fair Drug Pricing Act, as you recall, passed out of the Senate Health, Education, Labor, and Pensions Committee last June.

You noted in your testimony that the budget supports bipartisan drug pricing proposals. However, it does not support explicitly either the House-passed bill or my bipartisan Fair Drug Pricing Act.

We have talked a lot about transparency in this industry. Do you think pricing transparency would make it harder or easier for Congress to oversee the drug corporations and enact sensible policy that would bring down prices?

Secretary AZAR. We do support notions of drug price transparency. In fact, I tried to get—and you all supported me, thanks in particular to Senator Durbin’s great work—tried to get specific authorization to explicitly require that drug companies disclose their pricing in their direct to consumer advertising and we are now having to, rather astonishingly, litigate that issue in courts——

Senator BALDWIN. Yes.

Secretary AZAR [continuing]. Because the drug companies are embarrassingly ashamed to talk about their prices.

Senator BALDWIN. Right. So the drug—a Fair Drug Pricing Act would say if you want to raise the price you issue a report to your agency with justification and full transparency.

We talked probably around a year ago about whether we are even capable of showing a follow-the-dollar chart when you, say, have a drug that is priced right now—list price is set by the drug corporation at a hundred dollars what piece does the manufacturer take, what piece does the PBM (Pharmacy Benefit Managers) take, what piece does everyone along the way take of that.

And then when they double it, how does that change? Where does the extra $100 go? We do not even know that, and so I urge you to work with us to pass the bipartisan Fair Drug Pricing Act. I think it will so help our ability to rein in these prices.
SHORT-TERM HEALTH INSURANCE PLANS

In my few seconds left, I want to switch gears and talk about the vast expansion of junk plans that has occurred under this administration.

There was a study released just shortly ago that found these junk plans impose extraordinary costs on very vulnerable populations—those newly diagnosed with cancer.

According to the study, a patient that is newly diagnosed with lymphoma and covered by one of these junk plans could pay anywhere from $23,000 to $45,000 in out-of-pocket expenses in the first 6 months following their diagnosis.

The other issue that I wanted to point out is we are talking about coronavirus. We just had reporting out of Florida that somebody who had recently traveled to China presented for concerns that he might have contracted the coronavirus may be charged thousands of dollars in out-of-pocket costs for seeking care because he is covered by a junk plan.

How does the expansion of junk plans by this administration help us during severe outbreaks like the one we are currently experiencing and is very frightening as the—as we move forward and how does it help somebody who incurs cancer, who is diagnosed with cancer?

Secretary AZAR. So short-term limited duration plans are not right for everyone. We have been very transparent about that, and they existed under the Obama administration at the——

Senator BALDWIN. They were 3 months. Now they are 3 years.

Secretary AZAR. Actually, no. At the—in a midnight——

Senator BALDWIN. You are right.

Secretary AZAR. In a midnight regulation, they shortened them to 3 months and we restored that. They are not right for everyone.

Senator BALDWIN. Because of the impact on the rest of the market.

Secretary AZAR. Well, they are not right for everybody and we have enhanced actually the consumer protection notices, even from what the Obama administration had.

But some insurance for some people might be better than not being able to afford any insurance. These are 60 percent off and cheaper than Affordable Care Act plans for people who are not subsidized. So it is an option but it is not the right option for everybody and we have tried to be very transparent about that.

Senator BLUNT. Thank you, Senator Baldwin.

Senator Rubio.

CORONAVIRUS

Senator RUBIO. First, I want to acknowledge how difficult this issue has been because of where it originated, in China. They are less than transparent. Whatever numbers they put out every day I can assure you the numbers are higher as to the actual number of cases.

But to date, at least unless they shared it with the World Health Organization, they have not shared the original viral sample.
I know they put the code up online but they did not share the sample. They have not really been forthcoming about best practices on a host of issues.

Our response is complicated by the fact that we are dealing with a totalitarian government that is more interested, apparently, in PR (Public Relations) and in their image than they are in actually dealing with this the way we would if we had an outbreak of this kind. That is most certainly impeding our ability to develop things like a vaccine and so forth.

Secretary AZAR. We need full transparency and full cooperation from China as well as every country, and the WHO needs to hold every country accountable as they would the United States for that type of transparency and cooperation.

CORONAVIRUS EFFECTS ON DEVELOPING NATIONS

Senator RUBIO. Well, the second question is have we done any estimates or do you have any view on what would happen if this virus makes itself to a underdeveloped country with poor or no public health, for example, Haiti or Central America, and some nations in Central America, in particular?

The impact that would have on those societies, not to mention many nations in the African continent, what it would mean for migration flows, for the global economy.

Have we viewed—have we—do you have any thoughts about how destructive it would be. One thing is that it shows up in Italy or the Canary Islands or—another thing is that is shows up in a country that already lacks any sort of basic public health and the ability to address it.

Secretary AZAR. Obviously, it would be very concerning if this virus spreads, say, to Africa or other areas that have less developed public health infrastructure because they won’t be able to take the steps towards mitigation and containment that we can take here in the United States.

And so it would spread quite rapidly. This is why it is actually so critical to get better data out of China so that we know the severity and the—what the mortality rates really are here so we know what we are dealing with in terms of impact.

PHARMACEUTICAL SHORTAGES

Senator RUBIO. Now, we know that 80 percent of active pharmaceutical ingredients in the United States come from China, and I wrote a letter about this to the FDA commissioner. And I know there is a lot going on but we have yet gotten a response.

So I wanted to know a few things. Does the FDA have tools and information to track potential medical device or pharmaceutical shortages?

Secretary AZAR. We do under FDASIA (Food and Drug Administration Safety and Innovation Act) for—to be able to track with pharmaceuticals. They have to report to us if there is any potential shortage and we have not received any reporting yet about potential shortages connected to the China situation.

The medical device companies do not have to make those same kinds of proactive reports and that is actually part of what we have suggested in legislation.
Senator RUBIO. What can we do or what would we do to mitigate shortages of particularly critical medicines if in fact we saw one coming?

Secretary AZAR. It is a very difficult challenge because the supply chains with drugs as with the rest of our economy are very much globalized and entwined with China and elsewhere and one does not—one cannot stand up a manufacturing facility for pharmaceuticals just overnight.

And so if a drug company happened to have multiple manufacturing facilities that were qualified we would—they could transfer their manufacturing and we would certainly work at FDA to expedite any type of inspection regulatory approval to support that.

Senator RUBIO. Well, have we coordinated with any non-Chinese suppliers of products at least in an effort to sort of think forward about what we would do if in fact suddenly we face—again, we are not dealing with the most transparent government in the world in China.

So if this thing came upon us fairly quickly what option would we have to work with non-Chinese suppliers of these key ingredients?

Secretary AZAR. Well, we can work with any supplier that is FDA approved. One cannot just secure FDA approval overnight for either a generic ANDA (abbreviated new drug application) or for the manufacturer, of course, of an innovative product. And so we would work with those companies that hold licensing and hold patent rights to be able to expand their—in this country.

Senator RUBIO. But have we done any work just sort of putting some of that in place just in case this comes on quickly?

Secretary AZAR. Well, we are aggressively and proactively working with all of the drug companies and device companies and we have made it clear we are available to help them.

None of them has singled any potential problems in terms of supply. There are a couple manufacturers that do work in Hubei Province, the epicenter. But they report that they have large stockpiles of supply already—of product already.

But we are aggressively working on this because it is a concern when one has this global supply chain that is intermingled throughout the world including in China.

Senator RUBIO. Just as a last point, I think this instance calls to mind that perhaps it is not the greatest idea for the health—for Americans in need of healthcare to have 80 percent of our active ingredients come from one place in the world where it can potentially serve as strategic leverage at some point down in the future but is vulnerable to this sort of disruption.

At a minimum, you would agree that this is sort of a wakeup call that perhaps we are overly dependent on the supply chain so heavily concentrated in one place in the world?

Secretary AZAR. It is and has been, and you have been at the forefront of calling attention to this issue. The challenge is what the appropriate remedies are for that because if we start dictating where companies make product, that could increase costs, which would increase healthcare, and drug costs in the United States.
But we are happy to work with you and Congress on if there are supply chain management approaches that we should take that are more directive than Congress would want to authorize.

Senator ALEXANDER [presiding]. Thank you, Senator Rubio.

Senator Murphy.

CORONAVIRUS RESPONSE

Senator MURPHY. Thank you very much. Good morning, Mr. Secretary.

We can agree that when you are dealing with a response to a pandemic days and weeks matter, correct?

Secretary AZAR. We try to take advantage of every day we have been able to buy through our aggressive containment efforts and our public health response, absolutely.

Senator MURPHY. You presented a briefing to members of the Senate 3 weeks ago in which many of us expressed alarm that the administration had not sent a supplemental request to Congress at the outset of this epidemic.

We were told in that briefing that the administration believed that it had ample existing resources to handle this epidemic. That did not make sense to many of us who saw what was coming.

Last night, you sent word that you are now requesting that supplemental funding and we are hopeful to get some meat put on the bone so that we can get to work very quickly. That was a mistake now in retrospect to not request that funding weeks ago at the beginning of this pandemic, correct?

Secretary AZAR. No, not at all. We had $105 million that we are spending from the Infectious Disease Rapid Response Fund. We have not even started on the $136 million from the transfer authority that I have sent over to—I think last night we sent notice of the reprogramming and transfer plans that we have for that.

Three weeks ago was just 2 weeks into even knowing about this virus, which we have been very transparent, we are briefing and working with you on.

One cannot know the contours or nature of the disease or its progression to even know what to request at that point and what that would involve and, indeed, today we have seen one of your colleagues was questioning if we even know enough to make a request at this point.

And so we are making the request. We believe we know enough to do that now. We have not run out of money.

Senator MURPHY. Well, I think his point was in response to your statement regarding your inability to create a market until you have the funding, which speaks to the long process from the request of funding to Congress to the creation of a market that would answer some of the concerns that Senator Rubio has.

And so what was knowable 3 weeks ago is that when you make a request of Congress the money does not occur and be created overnight.

It is a process to come up with that legislation, and then you acknowledge yourself that even once you get that funding you then need to go out and create markets for some of the products that have shortages.
And so many of us did see the need early on because we knew that it would take a long time in order to get this funding through the process and I think we have lost critical days and weeks, and there were many people in that briefing who were asking you to present this earlier.

GLOBAL HEALTH SECURITY

Can I ask you about a program that the CDC was running I think, largely, with previous supplemental dollars that was—I have heard it referred to as an epidemic prevention account, Global Health Security Initiative, operating in about 50 countries.

Reports from about a year and a half ago suggest that as that money ran out and the CDC did not replace it with other funds, the number of countries in which we were forward deployed trying to train local public health staffs to identify pandemics and respond to them were reduced from 49 countries to 10 countries.

At the time, you received a letter from about 200 different public health organizations asking you to back fill and request new resources to make sure that those programs remained open.

You may not have an answer today. But can you confirm that that program is only running today in 10 countries compared to the 49 that it was running in—when that supplemental funding was still available?

Secretary AZAR. So what has happened is the—as the Ebola supplemental money was going down we were increasing the Global Health Security agenda funding through CDC. So, for instance, for 2021 appropriation we have requested $175 million, which is a $50 million increase there as we slope that up.

In terms of the countries, we are very committed to the Global Health Security agenda, as are you. The number of countries—our focus has moved to try to have a regional footprint and also to—as we have built labs and built capacities in countries, they stand on their own and we moved to other countries or moved our regional approach.

We can get you the precise countries where we are operating in now. But that has been the philosophy. It has not been a retrenchment. It has, though, been to have a regional deployable force instead of permanent infrastructure in every single country.

Senator MURPHY. The chairman is not here but I think the answer is that we are operating today in perhaps one-fifth the number of countries that we were several years ago and we were operating in 50 countries because we recognized we had a lot of work to do to train up staffs, especially in developing countries, to identify these outbreaks and treat them at the outset so they did not ultimately reach our shores.

And many of us have been, I think, sounding this alarm for years that budget cut after budget cut, proposed budget cut after proposed budget cut to the CDC was going to have an effect.

And I do not think today we can draw a straight line between the number of countries that have been cleaved off of this global pandemic prevention program and the outbreak that we are dealing with today.

But it is another alarm bell for us. We cannot continue to close our eyes to these developing pandemics. We are going to have to
be partnering with many other countries and under this administration, unfortunately, we are going the wrong way. We are operating in less countries abroad, not more countries.

But I will appreciate hearing the more detailed information from you in the coming days.

Senator ALEXANDER. Thank you, Senator Murphy.

Senator Hyde-Smith.

Senator HYDE-SMITH. Thank you, Mr. Chairman.

LIVER ALLOCATION POLICY

Secretary Azar, thank you so much for being here today and I want to start by making a few comments before I go to my question.

First, I know you have heard from Chairman Blunt repeatedly about his concerns regarding the allocation of livers for transplant.

I share the chairman’s concerns. Our only transplant program in Mississippi at the University of Mississippi Medical Center just completed its 250th liver transplant this past Friday, which is a very important milestone for us.

Since the program started in 2013, it has meant so much to critically ill Mississippians to be able to get this lifesaving care close to home and I am worried now the new liver policy will undercut that UMMC (University of Mississippi Medical Center) program.

I hope you will work with us to address these concerns and ensure the continued viability of new liver transplant programs just like the ones that we have in Mississippi.

DRUG COSTS

Secondly, I want to thank you for your focus on lowering the cost of prescription drugs for all Americans. Whenever I am in Mississippi, I constantly hear from constituents who are concerned about high out-of-pocket costs for their prescription drugs. But both you and the president have made this a issue of priority and I certainly thank you for that.

TELEHEALTH

Third, I was very pleased to see your budget request include legislative provisions from the Connect for Health Act to help expand telehealth at community health centers, rural health clinics, and Indian Health Services facilities.

As one of the six senators on the Senate Telehealth Working Group, I was very glad to be able to introduce this bill and I am working to get it enacted into law. Your support is extremely critical in that.

RURAL HOSPITALS

At this hearing last year, you and I discussed struggling rural hospitals in Mississippi. This continues to be a problem not only in my State but across the Nation.

The most recent data just released from 2019 shows that nearly 50 percent of rural hospitals are still operating in the red.

Last year, I was so pleased when you testified that, in part, because of some efforts from my office you had established a Rural
Health Task Force at HHS to find all ideas to help address the crisis in access in rural America.

I have also been pleased to support some of the early work on the task force including changes to the Medicare wage index that meant so much to our rural hospitals in Mississippi.

But I know the task force has been working very hard in recent months to do even more. Can you provide us with an update on the task force work and, specifically, how this subcommittee can help support you and your office in that?

Secretary AZAR. Thank you, Senator.

And yes, on the Rural Task Force we have now matured into the point that rural healthcare is a centerpiece of the president’s healthcare agenda and a centerpiece on the budget proposals.

There are really four pillars to it. The first is rural healthcare has to have a sustainable business model. We cannot just patch over it. It has to be something that economically works in our rural communities.

Second, we have to have prevention and health promotion in rural communities.

Third, we have to take advantage of telehealth and other innovation, and fourth, we need health professionals such as PAs—physician assistants—nurse practitioners, and others who are able to practice at the full extent of their training and licensure in these rural communities where we cannot often find just doctors to practice.

So we have many proposals in the budget. One of them which I am very excited about that would help with rural hospital closures would allow critical access hospitals to convert to emergency facilities with an emergency room and outpatient and not have to bear the burden of continuing inpatient bed facilities, and also get payment supplements on that.

So I think that could be a real lifeline to our rural communities if we can get that approved. We also have several provisions we have proposed on expanding access to telehealth and compensation both in rural America but also in Indian Country for facilities there.

And then we also want to modernize our payment for rural health clinics because our community health centers in rural health areas, in rural areas, can be an important backbone of our system also.

So we have got a whole suite of legislative proposals in there for rural health and combined with our budget increases that we would love to work with you on.

Senator HYDE-SMITH. Thank you very much.

Senator ALEXANDER. Thank you, Senator Hyde-Smith.

Senator Shaheen.

Senator SHAHEEN. Thank you, Mr. Chairman.

CORONAVIRUS BRIEFING

Secretary Azar, thank you for being here. I do not have any questions about the coronavirus because I was at the briefing this morning and I appreciated your comments to clarify some things.

The question that I have for you and whoever else in the administration or in the Senate is why that briefing was closed. I have
met with a number of constituents—in fact, right after the briefing—who were very concerned that they did not have information, and I think it would be very helpful to the public to be able to hear what is being said, and I did not hear anything this morning that I have not read in the newspaper already.

So I think to have some of those briefings open so the public can hear them would be a great benefit and I hope there will be something on websites to help companies prepare their employees to help the public understand what is going on.

So I give that to you to take back.

Secretary AZAR. And, actually, if I might, my understanding is Chairman Burr, the chairman of the Senate Intelligence Committee, asked that that briefing be held at the top secret level to ensure complete transparency with members of the Senate on any information.

I think what was found was in the discussion we are not relying on classified information.

Senator SHAHEEN. Right.

Secretary AZAR. We have tried to have radical transparency. And so I think by the end of it, it was realized nothing classified had been discussed and so that label was taken off of it.

But yes, we have tried to be completely transparent about what we know so and we——

Senator SHAHEEN. I think that would be helpful.

Secretary AZAR [continuing]. Absolutely support that kind of public disclosure——

Senator SHAHEEN. And I do not want to cut you off but I am about out of time. So my clock is running.

MEDICAID CUTS

New Hampshire has been really hard hit by the opioid epidemic, as you know, and it has become very clear that the Medicaid expansion has been our best tool in combating the epidemic.

According to the most recent data available, 23,000 Granite Staters have accessed substance use disorder treatment through the Medicaid expansion.

But your HHS budget proposal would slash Medicaid funding by $920 billion, including $744 billion in cuts that appear to gut the Medicaid expansion.

On page 112 of your budget it says that, and I quote, “As part of the president’s health reform vision, Medicaid spending will grow at a more sustainable rate by ending the financial bias that currently favors able-bodied working adults,” end quote.

So the only way I can read that is that you are suggesting that Congress should eliminate the match that are—is currently provided to States who participate in the Medicaid expansion. Am I reading that correctly?

Secretary AZAR. We do believe—I have said this for a couple years—that the enhanced match for Medicaid expansion for able-bodied adults actually prejudices against pregnant women, children, aged, blind, and disabled in traditional Medicaid and we think that needs to be corrected.

So yes, you are reading that correctly.
Senator Shaheen. And so are you suggesting that we should eliminate the match that can go to Medicaid expansion for States to use for treatment for substance use disorders, for example?

Secretary Azar. So what we have suggested in the budget is an allowance that would have us work with Congress to look at issues like that around what is the appropriate Federal matching rate for expansion compared to traditional Medicaid populations and what is a sustainable growth in that expansion population as well as what flexibility States would require.

So it is meant to be collaborative with—working with Congress. But there is a problem here, which is there is a real prejudice in the Medicaid system now in favor of able-bodied adults and State support of them because of the 90 percent match versus the average 60 percent Federal match for those core traditional populations of Medicaid like pregnant women, children, aged, and blind and disabled there. It is a real disparity in the system that we need to address.

Senator Shaheen. Well, I hear that. To address it in a way that would eliminate the match certainly puts at risk those thousands of people in States like New Hampshire, across this country, where they are getting their treatment for opioid disorders and without that Medicaid they would not be getting treatment. There is no alternative in a place like—in States like New Hampshire for providing that treatment.

So I am not going to ask you to comment on that. But just—I hope that that is something that you will think about and you will share with States like New Hampshire before making any changes, and I am sure Congress will want to weigh in.

Secretary Azar. And I do not believe we have suggested eliminate but, rather, regularizing it compared to traditional Medicaid.

E-CIGARETTES AND VAPING

Senator Shaheen. I want to go now to the issue with e-cigarettes and vaping because I have been very disappointed at the flip flop that we have really seen from the FDA and from the effort to try and scale back on what e-vaping products are available to young people and to the public.

And, you know, I thought initially the FDA was pretty clear that it was going to take all flavored vaping products off the market, including menthol, and yet they have failed to do that.

So I wonder if you can talk about what you are seeing in addressing vaping.

Secretary Azar. So I share your passion on the e-cigarette challenge and keeping these away from kids. Just to explain why there was a change in what we initially announced in September the 11th, we, within our original data set that we had, which was the National Youth Tobacco Survey, had tobacco flavor in one category and mint and menthol together, showing mint and menthol as a group was being used by kids.

That actually troubled our public health people because we have significant menthol combustible users and want to make sure there is an exit avenue for them that is available.

We then got after the announcement the Monitoring the Future Survey that finally gave us a breakdown of mint and menthol
showing it was really mint driving it and menthol was comparable to tobacco flavors.

And so we were able to leave menthol on the market, go after the mint there, and so that was the basis for why we made that change.

Senator SHAHEEN. Well, my time is up. But as I am sure you know, there is legislation that would mirror what is in the budget with respect to fees on e-cigarette companies and I hope that we can enact that as part of the budget this year.

Secretary AZAR. And we support that also.

Senator SHAHEEN. Thank you.

Senator ALEXANDER. Thank you, Senator Shaheen.

We will go to Senator Merkley. But on your comment about the briefing this morning, as the secretary said, the request for a briefing—a top secret briefing was made at the request of the chairman of the Intelligence Committee and other senators who wanted to make sure that senators knew there were not any secrets we were not being told.

And we were both there, but as a result of that I think what we learned was that everything we were told had already been available to the public. So that was the motive. That was the motive for it.

Senator Merkley.

Senator MERKLEY. Thank you, Mr. Chairman, and welcome, Mr. Secretary.

UNACCOMPANIED ALIEN CHILDREN

The administration has proposed a rule that would scrap the Flores agreement that sets humanitarian standards for the treatment of refugee children, and one of those changes instead of requiring 72 hours to move a child to the least restrictive setting would allow the indefinite detention of a child. Is not indefinite imprisonment of a child a human rights abuse?

Secretary AZAR. So, Senator, I appreciate your concern there. That would be a DHS (Department of Homeland Security) regulation. The HHS Flores regulation, I believe, largely tracks our requirements under the Flores settlement agreement. So I can speak to that. I cannot really speak to the DHS regulation.

Senator MERKLEY. Well, okay. We will leave that there then but I will follow up with you.

I want to switch to—when my team alerted your team I was going to ask you about a situation where a child has been trapped in ORR’s (Office of Refugee Resettlement) custody for 6 years now, and originally it was approved for her to go to live with her aunt in 2014.

She finally, after 6 years, signed an agreement to be deported, without ever being informed that her family, extended family, was still waiting and happy to accommodate her.

Many things about this bother me. But one is that 6 years in detention is an incredible impact on a child. Just it is a whole childhood disrupted or destroyed.

Second is that essentially by not informing her that her family wanted her it was extraordinarily misleading on top of everything
else she has gone through. She should have at least had the basic information for that decision.

I am not asking you to comment on this individual case. But I am asking you, outside of this hearing, to put this case on the top of your stack. Because there is just every now and then a situation arises that is so horrific where someone has fell between the cracks and been treated in such a manner that none of us would want this for anyone we know or any child anywhere at any time.

Would you be willing to take a close look at this case and try to make sure that we do not continue this—that we get some, perhaps, really high-level attention and fair treatment for this child?

Secretary AZAR. Absolutely. In fact, thank you. I am glad you—I had not seen the media report until you and your staff raised this to us about this and I, of course, validate anything in the media report.

But I have asked the team. I want to dig in on this one, find out what is going on. I completely agree with you. We certainly do not ever want a child to be with us for that length of time.

But there are sometimes—and I cannot speak to this individual circumstance—there are cases where sometimes there either is not family, family may not be willing to take someone in.

There may be an unsuitability there. But the shorter time a kid is with us—we have talked about this before—the better it is for the child and we want kids with us for as short a time as humanly possible, consistent with their safety.

So I will dig in on that personally to find out. I want to make sure she is treated fairly and her family is treated fairly.

Senator MERKLEY. I would like to be able to get weekly updates on where this case stands, if that is something you can commit to.

Secretary AZAR. I want to make sure I am able to do that consistent with the child’s privacy, individual rights here. But we will work to get you as transparent information as we can about her situation because I do want to make sure she is treated well.

Senator MERKLEY. Okay. I wanted to turn back to the Flores agreement. One of the proposed rule features in addition to indefinite imprisonment is to replace a hearing before a Department of Justice immigration judge with a hearing before an HHS officer but only if the child requests it.

How would any child ever know that they could request such a hearing?

Secretary AZAR. Well, all of our kids have the right to legal counsel and I believe there actually are phone banks as part of the counseling and case management process at the grantee facilities to ensure connectivity with counsel.

This is one of the changes that was made in the regulation compared to the way it is set up in the Flores agreement and I believe it has to do with a modification.

We can get you more information about this, but a modification in terms of the Justice Department and what they believe they are actually legally able to do in terms of administering hearings.

But we are happy to get you more information about that. It was not—it really was, I think, just a response to where DOJ (Department of Justice) felt they had to be on these hearing processes.
Senator MERKLEY. Okay. I have visited the children in internment camps, I have visited the children in the child prisons, and they have no idea that they would have this kind of right. Most of them did not have access to counsel.

Many of them do not speak the same language. You know, it is a fantasy to think a child would, except in rare circumstances, know to request such a hearing. So that disturbs me because it strips a fundamental protection in the system away from these children.

My time is expiring so I will just note this is the thing that the Flores settlement said it could be replaced by a regulation that implements the Flores settlement. But this regulation crushes it, steps on it, shreds it. It does not implement it.

And thus, as you could imagine, on behalf of these refugee children, I will be opposing it in every possible way and I hope that as you study it you might come to the same point of view. Thanks.

Senator ALEXANDER. Thank you, Senator Merkley.

Mr. Secretary, Senator has indicated we should go ahead and wrap up the hearing at this point, which I will do in just a moment. But I want to ask you a question and make a couple of comments and then we will conclude the hearing.

LOWER HEALTHCARE COSTS

You are familiar with the lower healthcare costs bill that passed the HELP committee 20 to 3 and I think you are very well aware that the House Energy and Commerce Committee and the HELP committee worked on an agreement and we pretty well came together between the House and the Senate committees on a version of that bill, which includes ending surprise billing, and about 40 more provisions that would lower healthcare costs, focusing on competition, transparency, and prescription drugs costs.

The House Education and Workforce Committee, chaired by Bobby Scott with Virginia Foxx, the ranking member, came up with basically a similar proposal. And now the Ways and Means Committee in the House has also come up with a version that is a little different on ending surprise billing.

So we have two House committees and the HELP committee in agreement. We have the Ways and Means Committee headed in the same direction. We have the president’s support, which is the question I am coming to.

So when you have the HELP committee 20 to 3—it was the chairman and Senator Murray—when you have Chairman Pallone and Ranking Member Walden, when you have Bobby Scott and Virginia Foxx all agreeing with the president’s support and you have the Ways and Means Committee headed in the same direction, it seems to me that is a good candidate for action to lower healthcare costs, especially since ending surprise billing, the other 40 provisions or so that would encourage competition, transparency, and lower drug costs and save enough money to fully fund community health centers for 5 years, that could all be done by the end of May when the community health center funding expires.

So my question for you, is this high on the president’s priority list and will you continue to work with this committee and the three House committees to get a result on ending surprise billing,
which includes the air ambulance and other provisions as well as the community mental health centers—community health centers?

Secretary AZAR. This is the—so as you know, this is a very high priority for the president—ending surprise medical bills—and we are very happy that we actually have consensus about the core, which is protecting the patient from surprise medical bills.

And what we are just trying to do is work with the committees on who then bears that cost—insurers, providers, hospitals, et cetera, on the back side, and we want to work with you to try to bridge that because you are right, it does need to get through. We want to get a bipartisan bicameral solution passed.

Senator ALExANDER. Thank you, and now here are my comments, and you do not need to respond to these if you do not want. I see the chairman is here and I will let him have his own committee back. But he made the mistake of giving me the chair.

PATIENT ACCESS AND PATIENT PRIVACY

So genomic information of newborn babies—blood taken from them—is used, importantly, in research and many members think that parents ought to give informed consent to that.

Some of the researchers are afraid that will limit the opportunity for research. My own view is I think the researchers are wrong about that. I think when parents go into the hospital and fill out all their forms and one of the forms says can the blood that we get from your newborn baby be used for research I think overwhelmingly they are going to agree to that.

And I would hope you would take a look at that and try to help us balance the privacy right and the research opportunity. I think it helps the researchers to go ahead and do this because that locks in the steady supply of that blood for research and avoids coming up and having a big problem with it sometime later.

And the other issue was interoperability. We dealt with that over in our authorizing committee. We had a whole lot of hearings about medical information blocking, and make it easier for patients to get their own healthcare data.

And the two things I would like to ask you to focus on is the one area where we had a lot of concern had to do with third-party people getting information from these things without us thinking about that very much.

And the final rules need to balance patient access and the privacy that needs to be addressed. In other words, we did not think the existing Federal rules really dealt with that issue very expertly.

We want to go ahead and give patients that access but we want to make sure that we deal with the privacy question. And then the other—and this is my own bias about interoperability.

I tried to get the Obama administration to slow down on implementing the various rules, and expanding about medical healthcare information because I thought it involved too many people and they were going too fast. We all want to get to the same place.

So I hope that you will not try to do too much too fast. I think our goal with the interoperability is to get there. But if we try to go too fast to get there we may create more problems than we solve.
So that is just admonitions from having dealt with this for several years. I just wanted to take this opportunity to mention those two issues to you.

Now, I will ask the Chairman if he wants to have his committee back.

Senator BLUNT [presiding]. Let us see. I think I got the critical information.

Senator ALEXANDER. Yes, and thank him for——

Senator BLUNT. Maybe not. I think I am good.

Senator ALEXANDER. No, I do—yes, I do have critical.

Senator BLUNT. Thank you, Senator Alexander.

Senator ALEXANDER. My pleasure, Senator Blunt.

Senator BLUNT. Well, if you were going to pick any individual on our committee who had a wide enough range of interest to keep you answering questions for the time everybody was gone, you would start with Senator Alexander.

So thank you. We got a few people that may come back. We are not going to go a whole lot longer here, Secretary.

MENTAL HEALTH

Let me talk a little about mental health. One of the things I have been interested in, as you know, is trying to get mental health on a truly even basis with all other kinds of health.

We have a pilot program that Senator Stabenow and I worked on establishing a few years ago in eight States. The fiscal year 2020 bill included $200 million for certified community behavioral health clinics to support this pilot.

You have actually proposed that that be increased by $25 million. I was pleased to see that increase. Also, something that we asked for in that bill was more information about what changes we are seeing in overall health costs when people's mental health is being treated like all other health.

My goal with this pilot was not to have the Federal Government takeover mental health but to try to create the kind of whole health information that would make it easier for States to determine what this really meant.

Are they spending no money extra when they treat mental health like all other health, which I think may be possible? Are they saving money, which may be possible, or are they spending only a little more money when they treat mental health like all other health?

It has just always seemed, Mr. Secretary, totally logical to me that if you are dealing with somebody's mental health problem that you are more likely to be able to deal with any other health problem they have in a much more cost effective way.

I do know that on the opioid effort in our State and the other seven States that have Excellence in Mental Health pilots that the ability to have mental health assistance unlimited by 14 days or 7 days or whatever it would have been is certainly making a difference in people's ability to deal with their opioid problem.

If you do not have a mental health problem when you become addicted to drugs, you certainly have one after you become addicted. So what I really need from you all is as quick a response as you can give. We ask for a response to that in 30 days.
It has been about 67 days, I think, now. But the reason that I would like to see that is to see if we are headed in the right direction and if there is another way we need to be compiling information so that you and I both have, and the Congress and State governments have, what they need to look at to know the difference it really makes.

Do you want to respond to that a little bit?

Secretary AZAR. We certainly agree that taking care of mental health is critical to overall health, and we will work on getting you that information as soon as possible.

As you know, and I think you alluded to this, the president's budget proposes a major change here, which would be to lift the IMD (Medicaid Institutions for Mental Disease) exclusion at a State option for serious mental illness of inpatient mental health facilities beyond the current IMD limit.

And so as we have done for substance use disorder but actually make it a State option to get into that, and that would make so that I think it would then be exempted from budget neutrality and some other restrictions that we have.

So very excited about that possible change for mental health in the United States.

Senator BLUNT. Thank you.

ENDING THE HIV EPIDEMIC

I do not know if you have had a chance to talk about the president's HIV initiative much today with everything else that is going on. But we did fully fund—Senator Murray and I worked together with our colleagues in the House to fully fund the request last year.

What kind of progress are you making there in the End HIV Initiative and what should we be thinking about, as we look at the number you asked for this year?

Secretary AZAR. So what we did up until the appropriation came out in December was supporting in the target counties the preparation activities. So we have got, of course, most of your new—half of our new cases are occurring in 57 target jurisdictions and so we worked there to get their plans in place and ready.

We had four jump-start jurisdictions that we were able to start moving on. Now that you funded it, we are now actually implementing the initiative in terms of diagnosing, treating, preventing, and responding.

The new money, so for 2021 would be year two of the full initiative, and that would be $716 million for year two. That is just the scale up—the $450 million scale up as we know implement those plans.

So that is expanding for the community health centers that are in the 57-target jurisdictions, expanding their ability to treat as well as to prescribe PrEP (Pre-Exposure Prophylaxis) and get people on PrEP.

It involves outreach to individuals and adherence programs to ensure people take their PrEP and get on it, stay on it, and that individuals who are diagnosed get on their anti-retrovirals, expanding Ryan White capabilities in the target jurisdictions, also at CDC.
having the Rapid Response Team able to go and deploy into clusters where we see new clusters of HIV—of HIV coming out.

So, really, across that at CDC and HRSA is now its implementation. So with the money you got us in December, we are beginning that State-by-State implementation and this would be the second year with just full-scale up into that.

Senator BLUNT. So in a meeting yesterday in my office where the topic came up on HIV, if you had said get on PrEP and stay on it, would this be an area where some kind of time-released medication where you took it once a week or once a month and it released on its own would have some real potential?

Secretary AZAR. Certainly, any kind of long acting on PrEP would be great. I do not know if the manufacturers are pursuing that. I have not seen if that is a formulation that they are working on. But yes, you would see—if you saw monthly, for instance, that would be fantastic.

Senator BLUNT. Yes.

Senator DURBIN. Thanks, Mr. Chairman.

Dr. Azar, thank you for your patience in waiting with the roll calls.

E-CIGARETTES AND VAPING

You and I have had so many good conversations about the issue of vaping and e-cigarettes. The President and First Lady, in the Oval Office in mid-September of last year, made some very strong encouraging statements about dealing with this.

Unfortunately, a few months later when the policy was announced there were some things in there that concerned me. The president’s promise to remove all flavored e-cigarette products from the market within a matter of weeks did not happen.

Instead, the president decided to exempt cheap disposable e-cigarettes like Mr. Fog’s bubble gum flavor, Puff—I cannot keep up with the names of these things—Puff Bar’s O.M.G. flavor, and Stig’s Mango Bomb flavor, not necessarily a product for people who are hardened smokers trying to quit. It is a product to attract kids, and over 80 percent of kids are attracted to that kind of junk and end up with a nicotine addiction.

I think it was a mistake to exempt these cheap disposable products from the president’s so-called flavor ban. I am concerned about his decision to exempt more than 15,000 flavors in the open tank vaping system.

I would like to get on the record what you have told me personally and privately about monitoring what is going to happen next and what the response would be from you and the FDA if it turns out that the extent of the ban, the extent of the restrictions are not adequate to stop this youth epidemic.

Secretary AZAR. Yes. First, Senator Durbin, thank you for your partnership on the e-cigarette issue. You have been—really, it has been wonderful to work with you to just keep this focus on keeping these e-cigarettes away from children.

In terms of the disposables, as we talked about, NJOY, which I believe is the largest disposable manufacturer, did pull of its fla-
vored disposable products from the marketplace, respecting the spirit of what we were trying to do here.

These other products, if they are targeted at kids and as we get—if we get data showing that they are—that kids are using these products we are going to go after them with enforcement with the full weight that we have got.

We have even talked to companies like Google to use advanced analytics that they have to help us get even earlier warning signs than, for instance, the National Use Tobacco Survey, which is more retrospective so we can see trends there.

Senator DURBIN. Let me ask you this. By court order, in May the FDA is going to have to—is going to receive applications for those who want to keep their devices and flavors on the market.

Do you believe that an e-cigarette application should be rejected by the FDA unless the company proves with scientific and medical evidence that the product actually helps adults quit smoking tobacco cigarettes, does not cause youth to start smoking and does not harm the user?

Secretary AZAR. So on the first part of your question, which is smoking cessation, that would be imposing a drug approval criteria in there because, of course, a smoking cessation device is an NDA, a new drug approval, that would be a different bar than what the Tobacco Control Act has, and I believe the standard is that it promotes public health. I believe it is something like that in terms of the standard for FDA.

Senator DURBIN. Not appropriate for the protection of public health is at least one reference.

Secretary AZAR. Right. Right.

Senator DURBIN. But, of course, is not that the marketing message of folks in e-cigarettes and vaping to quit tobacco cigarettes?

Secretary AZAR. If they use a smoking cessation messaging without drug approval for their product, we will enforce against them and in fact, we did issue a warning letter against a major manufacturer that was putting smoking cessation claims or implicit claims connected with their product.

UNACCOMPANIED ALIEN CHILDREN

Senator DURBIN. If I could switch to a much different topic. Thanks for your kind words on DTC. I want to talk about the zero tolerance issue and the fact that I joined with Senator Murray and others dealing with what happened to the kids who were forcibly separated from their parents at the border.

And there was a study done at our request, but it came back and said we cannot even find many of these kids or their parents. Can you tell me at this point how many children are currently still separated from their parents at the border.

And there was a study done at our request, but it came back and said we cannot even find many of these kids or their parents. Can you tell me at this point how many children are currently still separated from their parents at the border.

Secretary AZAR. So I want to make sure, and I will ask if we could get you for the record. I want to be sure of this. But I believe that we do not have in our care at ORR any children that remain as a result of the zero tolerance family—the zero tolerance policies.

So I believe that to be the case. I thought we were down to zero of them. But I want to make—we will make sure and get you that information for the record.
Senator DURBIN. And so as you sit there you believe that every parent whose child was taken into HHS custody has been reunited with their child?

Secretary AZAR. They have either been reunited or they have not been parents or they are unfit for reunification or they have disclaimed their rights to reunification. I want to be careful because I know there was one instance where there was an individual I think in Guatemala that we were still having trouble finding the parent.

But I believe that was resolved. That is why I want to be very careful to get back to you on the record to make sure we—I have got every bit correct.

Senator DURBIN. My closing point, and I hope we look into this. I hope we are sensitive to this. There remain in Mexico a program which is now—involves thousands of people and children.

There have been reports from human rights organizations about terrible abuse including sexual abuse of children and adults who are on the Mexican side of the border waiting for some sort of resolution of their status here in the United States.

Do you accept some responsibility to monitor that program in terms of its impact on these people?

Secretary AZAR. So I am not involved in the DHS Mexico migration policy. That is not—our authority does not go to that. Our authority really is just the unaccompanied children if they come across by themselves or if a parent leaves a child here on that returning to Mexico side of things.

Senator DURBIN. I understand the jurisdictional issue. But I just hope, and I know you are a caring person, that you understand that when we turn away asylees—people seeking asylum and leave them in Mexico, we at least have some role in this and should accept some moral responsibility for the outcome.

Thank you, Doctor.

Senator BLUNT. Senator Durbin, if you want to stay for a minute we are going to wrap up. But if you have another question we could——

Senator DURBIN. I do not. Thank you.

Senator BLUNT. Okay. Senator Murray.

UNACCOMPANIED ALIEN CHILDREN

Senator MURRAY. Mr. Secretary, I want to follow up on what Senator Durbin brought up, because I am really frustrated by the department’s failure to protect migrant children against harmful policies, especially when it comes to sharing information with the Department of Homeland Security.

Over the past couple of months, we have learned from news reports the White House hatched a plan to embed ICE agents within the Office of Refugee Resettlement and use information from unaccompanied children’s potential sponsors to target them for deportation.

And then we heard reports that ICE (Immigration and Customs Enforcement) is implementing a widespread policy to fingerprint unaccompanied children who turn 14 while they are in HHS custody without legal representation present.
And now we are hearing another bombshell that HHS has been sharing migrant children’s confidential therapy notes with ICE, who has then used them to weaponize that information to deny asylum claims.

Now, I am extremely worried about this. In the past, the care and protection of children was purposely separated from immigration and enforcement, and this is really alarming to me that these actions are being taken.

So just one question and I will follow up with you later. But I understand children were told that the conversations with their therapists were confidential.

Is the department now making clear anything children say in these sessions will be shared with ICE?

Secretary Azar. Those notes from therapists or mental health counselors talking to children should not be disclosed absent the child’s consent or the limited—the most limited information possible in the event of a threat to themselves or others that is disclosed. The sharing——

Senator Murray. Who decides that?

Secretary Azar. So that would be the therapist.

The sharing of that information that occurred we discovered this is August of 2019 that there had been a problem since a guidance that was issued in 2016 where some of our—where therapist notes were being provided over.

What should happen properly is limited information about the child’s protection or about the child’s threat to others should go into a serious incident report in the system. That should be the minimal information needed.

We found that some of our therapists were—grantee therapists were cutting and pasting notes, putting them in the SIRs or incorrectly the full notes.

Senator Murray. So are you telling your therapists now that they cannot share information with ICE or, conversely, are you telling the children that anything they say in those confidential therapies will be shared?

Secretary Azar. No. So as of—as of August 2019, we clarified our instructions that these notes should not be shared with anybody absent a child’s consent and that any—well, and any or, of course, but that is not——

Senator Murray. How do you ask a child, is it okay if I share this with somebody you had never met? Yes.

Secretary Azar. No, they do not. That would not—I would not hang up on that. They are not being shared unless a child were to consent. The information in these serious incident report would be if they threatened themselves or others.

Senator Murray. How do you ask a child if——

Secretary Azar. That would be put in the SIR and that would go over—that is a legal requirement.

Senator Murray. Okay. I will just tell you, saying to a child that this may be shared means nothing to them.

Secretary Azar. No, we are not saying it may be shared. We are saying it is the standard mental health professional requirements that if you threaten yourself or others that fact is discloseable and that would be disclosed.
Senator MURRAY. Well, I am deeply——
Secretary AZAR. But we stopped this. This was in error that those notes were going over and that was stopped in August of 2019, long before it became a media story.
Senator MURRAY. Okay. I hear that. But you also said that if the child consents, then they will be shared. How can a child consent? I would ask my attorney over here.
Senator DURBIN. It has been a long time since I practiced law. But if you are a child and do not have the capacity, how are you going to make this consent and what does it mean to a child?
Secretary AZAR. Well, it would be working—our children have legal counsel and so they would—that we pay for and so it would be working with them on that.
I will get back to you about that if——
Senator DURBIN. Would you please? I certainly think you may have——
Secretary AZAR. Certainly. But the most important issue is that this was a mistake. It should not have been happening as it was identified. It was stopped. We do respect the privacy of these mental health conversations.
As Chairman Blunt knows, we—I am very passionate about access to mental healthcare. We want to make sure this happens and that kids are protected, and it was a mistake. We fixed it and on a going forward basis it should not be happening.
Senator MURRAY. Okay. Can you get back to Senator Durbin and I as quickly as possible what the policy is on how you ask a child and when they are shared?
Secretary AZAR. You bet.
Senator BLUNT. Well, Secretary, thank you for staying with us. Thank you for the time you spent today in your leadership at the agency.

ADDITIONAL COMMITTEE QUESTIONS

The record will stay open for 1 week for additional questions. I would like to be included on any response on that last question. I think that probably is something that when you look back at your answer there is a—we need some clarification on that.
[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

QUESTIONS SUBMITTED TO HON. ALEX AZAR

QUESTIONS SUBMITTED BY SENATOR ROY BLUNT

EBOLA RESPONSE

Question. When this Subcommittee developed the fiscal year 2020 bill, with your Department’s technical assistance, we added funding and continued authority to the Infectious Disease Fund to be used for the ongoing Ebola response in the Democratic Republic of the Congo. How will the replenishment of the Infectious Disease Fund allow HHS to respond to both the coronavirus and Ebola outbreak simultaneously? How much does HHS expect to allocate to Ebola response in fiscal year 2020?
Answer. The Infectious Diseases Rapid Response Reserve Fund (IDRRF) has been a critical resource for the initial response to the COVID–19 pandemic. For the COVID–19 response, this fund was utilized for immediate planning and response needs, enhanced laboratory capacity, communication and education efforts, medical
screening, and surge capacity for ports of entry. As CDC is responding to COVID–19, we have also continued our response for the Ebola Outbreak that began in August 2018. In fiscal year 2020, $30 million was transferred from IDRRRF for Ebola Response, of which $7.68 million has been obligated. Infectious disease emergencies are unpredictable and can emerge at any time. Rapidly evolving outbreaks require flexibility to respond with the latest information. The IDRRRF will allow CDC to respond immediately and effectively in the future.

OPIOIDS

Question. The CDC recently announced that Americans’ life expectancy rose for the first time since 2014. This is certainly encouraging news, particularly because it speaks to the fact that the number of opioid deaths has declined for the first time in a long time. What can you say about the latest trends in opioid overdoses and what we need to do to keep up this positive momentum?

Answer. While the problem persists, overall total opioid prescriptions and overdoses are down from the preceding year, which demonstrates positive developments in this epidemic and underscores the need for sustained effort. More providers are trained to diagnose and treat substance use disorder since the opioid epidemic began. Prevention of overdose deaths through naloxone distribution, treatment capacity expansion for medication assisted treatment for opioid treatment programs and office based treatment, and provider education efforts through SAMHSA’s Provider Clinical Support System, among other Federal efforts, have all contributed to the reversing trend. Individuals who enter substance use disorder treatment often engage in other beneficial behaviors such as obtaining primary healthcare, decreased transmission of infectious diseases, decreased criminal justice involvement, and higher rates of employment. Quite simply, if substance use frequency has decreased, more individual resources can be used for healthier living like better nutrition and compliance with healthcare. Facilities and providers for treatment of opioid use disorder are often the catalyst for some of these other healthy behaviors. While there are several initiatives that should be pursued, continued commitment to the initiatives of provider education, treatment expansion, as well as both primary and overdose prevention is essential to maintain and build upon these successes. In addition, HHS launched a comprehensive 5–Point Strategy to empower local communities on the frontlines. The opioid epidemic is one of the Department’s top priorities; through the 5–Point Strategy and HHS’s Agency Priority Goal of Reducing Opioid Morbidity and Mortality, the Department continues to focus on most effective efforts for addressing opioid use disorder.

Question. Mr. Secretary, the $1.5 billion State Opioid Response grant is provided directly to States through a flexible grant so States can use funds as they see fit. Unfortunately, we continue to hear that States are not spending those funds in a timely manner. Does HHS know why this is the case? What can be done to increase the spending rates?

Answer. The State Opioid Response (SOR) grant was awarded to each State and territory to combat the current opioid epidemic. Funds have been used to provide evidence-based prevention, treatment and recovery support services. However, some States are having trouble with spending down their funds in a timely manner due to multiple barriers and challenges faced in their respective jurisdictions. Here are some examples of these barriers:
—Contract Procurement: Grantees have identified contract procurement as one of the biggest challenges that hinder their rapid spending of the SOR funds. The solicitation, contracting and purchasing process can be lengthy, which results in most of their SOR activities starting several months into the grant year.
—Workforce Development: Grantees have also indicated that they are having difficulty identifying, recruiting, and retaining qualified staff for treatment and recovery programs due to the lack of workforce in the field.

Many of these issues are at the local level. SAMHSA works regularly with grantees to provide increased training and education of providers to ensure that the workforce development needs are being addressed to the greatest extent possible.

ENDING THE HIV EPIDEMIC INITIATIVE

Question. The fiscal year 2021 budget requests $716 million for the “Ending HIV” initiative, more than double the first year of funding. The Committee is aware that this is a multi-year initiative that will continue to require resources in future years. Can we expect the request to more than double next year as well? What factors will drive future funding request?

Answer. Future funding requests will be developed through the annual budget process, which takes into consideration the current budget environment and other
Departmental priorities. Out-year costs for the Ending the HIV Epidemic (EHE) Initiative depend on several factors, including rates of infection, finding and linking those with HIV to care and treatment, and our ability to prevent new HIV infections by using evidence-based comprehensive prevention tools such as pre-exposure prophylaxis (PrEP). Future estimates will be driven by the ability to prevent new HIV transmissions, which will result in potential cost savings in later years of the EHE Initiative. Based on economic modeling, the primary drivers of costs associated with the EHE goals—a 75 percent reduction in HIV incidence in 5 years and a 90 percent reduction within 10 years—include:

**Diagnosis/Prevention:** Critical to the success of the Initiative will be our ability to test and diagnose people with HIV as early as possible and link them to care. Of the estimated 1.1 million people with HIV in the U.S., an estimated 1 in 7 do not know they are HIV-positive. For those who receive a negative test result, but who are at increased risk for HIV, the key to reaching the goals of the initiative will be to ensure they have access to comprehensive HIV prevention including PrEP medications and services. We estimate that of the approximately 1.1 million people who have an indication for PrEP medications, fewer than 20 percent are currently being prescribed PrEP. Costs associated with this pillar include testing, referrals, and systems necessary to reach the number of individuals who are estimated to have indications for PrEP, but for whom PrEP is not currently prescribed.

**Treatment:** Success will depend on our ability to treat people with HIV rapidly and effectively so that they achieve and sustain viral suppression. Scientific evidence shows that individuals who are virally suppressed cannot transmit the virus to others, also known as Undetectable= Untransmittable (U=U). Costs associated with this activity include the costs of antiretroviral therapies and wrap around services to ensure individuals stay in care and maintain viral suppression.

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**ALZHEIMER’S RESEARCH**

**Question.** Over the past 5 years, the Labor/HHS Subcommittee has prioritized the investment in Alzheimer’s research. One of the main reasons why is because Alzheimer’s is currently the most expensive disease in the U.S., and by 2050, the cost to treat an individual with Alzheimer’s is expected to be $1.1 trillion. But, even without a medical breakthrough, the effect of a research breakthrough that delays onset by 5 years would reduce the number suffering from the disease by 42 percent and cutting costs by one-third. When I spoke to the National Institute on Aging’s Director most recently, Dr. Richard Hodes, he said that we are at least several years away from a preventative treatment. Mr. Secretary, why did you cut funding to Alzheimer’s research? Even if you felt like you had to cut NIH funding, why would you not safeguard high-priority research in your budget request?

**Answer.** 5.8 million Americans are currently estimated to have Alzheimer’s disease (AD), and many thousands more have a related form of dementia (ADRD). The physical and emotional toll these diseases exact upon family, caregivers, and friends can be significant. Scientists agree that the number of affected individuals could increase significantly if current population trends continue—unless an effective treatment or preventive intervention can be identified.

We have now passed the halfway point between the establishment of the National Plan to Address Alzheimer’s Disease and the target date of effectively preventing and treating AD/ADRD by 2025. We have made significant progress towards this goal, and we are enthusiastic about the new scientific directions that we are now able to take as a result of recent discoveries.

Our drug discovery efforts have expanded to include both “traditional” (e.g., amyloid and tau proteins) and “non-traditional” AD/ADRD targets, including inflammation, neuroprotection, cell metabolism, viruses, pathogens, growth factors, oxidative stress and vascular targets. Investigators with the Accelerating Medicines Partnership-AD have identified over 500 novel candidate drug targets for AD/ADRD, and this data is shared openly for researchers to begin target validation and preclinical testing. Therapeutic strategies being pursued through the NIA-supported Alzheimer’s Drug Development Program and other initiatives include small molecule, immune, regenerative, and gene therapies.

The Institute currently supports about 230 active clinical trials, including early- and late-stage drug trials; studies of potential treatments for the often troubling neuropsychiatric symptoms of dementia, such as agitation, apathy, and psychosis; and trials of care and caregiver interventions. More than 100 of these trials are testing non-pharmacological interventions for both dementia patients and their caregivers, including (but not limited to) diet, exercise, and cognitive training, and are backed by improved data from cohort studies that span the life course and suggest—but don’t definitively prove—the power of lifestyle choices to support cognitive
Highly promising results recently came from the SPRINT–MIND study, which compared the effects of intensive blood pressure control—i.e., targeting a systolic blood pressure of less than 120 mmHg—with standard treatment toward a target of less than 140 mmHg on cognition and new cases of dementia among 9300 adults ages 50 and older at high risk of cardiovascular disease. The investigators found that intensive lowering of blood pressure significantly reduced mild cognitive impairment (MCI), a well-established risk factor and often a precursor to dementia. This is the first randomized clinical trial demonstrating that an intervention significantly reduces the occurrence of MCI. SPRINT–MIND was co-sponsored by NIA, the National Institute of Neurological Disorders and Stroke, the National Institute of Diabetes and Digestive and Kidney Diseases, and the National Heart, Lung, and Blood Institute.

Finally, NIA recently established the AD/ADRD Health Care Systems Research Collaboratory, which promotes development of pragmatic trials and disseminates best practices and guidelines with the goal of improving care for persons with dementia and their caregivers through health and long-term care systems.

**2020 PHYSICIAN FEE SCHEDULE FINAL RULE**

**Question.** Under the 2020 Physician Fee Schedule Final Rule, the agency finalized a policy regarding reimbursement regarding billing E/M by providers. Some physicians, due to the nature of their specialty, will face a Medicare reimbursement cut as a result. Was the impact of this policy change on seniors’ access to specialty physician services, particularly in rural and underserved areas, taken into account when creating this change?

**Answer.** The calendar year (CY) 2020 Physician Fee Schedule (PFS) final rule issued on November 1, 2019, adjusted the relative value units (RVUs) for office and outpatient evaluation and management (E/M) visit codes effective beginning in CY 2021. The Department finalized the proposal to establish values based on recommendations by the American Medical Association Specialty Society Relative Value Scale Update Committee (RUC), which were based upon a survey of more than 50 specialty societies. We generally believe that the RUC-recommended values for these codes accurately reflect the resources involved in furnishing office and outpatient E/M visits and used them, with minor modifications, to establish values for these E/M visits.

CMS included a table that shows the estimated specialty level impacts of these changes, exclusive of any other changes finalized for CY 2020. Those specialties that see the greatest decreases are those that do not generally bill office/outpatient E/M visits. These estimates can provide insight into the magnitude of potential changes, but do not take into account other changes to payment rates finalized for CY 2020. Any potential coding changes and recommendations in overall valuation for new and existing codes between the CY 2020 and the CY 2021 final rules could impact the actual change in the overall valuation of office/outpatient visits relative to the rest of the PFS.

**QUESTION SUBMITTED BY SENATOR LAMAR ALEXANDER**

**TENNESSEE MEDICAID BLOCK GRANT PROPOSAL**

**Question.** On November 20, Tennessee submitted its final Medicaid block grant proposal to the Center for Medicare and Medicaid Services (CMS). Tennessee already administers the Medicaid program, known as TennCare, under an 1115 waiver. This new proposal will give Tennessee more control over how to operate TennCare and allow the State to improve health outcomes for Tennesseans. If approved, the proposal will also save billions of dollars in healthcare spending. Tennessee has made clear that the State does not intend to reduce the benefits that current TennCare members receive, and that no changes to benefits for children under age 21 are contemplated as part of the block grant proposal. If the block grant is approved, Tennessee has already identified specific priorities to improve health outcomes. These priorities include investments in prenatal and postpartum health; covering additional populations through Medicaid; addressing other State-specific health crises, including the opioid epidemic and healthcare access in rural and underserved areas. CMS recently announced new flexibilities for States to better design and administer their Medicaid program. Many of these flexibilities are included in Tennessee’s proposal currently under review by CMS.
What is the review process for Tennessee’s Medicaid block grant proposal and when can Tennessee expect a response?

Answer. As you may be aware, section 1115 of the Social Security Act (Act) gives the Secretary of Health and Human Services authority to approve experimental, pilot, or demonstration projects that are found by the Secretary to be likely to assist in promoting the objectives of the Medicaid program. The purpose of these demonstrations, which give States additional flexibility to design and improve their programs, is to demonstrate and evaluate State-specific policy approaches to better serve Medicaid populations.

As with all demonstrations authorized under section 1115 of the Act, CMS plays an important role in reviewing and approving any project designs. Specifically, CMS performs a case-by-case review of each proposal to determine whether its stated objectives are aligned with those of Medicaid. CMS also considers whether proposed waiver expenditures are appropriate and consistent with Federal policies, including the degree to which they supplant State-only costs for existing programs or services and can and should be supported through other Federal and non-Federal funding sources. You asked specifically about Tennessee’s recent application. We are working through Tennessee’s application, which was submitted after CMS began development of the Healthy Adult Opportunity guidance, announced January 30, 2020. We are committed to working with Tennessee and any State that would like to put forward an innovative idea for improving their Medicaid program.

QUESTIONS SUBMITTED BY SENATOR SHELLEY MOORE CAPITO

ALZHEIMER’S DISEASE

Question. Can you share how the Department is beginning to implement the BOLD Infrastructure for Alzheimer’s Act across the country?


Question. What steps is the Department taking to screen, detect, and diagnose Alzheimer’s and related dementias in their earliest stages? Are there existing opportunities, such as the Welcome to Medicare initial exam and Medicare annual wellness which could be utilized to help achieve this?

Answer. Both the Welcome to Medicare and the Medicare Annual Wellness visit can be utilized to screen, detect, and diagnose Alzheimer’s disease and related dementias. In addition, CDC has created tools and training to fill knowledge gaps. These include the Healthy Brain Initiative State and Local Public Health Partnerships to Address Dementia: The 2018–2023 Road Map to assist State and local public health in creating dementia-friendly communities. The Road Map includes 25 actionable steps States can take to ensure their communities are prepared to meet the challenges ahead. These steps include screening, detecting, and diagnosing Alzheimer’s disease and related dementias.

In addition, to address educational gaps in healthcare provider training, CDC worked in partnership with the Alzheimer’s Association and the American College of Preventive Medicine and developed the online brain health curriculum for healthcare providers and students of public health. A Public Health Approach to Alzheimer’s and Other Dementias is an introductory curriculum that is intended to increase awareness of the impact of Alzheimer’s disease and other dementias as well as the role of public health.

CHILDHOOD CANCER STAR ACT

Question. Can you provide an update on the work being done by the Department on the implementation of the Childhood Cancer STAR Act of 2018?

Funding was specifically included in the Childhood Cancer STAR Act to be awarded to State cancer registries to enhance and expand infrastructure to track cancer in children, adolescents, and young adults. Is progress being made in this area?

Answer. Progress is being made on the implementation of the Childhood Cancer STAR Act. Activities being carried out by CDC include:

—Awarded a contract on September 29, 2019 to develop a software tool that will aid pediatric cancer reporting facilities with rapidly submitting cancer incidence to Central Cancer Registries (CCRs).
—Convened a roundtable meeting on Feb. 12th–13th to provide an overview of the STAR project, clarify expectations of the participating pilot States and gather information/input from States regarding features that would be optimal for the STAR tool that is being developed. This included 15 CCRs and two hospital facilities from the following States: LA, OH, GA, CA, NE, MN, TX, RI, NH, KY, FL, and UT.

—Conducting individual calls with 14 CCRs to better understand their staff, data collection methods, State laws, software, challenges, successes, and interest in the project.

—Contacting experts from pediatric cancer organizations, pathology labs, children’s hospitals, and other subject matter experts to gather information relative to use and dissemination of data.

—Establishing a set of criteria to select the CCR who will pilot the new software tool in December.

—Determining the histology and data elements that will be used for data collection.

—Working closely with the contractor to ensure scalability.

The following text summarizes progress in implementing sections of the Childhood Cancer STAR Act directed toward the National Institutes of Health (NIH), including those directed specifically to the National Cancer Institute (NCI).

Section 101: Children’s cancer biorepositories and biospecimen research. NCI convened a meeting in May 2019 of more than 60 extramural researchers and advocates, along with NCI scientific staff, to discuss challenges and opportunities to enhance biobanking for childhood cancers. Informed by this discussion, in fiscal year 2019 NCI provided a grant supplement award to Nationwide Children’s Hospital to support immediate enhancements to the Children’s Oncology Group Biorepository. NCI scientific leadership has identified additional opportunities to enhance and expand childhood cancer biospecimen collection and biobanking resources in fiscal year 2020 and will soon be moving forward to solicit applications.

Section 111: Inclusion of at least one pediatric oncologist on the National Cancer Advisory Board. There are currently two pediatric oncologists appointed to the National Cancer Advisory Board (NCAB). Dr. Peter Adamson of the Children’s Hospital of Philadelphia was appointed to NCAB in 2015 and his term concludes in 2020. In October 2019, President Trump announced the appointment of Dr. Andrea Hayes-Jordan, Surgeon-in-Chief at the University of North Carolina Children’s Hospital. Dr. Hayes-Jordan’s appointment is pending final approval, and her NCAB term is expected to conclude in 2024.

Section 112: Sense of Congress regarding pediatric expertise at the National Cancer Institute. In addition to pediatric oncology expertise on NCAB, other NCI advisory boards, groups, and committees continue to include pediatric oncologists, scientists with pediatric expertise, and patient advocates. This includes more than 40 subject matter experts with pediatric expertise across three relevant NCI National Clinical Trials Network Steering Committees, with a patient advocate serving on each committee.

Section 121: Reporting on childhood cancer research projects. NCI and NIH reporting on childhood cancer research projects will continue to include the annual NIH Pediatric Research Initiative Report to Congress, as well as the NIH Triennial Report. After the close of each fiscal year, NIH also makes estimates of funding for various Research, Condition, and Disease Categories (RCDC) available on its website, including a “Pediatric Cancer” category, which links through to a list of hundreds of research projects supported by several NIH Institutes and Centers. NCI also reports on activities across its childhood and adolescent and young adult (AYA) cancer research portfolio on its website through several pages focused on childhood and AYA cancer research and resources for patients and families.

Section 202: Grants to improve care for pediatric cancer survivors. NCI continues to conduct and support critical ongoing childhood and AYA survivorship research efforts, including NCI’s long-standing investment in the Childhood Cancer Survivor Study. In fiscal year 2019 NCI also supported several new childhood and AYA survivorship research projects, including three new projects funded through a request for applications (RFA) developed to align with Section 202 of the STAR Act. The second receipt date for this RFA was in January 2020. Peer review is currently underway for this second round of applications, and NCI expects to make several awards in fiscal year 2020. Additionally, in December 2019, NCI’s Board of Scientific Advisors approved a new RFA aligned with Section 202 of the STAR Act. This RFA is expected to post to the NIH Guide for Grants and Contracts later this year, with application receipt dates scheduled for 2021 and 2022.
Question. The “SUPPORT for Patients and Communities Act” created the Interagency Task Force on Trauma-Informed Care. I understand that the Task Force has met a number of times over the past year and is moving forward with its operating plan which should be released in April or May. Can you explain the role stakeholders are playing in the creation of this operating plan? Are other opportunities for public engagement being planned in regards to the Task Force?

Answer. Stakeholders will play a major role in the development of the National Strategy and in the development of the website. Through a human centered design approach, SAMHSA’s Center for Mental Health Services (CMHS), with assistance from the United States Digital Services, will engage the stakeholders specified in the legislation.

NON-OPIOID ALTERNATIVES IN SURGERY/POST-SURGERY SETTINGS

Question. It has been brought to my attention that current Medicare payment systems may incentivize the use of opioids over proven non-opioid alternatives—such as continuous peripheral nerve blocks and other treatments. Are you considering any further changes to Medicare’s payment systems in order to incentivize doctors and healthcare providers to use alternative methods over opioids?

Answer. In the calendar year (CY) 2019 final rule for the Medicare outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) payment system, we finalized a policy to unpackage and pay separately at average sales price (ASP) + 6 percent for the cost of non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting for CY 2019 due to an observed decrease in utilization of these drugs in the ASC setting.

As required under section 6082 of the SUPPORT Act, for purposes of the CY 2020 OPPS/ASC proposed rule, CMS conducted an evaluation of its payment policies for opioids and evidence-based non-opioid alternatives under these systems. The goal of this analysis was to determine whether our packaging policies reduced the use of non-opioid alternatives and incentivized the use of opioids. We believed that if CMS packaging policies discouraged the use of these non-opioid alternatives or impeded access to these products, our analysis would show a decline in utilization of non-opioid alternatives over time.

In our evaluation, we looked at several devices used in covered medical procedures to determine if the current packaging policy represented a barrier to access. For each product, the most recently available Medicare claims data as well as medical literature relating to use of these products being used as an alternative to opioids was examined. All of the alternatives examined showed consistent or increasing utilization in recent years, with no products showing decreases in utilization in the OPPS setting, suggesting that current payment policy does not present a barrier to access of these products.

Drugs that function as surgical supplies were examined over a 6-year time period (CYs 2013 through 2018). During our evaluation, we did not observe significant declines in the total number of units used in the hospital outpatient department for a majority of the drugs included in our analysis. In fact, under the OPPS, we observed the opposite effect for several drugs that function as surgical supplies. Similar to the findings associated with devices above, this trend indicated appropriate packaged payments that adequately reflect the cost of the drug and are not prohibiting beneficiary access.

The results of this review and evaluation of medical literature and claims data did not support evidence to indicate that our packaging policies had the unintended consequence of discouraging the use of non-opioid treatments for postsurgical pain management in the OPPS setting, including drugs that function as a surgical supply, nerve blocks, or neuromodulation products.

To broaden our analysis, the CY 2020 OPPS/ASC proposed rule also sought public comment on other non-opioid treatments for acute pain that might be affected by OPPS and ASC packaging policies and warrant separate payment. However, the public comments and data that CMS received regarding specific products did not provide sufficient evidence-based support that the current packaged payment policies for these non-opioid alternatives presented a barrier to access to care and warranted revised, separate payment to reduce incentives. We provide further analysis of our review of these specific products in the CY 2020 OPPS/ASC final rule (CMS–1717–FC) released on November 1, 2019.

We will continue to analyze the issue of access to non-opioid alternatives in the OPPS and the ASC settings for any subsequent reviews we conduct under Section 6082 of the SUPPORT Act. We are continuing to examine whether there are other
non-opioid pain management alternatives for which our payment policy should be revised to allow separate payment under the OPPS.

**FAST ACT IMPLEMENTATION**

**Question.** The FAST Act, which was enacted in December 2015, mandated that HHS issue technical guidelines for the adoption of hair testing as a federally-accepted alternative drug testing method within 1 year of the bill’s enactment. Unfortunately, that deadline, which was December 4, 2016, is now well over 3 years past due. Will you commit HHS to providing DOT guidelines that will provide trucking companies an extremely effective safety tool, as mandated by Congress in the FAST Act, to ensure that their drivers are not using prohibited substances?

**Answer.** The proposal for Mandatory Guidelines for Federal Workplace Drug Testing Programs—Hair is currently under Executive Branch and interagency review and coordination. When this process is complete, we anticipate publishing the proposed Guidelines in a Federal Register Notice.

**BIOSIMILARS**

**Question.** The President’s budget states support for changes to bring lower-cost generic and biosimilar drugs to patients, as a way to lower out-of-pocket costs for patients. Are there specific actions, regulatory or legislative, that you propose to improve uptake of biosimilars and ensure patients have access to these lower-cost treatment options?

**Answer.** FDA will continue to play a critical role in facilitating increased access to biosimilars. FDA continues to implement the Agency’s Biosimilars Action Plan (BAP), first announced in July 2018, to promote competition and affordability across the market for biologics and biosimilar products. The BAP applies many of the lessons learned from our experience with generic drugs to accelerate biosimilar competition with four key strategies including: (1) improving the efficiency of the product development and review process; (2) maximizing scientific and regulatory clarity for the product development community; (3) developing effective communications to improve understanding among interested parties; and (4) supporting market competition by reducing attempts to unfairly delay market competition. The Agency is also supporting uptake by educating clinicians, payors, and patients about biosimilar products and the rigorous evaluation they must go through. FDA is modernizing regulatory policies to accommodate new scientific tools that can better enable comparison between biosimilars and reference products that may reduce the need for clinical studies.

Relatively, FDA has also taken steps to ensure a smooth regulatory transition aimed at increasing patient access to insulin products used daily by millions of Americans to maintain stable blood glucose levels, as well as certain other biological products set to transition regulatory pathways in March. On March 23, 2020, each application for a biological product approved under the Federal Food, Drug, and Cosmetic Act (FD&C Act), including applications for insulins and other biological products, was deemed to be a license for the product under the Public Health Service (PHS) Act. For the first time, this enabled submission of applications for products that are proposed as biosimilar to, or interchangeable with, the transitioned products. As such, the transition of insulin products from approved drug applications to deemed biological product licenses will open up those products to potential biosimilar and interchangeable competition.

The availability of approved biosimilar and interchangeable insulin products is expected to increase patient access, adding more choices and potentially reducing costs of insulin products.

**QUESTIONS SUBMITTED BY SENATOR CINDY HYDE-SMITH**

**Question.** Secretary Azar, I was encouraged by the Administration’s 2019 Executive Order on Modernizing Influenza Vaccines in the United States to Promote National Security and Public Health. Many of the vaccines we use today are produced overseas, creating a national security vulnerability during a global influenza pandemic. The White House Council of Economic Advisors also issued a report, which detailed the significant health and economic impacts of a potential influenza pandemic as well as the advantages that new vaccine manufacturing technologies have by developing vaccines faster and better matching the influenza virus strains circulating in a given year. As we are considering fiscal year 2021 appropriations, please provide the Committee a copy of the National Influenza Vaccine Task Force report required in the Executive Order within 30 days.
Answer. The Task Force report is due June 2020, and is in the final stages of drafting at this time. We will provide the Committee with a copy as soon as the report is finalized.

Question. Secretary Azar, I was disappointed to see the Administration’s 2021 budget request propose a $200 million cut to BARDA’s Special Reserve Fund (SRF). As you know, the SRF funds procurement of medical countermeasures (MCMs) under FDA Emergency Use Authorization. Over the last 15 years, this successful program has stockpiled millions of doses of vaccines and treatments to prepare the United States against a chemical, biological, radiological, or nuclear (CBRN) event. It is a critical national security asset and has broad bipartisan support in this committee and the entire Congress. This stunning cut you’ve proposed—which would amount to 27 percent of the SRF budget—flies in the face of this year’s professional budget estimate prepared by the experts in the Public Health Emergency Medical Countermeasure Enterprise (PHEMCE). It also defies logic—why would we sacrifice preparedness against the most serious threats we face as a Nation?

Do you understand the national security consequences of gutting the SRF?

Answer. HHS identified an immediate need in fiscal year 2020 to promote the development of an Ebola medical countermeasures product. Congress provided an additional $535 million via supplemental appropriation in fiscal year 2020 directly for this purpose. The decision to reduce the SRF in the fiscal year 2021 budget request was based on the forward-funding of this Ebola candidate. At the diminished level, there are no long-term, significant impacts to the SRF of Project BioShield investments.

In fiscal year 2020, Congress appropriated $535 million in emergency supplemental funding to the PHSSEF to support procurement of Ebola vaccines, therapeutics and diagnostics. BARDA will use this funding to move forward with procurement of at least one vaccine, one therapeutic and potentially two diagnostics for the Ebola Zaire strain. BARDA will obligate an additional $200 million provided through the fiscal year 2020 PBS appropriations to support additional late-stage development activities to support licensure of the various medical countermeasures. These activities could include phase IV post-marketing requirements or commitments.

Question. Have you considered the long-term impact this cut will have on the Department’s partners in the private sector who are working on MCM research and development?

Answer. HHS identified an immediate need in fiscal year 2020 to promote the development of an Ebola medical countermeasures product. Congress provided an additional $535 million via supplemental appropriation in fiscal year 2020 directly for this purpose. The decision to reduce the SRF in the fiscal year 2021 budget request was based on the forward-funding of this Ebola candidate. At the diminished level, there are no long-term, significant impacts to the SRF of Project BioShield investments.

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Question. Will you commit to reevaluating the Administration’s proposed 2021 funding level for the SRF?

Answer. Based on what was described in the response above, there is no benefit or need to reevaluate the fiscal year 2021 proposal at this time.

Question. Secretary Azar, while this novel coronavirus has become an unexpected global epidemic, the emergence of deadly new viruses are one of the most predictable public health threats we face. As the saying goes, it’s not a matter of if but when the next outbreak will occur. I believe Congress should provide additional emergency funding to battle the coronavirus outbreak. And I worry that if we don’t, HHS and other agencies will be forced to pull funding from other accounts in the biodefense and pandemic preparedness space. The long term solution to this problem is a sustained response fund at HHS.

Can you share with us the consequences of not properly funding HHS’ response to the coronavirus outbreak?

Answer. Prior to the enactment of the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020, HHS was considering reallocating program funds to support a response. On February 2, 2020, HHS notified Congress of its in-
tent to transfer funds to support COVID–19 activities. The notification included a transfer of up to $75 million to support CDC, up to $52 million to support the Public Health and Social Services Emergency Fund, and up to $8.5 million to other parts of the HHS Office of the Secretary. After the enactment of the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020, the transferred funding was returned to the original appropriated accounts.

Question. What other accounts at HHS—such as SNS and BARDA—would suffer as a result of having to divert resources to the coronavirus response?
Answer. The Strategic National Stockpile (SNS) has met and continues to meet requests for personal protective equipment (PPE) from States. While the SNS has significant materiel on hand, HHS will also use supplemental funding for replenishment.

Question. How important is it to have a dedicated response fund at HHS/ASPR moving forward?
Answer. The Public Health Emergency (PHE) Fund is authorized to fund rapid response to immediate needs resulting from a PHE, or to rapidly respond to a potential PHE when the Secretary determines that there is a significant potential for a PHE; however, this fund has not received an appropriation in over twenty years.

Question. Secretary Azar, I believe the Strategic National Stockpile (SNS) will play a critical role in the U.S. response to the coronavirus outbreak. In the short-term, the SNS needs to distribute critical medical supplies to hospitals and other first responders. Over the long-term, the SNS will play a role in the purchase a distribution of medical countermeasures including vaccines and treatments.
Can you speak the role the SNS will play in HHS’ response to the coronavirus outbreak?
Answer. The Strategic National Stockpile (SNS) holds millions of face masks, N95 respirators, gloves and surgical gowns that are being deployed as State and local supplies are diminished due to the current COVID–19 response and commercial supplies are exhausted. The SNS has met and continues to meet requests for PPE from States. The SNS is filling these orders as quickly as possible to ensure the healthcare system is prepared and able to respond.

Recently, the SNS issued a request for proposals for 500 million N95 respirators plus additional personal protective equipment to protect frontline healthcare workers and first responders, with the goal of maintaining the resiliency of the American healthcare system. The intent behind the request for proposals is to surge domestic personal protective equipment manufacturing capabilities.

Question. Does the SNS need additional resources to carry out this role?
Answer. The funding provided by the supplemental will aid in the replenishment of supplies within the SNS.

Question. If so, what are the consequences to not providing these additional resources to the SNS?
Answer. No response needed as supplemental funding was provided.

Question. Secretary Azar, over the past few weeks, I have become concerned with China’s response to the coronavirus outbreak. Among other issues, I worry that China has taken an aggressive stance regarding the development of novel vaccines and therapeutics to combat the outbreak. China has stated publicly they intend to aggressively pursue the intellectual property and manufacturing capacity of coronavirus treatments.

How do we ensure the availability to new coronavirus treatments in the United States given this aggressive posture from China?
Answer. FDA is committed to working with medical product developers and other researchers and manufacturers, including those very early in the development process, to help expedite the development and availability for U.S. patients of medical products such as vaccines, antibodies, and drugs to prevent and treat COVID–19. As part of these discussions, FDA is willing to consider different strategies, as appropriate, to help facilitate and expedite development of novel vaccines and therapeutics. This includes not only pre-clinical and clinical trial design strategies, but also working closely with companies on manufacturing issues to allow them to scale up as necessary. With respect to vaccines, the Agency encourages developers, to the extent they are not already doing so, to leverage previous development work, including platform technologies from vaccines already in advanced development, in the development of COVID–19 vaccines.

We are leveraging all domestic resources to aid the development of safe and effective vaccines and therapeutics. BARDA has made five awards thus far: two vaccine candidates, two therapeutics, and one diagnostic. Additionally, the SNS recently launched a public-private partnership to create a U.S.-based, high-speed, high-volume emergency drug packaging solution. The new consortium for Rapid Aseptic Packaging of Injectable Drugs, or RAPID, will enable the SNS to fill and finish, on
a rapid basis, hundreds of millions of prefilled syringes to respond quickly and efficiently to widespread health emergencies, such as the novel coronavirus outbreak. Projects are under evaluation to expedite this process and could yield results within 6 months.

**Question.** Can you speak to the importance of a dedicated U.S. manufacturing capacity for coronavirus vaccines and treatments?

**Answer.** The increasing number of active pharmaceutical ingredient (API) manufacturing sites in China and other countries suggests that the United States’ reliance on Chinese and other foreign sources of API is growing. FDA has been working diligently in collaboration with industry and other Federal agencies to ensure that our reliance on foreign manufacturing does not pose a national security risk. While FDA cannot tell industry where they can and cannot manufacture APIs, the Agency can work with industry to utilize new technologies and new manufacturing methods to further incentivize domestic production of drugs and APIs. These new ways of making drugs could, with the proper strategies, revitalize pharmaceutical manufacturing in the United States.

Advanced manufacturing has the potential to bring greater efficiency and accuracy to the pharmaceutical manufacturing process. With increased U.S. investment, advanced manufacturing can help reduce the Nation’s dependence on foreign sources of APIs, increase the resilience of our domestic manufacturing base, and reduce quality issues that trigger drug shortages or recalls. Furthermore, advanced manufacturing can help improve the agility, flexibility, reliability, and reduce the cost of manufacturing processes for vaccines, cell and gene therapies, and other complex biological products. Advanced manufacturing can help to create a more robust and reliable manufacturing process with fewer interruptions in production, fewer product failures (before or after distribution), and greater assurance that the biologic products manufactured will provide the expected clinical performance. For example, with advanced manufacturing methods the vaccine supply could be more easily ramped up on short notice, and certain vaccines could be rapidly modified so that, once FDA-approved, they can be used to address emerging infectious diseases. The application of this kind of enabling technology to vaccine production has long been a strategic priority for the U.S. to help address both seasonal influenza and emerging infectious diseases.

In fiscal year 2019, Congress approved appropriations to promote domestic manufacturing with the intent that FDA advance modern drug and biological product technologies. The spending plan for these additional resources builds on FDA’s goals to improve overall staff understanding and expertise in advanced manufacturing by expanding support for these innovative technologies in assessment, policy, surveillance, and research, as well as by making programmatic improvements. In addition, this funding is used to reinforce extramural outreach with stakeholders via planned technology forecasting activities with the National Academies of Science, Engineering, and Medicine and other forums. Additionally, to support the application of novel technologies for advanced manufacturing, FDA enhanced its work on advanced manufacturing in its intramural regulatory science program and made several awards to support new efforts to foster innovation in the development and commercialization of modern, domestically-based manufacturing of complex biologics. These efforts help to bridge the knowledge and experience gaps in the adoption of emerging manufacturing technologies in the biological product sector.

It is important to reduce our reliance on foreign manufacturers. BARDA has supported domestic manufacturing capabilities for over a decade. Domestic manufacturing capabilities ensure we can develop products, as soon as they are available, without depending on international partners. In past outbreaks like H1N1 in 2009, we witnessed firsthand international partners shutting boarders and not supplying products.

**Question.** Secretary Azar, as we ramp up the U.S. response to this coronavirus outbreak, I hope we keep in mind the lessons of past response efforts. The Zika outbreak is a good example. As Zika became a significant public health threat in the U.S., Congress appropriated a small, one-time supplemental funding package. This funding was enough to sustain the initial response effort and begin a few clinical trials for a Zika vaccine. But after the Zika outbreak began to subside, this funding quickly expired. As a result, we still don’t have an approved Zika vaccine and we don’t have commercial partners to help develop one.

What progress have we actually made in developing a Zika vaccine if the virus were to come back? Do you think this is an example of how we need to have sustained funding for emerging infectious diseases, even when they aren’t on the evening news?
Answer. The National Institute of Allergy and Infectious Diseases (NIAID), a component of the National Institutes of Health, supports a comprehensive portfolio of basic, translational, and clinical research on emerging and re-emerging infectious diseases, including Zika virus. In fiscal year 2019, NIAID committed $131.9M for research on Zika and other related viruses, like dengue and West Nile virus, including $54.6M specifically for research on the Zika virus. The outbreak of Zika virus in the Americas and the response by the scientific and public health communities provided important lessons on how to prepare for and confront emerging and re-emerging pathogens in the future, and to make sure we are prepared for the next outbreak with critical diagnostics, vaccines, and therapeutics.

NIAID conducts and supports research on platform technologies that can quickly be specified for use during outbreaks of pathogens like Zika virus or the recent novel coronavirus that causes COVID–19. One such platform was used by the NIAID Vaccine Research Center to modify an investigational DNA vaccine for West Nile virus that had shown promise in initial testing to protect against Zika virus. NIAID recently supported a large, multi-national Phase IIb clinical trial of this vaccine candidate, VRC2823, for Zika virus in the Americas with results expected within the next year. VRC2823 was recently shown to significantly reduce viral infection, and subsequently reduce adverse pregnancy outcomes, in a non-human primate model of Zika virus disease. NIAID also recently completed a Phase I clinical trial of a live, attenuated Zika virus candidate vaccine, rZIKV/D4?30–713, in flavivirus-naive adults. NIAID scientists have also developed a live, attenuated dengue virus vaccine candidate, TV003, that has shown promise in several Phase II clinical trials and is being evaluated in a large Phase III study. A single vaccine that protects from both dengue and Zika virus, developed by NIAID scientists, is currently in preclinical testing.

NIAID also is supporting research to better understand the manifestations of Zika virus infection. NIAID, along with the Eunice Kennedy Shriver National Institute of Child Health and Human Development and the National Institute of Environmental Health Sciences, is supporting a large, prospective cohort study on Zika virus infection during pregnancy, called the Zika in infants and pregnancy study (ZIP). The ZIP study followed Zika virus-infected women and their infants, in ten sites in six countries, for at least 1 year after birth, and monitored for pregnancy outcomes, congenital anomalies, and other developmental abnormalities. A follow-up study is now enrolling that will follow these individuals for an additional one to 3 years and compare them to a matched Zika virus uninfected group.

Despite the lower numbers of Zika virus cases observed recently, NIAID expects to see periodic outbreaks and cases of this virus in areas where its insect vector, the Aedes aegypti mosquito, thrives. NIAID will continue to prioritize this research.

BARDA was able to support FDA clearance of four diagnostic or blood assay devices. In addition, BARDA supported two vaccine candidates. NIAID also is supporting research to better understand the manifestations of Zika virus infection. NIAID, along with the Eunice Kennedy Shriver National Institute of Child Health and Human Development and the National Institute of Environmental Health Sciences, is supporting a large, prospective cohort study on Zika virus infection during pregnancy, called the Zika in infants and pregnancy study (ZIP). The ZIP study followed Zika virus-infected women and their infants, in ten sites in six countries, for at least 1 year after birth, and monitored for pregnancy outcomes, congenital anomalies, and other developmental abnormalities. A follow-up study is now enrolling that will follow these individuals for an additional one to 3 years and compare them to a matched Zika virus uninfected group.

Despite the lower numbers of Zika virus cases observed recently, NIAID expects to see periodic outbreaks and cases of this virus in areas where its insect vector, the Aedes aegypti mosquito, thrives. NIAID will continue to prioritize this research.

Answer. Secretary Azar, I am concerned about all global health threats, including the threat of Ebola in the DRC and its potential to spread. We cannot afford to take our eye off the ball with Ebola. Please provide the Committee a 5 year spend plan for Ebola therapeutics, diagnostics and vaccines to counter this material threat.

Answer. Future funding requests will be developed through the annual budget process, which takes into consideration the current budget environment and other Departmental priorities. NIAID supports development and testing of candidate products to prevent or treat viral hemorrhagic fevers, including those caused by Ebola. The NIAID Vaccine Research Center (VRC) developed a protective Ebola vaccine in 2000 and conducted the first Phase I clinical trial in 2003. NIAID’s investments in vaccine development and testing supported the 2014–2016 Ebola outbreak response. These investments also allowed NIAID to rapidly launch a robust research response to the most recent outbreak in the Democratic Republic of the Congo (DRC). The monoclonal antibody mAb114 (ansuvimab) was isolated from a survivor of the 1995 Ebola outbreak in Kikwit, DRC, and further developed by scientists at the NIAID VRC in partnership with the DRC’s Institut National de Recherche Biomedical (INRB) and the U.S. Department of Defense (DoD). Ansuvimab has been used to successfully treat and cure hundreds of patients in the 2018–2020 Ebola outbreak in the DRC. Critical components of the recent response came from products and protocols developed through the PREVAIL studies, which enabled the evaluation of candidate vaccines and therapeutics during the 2014–2016 outbreak. These NIAID-supported Ebola studies demonstrated the feasibility of conducting scientifically and ethically sound clinical research during a major public health emergency.

NIAID supports the development of novel therapeutics targeting Ebola viruses as well as clinical trials to test the safety and efficacy of these treatments. NIAID worked closely with partners at DoD, BARDA, and the Food and Drug Administra-
tion (FDA) to advance the development and testing of ZMapp™, and during the West African outbreak led a clinical trial to test the safety and efficacy of ZMapp™ in infected people at sites in Liberia and the United States. Ansuvimab and ZMapp™ along with the broad-spectrum antiviral remdesivir and a cocktail of mAbs known as REGN–EB3, were recently assessed in a randomized controlled trial, the Pamoja Tulinde Maisha, which is Swahili for “Together Save Lives,” (PALM) trial, in the DRC through a partnership between NIAID, the World Health Organization (WHO), and the DRC’s INRB. This study was stopped early due to the observed safety and efficacy of REGN–EB3 and ansuvimab. An extension phase of the study is enrolling patients who received one of these two effective therapeutics. Final results from the primary study demonstrated statistically significant improvements in mortality for REGN–EB3 relative to ZMapp™ and for ansuvimab relative to ZMapp™.

Safe and effective Ebola vaccines are crucial tools in the response to future Ebola outbreaks, especially for situations like the most recent outbreak, in which conflict or other factors limit the healthcare response. Since 1999, NIAID has pursued the development of multiple Ebola vaccine candidates. One such vaccine candidate, supported by NIAID extramural funding, rVSV-EBOV (ERVEBO(r)), a vesicular stomatitis virus vector expressing Ebola virus proteins, was used in a ring vaccination campaign in the DRC during the most recent outbreak to immunize frontline workers, people potentially exposed to Ebola virus, and individuals who may have been in contact with them. The NIAID supported PREVAIL I study also evaluated immunogenicity and safety of the ERVEBO(r) vaccine during the 2014–2016 West Africa outbreak. Another vaccine, ChAd3–EBO, was advanced by the NIAID VRC in Phase I clinical trials and is currently being developed by the Sabin Vaccines Institute. The ChAd3–EBO and ERVEBO(r) vaccines have been evaluated by Phase I safety testing in the United States (along with the Walter Reed Army Institute of Research).

NIAID also supported the preclinical development and Phase I clinical evaluation of another Ebola vaccine candidate using Ad26.ZEBOV, which is based on an adenovirus vector expressing an Ebola virus protein, followed by MVA–BN(r)-Filo, a modified vaccinia virus expressing proteins from multiple hemorrhagic viruses. This vaccine regimen along with the ERVEBO(r) vaccine was evaluated in a Phase II study called Partnership for Research on Ebola VACCination (PREVAC) in Liberia, Sierra Leone, Guinea, and Mali. The ERVEBO(r) vaccine has been approved by the FDA and represents the first vaccine approved in the U.S. for use against Ebola. The data needed to support licensure of the Ad26.ZEBOV/MVA-BN-Filo vaccine candidate was submitted to the European Medicines Agency at the end of 2019 and is expected to be submitted to the FDA in 2021.

NIAID is advancing the development of diagnostics capable of detecting an array of viruses including Ebola. Many use novel technologies like aptamer-based capture molecules, microfluidics, optofluidics, nanohole biosensors, nanophotonics, and real-time monitoring. NIAID investigators, have worked with collaborators at the DRC’s INRB to implement assays developed with support from NIAID and partners, including the Xpert(r) Ebola PCR test and an immunoassay for vaccine studies.

NIAID remains committed to supporting highly meritorious research on Ebola virus countermeasures. The research performed during the most recent outbreak will help us to rapidly respond to future outbreaks of Ebola and other emerging infectious diseases.

Together with academia, industry, and national and international partners, NIAID will leverage lessons learned during prior outbreaks to continue to conduct and support high-priority research leading to diagnostics, therapeutics, and vaccines for Ebola. NIAID will continue to work closely with our global partners to gain a better understanding of the pathophysiology of Ebola virus infection and develop safe and effective medical countermeasures to treat and prevent Ebola.

**Question.** Secretary Azar, I was delighted to see the Administration put forward a request for almost $2.5 billion last night to help combat coronavirus, which we know is threatening the health and safety of all Americans. However, I’m concerned about the suggestion in the administration’s letter that we offset some of the funds by using unspent Ebola funds. I understand the desire to be fiscally responsible but I believe that we must not take our eye off of the threat of Ebola just because it’s off of the front pages. We know that a global health threat somewhere is a health threat to all Americans so I hope we in Congress can find other sources of funds.

**Answer.** HHS is not redirecting Ebola funds at this time. Appropriated funding for Ebola will continue to support investment in vaccines and therapeutics as planned.

**Question.** Secretary Azar, Last year, the fiscal year 2020 appropriations bill included language expressing the concern of the Committee that relapse following...
opioid detoxification is a contributing factor to the overdose crisis. SAMHSA has previously included language in grant notices stating that if funds are used to support detoxification it must be done in conjunction with relapse prevention medications. I applaud SAMHSA’s action on this, however there was concern that this recommendation was limited to a small number of patients undergoing detoxification.

The committee directed SAMHSA to go beyond just this narrow grant population and emphasize that all patients undergoing opioid detoxification should be made aware of the benefits of relapse prevention. Can you provide an update as to what the Department is doing to disseminate this recommendation and ensure that all patients, including those in rehabilitation and criminal justice settings, are aware of the recommendation?

Answer. SAMHSA’s grant programs that directly respond to the opioid crisis increase access to medication-assisted treatment using FDA-approved medications for the treatment of opioid use disorder (OUD) with appropriate behavioral supports, reduce unmet treatment need, and reduce opioid overdose related deaths through the treatment and recovery activities for OUD. In addition, SAMHSA requires that its Center for Substance Abuse Treatment’s services programs addressing substance use disorders and co-occurring mental disorders—including its criminal justice programs—support medication-assisted treatment and other clinically appropriate services to achieve and maintain abstinence. Regarding the use of naltrexone following opioid detoxification, SAMHSA updates its website to ensure that the most up-to-date information on naltrexone—to include its uses and applicable settings—is available to consumers and practitioners. A video for practitioners on the use and benefits of naltrexone is also being developed.

Question. Secretary Azar, as you know, independent community pharmacies serve on the front lines as healthcare providers and play an integral role as part of the Medicare Part D benefit. These small business providers are plagued with retroactive “pharmacy DIR fees”. This creates severe difficulties in terms of business operations and cash flow. In fact, CMS has recognized the issues with how DIR fees are reported by Part D plan sponsors, how these fees impact pharmacy business, and the resulting challenges they create for Part D beneficiaries. In addition, a new report by XIL Consulting, which is run by a former Express Scripts executive, focuses on how PBMs are gaming the system with these fees that are hurting pharmacies and patients. According to the report, payers and PBMs are profiting from these obscure pharmacy fees at a rate in excess of 500 percent per prescription as compared to the average PBM administration fee. PBMs are exploiting a loophole in the Part D program rather than offsetting prescription costs for seniors.

The report points out that in 2017, PBMs used the fees to squeeze more than $4 billion out of pharmacies. That practice, according to a recent National Community Pharmacists Association survey, is the main reason 58 percent of local pharmacists are not sure they can survive the next 2 years. Given the fact that these “fees” are detrimental to Part D beneficiaries and Part D pharmacy care providers, how will you work to resolve these concerns?

Answer. In the CY 2020 Medicare Advantage and Part D Drug Pricing Proposed Rule (CMS-4180-P) CMS solicited comment on a policy that would re-define negotiated price as the baseline, or lowest possible, payment to a pharmacy. The negotiated price for a drug is the price reported to CMS at the point of sale, which is used to calculate beneficiary cost-sharing and generally adjudicate the Part D benefit. Although CMS did not implement this policy for 2020, the agency appreciates...
the over 4,000 comments that were received on this potential policy approach. CMS is continuing to carefully review these comments and to consider policies that would lower prescription drug costs, address challenges that independent pharmacies face, and improve the quality of pharmacy care.

Question. Secretary Azar, The President and your agency have specifically focused on concerns with the “middlemen” in the drug supply chain, also known as Pharmacy Benefit Managers or PBMs. Over time, these companies have morphed into under-regulated entities that exploit their strategic position in the middle of nearly all drug transactions in the U.S. to extract profits from upstream and downstream trading partners while providing questionable value to the consumer. PBMs are also heavily involved in and reap enormous profits from their involvement in Federal supported or subsidized healthcare programs, while the government has very little oversight over PBM actions. Do you support more regulation of PBMs in government programs and what does that regulation look like?

Answer. We are open and eager to work with legislators on both sides of the aisle to address the high cost of prescription drugs.

—We would support a bipartisan and bicameral plan that would bring down the high costs of prescription drugs.

—Our priorities remain: (1) Lowering drug prices, (2) Lowering patients’ out-of-pocket costs, (3) Improving competition, and (4) Creating better conditions for negotiation.

—We share Congress’s goal of increasing transparency in the healthcare system.

—The status quo cannot remain and we will continue to offer technical assistance to lawmakers as they work to find a path forward.

Question. Secretary Azar, Many States have increased their oversight and regulation of Medicaid managed care programs, realizing that Pharmacy Benefit Managers or PBMs are pocketing billions in “spread” to the detriment of State funded programs, providers, patients and taxpayers. Currently, there are Federal legislative proposals to ban “spread” in all Medicaid managed care programs and reimburse providers to cover their acquisition cost of drugs and related dispensing costs. Do you support these proposals?

Answer. We are open and eager to work with legislators on both sides of the aisle to address the high cost of prescription drugs.

—We would support a bipartisan and bicameral plan that would bring down the high costs of prescription drugs.

—Our priorities remain: (1) Lowering drug prices, (2) Lowering patients’ out-of-pocket costs, (3) Improving competition, and (4) Creating better conditions for negotiation.

—We share Congress’s goal of increasing transparency in the healthcare system.

—The status quo cannot remain and we will continue to offer technical assistance to lawmakers as they work to find a path forward.

Question. Transparency is critical. COVID–19 has taught us that understanding genomic sequencing and the origins of emerging infectious diseases as soon as they emerge is critical for effective vaccine development. However, it has come to our attention that although the CDC largely makes the RNA sequence of influenza viruses available, the antigenic information including detailed source data is not made available to researchers for use outside the agency. The availability of this information could lead to faster and more effective vaccine development. We have additionally learned that similar information is shared publicly in the UK by its public health agency.

Why does the CDC not share this information with the broader research community?

Answer. CDC is committed to publicly sharing influenza data in a timely manner for the benefit of the broader scientific community. As recognized, influenza genetic sequence data is now shared rapidly because the CDC has moved to a ’Sequencing First’ paradigm to rapidly disseminate this information to the community via public databases. This genetic data is available because of arrangements with domestic and international partners to share the data, including through a specific database (GISAID/EpiFlu https://www.gisaid.org/) that recognizes originating laboratory contributions.

CDC also shares influenza antigenic data publicly in the form of scientific publications and other publicly available reports. To provide information to the broader scientific community, antigenic information is incorporated into a publicly available analysis (https://nextstrain.org/flu/seasonal ) through a collaboration supported by the CDC. This analysis shows the real-time tracking of influenza viruses based on a variety of different parameters, including genetic and antigenic data, using analytic and visualization tools to aid epidemiological understanding and improve outbreak response. The source information, or strain name (e.g., A/Pennsylvania/1020/
2019), associated with each data point is available in the analysis; however, some source information is deemed Personally Identifiable Information, and is therefore not included in public reports.

**Question.** Does CDC have plans to be more transparent in the future?

**Answer.** CDC is committed to transparency and communication of available data to inform evidence-based public health decisions, as evidenced by its collaboration with NextStrain to provide real-time tracking of influenza viruses to aid epidemiological understanding and effective control of influenza. Further, CDC continues to improve its frequency of publications to make data available more rapidly and to leverage technological advances and collaborations to enhance its data sharing capabilities, including through creating better online user interfaces.

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**QUESTIONS SUBMITTED BY SENATOR PATTY MURRAY**

**CDC SUICIDE PREVENTION PROGRAM**

**Question.** The budget eliminates a suicide prevention program at the CDC that was established in the fiscal year 2020 Bill. This elimination is particularly disturbing in light of the recent CDC National Center for Health Statistics Report on life expectancy, which showed that suicide rates continue to increase and serve as a major contributor to the leading causes of death in the U.S. This suicide prevention program supports a comprehensive public health approach to suicide prevention focused on these vulnerable populations, including veterans, rural communities, tribal populations, LGBTQ youth and the homeless, all of which have suicide rates higher than the general population. Suicide is a national public health crisis that requires a comprehensive evidence-based prevention approach and yet this budget eliminates the initiative. Please provide CDC’s analysis of how many people, representing which vulnerable populations, will be affected if the agency eliminates this suicide prevention program in fiscal year 2021.

**Answer.** CDC has prioritized suicide prevention for many years. With a dedicated funding line for suicide in fiscal year 2020, CDC is expanding its ability to provide data for States and communities to understand who dies by suicide, why, and how to prevent it. Towards that goal, CDC published a new notice of funding opportunity forecast on grants.gov that will fund States and emphasize vulnerable populations. CDC will not know which populations, including vulnerable populations will be the focus of this funding, until after applications are received and funded.

**HIV INITIATIVE**

**Question.** The budget expands the initiative Congress started last year aimed at ending our Nation’s HIV epidemic in the next decade through modest, but focused, increases for the Centers for Disease Control and Prevention, the Health Resources and Services Administration, and the Ryan White HIV/AIDS Program. However, the budget’s deep cuts to the Medicaid program would undermine efforts to eliminate new infections. The President’s efforts to repeal the Affordable Care Act and more than $1.5 trillion in cuts to Medicaid and Medicare would greatly reduce access to healthcare for people living with HIV, hurting efforts to end the epidemic domestically. Ending the HIV epidemic will require affordable, comprehensive health coverage and a robust and sustainable healthcare system, which are at odds with the Administration’s proposals and efforts. Please provide HHS’ analysis of how many people living with HIV/AIDS will be affected if the Administration is successful at striking down the ACA and Medicaid expansion?

**Answer.** The Budget does not propose cutting Medicaid, but rather maintains funding to at least fiscal year 2020 levels and slows annual growth of the program from 5.4 percent to 3.1 percent. The Ending the HIV Epidemic Initiative ensures that those who need treatment get treatment, and those who need prevention tools get those as well. The Budget proposes $716 million for fiscal year 2021, an increase of $450 million, to expand HIV testing and access to prevention and treatment services. This additional $450 million is disbursed between the following agencies: a $231 increase to CDC’s community partnerships to effectively diagnose, prevent, and respond to HIV infections; a $182 million increase to HRSA’s Health Center and Ryan White activities to increase access to treatment, prevention services, and retain people with HIV in care; a $27 million increase for IHS activities, including treatment, medication, public health surveillance, and data infrastructure efforts; and a $10 million increase to NIH to lead evaluation efforts to identify effective interventions to treat and prevent HIV. Additionally, last December HHS launched Ready, Set, PrEP, a national program that makes these PrEP medications available at no cost to individuals who lack prescription drug insurance coverage.
MATERNAL HEALTH

**Question.** The budget expands the initiative Congress created in 2018 aimed at ending our Nation’s maternal mortality crisis, which kills approximately 700 women each year. Every mother is at risk here, however Black and Native American women are disproportionately at risk. Despite these risks, the budget’s deep cuts to the Medicaid program would undermine efforts to eliminate this largely preventable public health crisis, as nearly half of all U.S. births are covered by Medicaid. The President’s efforts to repeal the Affordable Care Act and more than $1.5 trillion in cuts to Medicaid and Medicare would greatly reduce access to healthcare for women seeking maternal health services. How can communities fight the maternal mortality crisis if you undermine programs so many families rely on for care? Please provide HHS’ analysis how many women will lose access to maternal health services affected if the Administration is successful at striking down the ACA and Medicaid expansion?

**Answer.** As the single largest payer for maternity care in the United States, Medicaid plays an important role in perinatal and maternal health. In 2014, CMS launched its Maternal and Infant Health Initiative (MIHI) to explore program and policy opportunities to improve outcomes and reduce the cost of care for women and infants in Medicaid and CHIP. Since then, much work has been done, such as the Postpartum Care Action Learning Series, a learning collaborative of States to drive quality improvement around postpartum care.

CMS is currently evaluating activities over the past 5 years, which includes publishing three Issue Briefs on March 9, 2020, to describe initiatives undertaken in the first phase of MIHI. These Issue Briefs are:

—Lessons Learned About Payment Strategies to Improve Postpartum Care in Medicaid and CHIP: This brief outlines the lessons learned about payment strategies to improve postpartum care visit rates and summarizes the changes three States made related to paying for maternity care in order to improve postpartum care under the Postpartum Care Action Learning Series.1

—The Maternal and Infant Health Initiative Grant to Support Development and Testing of Medicaid Contraceptive Care Measures: The CMS MIHI grant program supported development and testing of Medicaid contraceptive care measures. This analytic brief discusses the MIHI grant program, describes the contraceptive care measures developed as part of this effort, summarizes data reported by the MIHI grantees, highlights uses of the data, and identifies lessons learned.2

—Improving Postpartum Care: State Projects Conducted through the Postpartum Care Action Learning Series and Adult Medicaid Quality Grant Program: This issue brief describes the quality improvement teams in the 10 States, their aims, the interventions they tested, their results, and lessons learned. In addition, this fact sheet provides summaries of the postpartum care-related projects that four States undertook as Adult Medicaid Quality grantees.3

In 2018, CMS announced the Maternal Opioid Misuse (MOM) model, which addresses the need to better align and coordinate care of pregnant and postpartum Medicaid beneficiaries with opioid use disorder (OUD) through State-driven transformation of the delivery system surrounding this vulnerable population. By supporting the coordination of clinical care and the integration of other services critical for health, wellbeing, and recovery, the MOM model has the potential to improve quality of care and reduce expenditures for mothers and infants. In December 2019, CMS announced the following 10 States were awarded MOM Model funding: Colorado, Indiana, Louisiana, Maine, Maryland, Missouri, New Hampshire, Tennessee, Texas, and West Virginia.

Additionally, CMS is reconvening an expert workgroup to help chart a course for the future of maternal infant health quality measurement and improvement. The workgroup will represent a wide variety of key stakeholders and Federal agencies and will provide updated recommendations for measurement, quality improvement and technical assistance opportunities.

In Medicaid and CHIP, the measures in the voluntary Child and Adult Core Sets assess the quality of care women receive at each step in their lifecycle and include quality measures associated with major drivers of pregnancy-related mortality and severe maternal morbidity. CMS has identified a subset of 11 Child and Adult Core

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1 Available at: https://www.medicaid.gov/medicaid/quality-of-care/downloads/postpartum-payment-strategies.pdf.
Set measures for 2020 that comprise a Core Set of Maternal and Perinatal Health Measures for Medicaid and CHIP (Maternity Core Set).\textsuperscript{4} The Maternity Core Set includes a measure of early elective delivery, along with measures that examine prenatal and postpartum care, low birth weight babies and well-baby care. Since the core sets were established in 2010 and 2012, States have made significant progress reporting these measures. With the passing of the Bipartisan Budget Act of 2018 (Public Law 115–123), State reporting of the Child Core Set, including maternal and infant health measures, will become mandatory beginning in 2024.

The Medicaid and CHIP Scorecard is a central component of CMS’s commitment to increase public transparency and accountability about the programs’ administration and outcomes.\textsuperscript{5} The Scorecard currently includes one maternal health measure (Postpartum Care), as well as two other measures from the Maternity Core Set: Well-Child Visits in the First 15 Months of Life and Live Births Weighing Less than 2,500 grams. Over time, the Scorecard will evolve to include health outcome metrics, and we are considering how the Scorecard can address maternal and infant health. CMS continues to work with States to encourage greater reporting to improve consistency across States.

\textbf{Question.} This budget cuts funding to the CDC by nearly $700 million and while it increases funding for Global Health Security, it comes at the cost of deep funding cuts to other global health and public health preparedness and response programs. In 2019, the U.S. experienced several large measles outbreaks. Ultimately, there were 1,261 cases in thirty-one States linked to travelers who brought measles back from other countries. Since 2000, when measles was declared eliminated from the U.S., nearly all domestic cases have been linked to international travel. We know that vaccines are cost-effective and that Americans remain at risk from other vaccine-preventable diseases like polio and pertussis. Yet, this budget cuts the global immunization program by $20 million. How many countries and international partnerships are supported by the global immunization program? How many children and adults are served by these programs? Please provide CDC’s analysis of how many children and adults would lose access to immunizations services if the global immunization program were cut by $20 million.

\textbf{Answer.} CDC’s global immunization program provides support to 64 countries as part of two international partnerships, the Global Polio Eradication Initiative (GPEI) and the Measles and Rubella Initiative (M&RI). To address increases of vaccine-derived polio outbreaks, CDC is intensifying focus-deploying an additional 97 technical experts since 2019. To address global measles outbreaks, CDC experts work with in-country and other global partners to analyze data, plan and implement outbreak response immunization campaigns, conduct laboratory analysis, and build surveillance capacity to detect and contain outbreaks quickly. In 2019, CDC supported measles activities in 14 countries, leading to 26 million people receiving measles vaccine. In February 2020, CDC’s Center for Global Health activated the Measles Incident Management System (MIMS) to focus additional effort on countries with large measles outbreaks and a high number of deaths.

In fiscal year 2019, CDC provided approximately 75 million doses of oral polio vaccine, 1 million doses of inactivated polio vaccine, and 72,800 doses of measles-containing vaccine totaling $15.1 million. CDC reached another 18.5 million children through an effort to provide vaccines to children for $1 per child ($18.5 million).

On March 17, 2020, the Administration transmitted a fiscal year 2021 Budget Amendment to Congress to increase funding for CDC to ensure that the Agency has the resources beginning October 1, 2020, to continue its critical public health mission. This amendment requests a total fiscal year 2021 funding level of $8,329,102,000 for CDC, which is $1,328,196,000 above the fiscal year 2021 Budget request. The additional funding will support priority CDC activities, including global health.

\textbf{Question.} Our public health preparedness and response programs build and maintain the infrastructure necessary to protect Americans during public health emergencies. This budget cuts CDC’s Public Health Preparedness and Response programs by $25 million. These cuts risk undermining the agency’s ability to support efforts to detect, respond to, and contain epidemic threats like the novel coronavirus. Please provide CDC’s analysis of how a $25 million cut to Public Health and Preparedness programs would affect our preparedness and response capabilities to sup-


\textsuperscript{5}Available at: https://www.medicaid.gov/state-overviews/scorecard/index.html.
port rapid analysis and exchange of syndromic data, medical countermeasures, biosurveillance, community resilience, incident management, information management, and surge management.

Answer. On March 17, 2020, the Administration transmitted an fiscal year 2021 Budget Amendment to Congress to increase funding for CDC to ensure that the Agency has the resources beginning October 1, 2020, to continue its critical public health mission. This amendment requests a total fiscal year 2021 funding level of $8,529,102,000 for CDC, which is $1,328,196,000 above the fiscal year 2021 Budget request. The additional funding will support priority CDC activities, including preparedness and response.

CDC will continue to focus on evaluation and program improvement through PHEP program activities such as Operational Readiness Reviews, and after-action reports on CDC response activities. CDC will continue to fund research for both CDC and its state and local partners to efficiently and effectively prepare for, respond to, and recover from public health emergencies and disasters. This research focuses on three broad areas: preparedness and response capabilities, emergency management activities, and factors affecting individual and community resilience to disasters and other adverse public health events.

CDC’s request for Preparedness and Response Capabilities will continue to support technological infrastructure and research to facilitate prevention of and response to public health emergencies. These activities include:

—Developing and exercising the preparedness capabilities upon which responses are built. This preparation impacts CDC’s ability to surge to meet new and emerging threats.
—CDC’s intramural preparedness and response program. Examples of recent work funded through this program include:
  —Researching the most effective use of medical countermeasures to inform clinical guidance and national decisionmaking for prevention and treatment.
  —Improvement of surveillance systems, processes, and strategies to increase the efficiency and effectiveness of the emergency response structure.
  —The Children’s Preparedness Unit, which serves as a key asset in addressing children’s needs in public health emergencies.
  —Applied research to help protect first responders, such as evaluating personal protective equipment effects and capabilities to protect against newly identified chemical and radiological threats.
  —Chemical terrorism response including maintaining and upgrading CDC laboratory response capacity.
  —Training for laboratories regulated under CDC’s Select Agent Program, to support them in improving compliance and increasing biosafety and biosecurity.
  —Inspections of these laboratories and other facilities that import, store, and manage infectious biological agents, to support essential research continuing with as little risk as possible.
  —Continuing to build and develop preparedness for nuclear or radiological incidents. This includes training, exercising, and equipment to ensure CDC is ready to provide the expertise and guidance that State, local, and territorial health departments will need following this type of emergency.
  —Smallpox research, including ensuring the availability of diagnostics that would be critical for early detection and recognition of smallpox if it were to be reintroduced.

CHILD CARE AND HEAD START

Question. President Trump’s fiscal year 2021 budget re-proposes a one-time, $1 billion investment for building the supply of child care in underserved communities. In order to be eligible for a grant, States would be required to identify and describe steps they will take to reduce regulatory requirements. Would the funds in this one-time proposal be subject to the health, safety and quality standards that were agreed to on a bipartisan basis in the Child Care Development Block Grant Act of 2014?

Answer. The one-time, $1 billion, investment is not intended to provide child care subsidies and direct services. Rather, the supply building activities specifically support the development of licensed family child care providers as a small business and entrepreneurship opportunity, provide incentives for businesses to develop cost effective models to offer child care support to their employees, and promote innovation and modernization of the child care business model. Health and safety requirements and quality standards will continue to apply to any subsidies/direct services funded by the Child Care and Development Fund (CCDF). Eliminating regulations and barriers are needed to maintain quality and reduce costs.
Question. On January 30, 2020, the Secretary exercised his authority to reduce service duration requirements for Head Start programs. The Secretary lowered the required percentage of a program's center-based slots that must operate for 1,020 hours or longer per year from 100 percent of slots to 45 percent of slots. The Office of Head Start assessed that 78 percent of Head Start center-based programs currently operate at least 45 percent of their slots at 1,020 hours per year. What steps is the Department taking to ensure that Head Start programs that are not currently meeting this requirement are able to meet the new service duration requirements by August of 2021? How much does the Department estimate that it would cost to bring these remaining programs up to the required 45 percent threshold?

Answer. The Office of Head Start (OHS) is working to make sure grantees are aware that the requirement has been lowered from 100 percent to 45 percent of a program’s center-based slots needed to meet 1,020 annual hours. In addition to officially lowering the requirement through the Federal Register Notice, OHS issued Program Instruction (PI) to grantees to further explain the lowered requirement. In the PI, OHS reminded programs that if they do not believe longer service duration best fits the needs of their community, then they can submit a waiver with an appropriate rationale to justify this, as required in the Head Start Program Performance Standards. OHS is also clarifying the requirement verbally for grantees as well as through alternate paths (waivers, locally designed options, etc.) conference presentations, webinars, and other formats. In addition, OHS is communicating to grantees that the fiscal year 2020 quality funding can be used to extend service duration for children, as allowed under the Head Start Act.

We estimate that it would cost approximately $150 million to bring up the remaining grantees to meet the 45 percent requirement. In this estimate we adjusted for recent funding increases such as the fiscal year 2020 COLA and quality funding.

Question. Has the Department provided any guidance directly to child care providers, Head Start grantees, families, and other social service providers about how they can prepare to respond to COVID–19?

Answer. OHS sent two e-blasts on March 6th and March 12th to all Head Start grantees regarding the Coronavirus Prevention and Response. The e-blasts provide prevention strategies, preparedness, and treatment information as it relates to COVID–19. OHS also held a conference call on March 3rd with the OHS Regional Program Managers (RPMs) where OHS Director Dr. Deborah Bergeron and Deputy Director Ann Linehan provided guidance to the RPMs regarding how the Regional Offices should be responding to grantee inquiries. The content aligned with the attached emails informing grantees to review CDC resources, reach out to their State and local health authorities, and work with their Health Services Advisory Committee.

—OHS updated its website’s landing page, the Early Childhood Learning and Knowledge Center, with information grantees and families can easily access.

—OHS is also directing grantees to an Information Memorandum published last year that answers questions about how they may use flexibilities and waivers in the Head Start and Early Head Start program to address the impact of the COVID–19 (General Disaster Recovery Flexibilities ACF–IM–HS–19–01).

—Dr. Bergeron recorded a VLOG for grantees, highlighting resources, good health and safety practices, and linking to the General Disaster Recovery Flexibilities for reference.

—in addition, OHS is sharing information from the CDC with grantees regarding COVID–19, such as this helpful resource: https://www.cdc.gov/coronavirus/2019-ncov/specific-groups/guidance-for-schools.html.

The Office of Child Care (OCC) has received questions from States, territories, and tribes regarding how they may use flexibilities and waivers in the CCDF program to address the impact of the coronavirus. We have been referring these grantees to an existing Information Memorandum on Flexibility in Spending CCDF Funds in Response to Federal or State Declared Emergency Situations (CCDF–ACF–IM–2017–02; https://www.acf.hhs.gov/occ/resource/im-2017-02). This Information Memorandum outlines the options available to Lead Agencies to use CCDF funds to address emergencies, which include:

a. Changing eligibility or priority criteria to permit uninterrupted child care;
b. Defining income and setting the income threshold for purposes of CCDF eligibility;
c. Waiving family co-payment requirements for families that meet criteria established by the Lead Agency—which may include, for example, families impacted by Federal or State declared emergency situations; and
d. Using quality dollars to provide immediate assistance to impacted families. In some cases, States may need to enact State legislation or regulation in order to take advantage of these flexibilities.
OCC has also received questions about steps that should be taken by local child care programs and providers. We have referred these inquiries to guidance from the Centers for Disease Control and Prevention (CDC) as well as State and local public health officials.

OCC is preparing to issue an announcement through its email distribution list to remind CCDF Lead Agencies and stakeholders of these resources.

OCC is sharing input with CDC regarding the informational needs of child care grantees and stakeholders to inform future messaging.

Question. The President’s fiscal year 2021 budget request includes additional funding to “support a capacity of 16,000 licensed permanent beds, depending on the operational need, as well as the periodic activation of influx shelter sites if they are needed”. How does ORR plan to create additional capacity in its permanent network? What steps will ORR take to open additional licensed shelters and to recruit additional licensed transitional foster care families?

Answer. ORR is using the Funding Opportunity Announcement (FOA) process to expand its network of State-licensed shelters and transitional foster care (TFC) programs. ORR just awarded grants for basic shelter and TFC from the FOA advertised in November 2019. In total, ORR approved grants for 6,300 shelter and transitional foster care bed capacity with a total grant budget of $728 million. ORR will have additional FOAs for specialty bed and long term foster care capacity this spring.

ORR will seek to maintain original awarded capacity levels for specialty beds and long term foster care.

Question. The fiscal year 2020 explanatory statement that accompanied the final conference report directed ORR to provide in the fiscal year 2021 Congressional Justification information on efforts to ensure developmentally appropriate care for tender age children, including placement options, services and staff training, as well as an assessment of circumstances under which very young children are referred to ORR. This information was not adequately provided.

Answer. ORR’s efforts to ensure developmentally appropriate care for tender age children begins when ORR receives the initial referral of the child. ORR Intakes critically reviews the information provided by the referring agency and uses that information to determine the most appropriate placement in ORR’s care provider network. ORR programs that accommodate all children, including tender age children, are licensed by the State in which they operate to provide a safe and developmentally appropriate environment for children of this age group. ORR Intakes only places children in programs that are licensed to care for children of their age and any special care needs known at the time of referral. Young children are prioritized for placement in Transitional Foster Care programs, following ORR policy.

Question. What changes is ORR making to ensure that young children in ORR care are receiving care that is developmentally appropriate, especially for children under the age of 5?

Answer. All children who are admitted into ORR care are interviewed by care provider staff who are trained to interview children in a child friendly, culturally sensitive way. Consistent with the Flores Settlement Agreement (FSA), all children receive appropriate routine medical and dental care, including a complete medical examination (including screening for infectious diseases) within 48 hours of admission.

Additionally, children receive an individualized needs assessment, which includes the various initial intake forms, when they arrive at an ORR shelter. This includes collection of essential data relating to the identification and history of the child and his or her family, identification of the child’s special needs including any specific problems that appear to require immediate intervention, an educational assessment and plan, an assessment of family relationships and interaction with adults, peers and authority figures. Also included is a statement of religious preference and practice; an assessment of the child’s personal goals, strengths and weaknesses; identifying information regarding immediate family members, other relatives, godparents or friends who may be residing in the United States and may be able to assist in connecting the child with family members. While in ORR care, and in accordance with the principles and provisions established by the FSA, each child also receives an individual service plan (ISP) that identifies placement and case outcome goals, tailored to their needs and age, with the child’s best interests in mind.

Furthermore, children receive at least one individual counseling session per week conducted by trained social work staff with the specific objective of reviewing the child’s progress, establishing new short-term objectives, and addressing both the developmental and crisis-related needs of each child. For complete information on the services children receive, please see the ORR Policy Guide, Section 3.3 Care Pro-
vider Required Services (available at: https://www.acf.hhs.gov/orr/resource/children-entering-the-united-states-unaccompanied-section-3#3.3). All services are provided in a manner that is appropriate to the age and individualized needs of the child, by care providers who are State-licensed to provide appropriate care.

Question. Please also provide an assessment of circumstances under which very young children are referred to ORR.

Answer. ORR receives referrals for very young children (e.g., under 5) in a variety of circumstances. In fiscal year 2020, ORR received 373 referrals of children between 0–5 years of age. Examples of frequently encountered situations are outlined below:
—Babies of teen UAC, who are placed in ORR care together with their parent.
—Children who have been separated from a parent by DHS for reasons such as parent’s criminal history, the parent was referred for prosecution, or the parent required hospitalization.
—Children who were apprehended with an adult who is not their parent or legal guardian (e.g., an aunt or grandmother).
—Groups of minors that include a young UAC (e.g., sibling groups).

Question. Across the country, there is an urgent need to reduce the number of child fatalities and near fatalities that occur due to child abuse and neglect. In 2016, the Commission to Eliminate Child Abuse Fatalities recommended that the establishment of uniform definition standards for child fatalities from maltreatment to be used by States to report more accurate and consistent data to the National Child Abuse and Neglect Data System (NCANDS).

What is the Secretary doing to improve the quality of child fatality and near fatality data collection efforts, and how will the Department hold States and local child welfare systems accountable for improving public reporting?

Answer. The National Child Abuse and Neglect Data System (NCANDS) was established as a voluntary system. States report certain data elements to the Children’s Bureau via NCANDS “to the extent practicable,” meaning there are not any fines or penalties for not reporting one or more fields. Each year the States report data to the Children’s Bureau, via NCANDS, about children known to child welfare agencies, including children who died due to maltreatment. NCANDS does not specifically identify near fatalities.

To improve the child fatality data quality, States consult sources outside of their Child Protective Services systems for deaths attributed to child maltreatment. States are asked during the annual data submission to confirm the child fatality counts and to provide information about which external agencies were sourced for the additional fatality data. The Child and Family Services Improvement and Innovation Act (Public Law 112–34) lists the following additional data sources, which States must include a description of in their State plan or explain why they are not used: State vital statistics departments, child death review teams, law enforcement agencies, and offices of medical examiners or coroners. Some States also collect child fatality data from hospitals, health departments, juvenile justice departments, and prosecutor and attorney general offices. After the passage of Public Law 112–34, several States mentioned that they implemented new child death reviews or expanded the scope of existing reviews. Some States began investigating all unexplained infant deaths regardless of whether there was an allegation of maltreatment. Information about child fatality reviews and which additional agencies are sourced for fatality data may be found in the annual Child Maltreatment report in Appendix D, State Commentary.

The child fatality counts in NCANDS reflects the fiscal year in which the deaths were determined as due to maltreatment. The year in which a determination is made may be different from the year in which the child died. The time needed to conclude if a child was a victim of maltreatment often does not coincide with the timeframe for concluding that the death was a result of maltreatment due to multiple agency involvement and multiple levels of review for child deaths. NCANDS added a field called “maltreatment death date” to differentiate the year in which the death was reported to NCANDS from the year in which the child died. States began reporting this field in fiscal year 2013 data. Approximately 85.0 percent of child fatality reviews determine whether the death is due to maltreatment within 2 years.

The Children’s Bureau and the NCANDS Technical Team work with State child welfare agencies to continuously improve data quality. Webinars, technical bulletins, virtual meetings, email, listserv discussions, and phone conferences are used regularly to facilitate information sharing and to provide technical assistance. Upon re-
receipt of data from each State, a technical validation review assesses the internal consistency and identifies probable causes for any missing data. If the reviews conclude that corrections are necessary, the State may be asked to resubmit its data.

Question. Describe the Department’s efforts to implement recommendations from the Commission’s report, Within Our Reach: A National Strategy to Eliminate Child Abuse and Neglect Fatalities, and outline Congressional actions that are required to achieve the recommendations in the report.

Answer. HHS provided a report to the Congress in 2016 describing in detail our responses to the Commission’s report. That report may be found here: https://aspe.hhs.gov/system/files/pdf/208766/ResponseReport.pdf. Since that report was developed, HHS has continued to make progress on the issues raised by the Commission. Highlights of these efforts include the following (organized under the topics focused on in the original report):

Promoting Prevention

The Children’s Bureau within ACF has made the prevention of child abuse and neglect a significant emphasis of their recent work. Implementation of the Title IV–E Prevention Services Program have been a particular focus. Three States and the District of Columbia currently have approved Title IV–E Prevention Plans and plans for another eight States are under review. In addition, the Children’s Bureau funded 13 Community Collaborations to Strengthen and Preserve Families in fiscal year’s 2018 and 2019. These cooperative agreements support the development, implementation, and evaluation of primary prevention strategies to improve the safety, stability, and well-being of families through a continuum of community-based services and supports.

CDC’s Essentials for Childhood emphasizes the primary prevention of child abuse and neglect by promoting safe, stable, and nurturing relationships and environments. This 5-year cooperative agreement began in September 2018. It focuses on preventing child abuse and neglect by supporting State health departments (CA, CO, KS, MA, NC, UT, and WA) to implement complementary strategies that provide safe, stable, nurturing relationships and environments for all children.

Recipients are implementing statewide comprehensive strategies and approaches designed to reduce child abuse and neglect (CAN) along with other adverse childhood experiences (ACEs) and related health consequences and disparities. Recipients use funding to implement projects that aim to decrease CAN risk factors and increase CAN protective factors by leveraging multi-sector partnerships and resources. Additionally, States have received supplemental funding to implement prevention strategies and activities to address risk and protective factors associated with opioid misuse, ACEs and CAN. Several recipients are partnering with and working on their State’s child fatality review boards, taskforces, and with their State legislatures to communicate how their work in upstream prevention of ACEs and CAN is essential in eliminating child abuse and neglect.

Finding New Solutions

Authorized under the Family First Prevention Services Act, the Title IV–E Prevention Services Clearinghouse is reviewing evidence on the effects of programs that offer services to children at imminent risk of foster care entry and their families. Additional evaluations of programs implemented by states that have ratings less than “well-supported” by the Clearinghouse will add to our evidence base about prevention programs. Additionally, 19 Regional Partnership Grants were awarded in fiscal years 2018 and 2019. These grants are intended to increase well-being, improve permanency, and enhance the safety of children who are in, or at risk of, an out-of-home placement as a result of a parent’s or caregiver’s opioid or other substance use.

The 2016 Report to Congress had noted that the U.S. Preventive Services Task Force had underway a review of primary care interventions to prevent maltreatment. That review has been completed (available here: https://www.ncbi.nlm.nih.gov/books/NBK534927/) and found that, “overall, the evidence on interventions provided in or referable from primary care to prevent child maltreatment does not consistently demonstrate benefit.” Additional research and program development is therefore needed to identify more effective interventions.
CDC is building the evidence base for the primary prevention of child abuse and neglect. In fiscal year 2018, CDC funded two cooperative agreements that are rigorously evaluating whether previous or current Federal, State, local, or organizational policies are effective at reducing or preventing multiple forms of violence that affect children, youth, and/or families (i.e., child abuse and neglect, youth violence, intimate partner violence, sexual violence, and/or suicide). In addition, CDC funded four rigorous evaluations or programs and policies to prevent ACEs in fiscal year 2019. The projects will rigorously evaluate the effectiveness of a trauma-informed youth resiliency program, an enhanced home visiting program, low income housing tax credits, and family economic policies on child abuse and neglect.

In addition, CDC supports existing evidence-based strategies with funding to 23 State health departments through Core State Violence and Injury Prevention Program (Core SVIPP). These efforts help States implement, evaluate, and disseminate evidence-based strategies that address the most pressing injury and violence issues including child abuse and neglect. The overall goal is to decrease injury and violence related morbidity and mortality and increase sustainability of injury prevention programs and practices. In addition, Core SVIPP enables three States to enhance their surveillance information by supporting data collection through the Adverse Childhood Experiences module of the Behavioral Risk Factor Surveillance System.

**Improving Child Death Statistics**

Efforts to improve child death statistics continue on a number of fronts. In particular, the National Center for Health Statistics (NCHS) is working with medical examiners and coroners (ME/C) to improve the detail and consistency of vital statistics data gleaned from death certificates so that these data consistently and reliably identify deaths related to maltreatment. More generally, the Division of Vital Statistics at NCHS has worked on collaborations, including providing support for pilot programs for improvements in ME/C data systems, such as better interoperability between ME/C case management systems and electronic death registration systems. NCHS also works with other Federal partners to improve understanding about death investigation practices, data collection and automation, and death certification. For more details on these efforts, see the answer to item (d) in this series of questions.

**Modernizing the Regulatory Infrastructure for Child Welfare Data and Information Systems**

At the time of the 2016 report to Congress, ACF had issued final regulations governing Comprehensive Child Welfare Information Systems (CCWIS). Since then, 46 States plus the District of Columbia, and Puerto Rico have expressed the intent to develop or transition to CCWIS systems; many of those systems are currently operational and will support the exchange of information among State agencies to improve responses to child abuse and neglect.

**Addressing Disproportionality (particularly by strengthening Tribes’ capacity to prevent and address child maltreatment)**

In August of 2017, the Children’s Bureau funded the Center for Native Child and Family Resilience. This Quality Improvement Center (QIC) will gather, generate, and disseminate knowledge regarding effective practice models for strengths-based, culturally relevant, trauma-informed, and preventive services and interventions for all forms of child maltreatment. A total of five projects have agreed to partner with the QIC to build and enhance their culturally-based prevention and intervention efforts. Each of the projects will implement and assess practice models that show promise in preventing child abuse and neglect, and that can be implemented or adapted in other tribal child welfare systems. Additional information is available here: https://cnacr.jbsinternational.com/. In addition, in fiscal year 2018, the Children’s Bureau funded seven tribal court improvement programs, intended to strengthen these courts’ handling of child welfare cases.

HHS has included in recent Budget submissions several proposals to streamline and provide additional flexibility to tribes in operating Federal child welfare programs. To date, Congress has not acted on these proposals.

**Question.** Describe the Department’s efforts to collect more accurate and complete data regarding the nature of fatalities and near fatalities due to child abuse and neglect, including supporting alignment across the Department in regards to the activities of the National Center for Fatality Review and Prevention, which is funded by the Health Resources Services Administration (HRSA), Maternal and Child Health Bureau (MCHB); the Centers for Disease Control's National Violent Death Reporting System, and the National Center for Health Statistics.

**Answer.** Efforts from the HRSA/MCHB National Center for Fatality Review and Prevention include the following:
—In 2017, the National Center for Fatality Review and Prevention (National Center) convened an international group of CAN experts to create a guide for multidisciplinary fatality reviews. The group of experts included representatives from State/local child fatality (death) review, State child welfare agencies, private business, child advocates, medical examiners, epidemiologists, Citizen Review Panels, child abuse pediatricians and child welfare organizations. Additionally, the Department of Defense participated in this meeting. The Administration for Children and Families (ACF) and HRSA provided feedback on the written guidance prior to publication. The guidance was released to the field in September 2018 and is available here: https://protect2.fireeye.com/url?k=3ac1341c-66943d0f-3ac10523-0cc47adb5650-0d6851b52efbee67fc&utm=https://www.ncfrp.org/wp-content/uploads/NCRPCD-Docs/CAN_Guidance.pdf.

—The National Center disseminated the guidance to its network of more than 1,500 local and State fatality review teams. Child death review teams are comprised of multidisciplinary membership often including law enforcement, coroners/medical examiner, pediatricians, child welfare, public health and many others. Additionally, this guidance has been used extensively by Within Our Reach, a program of the Alliance for Strong Families and Communities. Within Our Reach (described below) is funded by Casey Family Programs to implement the recommendations from the 2016 Commission Report.

—Since the release of this guidance, the National Center has held a webinar and released an infographic on CAN deaths using data from the National Fatality Review-Case Reporting System. The National Center promotes the CAN Guidance on its website, social media and training/technical assistance work. The webinar is archived and available here: https://protect2.fireeye.com/url?k=0b723585-57273c96-0b7204ba-0cc47adb5650-063308d218196d25c&a=https://www.ncfrp.org/tools-and-resources/archived-webinars-presentations/ and the infographic is available here: https://protect2.fireeye.com/url?k=6340058d-3f150c5e-634034b2-0cc47adb350-1cd1893d909b5fd2b&utm=https://www.ncfrp.org/resources/quick-looks/. The National Center continues to be an integral part of the National Coalition to End Child Abuse Deaths.

—The National Center has presented on the CAN guidance at numerous State and national conferences, including the National Children’s Alliance conference, CityMatCH, the Association for Maternal Child Health Programs in conference, and PREVCON. Additionally, the National Center has shared this guidance at the annual Department of Defense Fatality Review Summit and the Federal Interagency Workgroup on Child Abuse and Neglect.

—in 2019, the U.S. Department of Justice funded Within Our Reach to provide intensive training and technical assistance to five demonstration sites who are developing multidisciplinary strategies and responses to address serious or near-death injuries as a result of CAN. The ultimate goal of this project is to reduce CAN fatalities. The National Center is part of the technical assistance team supporting this project. The guidance will be an integral part of this work. In addition, CDC’s National Violent Death Reporting System (NVDRS) collects data from death certificates, coroner/medical examiner reports, law enforcement reports, and toxicology reports. These data provide valuable context about violent deaths, such as relationship problems; mental health conditions and treatment; toxicology results; and life stressors, including recent money- or work-related problems. In 2013, CDC added a variable to identify cases where abuse or neglect of a child led to death, in order to more readily report data on these cases. Further, Child Death Review/Child Fatality Review reports are often used by States as supplemental sources of information to add detail to NVDRS child death cases. CDC’s efforts have focused on improving death statistics as reported by medical examiners and coroners. They have a number of ongoing and long-standing efforts to improve the quality and consistency of information reported on death certificates, with the aim of improving information for all causes, and some of these activities are focused on medical examiners and coroners (ME/C) and the critical role they play in providing information from investigations. The Division of Vital Statistics at NCHS has worked on collaborations, including the examples below:

—Participating in professional conferences and workshops with ME/C, and serving as co-leads the Federal Medicolegal Death Investigation Working Group (MDI-WG). This group identifies both short and long term goals to develop and implement programmatic activities that support the MDI system, and in turn, support Federal public safety and public health national initiatives.

—Facilitating learning opportunities for ME/C on public health topics like drug overdose, suicides, infectious diseases, and more.
—Providing support for pilot programs for improvements in ME/C data systems, such as better interoperability between ME/C case management systems and electronic death registration systems.


—NCHS also works with other Federal partners to improve understanding about death investigation practices, data collection and automation, and death certification.

—CDC is currently in the process of validating several syndrome definitions, which can be used to query near real-time electronic medical record data from approximately 70 percent of emergency departments (EDs) across the U.S. for ED visits related to CAN, child sexual abuse (CSA), and ACEs. Once validated and finalized, these definitions will be disseminated through the National Syndromic Surveillance Program’s Electronic Surveillance System for the Early Notification of Community-based Epidemics (ESSENCE) platform, allowing epidemiologists across the U.S. to easily query their local and State-level syndromic surveillance data to identify CAN, CSA, and ACEs-related ED visits.

All of these efforts seek to improve reporting, not necessarily for a specific cause, but for all causes.

Question. The President’s fiscal year 2021 budget includes an increase of $16 million for Child Abuse Discretionary Activities to support demonstration projects focused on primary prevention of child abuse and neglect. What are the intended goals and outcomes for these demonstration projects? Consistent with these efforts, please provide examples of the type of guidance and technical assistance that the Department will issue to grantees receiving funding under CAPTA in order to meet these goals.

Answer. An additional $16 million in funding will support demonstration projects in an initiative to shift and expand the focus of child welfare toward primary prevention of child maltreatment. The goal of the projects is to improve the safety and stability of all families by enhancing the capacity of communities to offer broad-based family supports; to use data to inform and align strategies across sectors to address site-specific barriers; and to support strategic collaborations with traditional family serving agencies and non-traditional partners (such as libraries, the business community, foundations, community colleges or vocational education providers, and philanthropies).

Demonstration projects will provide services and resources for families that are voluntary; place-based and centrally located to ensure accessibility; coordinated with other public, faith-based, nonprofit, or private service providers that operate separate from government (but may receive funding from State or county sources); available universally and in non-stigmatizing ways; aimed at enhancing parental protective factors; and may include concrete supports such as limited financial, food, or housing assistance and/or legal and clinical services.

Projects will implement, test, and evaluate the effectiveness of a multi-system approach to primary prevention, including strengthening family capacity and preventing child abuse and neglect before more formal intervention is necessary. The demonstration projects will be partnerships of public and private agencies, parents, community members with lived experiences, nonprofits, faith-based organizations, and others to implement effective community-based prevention approaches. Strategies and outcomes will be coordinated, monitored, and reported across multisector partners. A cross-site evaluation will be conducted and technical assistance on program implementation and local evaluation will be provided.

Question. Research demonstrates that lesbian, gay, bisexual, transgender, and queer (LGBTQ) youth are overrepresented in the child welfare system, and that these youth are more likely to experience child abuse and neglect than their non-LGBTQ peers. What activities, technical assistance, and grant opportunities has the Department undertaken or considered to prevent child abuse and neglect specifically for lesbian, gay, bisexual, transgender, and queer youth?

Answer. We are working to gain an understanding of the scope of LGBTQ representation in foster care by proposing to require Title IV–E agencies to report whether family conflict related to the child’s expressed or perceived sexual orientation, gender identity, or gender expression was a circumstance at the child’s removal. We proposed that Title IV–E agencies report this to the Adoption and Foster Care Analysis and Reporting System in the 2019 Notice of Proposed Rulemaking (84
The Unified Agenda estimates the final rule will be published in May 2020.

**Question.** What steps is the Department taking to promote adoption permanency and improve outcomes for lesbian, gay, bisexual, transgender, and queer youth in the child welfare system, including under programs supported through the Adoption Opportunities Act?

**Answer.** The Department has created a National QIC on Tailored Services, Placement Stability & Permanency for LGBTQ Children and Youth. The QIC is conducting 4–6 projects in public child welfare system sites to test a set of interventions that support the permanency, well-being, and stability of LGBTQ, as well as two-spirit, children and youth in the foster care system. The QIC will complete an evaluation of each of the project sites and a cross-site evaluation to produce evidence-informed or evidence-based models of engagement, services, and interventions that demonstrate improved well-being outcomes and provide permanency and placement stability for LGBTQ children and youth in foster care. The target population is children and youth in foster care who identify as LGBTQ within the service area of the selected State, county, or tribal child welfare systems.

**Expected outcomes for the QIC include:**

—Development and implementation of four to six research projects in State, county, and tribal child welfare systems that commit to building effective practice models to improve permanency, well-being, and placement stability outcomes for LGBTQ children and youth in foster care;

—Integration of identified practice models within the project site system, including the policies, programs, and practices that impact LGBTQ children and youth in foster care;

—Promising practices and evidence-informed/evidence-based models of engagement, appropriate collective and individual services and intervention that can be linked to improved outcomes for the target population;

—Improved permanency, well-being, and placement stability outcomes for LGBTQ children and youth in foster care implemented in selected project sites;

—Through comprehensive, project-specific evaluation activities, development of a catalogue of LGBTQ-responsive strategies and practices to lay the groundwork for further development of evidence-informed/evidence-based models of intervention for LGBTQ children and youth in foster care, with supporting protocols, tools and products that child welfare systems seeking to implement improved LGBTQ services can look to for guidance, insight, and replication; and

—A cross-site evaluation that will build a body of knowledge regarding the appropriate elements to consider and address when building and implementing a comprehensive model of effective engagement, services, and interventions for LGBTQ children and youth in care.

**Question.** It is vital to support Indian Tribes in strengthening families to prevent child abuse and neglect in Indian Country. Please provide a list of resources and activities developed or supported by the Department to address complex issues like child abuse and neglect prevention in Indian Country, and a description of the outreach conducted by the Department to make Indian Tribes and Tribal Organizations aware of such resources and activities. What efforts has the Department undertaken to identify, develop, or support culturally-based child abuse and neglect prevention programs and activities?

**Answer.** The Children’s Bureau recognizes the vital need to provide support to Indian Country to strengthen families to prevent child abuse and neglect. The Children’s Bureau provides this support in several different ways, including:

**Community-Based Grants for the Prevention of Child Abuse and Neglect Tribal and Migrant Programs**

The Children's Bureau oversees the award and implementation of Community-Based Grants for the Prevention of Child Abuse and Neglect Tribal and Migrant Programs. The purpose of this grant is to provide financial support to selected tribes, tribal organizations, and migrant programs for child abuse prevention programs and activities that are consistent with the goals outlined by Title II of the Child Abuse Prevention and Treatment Act. This legislation specifies that 1 percent of the available funding from Title II will be reserved to fund tribes, tribal organizations and Head Start migrant programs.

The goal of the programs and activities supported by these funds is to prevent child abuse and neglect within tribal and migrant populations. The funds must support more effective and comprehensive child abuse prevention activities and family support services that will enhance the lives and ensure the safety and well-being of migrant and Native American children and their families. Grants were awarded in September 2016 for a 5-year grant period. The current grantees are: Child Abuse
Prevention Services, Inc. (IA); Yakima Valley Farm Workers Clinic (WA); and Kickapoo Tribe in Kansas (KS).

**National Quality Improvement Center (QIC) for Preventive Services and Interventions in Indian Country**

The Center for Native Child and Family Resilience (Center), originally named the “National Quality Improvement Center (QIC) for Preventive Services and Interventions in Indian Country,” is a Children’s Bureau 5-year cooperative agreement awarded to JBS International, Inc. in August 2017.

The Center provides support to enhance resilience-related approaches to Tribal child welfare by developing evidence-based standards for programs aimed at the prevention and intervention of child abuse and neglect in American Indian/Alaska Native communities. The Center promotes awareness and use of culturally relevant child welfare programs grounded in community-based evaluation to demonstrate the effectiveness of these efforts, designed to improve holistic services for children and families who have experienced or are at risk of child abuse or neglect.

The Center team works to gather, generate, and disseminate knowledge and information regarding effective practice models for strengths-based, culturally relevant, and trauma-informed preventive services and interventions for child maltreatment, supporting the transfer of knowledge from the Center projects to the field.

**QUESTIONS SUBMITTED BY SENATOR RICHARD J. DURBIN**

**DTC PRICE TRANSPARENCY**

**Question.** Secretary Azar, your budget request includes a $135 billion “allowance” for savings from drug pricing legislation—essentially a placeholder for what Congress is working to pass. As you know, I’ve been working for years on a simple measure to require pharmaceutical companies to put a price tag in their direct-to-consumer ads. The fiscal year 2019 Labor-HHS bill passed the Senate with an amendment from Senator Grassley and me to require this disclosure.

When drug companies spend $6 billion to flood the air with ads that steer patients—more than the entire budget of the FDA by the way—I believe patients deserve to know how much the drug costs. We know the result otherwise, the 20 most-advertised drugs on television cost Medicare and Medicaid a combined $34 billion in 2018.

Do you support including DTC language—similar to the Durbin-Grassley language in the fiscal year 2019 Senate Labor-H bill—in the fiscal year 2021 Labor-HHS bill, or any other related larger package moving in the Senate?

**Answer.** Since the Administration issued American Patients First, its blueprint to lower drug prices and out-of-pocket costs, FDA has promoted competition in drugs and biologics, advanced a strong framework for biosimilars, and modernized regulatory oversight of generic drugs. FDA does not set drug prices, but can help lower prices by bringing efficiencies to the drug development and review process and by promoting robust competition for established drugs. FDA-approved generic drugs now account for 90 percent of the prescriptions dispensed in the United States, and in 2018 competition from generic drugs saved the healthcare system an estimated $293 billion.

**RURAL HOSPITALS**

**Question.** Secretary Azar, the fiscal year 2021 budget request proposes to allow Critical Access Hospitals to voluntarily convert to an emergency outpatient clinic paid at the OPPS rate plus an add-on payment for capital costs, I think it is an idea that merits some consideration.

But I am concerned that we may be several years away from developing that new payment and delivery model, yet we have a crisis right now with rural hospital closures. Illinois has thankfully been mostly spared, in part because we expanded Medicaid under the Affordable Care Act, but nationwide we have seen 120 rural hospitals close in the past decade. Last year was the worst year yet for this grim trend. A new report in February from the Chartis Center for Rural Health found that one in four rural hospitals are at risk of closure.

Once a hospital closes, doctors leave, jobs disappear, businesses struggle, and families pull up roots. Senator Lankford and I have a bill to provide immediate relief by allowing a narrow set of vulnerable, rural hospitals to obtain Critical Access payment status, which is a model that works well for 57 hospitals already in my State.
Do you support the intent of our effort (S.3103) to provide an immediate lifeline through a proven model for a universe of certain rural hospitals that need relief now and cannot afford to wait around to test new approaches to rural health delivery?

Answer. There are 57 million Americans living in rural communities. Rural Americans face many unique health challenges, including hospitals that are closing or in danger of closing; difficulty recruiting and retaining physicians, nurses, and other providers; and increased likelihood of dying from many leading causes of avoidable death such as cancer and heart disease.

HHS’s 4-Point Strategy to Transform Rural Health builds on current HHS initiatives in the following areas:
—Build a Sustainable Health Model for Rural Communities;
—Leverage Technology and Innovation;
—Focus on Preventing Disease and Mortality; and
—Increase Rural Access to Healthcare.

The Budget supports rural communities through programs such as the Rural Communities Opioids Response and the Telehealth Network Grant Program at HRSA, which supports substance use prevention, treatment, and recovery support services in high-risk rural communities, and promotes telehealth technologies for healthcare delivery. Project AWARE (Advancing Wellness and Resiliency in Education) will increase mental health awareness training in rural communities. In response to American Indian and Alaska Native communities’ demand for telebehavioral services, IHS expands the Telebehavioral Health Center of Excellence with funding for new space, updated equipment, and additional behavioral health providers.

CHILD TRAUMA—UPDATE ON TASK FORCE

Question. Last year’s appropriations bill included $50 million in historic new funding for the NIH and CDC to conduct gun violence research. The Labor-HHS bill also dedicated nearly $4 billion for opioid treatment and response efforts. These are important investments, I commend the Chair and Ranking Member for their leadership. I believe prevention is an essential part of addressing these, and other, societal and health challenges.

Experiencing serious traumatic events—such as witnessing violence or a parent’s drug abuse—can have profound effects on a young person . . . creating stress that can harm brain and behavioral development. Decades of research, including the Centers for Disease Control and Prevention’s Adverse Childhood Experiences (ACEs) study, have established the link between a child’s exposure to trauma, its effect on neurological and behavioral development, and long-term negative outcomes. Exposure to trauma contributes to many of the societal challenges we face today, including the opioid crisis, chronic disease development, mental illness, violence, unemployment, and the academic achievement gap. If you’ve had four Adverse Childhood Experiences (ACEs) you are up to 10 times more likely to use heroin and 12 times more likely to attempt suicide.

Scores of Federal grant programs provide services to children and families in each of these settings. Child- and family-serving professionals should have the tools and resources to prevent and mitigate the impact of trauma and ACEs. At the same time, our Federal Government needs an over-arching strategy to place the impact of trauma at the center of programmatic efforts—it will help to fulfill the missions of each member agency while mitigating costly, negative long-term outcomes.

In 2018, Senator Capito and I passed legislation as part of the SUPPORT Act to better train teachers, doctors, and social service providers to identify and support young people who have experienced trauma. One provision (Sec. 7132) created a task force of 26 Federal agencies to bring this understanding of trauma to every Federal grant program . . . including Head Start, Home Visiting, education, health, social services. The intent of Section 7132 is to bring the expertise, reach, and resources of the Federal Government to bear to enhance coordination, identify trauma-informed best practices, and promote models to prevent, screen, appropriately refer, and implement supportive interventions for children and their families who have experienced trauma.

We believe this Trauma Task Force can transform the way that our Federal agencies address gun violence, addiction, mental illness, poverty, and many other challenges.

So I was disappointed to see that your budget did not mention this effort—despite clear support from this Subcommittee in each of the past three Labor-HHS bills. Secretary Azar, can you provide an update on the activities of the Interagency Task Force on Trauma-Informed Care to date? Can you commit to implementing this Task Force in accordance with the statute’s direction on timing and engagement
with public stakeholders, letting us know if there is funding you need, and keeping our offices better informed on your progress?

Answer. SAMHSA created an interagency Task Force to make recommendations regarding best practices to identify, prevent, and mitigate the effects of trauma on infants, children, youth, and their families, and to better coordinate the Federal response to families impacted by substance use disorders and other forms of trauma. The Task Force is required to develop a set of best practices regarding prevention strategies, identification of trauma, community-based practices, and state and local level partnerships to support children and their families. Calls for a national strategy have been conducted on how Federal agencies can implement a coordinated response by coordinating existing Federal authorities and grant programs where trauma-informed practices have been implemented. SAMHSA is committed to implementing the Interagency Trauma Task Force as specified in legislation. The Task Force is developing the operating plan and will submit it by the deadline specified in the legislation (October 2020). Interagency Task Force in-person meetings were held on May 31, 2019, July 12, 2019, and February 3, 2020. Future in-person meetings are scheduled for May 1, 2020, August 14, 2020, and November 2, 2020. Monthly telephone calls are scheduled to fill in the gap months between in-person meetings. The Task Force is also committed to engaging public stakeholders and are identifying the best measures to take to achieve this effort. Moving forward, SAMHSA will continue to implement this Task Force in accordance with the statute's direction and will keep Congress informed on its progress.

QUESTIONS SUBMITTED BY SENATOR JACK REED

Question. I am extremely disappointed that this Administration has continued to propose eliminating the Low Income Home Energy Assistance Program (LIHEAP), which helps low-income households and seniors with their energy bills. The number of households eligible for LIHEAP already exceeds the program’s capacity, and for many who do receive energy assistance, the purchasing power of the grant has decreased over the past several years. These cuts have consistently been rejected by Congress and the program enjoys bipartisan support, including from members of this Committee. As such, I am deeply concerned that, although Congress increased LIHEAP funding by $50 million in fiscal year 2020 to help meet the needs of more Americans, the Department of Health and Human Services announced its intention to reprogram $37 million from this account for coronavirus response. Diverting LIHEAP dollars that people depend on in the middle of winter is not the right approach. There are better ways to dedicate the necessary resources to protect Americans from the coronavirus threat. Do I have your commitment that you will not reprogram any LIHEAP funds in fiscal year 2020 and will instead distribute them immediately to States so that they can be used for their intended purpose?

Answer. Yes, funds originally transferred from LIHEAP for COVID–19 response were returned to LIHEAP and released to States per the requirements of the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (Public Law 116–123).

Question. Can you comment on your Department’s proposed cuts to critical global health and public health programs and explain how those cuts will prepare us against new and emerging outbreaks like Coronavirus and Zika? We have all learned over the last several years that new disease outbreaks are not isolated incidents. Public health funding is an investment that needs to be made over the long term to build our public health infrastructure. In particular, can you explain the $7 million cut to NIH’s Fogarty International Center, which helps train public health officials worldwide, build relationships between our public health officials and those in other countries, and stand up public health efforts internationally?

Answer. The Fogarty International Center (FIC) plays an important role in global health research by strengthening the scientific workforce in the United States and abroad to address existing and future health threats that affect us all. To date, FIC grants have resulted in a cadre of over 6,000 trainee alumni throughout the world. Fogarty trains scientists for global health research, fosters international research networks, and strengthens the research infrastructure abroad. Notably, these programs are built on long-standing partnerships between U.S. and developing country institutions. FIC invests strategically in future leaders and institutions, both here in the U.S. and abroad. FIC will continue to build public health research capacity where health problems are most prevalent. For example, FIC-supported programs are training scientists on the ground in developing countries to study emerging infections, epidemics and pandemics at their point of origin, which will help to quickly contain
outbreaks and prevent or limit the spread of communicable diseases to the United States and globally. In addition, Fogarty's in-house research unit uses data-driven modeling and computational tools to improve the study of the spread of disease and inform policy. This team is currently focused on the urgent need to study the epidemiology and transmission dynamics of Coronavirus (COVID–19) in China. Plans are underway to model the impact of interventions like social/physical distancing and isolation.

Question. Like many of my colleagues, I am deeply disturbed by the proposed cuts to Medicaid in the President's fiscal year 2021 budget request. This budget proposes cutting nearly $1 trillion from Medicaid. What's worse, this budget request provides no details for who these cuts would target. A cut of this magnitude would endanger Medicaid as we know it and deny access to care for millions of Americans, including our most vulnerable citizens. Can you provide estimates for how many seniors, children, and people with disabilities you expect to lose coverage because of this cut?

Answer. HHS's proposed budget slows the average annual growth of Medicaid from 5.4 percent to 3.1 percent, never spending less than in fiscal year 2020. Medicaid spending will grow at a more sustainable rate by ending the financial bias that currently favors able-bodied working-age adults over the truly vulnerable. Medicaid's open-ended financing structure and recent growth have made it the number 1 or 2 budget item for most States, consuming an average of 30 percent of total State budgets; budget reforms ensure the program remains a safety net for generations to come. CMS does not have estimates regarding change in coverage due to these reforms; the intent of these reforms is not to reduce coverage, but rather to make the program fiscally sustainable and therefore available for generations to come.

Question. As you know, the Childhood Cancer Survivorship, Treatment, Access, and Research (STAR) Act, which I authored and worked on a bipartisan basis to pass in 2019, included a number of provisions to help advance our understanding of the needs of survivors of childhood cancer and to improve treatment and quality of life for these childhood cancer survivors. In particular, Section 201(b) of this law requires HHS to conduct a review of Federal workforce development efforts for healthcare professionals who treat pediatric cancer patients and survivors and report to Congress by June 5, 2020. I look forward to reviewing the report later this year. In addition, Section 201(a) authorizes pilot programs to explore model systems of care for pediatric cancer survivors. Can you provide an update on implementation of Section 201(a) and in particular, how much funding will be required to bring this effort to fruition?

Answer. Progress is being made on the implementation of the Childhood Cancer STAR Act. Including the activities listed below, HHS is currently assessing how to fully implement Section 201. Activities being carried out by NIH and AHRQ include:

— **Section 101:** Children's cancer biorepositories and biospecimen research. NCI convened a meeting in May 2019 of more than 60 extramural researchers and advocates, along with NCI scientific staff, to discuss challenges and opportunities to enhance biobanking for childhood cancers. Informed by this discussion, in fiscal year 2019 NCI provided a grant supplement award to Nationwide Children’s Hospital to support immediate enhancements to the Children’s Oncology Group Biorepository. NCI scientific leadership has identified additional opportunities to enhance and expand childhood cancer biospecimen collection and biobanking resources in fiscal year 2020 and will soon be moving forward to solicit applications.

— **Section 111:** Inclusion of at least one pediatric oncologist on the National Cancer Advisory Board. There are currently two pediatric oncologists appointed to the National Cancer Advisory Board (NCAB). Dr. Peter Adamson of the Children’s Hospital of Philadelphia was appointed to NCAB in 2015 and his term concludes in 2020. In October 2019, President Trump announced the appointment of Dr. Andrea Hayes-Jordan, Surgeon-in-Chief at the University of North Carolina Children’s Hospital. Dr. Hayes-Jordan’s appointment is pending final approval, and her NCAB term is expected to conclude in 2024.

— **Section 112:** Sense of Congress regarding pediatric expertise at the National Cancer Institute. In addition to pediatric oncology expertise on NCAB, other NCI advisory boards, groups, and committees continue to include pediatric oncologists, scientists with pediatric expertise, and patient advocates. This includes more than 40 subject matter experts with pediatric expertise across three relevant NCI National Clinical Trials Network Steering Committees, with a patient advocate serving on each committee.

— **Section 121:** Reporting on childhood cancer research projects. NIH and NCI reporting on childhood cancer research projects. NCI and NIH reporting on childhood cancer research projects will continue to include the annual NIH Pediatric Research Initiative Report to Congress, as well as the NIH
Triennial Report. After the close of each fiscal year, NIH also makes estimates of funding for various Research, Condition, and Disease Categories (RCDC) available on its website, including a “Pediatric Cancer” category, which links through to a list of hundreds of research projects supported by several NIH Institutes and Centers. NCI also reports on activities across its childhood and adolescent and young adult (AYA) cancer research portfolio on its website through several pages focused on childhood and AYA cancer research and resources for patients and families.

—Section 201: Section 201 directs HHS to conduct a review of Federal workforce development efforts for healthcare professionals. AHRQ is currently assessing how they could fully implement Section 201. This includes assessing resources that would be needed to implement the pilot programs and dedicate staff with expertise in pediatric cancer and management of cancer survivors. These pilots would be informed by ongoing AHRQ work to conduct three separate evidence reviews focusing on the transition of care from pediatric to adult services for childhood and adolescent cancer survivors; models of pediatric survivorship care; and disparities and barriers to survivorship care and strategies that have been proposed to address these barriers (Section 203). Section 201(b) of this law requires a review of Federal workforce development efforts for healthcare professionals.

—Section 202: Grants to improve care for pediatric cancer survivors. NCI continues to conduct and support critical ongoing childhood and AYA survivorship research efforts, including NCI’s long-standing investment in the Childhood Cancer Survivor Study. In fiscal year 2019 NCI also supported several new childhood and AYA survivorship research projects, including three new projects funded through a request for applications (RFA) developed to align with Section 202 of the STAR Act. The second receipt date for this RFA was in January 2020. Peer review is currently underway for this second round of applications, and NCI expects to make several awards in fiscal year 2020. Additionally, in December 2019, NCI’s Board of Scientific Advisors approved a new RFA aligned with Section 202 of the STAR Act. This RFA is expected to post to the NIH Guide for Grants and Contracts later this year, with application receipt dates scheduled for 2021 and 2022.

QUESTIONS SUBMITTED BY SENATOR JEANNE SHAHEEN

MEDICAID BLOCK GRANTS

Question. The Department recently proposed guidance to States that would allow States to waive Medicaid rules and convert their Medicaid expansion programs into a block grant that does not keep pace with the cost of providing care. If New Hampshire were to take up such a block grant, it could be devastating to our effort to combat the substance misuse epidemic through Medicaid expansion. The State would likely need to limit benefits, impose new costs on patients or cut payments to providers in order to keep within the block grant allotment. At a time when New Hampshire and so many other States that are hard-hit by the opioid epidemic are using the Medicaid expansion to get people the treatment they need, why is the Department of Health and Human Services (HHS) proposing block grants that would erode the Medicaid expansion?

Answer. The Healthy Adult Opportunity (HAO) is not a mandatory change in the Medicaid program’s structure or financing. This is an optional demonstration opportunity, and no State is under any obligation to participate. It is also not permissible for States to strip benefits or limit eligibility—under HAO, participating States must still meet minimum benefit requirements and cannot cap or limit adult enrollment while still receiving enhanced Federal funding. A number of States have already publicly expressed interest in HAO, and are supportive that the demonstration represents an innovative and historic approach to surmounting Medicaid’s structural challenges. It provides rigorous protections for all Medicaid beneficiaries, and for the first time it aligns financial incentives to improve quality of care and health outcomes for Medicaid adults by giving States unprecedented flexibility to administer and design their programs to meet this population’s unique needs. In exchange for this flexibility, States accept greater accountability for managing the program and demonstrating real results. States have a long history of managing budgets. Every State has already accepted the risk of capped Federal funding through either their CHIP program or an 1115 waiver.

Question. As a part of questions for the record following Secretary Azar’s appearance before the Subcommittee on April 4, 2019, I asked questions regarding Med-
icad block grants, including a request for an explanation of the “statutory authority you rely on to make such a change.” At that time, you did not answer the statutory authority question and instead noted that “this topic is still under development.” Now that a proposal has been issued, I ask again: what statutory authority do you rely on to make this change?

**Answer.** The Healthy Adult Opportunity (HAO) would use section 1115 waiver and expenditure authority to allow States’ proposed HAO demonstrations to go into effect.

Under the demonstration authority granted by section 1115(a) of the Act, in the case of a demonstration that CMS determines is likely to assist in promoting the objectives of the Medicaid program, CMS can waive under section 1115(a)(1) of the Act, or not apply under section 1115(a)(2) of the Act, many Federal requirements so that States can test new or existing ways to deliver and pay for healthcare services under the Medicaid program. CMS can provide expenditure authority under section 1115(a)(2) of the Act to allow States to provide coverage to individuals not eligible under the State plan, which can offer significantly more flexibility without the need for individual section 1115 waivers. The HAO initiative will involve the use of section 1115(a)(2) authority to provide coverage to individuals not eligible for benefits under the State plan, while affording States maximum flexibility in the administration of benefits for such individuals.

**MEDICAID FISCAL ACCOUNTABILITY RULE**

**Question.** Healthcare providers across New Hampshire have expressed concerns to me that if finalized, your administration’s “Medicaid Fiscal Accountability Rule” (MFAR), could severely curtail access to care in New Hampshire. The rule is expected to significantly alter hospital supplemental payments and cripple State Medicaid program financing. New Hampshire healthcare providers are concerned that rather than simply clarifying current policies regarding providers' roles in funding the non-Federal share of Medicaid, the rule would introduce vague standards that are unenforceable and inconsistent with the statutory authority of the Centers for Medicare and Medicaid Services (CMS).

A recent study by Manatt Health analyzed the potential financial impact of the proposed rule and found that, nationally, the Medicaid program could face total funding reductions between $37 billion and $49 billion annually, or 5.8 percent to 7.6 percent of total program spending. Hospitals specifically could see reductions in Medicaid payments of $23 billion to $31 billion annually, representing 12.8 percent to 16.9 percent of total hospital program payments.

For New Hampshire and other rural States, access to care is already in jeopardy. New Hampshire healthcare providers are concerned that this rule could compound those access issues.

How do you plan to protect beneficiaries’ access to care should this proposed rule be finalized? If a Medicaid beneficiary loses access to their providers or their coverage as a result of this rule, how will CMS ensure that the beneficiary’s access to care is restored?

**Answer.** CMS believes it is important to ensure a process for public notice and comment that provides for a meaningful level of public input, including input regarding the impact of the proposed rule on Medicaid beneficiary access to care. As you know, the proposed rule (CMS–2393–P) was issued on November 12, 2019 and published in the November 18, 2019 issue of the Federal Register, with a 60-day comment period that closed on January 17, 2020. The comment period, which was subsequently extended by fifteen days, and ultimately closed on February 1, 2020. We will take into consideration all relevant comments that were received during the extended public comment period.

While we review the comments we received, I want to assure you that we are committed to ensuring State compliance with section 1902(a)(30)(A) of the Social Security Act, which requires Medicaid provider payments to be “consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers” to provide access to care and services comparable to those generally available. We will continue to monitor access to care and services for Medicaid beneficiaries, and have announced a new comprehensive strategy for monitoring access to care in Medicaid on July 11, 2019. That strategy may be accessed here: https://www.medicaid.gov/sites/default/files/Federal-policy-guidance/downloads/CIB071119.pdf.

We note that the proposed rule does not eliminate States’ ability to make supplemental payments to inpatient and outpatient facilities under the Medicaid State plan. It also does not propose to prevent States from targeting necessary payments...
to important safety net providers. As such, we do not anticipate the proposed rule, once finalized, will impact beneficiary access to care.

Question. Has your Department analyzed how beneficiaries would be affected by this rule given it will take billions of dollars out of the program? If not, how can CMS proceed with this major rule affecting how states finance their Medicaid programs without conducting any analysis of the impact of the rule?

Answer. Nothing in our proposed rule would stop States from using supplemental payments, provided that they are used and financed in a way that is in compliance with Federal statute and regulations. This proposed rule is not intended to reduce Medicaid payments, we believe these estimates of funding loss and lower beneficiary access are overblown.

If States have arrangements that need to evolve to comply with any final rule, we would work with them to make that a successful transition. HHS has a responsibility to answer the calls from oversight bodies and address practices that have allowed States to avoid contributing their fair share to the program, effectively increasing the Federal contribution above what the law provides. Failure to do so would be deeply unfair to the Federal taxpayers and to States that have played by the rules, and provide them little reason to continue their sound practices.

In regards to impact analysis of the rule CMS believes effects may be limited and are hard to quantify due to a number of reasons, including:

—Many of the proposals reflect clarifications of existing policy, not new legal requirements, and would not be expected to have a significant impact on State financing arrangements apart from changes that may be necessary for certain States to come into compliance with current Federal requirements.

—The potential decrease in Medicaid reimbursements for providers receiving supplemental payments could be mitigated if States take action to increase Medicaid provider base payments, which would thereby increase the amount that could be paid out in Medicaid supplemental payments.

—CMS does not have sufficient data to predict or quantify the impact of the proposed provisions on health-care related taxes.

—CMS expects that States may modify existing State tax policy or arrangements where those taxes or arrangements would be newly considered healthcare related under the proposed provisions, reducing the fiscal effect of the rule.

POSITION ON MEDICARE DRUG PRICE NEGOTIATION

Question. When President Trump was running for office in 2016, he frequently expressed support for allowing Medicare to negotiate prescription drug prices. This is a proposal that I have also long supported. As recently as September, the President tweeted out his support for the House bill that would allow Medicare to negotiate the price of medications and would reduce prices for many common prescriptions, like insulin, by 55 percent on average. Those savings would mean the world to Granite Staters like Bob Slavin from Franklin, New Hampshire, who says he is maxing out credit cards to pay for the skyrocketing cost of insulin. Yet, in December when it came time for a House vote on the drug price negotiation bill, President Trump said he would veto the bill.

Why did the President change his mind and decide to oppose legislation to allow Medicare to directly negotiate the price of prescription drugs?

Answer. President Trump has made it clear how important tougher negotiation is. That is exactly what our Administration has been doing for Medicare, in an effective and targeted fashion. We are working to make negotiation more effective than it is today in our prescription drug program, Part D, and to bring negotiation to where it doesn’t exist, in physician administered drugs, Part B.

While some believe Medicare could save tons of money by negotiating directly for drugs, this just isn’t true. If the government were to directly negotiate we would have to create a single formulary. This would be a highly restrictive uniform formulary for every senior citizen in America. One approach to this problem could be to replace negotiation with a price setting mechanism. For example, by setting a penalty so high that there really is no opportunity to negotiate. However, price setting does not get us closer to negotiation, and it will reduce access and innovation over time.

We can see in Medicare Part D that negotiation works. Pharmacy Benefit Managers (PBMs) play an important role negotiating lower prices for America’s seniors, and offer them to beneficiaries through a number of private plans. Having such a robust landscape means people can vote with their feet and choose the plan with the formulary that best meets their needs. We just need to ensure that these lower prices are being passed on to patients.
AFFORDABLE CARE ACT COURT CASE

Question. The HHS budget proposal has an increased focus this year on reducing maternal mortality and improving maternal health. I agree that this is an area where we must do more to improve health outcomes for so many women. However, at the same time, the Trump Administration is backing a lawsuit in Federal court that would strike down the Affordable Care Act (ACA) in its entirety. If the courts strike down the ACA, insurance companies will be able to return to the days when they can deny coverage to women for pre-existing conditions. Insurers will be able to eliminate maternity care coverage. Insurers will even be able to charge women higher premiums than men.

How does the Department square this budget’s purported support for improving maternal health with this administration’s support for a lawsuit that would tear down the ACA and eliminate the health protections that pregnant women and new mothers rely upon?

Answer. As the single largest payer for maternity care in the United States, Medicaid plays an important role in perinatal and maternal health. In 2014, CMS launched the Maternal and Infant Health Initiative (MIHI) to explore program and policy opportunities to improve outcomes and reduce the cost of care for women and infants in Medicaid and CHIP. Since then, much work has been done, such as the Postpartum Care Action Learning Series, a learning collaborative of States to drive quality improvement around postpartum care.

CMS is currently evaluating activities over the past 5 years, which includes publishing three Issue Briefs on March 9, 2020, to describe initiatives undertaken in the first phase of MIHI. These Issue Briefs are:

—Lessons Learned About Payment Strategies to Improve Postpartum Care in Medicaid and CHIP: This brief outlines the lessons learned about payment strategies to improve postpartum care visit rates and summarizes the changes three States made related to paying for maternity care in order to improve postpartum care under the Postpartum Care Action Learning Series.

—The Maternal and Infant Health Initiative Grant to Support Development and Testing of Medicaid Contraceptive Care Measures: The CMS MIHI grant program supported development and testing of Medicaid contraceptive care measures. This analytic brief discusses the MIHI grant program, describes the contraceptive care measures developed as part of this effort, summarizes data reported by the MIHI grantees, highlights uses of the data, and identifies lessons learned.

—Improving Postpartum Care: State Projects Conducted through the Postpartum Care Action Learning Series and Adult Medicaid Quality Grant Program: This issue brief describes the quality improvement teams in the 10 States, their aims, the interventions they tested, their results, and lessons learned. In addition, this fact sheet provides summaries of the postpartum care-related projects that four States undertook as Adult Medicaid Quality grantees.

In 2018, CMS announced the Maternal Opioid Misuse (MOM) model, which addresses the need to better align and coordinate care of pregnant and postpartum Medicaid beneficiaries with opioid use disorder (OUD) through State-driven transformation of the delivery system surrounding this vulnerable population. By supporting the coordination of clinical care and the integration of other services critical for health, wellbeing, and recovery, the MOM model has the potential to improve quality of care and reduce expenditures for mothers and infants.

In December 2019, CMS announced the following 10 States were awarded MOM Model funding: Colorado, Indiana, Louisiana, Maine, Maryland, Missouri, New Hampshire, Tennessee, Texas, and West Virginia.

Additionally, CMS is reconvening an expert workgroup to help chart a course for the future of maternal infant health quality measurement and improvement. The workgroup will represent a wide variety of key stakeholders and Federal agencies and will provide updated recommendations for measurement, quality improvement and technical assistance opportunities.

In Medicaid and CHIP, the measures in the voluntary Child and Adult Core Sets assess the quality of care women receive at each step in their lifecycle and include quality measures associated with major drivers of pregnancy-related mortality and severe maternal morbidity. CMS has identified a subset of 11 Child and Adult Core

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Set measures for 2020 that comprise a Core Set of Maternal and Perinatal Health Measures for Medicaid and CHIP (Maternity Core Set). The Maternity Core Set includes a measure of early elective delivery, along with measures that examine prenatal and postpartum care, low birth weight babies and well-baby care. Since the core sets were established in 2010 and 2012, States have made significant progress reporting these measures. With the passing of the Bipartisan Budget Act of 2018 (Public Law 115–123), State reporting of the Child Core Set, including maternal and infant health measures, will become mandatory beginning in 2024.

The Medicaid and CHIP Scorecard is a central component of CMS's commitment to increase public transparency and accountability about the programs' administration and outcomes. The Scorecard currently includes one maternal health measure (Postpartum Care), as well as two other measures from the Maternity Core Set, Well-Child Visits in the First 15 Months of Life and Live Births Weighing Less than 2,500 grams. Over time, the Scorecard will evolve to include health outcome metrics, and we are considering how the Scorecard can address maternal and infant health. CMS continues to work with States to encourage greater reporting to improve consistency across States.

The Supreme Court will consider in its next term whether the Affordable Care Act's individual mandate is unconstitutional and, if so, the status of the remainder of the Act. Meanwhile, HHS will continue administering and enforcing all aspects of the ACA as it had before the Fifth Circuit issued its decision. The appellate court decision does not require HHS to make any changes to any of the ACA programs it administers or its enforcement of any portion of the ACA at this time. The Trump Administration has consistently supported preserving protections for all Americans with pre-existing conditions, including pregnant women and new mothers. The administration stands ready to work with Congress on policy solutions like those in our Budget and increase access to maternal health services.

**Question.** In recent rulemakings for Medicare payments under the Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) payment system, the administration has agreed to examine its packaging policies and pay separately for non-opioid pain management treatments. However, CMS has made it clear that it will only change its packaging policies if it finds that its own payment systems (either the OPPS or ASC) present a barrier to the use of non-opioids. The Department is effectively suggesting that it will only take action if it finds that its own packaging policy has unintentionally contributed to the opioid crisis.

In response to a recent letter I wrote to CMS, the agency indicated between 2013 and 2018, it had not observed significant declines in the total number of units used in hospital outpatient departments for drugs and related items deemed to be non-opioid alternatives. CMS noted that in some cases the agency observed increases in the number of units used in hospital outpatient departments for certain non-opioid alternative drugs during the 6-year period. CMS suggests that the lack of decrease in the number of units of non-opioid drugs that were used in hospital outpatient departments between 2013 and 2018 is proof that Medicare payment policies do not deter the use of non-opioid alternatives. However, to date, CMS responses have not compared the change in overall units of non-opioid drugs used in hospital outpatient departments with changes in the overall number of surgeries performed in hospital outpatient departments where non-opioid drugs could be used to treat post-surgical pain.

Can you provide data to show the rate of change in units of non-opioid drugs used in hospital outpatient departments compared to the growth in hospital outpatient surgeries for which non-opioid alternatives could be a candidate for treating post-surgical pain?

**Answer.** As required under section 6082 of the SUPPORT Act, for purposes of the calendar year (CY) 2020 proposed rule for the Medicare hospital outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) payment system, CMS conducted an evaluation of its payment policies for opioids and evidence-based non-opioid alternatives under these systems. The goal of this analysis, as articulated by law, was to conduct a review of payments for opioids and evidence-based non-opioid alternatives for pain management ensure that there are not financial incentives to use opioids instead of non-opioid alternatives. We believed that if CMS packaging policies discouraged the use of these non-opioid alternatives or impeded
access to these products, our analysis would show a decline in utilization of non-opioid alternatives over time.

In our evaluation, we looked at several packaged drugs and devices used in covered medical procedures to determine if the current packaging policy represented a barrier to access. For each product, the most recently available Medicare claims data as well as medical literature relating to use of these products being used as an alternative to opioids was examined. All of the alternatives examined showed consistent or increasing utilization in recent years, with no products showing decreases in utilization, suggesting that current payment policy does not present a barrier to access of these products.

Drugs that function as surgical supplies were examined over a 6-year time period (CYs 2013 through 2018). During our evaluation, we did not observe significant declines in the total number of units used in the hospital outpatient department for a majority of the drugs included in our analysis. In fact, under the OPPS, we observed the opposite effect for several drugs that function as surgical supplies. Similar to the findings associated with devices above, this trend indicated appropriate packaged payments that adequately reflect the cost of the drug and are not prohibiting beneficiary access.

The results of this review and evaluation of medical literature and claims data did not support evidence to indicate that our packaging policies had the unintended consequence of discouraging the use of non-opioid treatments for postsurgical pain management in the OPPS setting, including drugs that function as a surgical supply, nerve blocks, or neuromodulation products.

To broaden our analysis, the CY 2020 OPPS/ASC proposed rule also sought public comment on other non-opioid treatments for acute pain that might be affected by OPPS and ASC packaging policies and warrant separate payment. However, the public comments and data that CMS received regarding specific products did not provide sufficient evidence-based support that the current packaged payment policies for these non-opioid alternatives presented a barrier to access to care and warranted revised, separate payment to reduce incentives. We provide further analysis of our review of these specific products in the CY 2020 OPPS/ASC final rule (CMS–1717–FC) released on November 1, 2019.

We did not specifically analyze the rate of change in each unit of packaged drugs and devices relative to the number of aggregate hospital surgeries each year. We note that there are many factors that are independent of payment policy, including the availability of other treatment options, the clinical needs and profile of patients, and provider decisions regarding drug formularies and device purchasing, that could influence those trends. Therefore we determined that the changes in actual utilization of items and services is the best available indicator of whether existing payment policies pose a barrier to access to those products.

We will continue to analyze the issue of access to non-opioid alternatives in the OPPS and the ASC settings for any subsequent reviews we conduct under Section 6082 of the SUPPORT Act. We are continuing to examine whether there are other non-opioid pain management alternatives for which our payment policy should be revised to allow separate payment under the OPPS.

Question. Given the severity of the Nation’s crisis, is it now time for the Department to take a more active role in promoting the use of non-opioids, by paying separately for non-opioid therapies with an FDA-approved indication for pain reduction?

Answer. As required under section 6082 of the SUPPORT Act, for purposes of the calendar year (CY) 2020 proposed rule for the Medicare hospital outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) payment system, CMS conducted an evaluation of its payment policies for opioids and evidence-based non-opioid alternatives under these systems. The goal of this analysis was to determine whether our packaging policies reduced the use of non-opioid alternatives and incentivized the use of opioids. We believed that if CMS packaging policies discouraged the use of these non-opioid alternatives or impeded access to these products, our analysis would show a decline in utilization of non-opioid alternatives over time.

In our evaluation, we looked at several devices used in covered medical procedures to determine if the current packaging policy represented a barrier to access. For each product, the most recently available Medicare claims data as well as medical literature relating to use of these products being used as an alternative to opioids was examined. All of the alternatives examined showed consistent or increasing utilization in recent years, with no products showing decreases in utilization, suggesting that current payment policy does not present a barrier to access of these products.
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**MEDICAID WORK REQUIREMENTS**

**Question.** Earlier this month a three-judge panel of the U.S. Court of Appeals for the District of Columbia unanimously struck down Medicaid work requirements in Arkansas. New Hampshire was headed for a similar outcome until the State delayed implementation of its program and after a Federal District Court blocked implementation of New Hampshire’s “work requirement” program. As you likely also know, every lawsuit challenging CMS’s approval of Medicaid work requirements has succeeded.

Given that the courts keep rejecting Medicaid work requirements, why are you still promoting this illegal, expensive, and administratively burdensome initiative?

**Answer.** The Department of Health and Human Services (HHS) supports States’ efforts to determine how to manage their Medicaid programs, including the ability to test community engagement requirements. HHS is evaluating its options in seeking further review by the courts; no final decision has been made at this time. This Administration is committed to considering proposals that would give States more flexibility to engage with their working-age, able-bodied citizens through demonstrations that will help them rise out of poverty to create a better life for themselves and their families.

**Question.** Does HHS plan to appeal the recent decision from the U.S. Court of Appeals for the District of Columbia to the United States Supreme Court?

**Answer.** HHS is evaluating its options in seeking further review; no final decision has been made at this time.

**QUESTIONS SUBMITTED BY SENATOR JEFF MERKLEY**

**FISCAL YEAR 2021 BUDGET REQUEST FOR ORR**

**Question.** Secretary Azar, the fiscal year 2021 Department of Health and Human Services (HHS) budget request notes an increase in funds for the Office of Refugee Resettlement. President Trump has cut the refugee admission ceiling to its lowest recorded level since the Refugee Act of 1980. We are welcoming just 18,000 people for fiscal year 2020. This is less than 10 percent of how many new community members we were settling during the 1980 high water mark of over 207,000 new community members that came to America.

At a time when over 70 million people around the world are displaced from their homes, do you feel that the United States is doing everything it can to show leadership and commitment to our ideals of freedom and peace by cutting off refugee admissions at just 18,000 during this humanitarian crisis?
Answer. The U.S. Department of State (DOS) is charged with overseeing the refugee admissions process. The DOS Report to Congress on Proposed Refugee Admissions for fiscal year 2020 states that the "...refugee admissions ceiling reflects the urgent need to address the border security and humanitarian crisis caused by the massive surge of aliens seeking protection at the U.S. southern border. It also reflects the backlog of nearly one million asylum-seekers who are awaiting adjudication of their claims inside the United States."

Question. When the President's refugee ceiling is set at 18,000—why does the HHS fiscal year 2021 assumption state an estimated 91,000 new arrivals?

Answer. ORR is charged to serve the following eligible populations: refugees, asylees, victims of human trafficking, Special Immigrant Visa holders (SIVs), and Cuban/Haitian entrants. The HHS fiscal year 2021 assumption estimates approximately 91,000 arrivals broken down in the following categories, including dependent family members:

—18,000 refugees
—45,600 asylees
—920 victims of human trafficking
—10,000 SIVs
—16,000 Cuban/Haitian entrants

Question. The number of unaccompanied children in your care has stabilized at a substantially lower number than last year. In February 2019, you reported that you had an average of 11,473 children in your care. The most recent numbers released for this year show you have an average of 4,236 kids in your custody.

Why does the HHS refugee resettlement budget requests a $680 million increase in funding for unaccompanied children?

Answer. Given the historic fluctuation in the number of children requiring shelter, there is no guarantee that the number of children in care has stabilized. The budget request reflects the level of funding we estimate will be necessary to support a capacity of 16,000 State-licensed permanent beds, depending on operational need, as well as the periodic activation of temporary influx beds if they are needed.

Question. Is this increase in funding going to be used to prioritize State-licensed not-for-profit care facilities, Flores protections, and quality legal services for kids?

Answer. This funding will support care, compliance with the standards set forth in the Flores Settlement Agreement, and services for UAC, including legal services as well as home study, child advocate, and post-release case management. Both not-for-profit and for-profit youth care organizations are eligible to apply for grants to shelter UAC and provide transitional foster care and long term foster care services. ORR advertises these grants openly through Funding Opportunity Announcements.

FLORES SETTLEMENT AGREEMENT PROTECTIONS

Question. On May 22, 2019, your team informed State-licensed facilities for refugee children that HHS would not pay for recreation or education, despite the fact that the 1997 Flores Settlement Agreement mandates these care standards. This is an apparent violation of Flores.

Why does HHS believe that children in your care should not be provided education or recreation—a chance to go play soccer, or learn how to read and write?

Answer. ORR complies with all minimum standards as set forth in the Flores Settlement Agreement. ORR provides educational services appropriate to the unaccompanied alien child’s level of development and communication skills in a structured classroom setting Monday–Friday, which concentrates primarily on the development of basic academic competencies and secondarily on English Language Training. Basic academic areas of study include Science, Social Studies, Math, Reading, Writing, and Physical Education. Educational services must provide children with appropriate reading materials in languages other than English for use during leisure time.

In addition, care provider programs must provide daily outdoor activity, weather permitting, with at least one hour per day of large muscle activity and one hour per day of structured leisure time activities (that should not include time spent watching television). Activities should be increased to a total of three hours on days when school is not in session.

For complete information on the minimum required services, please see the ORR Policy Guide, Section 3.3 Care Provider Required Services (available at: https://www.acf.hhs.gov/orr/resource/children-entering-the-united-states-unaccompanied-section-3#3.3). Question. Was this directive to cease recreation or education funding implemented?
Answer. At the time, ORR entered deficiency status under the Anti-Deficiency Act (ADA), which limited ORR’s ability to make obligations for any activities that did not directly support life, health, and safety under the exception to the ADA. UAC education and recreation services did not qualify for the exception to the ADA.

For grants awarded on or after May 22, 2019, ORR included a provision on the Notice of Grant Award that stated:

"RESTRICTION ON RELEASE OF FEDERAL FUNDS

The Unaccompanied Children Program is currently operating under a deficiency apportionment, as outlined in 31 U.S.C 1515. As a result, all costs budgeted for recreational or educational activities, including personnel associated with these activities, are hereby restricted from drawdown. This restriction applies only to funds awarded to grant 90ZU0208 on or after May 22, 2019 and will remain in effect until further notice from the awarding agency."

On June 14, ORR issued additional information to care providers. State-licensed or federally-contracted facilities for the care of children could use any previously obligated funds for these services.

Finally, on June 28, ORR issued Notice of Grant Award to lift this restriction on all grantees with passage of the supplemental appropriations.

Question. Does the Office of Refugee Resettlement currently provide all kids in your care the Flores-protected right to education and healthy physical activity?

Answer. Yes. ORR provides all Flores mandated services in compliance with the terms of the FSA and ORR policy.

Question. Your recent proposed regulatory changes undermine the protections for kids that Flores established. Can we agree that the Flores protections are not optional, are necessary to uphold, and that regardless of where we come from or the color of our skin, all kids deserve a good childhood?

Answer. The HHS provisions of the Flores Final Rule are consistent with mandatory service and placement requirements for UAC under the FSA, read together with subsequently enacted laws.

Question. Your recent proposed regulatory changes include numerous instances where the mandatory protections in the Flores Settlement are replaced with discretionary language. For example, while Settlement ¶11 states that the government "shall place each detained minor in the least restrictive setting," the regulation states that the government "places each UAC in the least restrictive setting." 45 C.F.R. § 410.201(a).

Please explain how removing these protections is consistent with the government's obligations under the Flores Settlement.

Answer. The provisions are read as mandatory. Under the regulation, the government is required to place children in the least restrictive setting.

Question. Please explain why you think removing these mandatory protections helps to protect children’s health, safety, and welfare.

Answer. The provision does not remove mandatory protections, the language is not discretionary. In provisions that require the government to provide services or benefits to UAC, the regulatory text uses the words "will," "shall," and "must." For example, in §410.402 that replicates the requirements of Exhibit 1 of the FSA, it clearly states that "Licensed programs must..." and then lists all required services. On the other hand, when it could benefit the UAC that the government not act in a strict manner, the regulatory text uses "may." (See HHS response to comments related to 45 CFR 201 available at: https://www.Federalregister.gov/documents/2019/08/23/2019-17927/apprehension-processing-care-and-custody-of-alien-minors-and-unaccompanied-alien-children).

Question. Your recent proposed regulatory changes undermine the bond hearing protections for children established in Flores Settlement ¶24A guarantees class members a “hearing before an immigration judge in every case, unless the minor indicates on the Notice of Custody Determination form that he or she refuses such a hearing.” The regulations replace immigration judges with HHS employees and requires children to affirmatively request a bond hearing. 45 C.F.R. §410.810.

Please explain how replacing immigration judges with HHS employees is consistent with the Flores Settlement.

Answer. HHS is responsible for the care and custody, as well as placement decisions for all unaccompanied alien children. Properly trained HHS personnel (who are neutral arbitrators, such as Federal career Administrative Law Judges or hearing officers with HHS’ Departmental Appeals Board) would be able to provide more child friendly, trauma-informed hearings, designed by child welfare experts, while maintaining independence from ORR.

Also, the Flores Settlement was entered into by the former Immigration and Naturalization Service (INS), within the Department of Justice (DOJ). Then as now,
DOJ also oversaw the immigration courts, through the Executive Office for Immigration Review (EOIR). It is thus consistent with the Flores Settlement and child welfare interests for independent adjudicators within the same agency to preside over these hearings. Note, under the rule, HHS would provide independent bond hearings, but any immigration judges would continue to adjudicate UAC’s removal proceedings.

Question. Please explain how changing bond hearings from an opt-out to an opt-in process is consistent with the Flores Settlement.

Answer. For policies related to requesting a Flores bond hearing, see ORR Policy Guide, section 2.9 Bond Hearings for Unaccompanied Alien Children (available at: https://www.acf.hhs.gov/orr/resource/children-entering-the-united-states-unaccompanied-section-2#2.9). The Flores Final Rule’s hearing process is consistent with the current process.

Currently, the Flores bond hearing process for UAC is, effectively, an opt-in process. This is because, as a result of changes in the law since the Flores Agreement was signed, very few UAC actually benefit from them. In the ORR context, bond hearings only determine whether a child is a danger to self or others. Very few children are ever determined to be a danger to self or others such that this decision would impact their release from ORR custody. Therefore, in all other instances, the hearings would be uncontested with both parties agreeing that there was no issue of dangerousness to be decided by the immigration judge. Children that ORR determines are a danger to self or others are given instructions on how to request a Flores bond hearing. (Note, ORR does not make release decisions based on risk of flight).

Question. Your recent proposed regulatory changes do not require that children receive “instruction and educational and other reading materials in such languages as needed,” as required by Flores Settlement Exhibit 1 (A)(4). Your agency’s response to this omission was that “[i]n practice, most educators who teach at FRCs are bilingual, typically in English and Spanish, and provide individualized education in a manner designed to be most effective for the minor.” 84 Fed. Reg. at 44,440. That response clearly misses the point—while a teacher may be bilingual in English and Spanish, that has nothing to do with the provision of instructional materials in the appropriate language, and many children in government custody do not speak either English or Spanish.

Please explain how the regulation’s language is consistent with the education requirements in the Flores Settlement.

Answer. The provision referenced is part of the DHS portion of the final rule, related to educational requirements in Family Residential Centers (FRCs) managed by Immigration and Customs Enforcement (ICE). Because it does not refer to ORR, HHS defers to DHS for a response.

Question. Please explain how flouting the Flores Settlement’s education requirements is in the best interest of children.

Answer. See response to question 7(a). HHS defers to DHS for a response.

FISCAL YEAR 2021 BUDGET REQUEST FOR CDC AND NIH

Question. In a bipartisan move last December, Congress approved a $25 million investment in research to prevent gun deaths with the Centers for Disease Control (CDC) and the National Institute of Health (NIH). You were tasked with the mission to help reduce the needlessly-high rates of gun death. Gun violence and suicide continue to kill over 40,000 people annually in the United States. Yet your budget justifications for the CDC and NIH appear to zero out continued funding to study this problem.

Have the CDC and NIH already accomplished the mission of reducing gun deaths in the 3 months since funding was given to the CDC and NIH?

Answer. On February 21, 2020, CDC released a new research funding opportunity announcement to solicit investigator-initiated research to understand and prevent firearm-related injuries, deaths, and crime. CDC anticipates supporting up to 20 research grant awards in fiscal year 2020. The total amount awarded, and the number of awards will depend upon the number, quality, and cost of applications received and selected for funding.

On March 20, 2020, NIH published two Funding Opportunity Announcements (FOAs) in the NIH Guide for Grants and Contracts and on Grants.gov—Search Grants. Research encouraged by these FOAs is consistent with a broad public

health approach to firearm injury and mortality prevention including identifying those at risk for firearm injury and mortality (both victims and perpetrators), development and evaluation of theoretically-grounded programs to prevent firearm injury and mortality, and implementation research to explore the barriers and facilitators to support broader adoption of effective programs.

Question. If not, please explain why you’ve proposed to eliminate funding for this lifesaving research.

Answer. We take our responsibility for supporting research on mental illness and causes of violence seriously. Congress provided funds in fiscal year 2020 for firearm mortality prevention research, and CDC and NIH are already underway to operationalize that funding. However, in drafting the fiscal year 2021 Budget we faced difficult choices in order to rein in spending and put America on a sustainable financial path, and we have prioritized programs that provide direct services and focus on infectious diseases and emergency preparedness and response activities.

The Budget includes $24 million for the National Violent Death Reporting System (NVDRS). In fiscal year 2021, CDC will support 52 recipients to collect NVDRS data. Since fiscal year 2018, CDC has expanded the NVDRS to all 50 States and DC. In addition, we invest in Project AWARE and other activities that seek to address youth and young adult mental health to help improve school safety. These activities receive an increase to $156 million (+$2 million above fiscal year 2020) for mental health services and training to recognize signs and symptoms of mental disorders, particularly serious mental illness.

NIH invests in research on a full range of threats to Americans’ well-being, and that includes violence with firearms.

FISCAL YEAR 2021 BUDGET REQUEST FOR THE BUREAU OF PRIMARY HEALTH CARE

Question. In fiscal year 2019 and fiscal year 2020 this committee included language in the conference report supporting the work of the Bureau of Primary Health Care (BPHC) in facilitating better coordination between health centers and home visiting programs, specifically encouraging BPHC to indicate how home visiting programs fit within health centers’ scope of practice.

We know that enhanced integration between healthcare providers and home visiting programs like Nurse-Family Partnership can help transform the lives of mothers working to lift themselves and their children out of poverty and the poor health outcomes that come along with living in poverty. These programs are skilled at reaching underserved populations and can serve as a worthwhile supplement to the primary care provided by health centers.

Nurse-Family Partnership is an example of one of these programs. NFP partners first-time, at-risk mothers with registered nurses early in pregnancy, working with them through their child’s second birthday to improve a range of health and child development outcomes. NFP currently partners with 22 health centers throughout the country—including in my state—resulting in improved livelihoods for moms and babies who are enrolled in NFP.

What progress has the Department made in improving coordination between health centers and home visiting programs? What is your perspective on how home visiting programs fit within the scope of practice for health centers?

Answer. HRSA has convened health centers and HRSA-funded home visiting program participants to increase knowledge and awareness of the respective programs, build sustainable partnerships, and facilitate integration of the services they offer, to the extent possible, with the shared goal of improving maternal and child health outcomes. The following is an update on this collaboration:

—In June 2019, HRSA hosted a webinar titled, “Primary Care and Home Visiting Partnerships to Promote Maternal and Children Health”. The objective of the webinar was to provide an overview of evidence-based home visiting programs and demonstrate how health center and home visiting programs can support one another in improving patient outcomes.

—In September 2019, HRSA hosted a webinar titled, “Strategies for Addressing Maternal Depression through Primary Care and Home Visiting Partnerships”. The objectives of this webinar were to: (1) provide an overview of the scope and impact of maternal depression; (2) discuss how primary care and home visiting partnerships can enhance efforts to prevent, identify, and treat maternal depression; and (3) share insights from maternal depression subject matter experts from the HRSA-funded Home Visiting Collaborative Improvement and Innovation Network (HV CoIIN), administered through HRSA’s Maternal and Child Health Bureau (MCHB).

—MCHB funded a cooperative agreement awarded to the National Nurse-Led Care Consortium (NNCC). NNCC partnered with the Nursing-Legal Partner-
ship Model for Community Health Centers, funded through MCHB, to facilitate a learning collaborative and develop training and technical assistance resources for health centers. This learning collaborative consists of health centers and community partners to explore the efficacy of evidence-based home visiting programs, such as Nurse-Family Partnership and Parents and Teachers, for health centers.

Our HRSA collaboration activities to date have shown that health centers can work closely with evidence-based home visiting programs to ensure that a comprehensive range of supportive services are made available to the families and children that both programs serve.

QUESTIONS SUBMITTED BY SENATOR BRIAN SCHATZ

CORONAVIRUS

Question. Does the Department of Health and Human Services plan to fully reimburse States for the costs they are incurring as part of the Federal Government’s coronavirus response?

Answer. With funding appropriated through the Coronavirus Aid, Relief and Economic Security (CARES) Act and the Paycheck Protection Program and Health Care Enhancement (PPPHCE) Act, HHS is providing relief funds to hospitals and other healthcare providers on the front lines of the coronavirus response. This Provider Relief Fund (PRF) will be used to support healthcare-related expenses or lost revenue attributable to COVID–19 and to ensure uninsured Americans get care related to COVID–19. HHS began issuing payments on April 10 and will continue making payments on a rolling basis until the funds are expended. While not directly linked to State coronavirus expenditures, relief payments are being provided to healthcare providers across all 50 States and the District of Columbia. Information about disbursements will be posted on the HHS website and updated on a regular basis.

For example, a State-by-State breakdown of the initial $30 billion distribution is available at: https://www.hhs.gov/sites/default/files/state-by-state-breakdown-delivery-of-initial-30-billion-cares-act.pdf.

Question. Has HHS provided guidelines to states on how they should track the costs they are incurring as part of the Federal government’s coronavirus response? If not, when will HHS provide such guidelines?

Answer. HHS has not issued any additional specific guidance to States to track costs they incur under COVID–19 emergency supplemental appropriations. Recipients are required to track and report costs per 45 CFR 75 and are subject to Part F audit requirements, as is standard with all awards.

Question. Secretary Azar stated that emergency supplemental funding would be used in five key areas of response. Please provide more information on each of those five areas, and how funding will be used in those areas.

Answer. First, funds are being used to expand our surveillance work, building on existing systems we have within CDC’s influenza surveillance network. Second, funds are supporting public health preparedness and response for State and local governments . Third and fourth, funds are supporting the development of therapeutics and the development of vaccines. Finally, funds are being used for the purchase of personal protective equipment for the Strategic National Stockpile.

TOBACCO AND YOUTH VAPING

Question. Given that the 2019 National Youth Tobacco Survey found that types of open-tank systems that can be filled with thousands of flavored e-liquids are among the most popular e-cigarette devices among high school students, what is the justification for leaving all open-tank and menthol-flavored products on the market? Does HHS have evidence that youth will not simply switch to those products? If yes, please provide that evidence.

Answer. FDA focused its enforcement priorities-consistent with the best available data-on flavored, cartridge-based ENDS products (other than tobacco- and menthol-flavored). Importantly, FDA is also prioritizing enforcement against all other products (both cartridge-based or otherwise) including menthol-, tobacco-, and non-flavored ENDS products for which the manufacturer has failed to take adequate measures to prevent minors’ access, as well as all ENDS products that are targeted to minors or likely to promote use of ENDS by minors. Additionally, should FDA become aware of an increase in youth using non-cartridge-based and menthol- and tobacco-flavored cartridge-based ENDS products, the Agency may revise its enforcement priorities.
Additionally, under the policy tobacco- and menthol-flavored cartridge-based ENDS products, along with all other ENDS products, are subject to the September 9, 2020, submission date for marketing applications. FDA intends to prioritize enforcement of all ENDS products offered for sale after September 9, 2020, and for which the manufacturer has not submitted a premarket application.

This approach strikes an appropriate balance between restricting youth access to such products, while maintaining the availability of potentially less harmful options for current and former adult smokers who have transitioned or wish to transition completely away from combusted tobacco products. FDA is continuously evaluating new information and adjusting its enforcement priorities in light of the best available data, and it will continue to do so with respect to these products, FDA will take appropriate action regarding tobacco products that are marketed without premarket authorization, including as warranted based on changed circumstances, new information, or to better address minors’ use of those products.

FDA is prioritizing cartridge-based ENDS products, in part because data from the 2019 NYTS indicate that youth overwhelmingly prefer these types of ENDS products, and the Agency has found that these products are easy to conceal, can be used discreetly, may have a high nicotine content, and are manufactured on a large scale. The 2019 survey instrument included a measure for the “usual brand” of e-cigarette used in the past 30 days. Most youth who were current e-cigarette users reported a cartridge-based e-cigarette as their usual brand. In fact, the leading brand is a cartridge-based product that commands approximately 70 percent of the market.

While FDA does not currently have data specific to youth switching to other products, the Agency will closely monitor the marketplace and make adjustments as necessary.

**Question.** Since FDA’s enforcement policy against certain unauthorized flavored e-cigarette products was announced, what has FDA done to monitor whether rates of e-cigarette use among youth are declining, or whether youth are switching to other flavored products? Please provide any data that is available.

**Answer.** The Agency is closely monitoring the use rates of all types of e-cigarette products, including disposable products, tobacco, and menthol flavored e-cigarettes among youth. FDA utilizes multiple strategies for monitoring youth use of tobacco, including traditional surveillance (such as national surveys) as well as social media monitoring and monitoring complaints to reporting systems. National surveys and other monitoring approaches are on-going.

On November 5, 2019, findings from the 2019 National Youth Tobacco Survey (NYTS) showed that more than 5 million youth were current (past 30-day) e-cigarette users in 2019, reaching an alarming level for the second year in a row. The prevalence of current e-cigarette use was 27.5 percent among high school students and 10.5 percent among middle school students. The data also showed that the majority of youth who currently only used e-cigarettes used a flavored e-cigarette. Among high school exclusive e-cigarette users, the NYTS measured a significant increase in the use of menthol- and mint-flavored e-cigarettes from 2016–2019, however because the NYTS survey instrument groups mint- and menthol-flavored products together, it is not possible to differentiate youth use of mint and menthol flavors separately based on the NYTS data.

Data from the 2019 Monitoring the Future Study (MTF) were also published on November 5, 2019. These data showed that approximately two-thirds of 8th, 10th, and 12th grade students who reported past 30-day vaping of any nicotine product reported using JUUL in the past 30 days. Among those who reported using JUUL in the past 30 days, the use of mango- and mint-flavored JUUL ranked highest, followed by fruit-flavored. The reported use of menthol and tobacco flavors were among the lowest ranked options.

In January 2020, FDA finalized a guidance outlining our enforcement priorities for ENDS products and other unauthorized deemed tobacco products. The Agency is prioritizing enforcement against illegally marketed ENDS that appeal to children by focusing on flavored, cartridge-based ENDS products (other than tobacco- or menthol-flavored). Additionally, the Agency will prioritize enforcement against all...

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14 Id. Unpublished data from the 2019 survey list other brands that are used by youth, some of which are available in both cartridge-based and non-cartridge-based forms.

other ENDS products for which the manufacturer has failed to take (or is failing to take) adequate measures to prevent minors’ access and any ENDS product that is targeted to minors or whose marketing is likely to promote use of ENDS by minors.

The 2020 National Youth Tobacco Survey (NYTS) is currently in data collection mode. FDA is working with CDC to get access to this data as soon as possible.

**Question.** What steps has the FDA taken to monitor the marketplace for products that may be renamed as menthol products so that the enforcement policy does not apply?

**Answer.** FDA will monitor the marketplace for products that may be renamed as menthol products to try to evade enforcement. FDA’s decision as to whether to take action with respect to particular products will be determined on a case-by-case basis, informed by the enforcement priorities described in its compliance policy and any other relevant factors. Additionally, for all unauthorized ENDS products, including tobacco-, menthol-, or non-flavored e-cigarette products, FDA intends keep a close watch on—and prioritize enforcement against—products for which the manufacturer has not taken or is not taking adequate measures to prevent minors’ access to these products.

The final guidance also outlines FDA’s intent to prioritize enforcement of any ENDS product that is offered for sale in the United States after May 12, 2020, and for which the manufacturer has not submitted a premarket application. The Agency also retains discretion to pursue enforcement action at any time against any deemed new tobacco product marketed without premarket authorization, regardless of whether it falls within one of these categories of enforcement priorities.

**Question.** The FDA has promoted the use of its “Age Calculator” smartphone application as a tool for retailers to use in implementing the new tobacco to 21 policy. However, this age calculator does not verify the authenticity of driver licenses and other forms of identification. What steps has FDA taken to inform retailers that the age calculator does not authenticate identification?

**Answer.** FDA has a number of tools to assist retailers in complying with the new Tobacco 21 legislation. This includes detailed training to help retailers calculate the age of tobacco purchasers and comply with the law. These resources include FDA’s This is Our Watch retailer assistance materials that includes an age calculation calendar and the FDA Age Calculator smartphone application (app), as well as the Tobacco Retailer Training Programs guidance document and a “Tips for Retailers” compliance training webinar, which, among other things, help retailers determine whether identification is valid.

The FDA Age Calculator app is available for free in both the Apple App Store and Google Play. The app is a voluntary smartphone application to help retailers comply with the Federal age restriction for selling tobacco products. Although the app does not help a retailer to determine the validity of the identification, it does assist retailers and their employees in accurately calculating the age of the purchaser based on the date of birth.

FDA has promoted this app as a calculator to help retailers determine the age of a customer. The description of the app in the app stores and the disclaimer provided in the app both contain language that indicates that the app is a calculator to determine age and does not work in conjunction with third-party systems. As this app does not work in conjunction with third-party systems, it differs from software used to determine whether identifications are valid. That software must interface with national databases and contain a two-part verification process in order to validate the data. FDA is exploring additional ways to clarify for retailers that the app and calendar do not verify the authenticity of an ID. The Agency will keep your office informed of its work in this area.

Although the app and calendar do not authenticate an ID, FDA does have other resources to help retailers determine whether identification is valid. FDA’s Tobacco Retailer Training Programs guidance document and “Tips for Retailers” compliance training webinar both contain information on determining whether a photographic identification is valid or might have been altered.

**Question.** What is the rationale for why a new agency within HHS to regulate tobacco products, instead of the FDA, would do a better job at regulation? How would creating such a new agency not create more disruption in the regulation of tobacco products at the same time that the country faces an epidemic of youth vaping?

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16 This guidance does not reflect the new minimum legal sale age of 21 and is cited here as setting out nonbinding recommendations for how retailers can implement training programs to help with compliance.

17 This webinar does not reflect the new minimum legal sale age of 21 and is cited here as setting out general tips on retailer compliance with Federal tobacco restrictions.
A new agency with a mission focused on tobacco and its impact on public health would have greater capacity to respond rapidly to the growing complexity of new tobacco products. In addition, this reorganization would allow the FDA Commissioner to focus on its traditional mission of ensuring the safety of the Nation's drug, food, and medical products supply.

Question. The budget eliminates $230 million in funding for the National Tobacco Control Program, and instead proposes an America's Health Block Grant of $350 million for all chronic disease prevention activities. Mathematically, would this mean that states will spend less on tobacco control prevention activities?

Answer. The fiscal year 2021 President's Budget combines funding for tobacco control and other chronic diseases into the America's Health Block Grant. States would have the flexibility to organize prevention and control efforts and deploy evidence-based interventions in a manner that makes the most sense to their jurisdictions and circumstances, which could result in some States deciding to spend more or less on tobacco prevention and control activities.

On March 17, 2020, the Administration transmitted an fiscal year 2021 Budget Amendment to Congress to increase funding for CDC to ensure that the Agency has the resources beginning October 1, 2020, to continue its critical public health mission. This amendment requests a total fiscal year 2021 funding level of $8,329,102,000 for CDC, which is $1,328,196,000 above the fiscal year 2021 Budget request. The additional funding will support priority CDC activities, including additional funding for the proposed America's Health Block Grant to allow States and localities to address their most pressing non-infectious disease activities.

Question. The CDC calls tobacco prevention a “public health best buy,” and the National Tobacco Control Program has been shown to reduce the number of people who smoke, reduce disease and death, and result in significant savings. Data show that every dollar spent on tobacco prevention means $55 in savings in tobacco-related healthcare savings. Will the elimination of this program and less funding devoted to tobacco prevention activities simply increase healthcare spending and result in poorer health outcomes?

Answer. The fiscal year 2021 President's Budget proposes the America's Health Block Grant, which will provide flexibility to grantees and focus on the leading public health challenges faced by States, Tribes, localities, and territories. States that have made larger investments in comprehensive tobacco control programs have seen larger declines in cigarette sales than the United States as a whole, and the prevalence of smoking among adults and youth has declined faster as spending for tobacco control programs has increased.18,19,20

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CDC CUTS TO CHRONIC DISEASE PREVENTION

Question. Have States requested that HHS combine all chronic disease prevention funding into one block grant?

Answer. The fiscal year 2021 President’s Budget carries forward the fiscal year 2019 and fiscal year 2020 President’s Budget proposals of a new 5-year block grant program, America's Health, which will provide flexibility to grantees and focus on the leading public health challenges faced by States, Tribes, localities, and territories.

Question. One of your priorities as HHS Secretary is value-based care. Every dollar invested in an evidence-based prevention program yields over $5 in savings. Therefore, how does this priority align with the budget’s reduced funding for chronic disease prevention activities?

Answer. Chronic disease prevention is an important public health issue and CDC is committed to continuing our efforts. In constrained budget environments difficult

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decisions must be made across Federal agencies, including CDC. CDC will continue to utilize resources strategically and effectively. The fiscal year 2021 President’s Budget carries forward the fiscal year 2019 and fiscal year 2020 President’s Budget proposals of a new 5-year block grant program, America’s Health, which will provide flexibility to grantees and focus on the leading public health challenges faced by States, Tribes, localities, and territories.

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**TELEHEALTH**

Question. The fiscal year 2018 omnibus spending bill (Public Law 115–141) required HHS to submit a report evaluating the use of telehealth under programs and pilots in Medicare, yet this report is almost 1 year overdue. When will this report be delivered? Given the administration’s focus on telehealth, what is the reason for this report being so delayed?


Section 3704 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act, Public Law 116–136) allows FQHCs and RHCs to be eligible to furnish and be paid for distant site telehealth services during the COVID–19 public health emergency. In the March 30 IFC, CMS is revising Medicare payment rates to implement these changes. Section 3703 increases Medicare telehealth flexibilities more generally during the public health emergency, including eliminating the requirement that the provider have an established relationship with a beneficiary before using telehealth services. Sections 3705, 3706, and 3707 enhance the ability for Medicare providers and beneficiaries to utilize telehealth for home dialysis, hospice, and home health during the emergency period.

The fiscal year 2021 President’s Budget proposed a comprehensive package of legislative proposals to promote rural access to care and telehealth in Medicare fee-for-service. We look forward to working with Congress on these and other legislative proposals that would further expand the availability of telehealth services:

— **Modernize the Medicare Telehealth Benefit to Promote Value-Based Payment.**—

Medicare payment for telehealth services is statutorily limited to circumstances where beneficiaries receive those services at particular healthcare settings, known as originating sites, and the originating site is located in a rural health professional shortage area or a Federal telemedicine demonstration project. Medicare also limits the types of practitioners that can furnish telehealth services and pays for such services at the same rates as in-person services. This multifaceted proposal expands Medicare Fee-for-Service’s telehealth benefit by removing existing barriers to telehealth services for providers participating in Medicare fee-for-service advanced Alternative Payments Models, which require more than nominal financial risk. This proposal would also require the Secretary to value telehealth services separately from similar services provided face-to-face for purposes of setting reimbursement rates in Medicare. This proposal broadens beneficiary access to Medicare telehealth services and addresses longstanding stakeholder concerns that the current statutory restrictions hinder beneficiary access, while ensuring Medicare is paying for value over volume.

— **Enhance Medicare Telehealth Services for federally Qualified Health Centers and Rural Health Clinics.**—Medicare only pays for telehealth services if furnished by physicians or certain non-physician practitioners as the distant site providers to the beneficiaries at certain originating sites located in certain geographic areas. This proposal allows Rural Health Clinics and federally Qualified Health Centers to be distant site providers for Medicare telehealth and reimburses for these services at a composite rate similar to payment for comparable telehealth services under the Medicare Physician Fee Schedule. This proposal levels the playing field by allowing these critical healthcare facilities to participate in the existing Medicare telehealth program. It also increases beneficiary access to care in rural areas where these clinics and centers are often the only source of primary care.

— **Extend Medicare Telehealth Services for IHS and Tribal Facilities.**—Medicare covers some types of telehealth services, but does not expressly cover telehealth
services provided across State lines. In the Indian Health Service (IHS) system, telehealth practitioners are often located in a different State from the patient and are not licensed, registered, or subject to the law of the State where the patient is located and receiving such services. This IHS proposal allows all IHS and tribal facilities to bill Medicare for telehealth services as originating and distant sites under the Physician Fee Schedule, even if the facility does not meet the requirements for being located in certain rural or shortage areas, including coverage for telehealth services provided across State lines. Explicitly authorizing IHS and tribal health programs to receive Medicare payment as originating and distant sites for telehealth services will accommodate the unique structures and Federal authorities that allow IHS and tribal health programs to operate across State lines.

PROJECT ECHO

Question. I and many of my Senate colleagues recently sent you a letter on Project ECHO and other technology-enabled collaborative learning and capacity-building models. The letter encourages the Department to explore ways to support and sustain the integration of these successful models into the healthcare delivery system. Does CMS plan to issue guidance to States on financing strategies for these models available through existing Medicaid authorities?

Answer. The Department, including CMS, is always available to provide technical assistance to States about models comprised of specific services that can be covered and reimbursed by Medicaid. Fostering State innovation and pairing it with enhanced accountability and integrity can improve health outcomes for beneficiaries, and we look forward to hearing how States are exploring ways to successfully incorporate ECHO into their Medicaid programs and how participation in ECHO has improved beneficiary access to and quality of care.

QUESTIONS SUBMITTED BY SENATOR CHRISTOPHER MURPHY

Question. In fiscal year 2020, Congress provided $12.5 million each for the CDC and NIH to conduct research on gun violence. The fiscal year 2020 Appropriations bill required the Directors of CDC and NIH to report to our Committee within 30 days of enactment on implementation schedules and procedures for grant awards. I understand the CDC has, but the NIH has not yet done so.

The CDC recently announced a funding opportunity of up to $8 million for Research Grants to Prevent Firearm-Related Violence and Injuries. When will CDC roll out the funding to grantees? The agency was appropriated $12.5 million for this field of research. When will CDC issue the request for applicants for the remaining $4.5 million it was appropriated? When does the NIH plan to issue its request for applicants for funding?

Answer. CDC is working diligently to ensure the research grants to prevent firearm-related violence and injuries will be awarded no later than September 2020. In addition to directly supporting research, CDC is also undertaking efforts to strengthen data at the local, State, and national level. Improving data to monitor the burden of firearm deaths and injuries and answer research questions is critical to advance Firearm Injury and Mortality Prevention efforts. CDC will also retain a portion of the Congressional appropriation for staffing and operations to support these efforts.

The NIH Report to Congress on firearms research was sent to the Committee on January 31st.

On March 20, 2020, NIH published two Funding Opportunity Announcements (FOAs) in the NIH Guide for Grants and Contracts22 and on Grants.gov—Search Grants.22 Research encouraged by these FOAs is consistent with a broad public health approach to firearm injury and mortality prevention including identifying those at risk for firearm injury and mortality (both victims and perpetrators), development and evaluation of theoretically-grounded programs to prevent firearm injury and mortality, and implementation research to explore the barriers and facilitators to support broader adoption of effective programs.

—NOT–OD–20–089, Notice of Special Interest: Competitive Revisions for Firearm Injury and Mortality Prevention Research.23 This Notice solicits competitive re-

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vision applications to support the expansion of existing R01 and R21 programs well poised to expand their focus to include firearms research.

—PAR–20–143, Firearm Injury and Mortality Prevention Research (R61 Clinical Trial Optional). This Program Announcement with special receipt, referral, and/or review considerations (PAR) invites new research applications to improve understanding of the determinants of firearm injury, the identification of those at risk of firearm injury (including both victims and perpetrators), the development and evaluation of innovative interventions to prevent firearm injury and mortality, and the examination of approaches to improve the implementation of existing, evidence-based interventions to prevent firearm injury and mortality.

Please refer to the FOAs for a detailed description of priority areas. Awards will be funded by September 30, 2020.

Question. The SUPPORT for Patients and Communities Act included “Sec. 1001. At-risk youth Medicaid protection” to prevent a State from terminating a young person who is otherwise eligible for Medicaid because he or she is in the juvenile justice system. This allows a young person to continue treatments and other healthcare coverage immediately following release.

What is the status of Medicaid guidance to assist States in adopting section 1001 of the SUPPORT for Patients and Communities Act?

Answer. Guidance to States on section 1001 of the SUPPORT for Patients and Communities Act is under development. To support States in their efforts to implement the provision, CMS hosted a webinar for State staff on strategies for connecting justice-involved populations to substance use disorder treatment. The webinar iterated the intersection of Medicaid and justice-involved populations, including State Medicaid coverage initiatives.

Question. Research shows that the early years of a child’s life offer the best opportunity to shape key academic, social, and cognitive skills that lay the foundation for future success. Authorizing the Preschool Development Grant Birth through Five (PDG B–5) program through the Every Student Succeeds Act (ESSA) was critical to improve program quality, collaboration, and transitions within early learning and care programs. Although 46 States applied for funding this past year, only 20 States, including my home State of Connecticut, were awarded funding due to budget constraints. States rely on this funding to coordinate existing early childhood services and serve more children effectively in a mixed delivery system, and while there has been an increase in the number of children enrolled in preschool in the United States, children still have uneven access to quality, affordable programs.

What is the administration’s reasoning for proposing to eliminate the PDG B–5 program when there is overwhelming interest and need for these programs across the country? How would the department ensure that States are improving the overall quality of their early childhood education programs if this program were to discontinue?

If PDG B–5 is funded in fiscal year 2021, how can the Federal Government leverage States’ best practices for improving coordination of existing early childhood services and funding streams to improve the use of Federal funds and overall quality of early childhood education programs, while ensuring equitable access to early learning environments?

Answer. We have already created a template for States to annually share best practices, efforts to blend and braid funding, new and improved partnerships, innovative practices or new procedures, new policies or legislation that has come about as a result of PDG B–5 funding, successful efforts made to improve the access to and quality of early childhood care and education programs, any infrastructure, policy, governance and/or funding put in place to sustain the strategies and activities going forward, and improvements in meaningful parent engagement activities. As mentioned previously, we will be including all States in any upcoming webinars, sharing any new tools or resources developed, alerting them to other funding opportunities made available by other Federal agencies, and inviting all States to participate in any annual meetings or other learning events where they can share and learn about best practices and lessons learned with one another.

Question. In 2016, the FDA proposed to ban electrical stimulation devices (ESDs) used for self-injurious or aggressive behavior because they present an inhumane and substantial risk to public health and they have been used on children with intellectual and developmental disabilities. The agency recognizes that these devices present substantial and unreasonable risks of illness or injury that cannot be corrected or eliminated by labeling or a change in labeling.

When will the FDA issue the final ban of ESDs used to treat self-injurious or aggressive behavior?

**Answer.** On March 4, 2020, FDA published a final rule to ban electrical stimulation devices (ESDs) used for self-injurious or aggressive behavior because they present an unreasonable and substantial risk of illness or injury that cannot be corrected or eliminated through new or updated device labeling. More information is available on its website here: https://www.fda.gov/news-events/press-announcements/fda-takes-rare-step-ban-electrical-stimulation-devices-self-injurious-or-aggressive-behavior.


**Question.** The FDA has yet to formally begin the rulemaking process for medical gas, despite having the authority to do so since 1978. In 2012, Congress enacted historic and bipartisan reforms for medical gases in the Food and Drug Administration Safety and Innovation Act (FDASIA Section 1112) that required FDA to promulgate new regulations for medical gases by July 9, 2016. When that statutory deadline was missed, the fiscal year 2017 Consolidated Appropriations Act pressed the agency to do so by July 2017. In 2018, the FDA convened three public meetings with stakeholders, with a proposed rule on medical gases included in all subsequent Unified Agendas.

When does the FDA plan to issue the proposed rule for medical gases?

**Answer.** FDA is actively working to revise Federal drug regulations with respect to medical gases. As you have noted, FDA has held three comprehensive public workshops that have covered several areas of FDA’s regulation of medical gases, including labeling, current good manufacturing practice, postmarket safety reporting, certification of designated medical gases, and drug registration and listing. The Agency is also actively considering proposed regulatory changes submitted to the public docket by stakeholders as FDA develops revisions to the drug regulations that apply to medical gases. The proposed rule is listed on the public Unified Agenda which can be found at: https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201910&RIN=0910-AH96.

The Agency understands the need for drug regulations to be better tailored to medical gases and intends to issue a comprehensive proposed rule.

**Question.** The Department recently implemented reforms to how livers are allocated for transplant. In regions such as New England, there are sick patients who recently received liver transplants who would otherwise have died under the previous allocation system. The new liver distribution system is working and the most urgently ill patients are the beneficiaries.

Will the Department continue to uphold the new policy that prioritizes the medical needs of patients?

**Answer.** The Organ Procurement and Transplantation Network (OPTN) implemented the new liver and intestinal organ distribution policy, referred to as the Acuity Circles policy, on February 4, 2020. The new policy replaces the use of decades-old geographic boundaries of 58 donation service areas and 11 transplant regions. It emphasizes the medical urgency of liver transplant candidates.

The OPTN is responsible for organ allocation policy and Health Resources and Services Administration (HRSA) is charged with oversight of the OPTN. Please be assured that HRSA and the OPTN are committed to the equitable allocation of livers for transplantation for patients across the country and will carefully monitor the outcomes of the Acuity Circles policy.

**QUESTIONS SUBMITTED BY SENATOR JOE MANCHIN, III**

**CORONAVIRUS**

**Question.** Secretary Azar, the President sent a letter to Congress requesting an additional $2.5 billion to help combat the spread of coronavirus. This request includes $1.25 billion in new funding through the Department of Health and Human Services, as well as requests to shift other funding within HHS to prioritize response to this disease. With almost 79,000 cases in 30 countries, and 14 confirmed cases in seven States in the U.S., we need to ensure that our hospitals and local health departments are prepared. Our State and local health departments are on the front line of the response to this virus, and major investments are needed to ensure the Nation’s health. In West Virginia we have 31 Community health Centers that serve over 467,000 people across the State, representing 1 in 4 West Virginians.

Secretary, what is your estimate of the need for continued response at the Federal, state, and local level if this virus starts to spread among the community?

To sustain this, do you think more funding is needed at each level?
Answer. As you know, the President, HHS, and Congress worked closely together to create and pass an $8.3 billion supplemental funding package, the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020. On March 11, five days after the President signed the supplemental funding bill, HHS announced that over $560 million will go to State, local, territorial, and Tribal governments. This funding will support surveillance, epidemiology, laboratory capacity, infection control, mitigation, communications, and other preparedness and response activities. The supplemental appropriation augments HHS’s response and focuses on five priorities: (1) expanding our surveillance work; (2) providing funds to support public health preparedness and response for State and local governments; (3) developing therapeutics; (4) developing vaccines; and (5) funding the purchase and manufacture of personal protective equipment for the Strategic National Stockpile.

The Department has received additional supplemental funding to support Coronavirus. The Second Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 in the Family First Coronavirus Response Act, enacted March 18, 2020 (Public Law 116–127), provided $1.314 billion in emergency supplemental funding to the Department of Health and Human Services (HHS) for Coronavirus preparedness and response activities. With these resources, HHS will support COVID–19 testing capacity across the Indian Health system; provide nutritious meals via home-delivery, drive-thru, and grab-and-go options for vulnerable older adults; and reimburse providers for the COVID–19 testing for uninsured patients. The Coronavirus Aid, Relief, and Economic Security (CARES) Supplemental Appropriations Act provided $142.8 billion in emergency supplemental funding to the Department for Coronavirus preparedness and response activities. The Paycheck Protection Program and Health Care Enhancement Act provided $100 billion, which includes $11 billion in awards to States, Territories, Tribes, and localities to develop, purchase, administer, process, and analyze COVID–19 tests, conduct surveillance, trace contacts and related activities. The Department continues to assess response needs as we monitor the development of COVID–19.

PREEXISTING CONDITIONS

Question. There are over 800,000 West Virginians and 133 million Americans living with a pre-existing condition. Their ability to access affordable healthcare literally hangs in the balance as the courts continue to review Texas v. U.S. The healthcare laws on the books today include clear protections that prohibit insurance companies from discriminating against individuals with pre-existing conditions. With the future of the ACA in the balance, your budget provides no alternative, no replacement, no hope for the Americans with pre-existing conditions. Additionally, your budget continues to push the sale of short-term or “junk” health plans that threaten access to quality and affordable care for Americans with pre-existing conditions. These plans make it easier for insurance companies to discriminate against people who desperately need prescription drugs, maternity care, and mental health or substance use disorder treatment.

Secretary, will you commit to working with me to build on the successes of the ACA to protect and expand access to affordable care for all Americans?

Answer. The Trump Administration stands ready to work with Congress on policy solutions that increase affordability while continuing to protect individuals with pre-existing conditions. The Supreme Court will consider in its next term whether the Affordable Care Act’s individual mandate is unconstitutional and, if so, the status of the remainder of the Act. Meanwhile, HHS will continue administering and enforcing all aspects of the ACA as it had before the Fifth Circuit issued its decision. Americans have the best healthcare in the world, but rising costs are an unsustainable financial burden for too many Americans and, increasingly, too many States. President Trump’s Health Reform Vision will protect the most vulnerable, especially those with pre-existing conditions, while also providing the affordability, choice, and control that Americans want, along with the high-quality care that all Americans deserve. Right now, many Americans, particularly those who do not qualify for subsidies, are being priced out of insurance coverage or left with coverage options that do not fit their needs. This Administration’s efforts to expand access to affordable coverage, such as short-term, limited-duration insurance, offer needed options, particularly for many middle-class Americans without employer-sponsored coverage who are not eligible for subsidies under the ACA. These plans may not work for everyone and may not offer the same benefits as other plans, but they can provide dramatically more affordable options, and for those Americans who are priced out of ACA-compliant plans, access to short-term, limited-duration insurance may mean the difference between some insurance and no insurance at all. In the final rule, we instituted robust notice requirements for informing consumers about
the limits of this type of coverage so consumers can understand what they are purchasing. Both the CMS Office of the Actuary and the Congressional Budget Office estimate that this the expansion of short-term, limited-duration plans through this rule will increase the number of people with some type of health insurance coverage.

OPPIOID FUNDING

Question. Secretary Azar, my State of West Virginia has been devastated by the opioid epidemic. We are the hardest hit State in the Nation and have the highest overdose death rate. Our State also faces the largest per-capita economic burden in the country: the opioid epidemic is costing our economy an estimated $8.8 billion per year, forcing us to dedicate the largest share of our GDP of any State to costs related to the crisis: 12 percent. This is a staggering cost for a small State like ours. That is why I pushed for and was glad to see the 15 percent set aside for the hardest hit states—those with the highest mortality rates like West Virginia. However, recent studies have shown that rural counties are still not getting their fair share. The study found a number of rural counties, including 40 of 95 in one State, received no direct Federal funding.

Will you commit to working with me to ensure that rural counties with high mortality rates related to opioid overdoses get the share of the Federal resources that they need to address this crisis, including of Federal funding not subject to the 15 percent set aside requirement?

Answer. SAMHSA is committed to ensuring all communities with need receive the necessary resources to provide the full array of substance use disorder prevention, treatment, and recovery support services. The 2018 and 2019 State Opioid Response (SOR) funding was awarded to States via formula and State allocations were based on the following two elements weighted equally: 1. The State’s proportion of people who meet criteria for dependence or abuse of heroin or pain relievers who have not received any treatment (NSDUH 2015–2016), and 2. The State’s proportion of drug poisoning deaths (2016 CDC Wide-ranging ONline Data for Epidemiologic Research (WONDER)). States are expected to distribute the funds throughout their communities based on the needs assessment conducted for their State Targeted Response (STR) grant. Based on West Virginia’s needs assessment, they have prioritized geographic areas and populations at higher risk for opioid use disorder (OUD) and on pregnant and parenting women. Grantees are specifically encouraged to use innovative telehealth strategies in rural and underserved areas to increase the capacity of communities to support OUD prevention, treatment and recovery. To accomplish this goal, most States contract with universities, community organizations, local governments, and other entities to provide the relevant services needed within the communities.

In West Virginia specifically, individuals with OUD are eligible to receive free public transit to the States’ treatment centers. The West Virginia Public Transit Association provides both urgent and non-urgent transport available within 24 to 72 hours. This initiative aims to improve access to treatment and recovery resources to individuals, families and communities across the State. West Virginia has also expanded its Comprehensive Opioid Addiction Treatment (COAT) program. The COAT program has developed four regional Hubs in addition to WVU’s mega-hub and is standing up spokes to provide treatment and support services in geographically isolated and underserved areas of the State. To date, through SOR funding, the COAT program has added 14 facilities (spokes) to its treatment system. SAMHSA is engaged in several activities and is developing products specifically related to rural communities, including:
—Rural Emergency Medicine Services Training Program
—Rural Opioid Technical Assistance Program
—SAMHSA Advisory: Addressing Opioid Use Disorder in Rural and Frontier Communities
—Partnering with USDA to Create Recovery Housing in Rural Communities

SAMHSA will continue to support efforts and explore ways to address OUD in underserved, including rural communities.

HOMELESS CHILDREN AND YOUTH

Question. Secretary Azar, as you may be aware, most recent Federal data reports more than 1.5 million students experienced homelessness in the 2017–2018 school year. In my State of West Virginia, we had more than 10,500 students identified as homeless during the last school year alone. However, we know that both numbers are much higher due to challenges associated with identifying and providing services to children and youth experiencing homelessness. The Administration of Children and Families (ACF) is tasked with promoting the economic and social well-being of fami-
lies and children, including those experiencing homelessness. I am pleased to know that ACF hosted a number of listening sessions in 2019 across this country to better understand the challenges and roadblocks that make it more difficult to assist families experiencing homelessness. As noted in the report summary of those sessions, family homelessness is still increasing in every region of this country, which contributes significant trauma for both parents and children. That is why I’m most concerned about the section outlining that ACF has numerous resources available to assist these families, but those resources are “overlooked and under-appreciated”.

Can you please outline how the President’s budget request for the Administration for Children and Families enables and empowers them to better assist homeless children and youth along with their families?

Specifically, how does this budget help expand access to the vital resources provided by ACF?

**Answer.** The ACF budget promotes work, strong families, healthy marriage, strong social networks, and programs to reduce adolescent pregnancy, reduce family and youth homelessness, and increase self-sufficiency. The budget also includes funding for community-based interventions that support primary prevention strategies to keep families together and reduce the number of children removed for abuse and neglect.

One barrier for individuals and families seeking services is the fragmented nature of Federal and State funding. Funds come to States and localities primarily through program specific formula or discretionary grants appropriated or awarded to government entities, tribes, institutions of higher education, and faith-based and community organizations. Families and youth do not necessarily look to government first when in need of assistance, but many will seek assistance from local, community, or faith-based service providers who may or may not know about the various resources available unless they create intentional partnerships with other nonprofits and/or State agencies.

Local departments of social services (government) do not generally provide services across the ACF continuum as programs are managed by the various entities that receive Federal funding including: workforce commissions, departments of education, departments of aging and disability services, child care providers, Head Start agencies, departments of agriculture (SNAP, WIC), health departments (Medicaid eligibility), domestic violence facilities, shelters for runaway and homeless youth, and others.

One example of how ACF is working to expand access to resources is in the Runaway and Homeless Youth (RHY) program. The RHY program encourages grantees to connect youth with local resources including those in schools and education systems through McKinney-Vento (M-V) liaisons. These liaisons are required to make sure homeless youth are enrolled in school receive categorical eligibility for certain resources including free textbooks, transportation, and Title I services. ACF is also working with colleagues at Department of Education to connect the M–V liaisons with State child welfare directors, runaway sheltering programs, domestic violence sheltering programs, and service providers. ACF serves on the Department of Housing and Urban Development workgroup to inform their Foster Youth Initiative, a new opportunity for tenant vouchers for youth in need of transitional housing.

Another example of expanding access to resources is the recent partnership between ACF’s RHY program and Early Head Start. These two Federal programs worked together to communicate to their respective grantees that pregnant and parenting youth and their young children in RHY shelters have priority placement in Early Head Start programs. Early Head Start programs focus on teen parents and children experiencing homelessness through targeted outreach and facilitated enrollment. By combining the resources of both RHY and Early Head Start, pregnant and parenting teens, including fathers, receive many wrap around supporting services designed to lift them out of poverty and onto a trajectory for success.

The President’s Budget supports prevention of homelessness and funds systems to ensure that homelessness is temporary and short-term. Strategies include expanding access to services and increasing service capacity. Examples include:

—A $1 billion competitive fund to increase the capacity of childcare services for low income working families while stimulating employer investment;
—A flexible funding proposal for foster care that would allow States to support more prevention services to keep families together in their own homes;
—Demonstration funding for improving permanency (adoption, guardianship, kinship or other permanent connects) for youth in foster care before they age out of the system and find themselves homeless and in need of services;
—Continued support for early childhood education by funding Head Start and Child Care for low income working families at historically high levels;
—Improved enforcement tools to engage more parents in payment of child support while encouraging father engagement and child well-being;

—Continued funding to develop a model intervention for young adults with child welfare involvement who are at-risk of homelessness;

—A $16 million increase in Child Abuse Discretionary grant funding to support primary prevention to keep families in their homes and reduce child removals;

—Continued support ($132 million) for ACF Runaway and Homeless Youth programs to provide comprehensive services to an estimated 63,401 homeless youth. The President’s Budget also proposes to create a performance-based contracting demonstration program for the Transitional Living and Maternity Group Home programs that will encourage grantees to focus more on outcomes in the design and delivery of their services.

—Continued support for domestic violence prevention services to include development of safety plans, counseling, peer support and referrals to community services both before and after victims find themselves homeless;

—Funding to aid foster youth in the successful transition to adulthood including education and housing voucher programs;

—Over $100 million in support of adolescent pregnancy prevention programs to prevent pregnancy and youth in setting goals including completion of high school, getting a full time job and waiting until marriage to have children, dramatically reducing their risk of homelessness; and

—A $40 million increase for Regional Partnership Grants to address the significant problem of substance misuse and child welfare involvement, which may lead to homelessness.

One of the benefits of the ACF listening sessions on family homelessness, was the opportunity for service providers, local government agencies, and individuals to learn about the menu of ACF programs, meet program staff and regional nonprofit leaders, and network with other providers and government leaders. ACF is committed to continuing efforts to strengthen collaboration at the Federal, State, and local level to increase awareness of and access to ACF-related services, and critical services provided by other Federal partners.

THE JESSICA GRUBB’S LEGACY ACT

Question. Secretary Azar, as you know, the 42 CFR Part 2 regulations govern the confidentiality and sharing of substance use disorder treatment records within our healthcare system. Unfortunately, at a time when we are working toward greater care coordination, this regulation has acted as a barrier to communication between healthcare providers serving individuals with substance use disorders. I introduced the Jessica Grubb’s Legacy Act in honor of a young woman that we lost too soon to an opioid overdose because her medical records did not adequately indicate her past addiction and—while in recovery—with 50 oxycodone pills. This bill would simply align the privacy standards for substance use disorder treatment records with HIPAA—the privacy standard that governs all other physical and mental healthcare records. It would preserve patient privacy, but ensure that medical professionals have access to the vital information that they need to properly coordinate the care of their patients with substance use disorders. As the agency that oversees 42 CFR Part 2, SAMHSA has said that they are encouraged that Congress is examining “the benefits of aligning Part 2 with HIPAA” because “healthcare providers must have secure access to patient information, including substance use disorder information, in order to provide integrated and effective care.”

Secretary Azar, will you commit to working with me to pass the Legacy Act (S. 1012) to align Part 2 with HIPAA and ensure that those recovering from substance use disorders are able to receive quality, coordinated healthcare?

Answer. Yes, HHS supports the alignment of 42 CFR Part 2 and HIPAA Privacy Rule, 45 CFR Parts 160 and 164, Subparts A and E, and was pleased to see the Congressional action to align HIPAA and 42 CFR Part 2 by passing similar language to your bill in the CARES Act. HHS is committed to working to reduce barriers to care for those with substance use disorders (SUD). HHS believes that the statutory provision that 42 CFR Part 2 implements, while well intended, may sometimes serve as a barrier to care and has contributed, in some ways, to the increased stigma around SUDs. HHS, through the Substance Abuse and Mental Health Services Administration (SAMHSA), has worked to modify 42 CFR Part 2 regulations through a Notice of Proposed Rulemaking Process. SAMHSA has proposed modifications to make it easier for primary care providers to receive information from SUD treatment facilities and document such information into the providers’ records without additional burden to the primary care provider. SAMHSA proposals also make
it easier to communicate in times of emergency and would further enhance the ability of patients to get needed benefits such as Social Security benefits without additional paperwork.

**DRUG TESTING**

**Question.** Federal law requires trucking companies to drug test new drivers and randomly test existing drivers using methods established by the Department of Health and Human Services. FMCSA’s newly established Drug and Alcohol Clearinghouse has received over 8,000 DOT drug and alcohol violations in less than 2 months, and many trucking companies have adopted hair testing as a tool to detect drug use in their company policies. Unfortunately, while hair testing provides employers a longer detection window, ease of collection, and makes it more difficult for testers to adulterate than urinalysis, it is not a federally-accepted alternative drug testing method. The FAST Act mandated that HHS issue technical guidelines for the adoption of hair testing as a federally-accepted alternative drug testing method within 1 year of the bill’s enactment. While that deadline has long since passed, HHS submitted proposed guidelines for OMB review this past summer.

Mr. Secretary, will you commit HHS to providing DOT guidelines that will provide trucking companies this safety tool mandated by Congress in the FAST Act to ensure that their drivers are not using prohibited substances?

**Answer.** The Proposal for Mandatory Guidelines for Federal Workplace Drug Testing Programs.—Hair is currently under Executive Branch and interagency review and coordination. When this process is complete, we anticipate publishing the proposed Guidelines in a Federal Register Notice.

QUESTIONS SUBMITTED BY SENATOR PATRICK J. LEAHY

**OPIOD MISUSE AND ADDICTION RESEARCH**

**Question.** Opioid abuse and addiction continues to debilitate millions of families throughout the United States, particularly in rural areas such as Vermont. Preliminary data from the Vermont Department of Health shows that in 2018, 110 Vermonters suffered an opioid-related fatality (17.6 fatalities per 100,000 Vermonters). Nationally, according to the National Institute on Drug Abuse (NIDA), the opioids were involved in more than two-thirds of all drug overdose deaths in 2017.

Since fiscal year 2018, Congress has appropriated $1.5 billion to the National Institutes of Health (NIH) for research related to opioid addiction, development of opioid alternatives, pain management, and addiction treatment. In fiscal year 2020 alone, Congress appropriated $500 million to NIH for these purposes. What programs and initiatives are these funds supporting, and how?

**Answer.** The NIH Helping End Addiction Long-term (HEAL) Initiative seeks to develop scientific solutions to the opioid crisis from all angles and disciplines, and across the full spectrum of biomedical research. In September 2019, NIH directed $945 million in funding towards more than 375 projects across 41 States through the HEAL Initiative. Research supported through the Initiative is working to discover safer and more effective treatment options for pain, and to expedite the development of therapies to treat opioid use disorder and overdose. Projects employ a range of approaches, including validation of new targets for pain therapeutics, identification of individuals most at risk of relapse and opioid overdose, and prevention of at-risk adolescents from developing opioid use disorder. Additionally, implementation science efforts will seek to integrate evidence-based interventions for opioid addiction in healthcare and justice settings and in communities in States most affected by the opioid crisis. As part of its response to this crisis, NIH intends to maximize the availability of HEAL research findings and publications as well as the sharing of underlying data to promote dissemination of new knowledge, enhance reproducibility, and accelerate research to develop scientific solutions to the opioid crisis through the NIH HEAL Initiative research.

**Question.** What progress has been made at the NIDA and the National Institute of Neurological Disorders and Stroke (NINDS) on developing non-opioid chronic pain medications to alleviate pain and to treat addiction?

**Answer.** Studies are underway to identify compounds that target receptors and ion channels integral to non-opioid pain pathways in the nervous system. Through the HEAL initiative, NIH is supporting discovery research on new targets for novel medications and devices to treat pain. Many of these studies focus on new receptors and channels for treatment of neuropathic pain such as diabetic nerve pain, and orofacial pain such as headache and temporomandibular joint pain. In addition, NIH
supports studies on anti-inflammatory compounds to treat chronic pain conditions such as neuropathic pain and osteoarthritis. Through the NIH Blueprint Neurotherapeutics Program for drug discovery and development, the National Institute of Neurological Disorders and Stroke (NINDS) funds studies to develop non-addictive kappa opioid receptor antagonists for treatment of migraine and a safe, non-opioid analgesic, which is a soluble epoxide hydrolase inhibitor that can be taken orally to reduce diabetic nerve pain. NIH supported basic science research that led to the understanding of the role of calcitonin gene-related peptide therapy for migraine and nerve growth factor therapy for inflammatory pain. Drugs that target these molecules’ function are now approved by the FDA to treat migraine and osteoarthritis pain, respectively.

As NIH works to develop new, non-addictive therapies for pain, efforts are also underway to find new ways to treat opioid addiction. NIDA leads efforts under the HEAL Initiative to support a series of targeted studies with the goal of submitting approximately 15 investigational new drug and five new drug applications to the FDA for medications to prevent and treat opioid use disorder (OUD) and overdose. The program aims to accelerate the discovery and development of novel medications to treat all aspects of the opioid addiction cycle, including progression to chronic use, withdrawal symptoms, craving, relapse, and overdose. This includes novel formulations of existing medications for OUD such as buprenorphine and naltrexone and stronger, longer-duration formulations to counteract opioid overdose. The program also includes support to study novel medications to treat withdrawal, craving, progression, and relapse and to identify new medication targets to treat OUD. Together, these studies will range from early stage drug development to Phase I and Phase II clinical trials of drugs. Some of the drugs under investigation target the opioid signaling system directly, while others affect novel targets in other signaling systems that can play a role in opioid addiction or withdrawal which could lead to the development of additional OUD treatments that may work better for some patients or have a more tolerable side effect profile.

Question. Could you please explain, with specific examples, how NIH has expanded scientific activities related to research on non-opioid chronic pain therapies?

Answer. Through the HEAL Initiative, NIH supports programs to accelerate development of new medications and devices to treat pain. To test new non-addictive pain treatments, newly established and highly innovative preclinical screening platforms will use animal-based and human cell-based models such as neural tissue chips for rapid screening of molecules or devices for analgesic relevant biological and behavioral activity. Through HEAL, NIH is also partnering with academia and industry to bring in promising new drugs and devices for early phase testing of novel therapeutics in the newly established Early Phase Pain Investigation Clinical research network (EPPIC–NET), which supports trials on the safety and efficacy of novel drugs and devices. This network also will support discovery research on different pain conditions. Through HEAL, NIH also established the Pain Management Effectiveness Research Network which supports phase III effectiveness trials on pharmacological and nonpharmacological therapies for many different pain conditions, including post-surgical pain, chronic musculoskeletal pain, knee osteoarthritis, and cancer pain.

NIH is working with Federal partners to address research gaps for non-pharmacological treatments by providing the foundation for implementing these treatments into healthcare systems and leading ultimately to their broader dissemination. Through the HEAL initiative’s PRISM (PRagmatic and Implementation Studies for the Management of Pain to Reduce Opioid Prescribing) program, NIH will support pragmatic clinical trials on how best to imbed effective non-pharmacological treatments for pain into large healthcare settings. PRISM currently supports implementation trials to manage low back pain, fibromyalgia and post-operative pain.

Question. Could you please provide Congress with the Department’s timeline for developing these non-opioid alternatives?

Answer. The timeline for developing a novel drug, from early stages to approval, can take many years. However, in considering the timeline for developing non-opioid alternatives, it is important to note that several potential drugs are already at various stages along the development pipeline in NIH and the private sector, including some industry-sponsored phase III clinical trials. Furthermore, drugs on the market for other conditions may prove effective as an opioid alternative for other specific pain conditions, and a variety of non-drug interventions are also at various stages of testing for pain. The HEAL Initiative is aggressively exploring all of these potential alternatives to make non-opioid options available as soon as possible.
HEADACHE DISORDERS & MIGRAINE

Question. Migraine is currently the second leading cause of all global disability. One in seven Americans will experience a migraine attack this year and cluster headache is widely reported to be the most severe pain that humans can experience.

Unfortunately, due in part to limited research and treatment, inappropriate opioid prescriptions for migraine present Americans with ongoing risks of opioid use disorders and have worsened outcomes in patients. The NIH website on disease burden shows “migraine” to have received by far the lowest level of research funding in 2015, among those diseases with the highest burden. In 2017, only 53 extramural investigators were funded for headache research, compared to 215 for epilepsy and 385 for schizophrenia, each of which has far lower burden than migraine.

In 2018, NIH announced the Helping to End Addiction Long-term (HEAL) initiative, a trans-agency effort to speed scientific solutions to stem the national opioid epidemic. While headache disorders and migraine grant proposals are eligible for consideration under the HEAL RFAs recently issued for pain research, I am very concerned that these will fail to attract enough investigators to this historically under-funded research area.

Does NIH have plans to issue specific RFA programs for headache disorders and migraine research, comparable in scope to the BACPAC group of RFAs for research on back pain?

Answer. All HEAL solicitations called for research on any pain conditions including headache, and many specifically called for headache research. The few exceptions were targeted RFAs for low back pain and hemodialysis pain. Both of these pain conditions differ from headache disorders in that they are associated with high rates of opioid prescribing and lack essential research resources to move their fields forward. While opioids are sometimes used for chronic headaches and acute headaches in emergency room settings, prescribing rates are curbed by practice guidelines that recommend not using opioids in either situation. The NIH HEAL BACPAC program was established to meet objectives, not only to reduce reliance on opioids, but also to address the lack of essential research resources for low back pain, such as accurate diagnostic tools, meaningful clinical endpoints and case definitions needed to advance quality research. These research essentials for headache disorders are established, in part through NIH support, and widely accepted by the research community.

An important HEAL objective is to improve pain management, and NIH recognizes that advancing headache research is needed to improve care. Therefore, the NIH staff aggressively promoted HEAL RFAs inclusive of all pain conditions to inform the headache research community of these opportunities. HEAL proposals for headache research were awarded to: (1) understand trigeminal nerve circuitry which is the nervous system component that underlies headache disorders, (2) discover markers that predict persistent headache after head trauma, (3) explore how dysfunction of an ion channel called TRESK mediates headache trigeminal pain and predisposes women to migraines, (4) explore the therapeutic potential of TRP channels for orofacial pain, and (5) study a novel CGRP receptor, AMY1, that mediates migraine induced behaviors. Many other compounds are being developed and tested as safe analgesics for a broad spectrum of chronic pain conditions, which might also be helpful in relieving headache and other trigeminal pain. In addition to the HEAL initiative, many NIH Institutes and Centers support initiatives whose scope includes headache disorders for a broad range of research, from neural mechanisms that cause headache, to development of treatments, to dissemination of effective therapies into the clinic. NIH continues to solicit research on pain mechanisms and pain management and has established communication channels to ensure that the headache research community is up to date on funding opportunities.

Question. How many HEAL RFAs related to headache disorders and migraine grant proposal have been submitted since the launch of NIH’s HEAL initiative? How many of those grant proposals have been awarded?

Answer. Research on headache disorders, including migraine, is within the scope of research solicited by all prior and current HEAL RFAs for preclinical and clinical pain research, other than those for BACPAC and hemodialysis pain. For example, HEAL priorities include enhanced understanding of pain, discovery and validation of novel pain targets, testing therapies in clinical settings, and accelerating development of better therapies for patients. HEAL funding opportunity announcements relevant to pain and pain management called for research on all pain conditions and for a broad range of research proposals including biomarker discovery, analgesic device and drug optimization clinical trials to compare effectiveness of interventions, and studies, to determine how to bring effective therapies into real world healthcare settings. Headache research is within the scope of all these solicitations, and NIH
engaged with the headache research community to inform them of such research opportunities and encouraged them to submit applications. HEAL proposals in headache research were awarded to: (1) understand trigeminal nerve circuitry which is the nervous system component that underlies headache disorders, (2) discover markers that predict persistent headache after head trauma, (3) explore how dysfunction of an ion channel called TRESK mediates headache trigeminal pain and predisposes women to migraines, (4) explore the therapeutic potential of TRP channels for orofacial pain, and (5) study a novel CGRP receptor, AMY1, that mediates migraine induced behaviors. Many other compounds are being developed and tested as safe analgesics for a broad spectrum of chronic pain conditions, which might also be helpful in relieving headache and other trigeminal pain. These awards will contribute to gap areas in headache research.

**MEDICAID**

**Question.** The Department’s fiscal year 2021 budget proposes to cut Medicaid by $920 billion over the next 10 years. The budget also proposes to overhaul the program into block grants and caps that would restrict States’ abilities to respond to public health issues such as the opioid epidemic. Vermont, for example, has been able to utilize Medicaid to help create their Hub and Spoke approach to combat opioid addiction, which has become a national model in the fight against opioid misuse and addiction. Additionally, the administration’s Medicaid block grant proposal includes vague guidelines on how the Federal matching dollars can be spent. How will these proposed cuts to Medicaid help States such as Vermont be more responsive to public health issues that require increased health investments such as the opioid epidemic or coronavirus?

**Answer.** HHS’s proposed budget will have Medicaid spending grow at a more sustainable rate by ending the financial bias that currently favors able-bodied working-age adults over the truly vulnerable.

The President's Budget increases funding for the opioid and meth epidemic by $5.2 billion, an increase of $169 million or +3 per cent, above fiscal year 2020 to combat the opioids and meth crisis. In 2018, overdose deaths declined for the first time since 1990, falling by 5 per cent and ending 3 decades of increases. HHS continues the fight against opioid addiction and is using our 5-part strategy to halt a rise in meth and other stimulants use.

**Question.** How will the administration’s Medicaid block grant proposal ensure continued access to health insurance and health services for the millions of Americans who obtained health insurance coverage under the Affordable Care Act’s Medicaid expansion provision?

**Answer.** The Healthy Adult Opportunity (HAO) is not a mandatory change in the Medicaid program’s structure or financing—this is an optional demonstration opportunity, and no State is under any obligation to participate. It is also not permission for States to strip benefits or limit eligibility—under HAO, participating States must still meet minimum benefit requirements and cannot cap or limit adult enrollment while still receiving enhanced Federal funding.

A number of States have already publicly expressed interest in HAO, and are supportive that the demonstration represents an innovative and historic approach to surmounting Medicaid’s structural challenges while still providing rigorous protections for all Medicaid beneficiaries.

**Question.** What guardrails does the administration plan to put in place to ensure that the Federal matching dollars within the Medicaid block grant proposal are spent on health matters and not unrelated States priorities?

**Answer.** Please see page 20 of the HAO SMD, if the State achieves certain performance metrics and spends less than its projected spending: After CMS determines that a State has qualified for shared savings under the demonstration, we anticipate exercising expenditure authority for reinvestment during the State’s next demonstration year in programs which could include matching State expenditures up to a percentage for existing State-funded health programs that have not previously qualified for Federal funding (limited to 30 percent of the total amount eligible for shared savings reinvestment) or for new health-related initiatives targeting the demonstration population or other Medicaid beneficiaries that would not otherwise be eligible for matching funds under the State plan or another demonstration. Examples of initiatives that could be funded with matching funds through shared savings include providing Medicaid services for populations not currently covered by the State’s State plan or another demonstration, such as supported work or service coordination; paying for services not included in the State plan or another demonstration for Medicaid beneficiaries, such as pre-vocational services; initiatives designed to improve the quality of and access to care provided to Medicaid bene-
ficiaries; and allowable benefits and services designed to address certain social determinants of health. For programs or initiatives funded through shared savings to be eligible, CMS will need to determine that they will be likely to promote the objectives of the Medicaid program. Any shared savings for which a State may be eligible based on its performance in a particular demonstration year would be expected to be available to States for the next 3 years only, including into a new demonstration period if the 3-year period extends into a new demonstration period and CMS has approved a demonstration renewal. Shared savings should not be used to supplant or duplicate other Federal funding. In some cases, States may seek to use a portion of the shared savings expenditure authority to invest in existing State-funded programs. For example, the State may be operating State-funded tobacco cessation program that supports many Medicaid beneficiaries. Earning Federal share for investing in this program would free existing State resources that States could choose to reinvest in expanded services or benefits for other Medicaid enrollees, including mandatory State plan populations not covered under this demonstration.

Question. Could you please explain how the Medicaid block grant proposal will expand patient access to health insurance coverage?

Answer. As noted in the response above, States may seek to use a specified portion of any achieved shared savings expenditure authority to invest in existing State-funded programs. For example, the State may be operating a State-funded tobacco cessation program that supports many Medicaid beneficiaries. Earning Federal share for investing in this program would free existing State resources that States could choose to reinvest in expanded services or benefits for other Medicaid enrollees, including mandatory state plan populations not covered under this demonstration.

LOW INCOME HOME ENERGY ASSISTANCE PROGRAM

Question. The Low Income Home Energy Assistance Program (LIHEAP) provides essential assistance to Americans to heat or cool their homes. This is especially important in Vermont. It is extremely disappointing that the administration’s budget again proposes the elimination of LIHEAP. Furthermore, the administration’s proposal to remove funding from LIHEAP to support the coronavirus is shortsighted because of the very real immediate health consequences of home heating and cooling.

This program provides benefits across the county, including to over 20,000 households in Vermont. In cold weather States, home heating costs can be exceptionally high and LIHEAP benefits are often insufficient. Vermont families often expend their full annual benefits early in the heating season and depend on emergency funds to heat their homes for the remainder of the season. I am concerned that it took over 2 months for the administration to allocate the remaining 10 percent of fiscal year 2020 LIHEAP funding.

How can you more efficiently and expeditiously allocate final LIHEAP funding, should the government find itself receiving full year funding through a spending bill following a continuing resolution?

Answer. HHS and the Office of Management and Budget (OMB) have worked in partnership for a number of years to ensure that LIHEAP receives as much of its funding as possible as early as possible in the fiscal year, as opposed to following a more typical quarterly allocation process.

Whenever LIHEAP is subject to a continuing resolution, HHS has historically requested, and OMB has concurred, with releasing 90 percent of the funding in the early fall. Absent a final appropriation, HHS is unable to issue 100 percent of LIHEAP funding without jeopardizing Congress’ final funding prerogative or burdening grantees with returning funding that they may have already made legal commitments against.

Even with receiving funding in October, grantees still make many program decisions prior to receipt of Federal funding in order to ramp up the start of their heating or year-round programs in the fall. This includes outreach activities, mailing applications to prior year recipients (particularly vulnerable households on fixed incomes), entering into agreements with subgrantees to prepare intake services, etc.

For fiscal year 2020, HHS released 90 percent of LIHEAP funds available under the Continuing Resolution in November of 2019. Additional funds were released in February of 2020, after passage of the full year appropriation. All remaining LIHEAP funds provided by the full year appropriation have been released. Funds originally transferred from LIHEAP for COVID–19 response were returned to LIHEAP and released per the requirements of the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (Public Law 116–123).
Question. As the administration continuously—and cruelly—proposes elimination of the LIHEAP program, what would you say to the thousands of American families who rely on this assistance every year? Do you think they are just simply out of luck?

Answer. LIHEAP does not require grantees to report on outcome metrics and the program is, therefore, unable to demonstrate strong performance outcomes, such as improved self-sufficiency. In addition, many State and local governments now provide significant heating and cooling assistance and the majority of States prohibit utilities from discontinuing heating during the winter months. With our limited resources and based on the review of local policies, we determined that continued funding of the LIHEAP program is not the best use of taxpayer dollars and have proposed eliminating future funding for this program.

SUBCOMMITTEE RECESS

Senator BLUNT. The committee will stand in recess.

[Whereupon, at 12:37 p.m., Tuesday, February 25, the subcommittee was recessed, to reconvene subject to the call of the Chair.]